# Randomized 1-month study to compare the efficacy of meditating with EEG-neurofeedback tool and meditation app on mental and physical health and health behaviors in university students

## Abstract

### **Background**

Young adults in college experience high levels of stress, anxiety, and depression, which can lead to maladaptive behaviors and chronic health issues including inflammation and HPA-axis dysregulation. University mental health centers are seeking effective programs that teach coping skills to self-manage stress, with low stigma, that are easy to implement in large scale. The aim of this protocol is to describe the design of a study aiming to evaluate the effectiveness of a one-month self-guided meditation program for university students comparing various tools to improve mental health, physical health and health behaviors, and explore moderators. Secondary aims include reaching a diverse audience and documenting adverse experiences.

### **Methods**

A Randomized Controlled Trial will be conducted to examine the effectiveness of a self-guided meditation program aiming to promote mental health, physical health and health behavior using either 1) meditation app (“app group”), or 2) meditation app, plus Muse neurofeedback device (“Muse group”). A multi-method approach (i.e., validated self-response measures, physiological measurements, frequent mini surveys) approach will be used to assess primary outcomes (stress, anxiety and depression), secondary outcomes (e.g., physiological outcomes, sleep, eating behavior), as well as specific moderators (e.g., demographics, adherence, motivation, self-esteem, baseline mental health severity).

### **Discussion**

The current study will provide information on the comparative effectiveness of a self-guided meditation program for university students using a meditation app, with and without access to an additional tool for meditating with neurofeedback. It is of crucial importance that university mental health centers can provide students with effective, low-risk and low-cost intervention programs to promote student mental wellbeing, and to determine if such programs also have immediate effects on physical health and health behaviors.

### **Trial registration**

Clinical Trial Register number NCT03402009. Registered 17 January 2018.

**Introduction**

Young adults in college experience high levels of stress, anxiety, and depression, which have been linked to behavioral, physical, and physiological consequences (American College Health Association, 2019; Beiter et. al, 2015). Foremost among the physiological consequences of stress and anxiety is lack of sleep. Among college students in the United States, up to 60% of college students suffer from poor sleep quality (Schlarb et al., 2017), which increases the risk of impaired mood and risk behaviors (Trockel et al., 2000). Furthermore, extended periods of stress/anxiety can lead to inflammation and HPA-axis dysregulation (Faravelli, 2012; Black & Slavich, 2016), which are associated with chronic health issues and may even increase the risk of severe symptoms of COVID-19 (REF).

Mental health issues can be exacerbated by maladaptive coping (Mahmoud et al., 2012) and can contribute to a variety of detrimental consequences that can impair long-term health (Epel et al., 2004; Lupien et al., 2007, 2009, and many others). Tools that improve coping and build resilience may help dealing with stress and anxiety, which should also improve downstream behavioral, physical and physiological consequences.

A potential supplement to improve coping strategies can be found within the practice of mindfulness meditation. Mindfulness meditation focuses on training the mind to pay attention in a particular way: to become aware of present moment experience with an attitude of curiosity and acceptance (Bishop et at., 2004). Mindfulness meditation shows promise in both healthy and clinical populations to improve a variety of markers for health, aging, and well-being, including mood-related (e.g. stress, anxiety, and depression;Burns, Lee, & Brown, 2011; Hofmann, Sawyer, Witt, & Oh, 2010; Hoge et al., 2014; Kang, Choi, and Ryu, 2009; Miller, Fletcher, & Kabat-Zinn, 1995; Shreiner & Malcolm, 2008), cognitive (e.g. attention, focus;Bhayee et al., 2016; Bueno et al., 1985), and physical (e.g. pain, fatigue, inflammation;Kabat-Zinn, Lipworth, & Burney, 1985; Monroe, Greco, & Weiner, 2008; Rosenzweig et al., 2010) symptoms.

Applications and online platforms are increasing in popularity and demand as teaching and learning tools. Online education has been rapidly growing for over a decade; 35.3% of college and university students participated in online education in 2018, while 21% of public schools and 13% of private schools offered at least one fully online course (U.S. Department of Education, 2019). The COVID-19 public health crisis has further accelerated the growth of online learning both inside and outside of the academic sphere, making it paramount that remote education efforts are refined and relevant in the long-term. As the modern learning environment moves into online space, university mental health centers are seeking effective tools that help students address coping skills and managing their mental health concerns.

In the most simple form, offering students a meditation app may promote mental health and well-being. However, new technological tools are increasingly available to assist people in developing a personal meditation practice, ranging from free software apps and web links to costlier electroencephalogram (EEG) neurofeedback devices available for consumer purchase (Pospos et al., 2018). Muse by Interaxon is an EEG-neurofeedback device sold on Amazon.com. Interaxon markets the Muse as a meditation tool that connects to the Muse phone app that rewards the user with points for being ‘calm’. More specifically, Muse rewards users for achieving a pattern of electrical activity that is proprietary to Interaxon, that the company claims is a proxy for being in a meditative state they label as ‘calm’. Previous studies have shown the Muse headband to be a tool to increase interest in meditation in neuroscience in the undergraduate population (Segawa, 2019). To best assist college students using meditation to self-manage stress, it is important to determine if different meditation tools lead to different benefits. It is presumed that college students prefer tools that are inexpensive, or easy to access and utilize. While most of the scientific evidence supporting the benefits of mindfulness meditation come from studies that use intensive eight-week programs such as Mindfulness Based Stress Reduction (MBSR), new studies are showing that 4-6 week mindfulness-based interventions can also be helpful (Jain et al., 2007; Mackenzie et al., 2006; Demarzo et al., 2017). A recent meta-analysis that examined the effectiveness of online mindfulness-based interventions found improvements in mental health measures including depression, anxiety, and stress as compared to controls (Spijkerman et al., 2016).

The purpose of this study is to evaluate the effectiveness of a one-month self-guided meditation program for university students on critical markers of mental health, physical health and health behaviors, and to explore potential effect moderators. Secondary aims include reaching a diverse audience and documenting adverse experiences. Two treatment groups will be compared, both having access to the 10% Happier App, and one having additional access to the Muse Neurofeedback Tool, to determine if the neurofeedback tool provides additional benefits beyond the meditation app alone, for any outcome.

Hypotheses tested will include:

1. Self-guided mindfulness-meditation program will improve 1) mental health outcomes, 2) physical health outcomes, 3) health behaviors.
2. Neurofeedback will enhance effectiveness of some outcomes, more than using only a meditation app.
3. Mindfulness-meditation will lead to equal improvements in mental health outcomes across demographic groups.
4. Neurofeedback group will report more issues or adverse experiences.
5. Baseline levels of self-esteem, motivation, mental health severity, and program adherence will moderate changes in mental health outcomes within groups.
6. Increases in emotion regulation will be associated with improvements in behavioral outcomes.

**2. Method**

*2.1 Participants*

A total of 140 university students who were seeking to develop a meditation practice to self-manage stress participated in the study. Participants were recruited from the student population at the University of Connecticut using IRB-approved flyers, campus-wide email distribution, and an online database for introductory psychology classes. The study was open to both undergraduate and graduate students. Participants responded via email if interested in the study. Participants then received two emails, one to obtain informed consent electronically and one to determine inclusion/exclusion criteria. Participants were excluded if they were under age 18, had difficulties understanding English, or had engaged in previous meditation practice.

*2.2 Procedure*

Participants advanced through the stages of the study as follows: 465 participants demonstrated interest. Of these 465, 140 chose to begin the study. Random assignment was accomplished by assigning a random number between one and two to each participant. Individuals were randomly assigned to either the 1) Muse meditation intervention (*n* = 66, “Muse group”), or 2) the apps-only meditation intervention (*n* = 74, “App group”). Participants were then assigned to an orientation time slot via email according to their preference. Participants from the Muse group then attended a one-hour group orientation led by the study coordinator (a meditation instructor with 15 years teaching experience); the session included an introduction to mindfulness meditation, guided meditation, group discussion, and an introduction to the Muse device. The guided meditation included learning how to mindfully place and return attention to a single point of focus (e.g., breath counting, breath sound, sensation, color visualization, or mantra). All anchor points were practiced as a group, and participants were told to select which anchor worked best for them. Instruction was also provided on the fundamental elements of mindfulness, along with tips for helping to integrate the habit of meditation and mindfulness into daily life. The App group attended a similar orientation, without the introduction to the Muse device.

*2.2.1 Saliva Selection Subset*

Each participant was informed during orientation, both through writing and verbal instruction, that they would be required to provide a saliva sample pre-intervention and post-intervention. Both CRP and cortisol have been shown to follow a circadian alignment (Wright et al., 2015). To track these physiological mechanisms, Desantis et. al. proposed a saliva sample when the participant woke up, one a half hour later, and one in the late evening (2015). Participants were given three labeled vials with color-coded caps that stated the participant ID and collection times for the saliva sample: the red-capped vial was for as soon as the participant woke up, the yellow-capped vial was for 30 minutes after waking, and the blue-capped vial was for the evening. The participants were then instructed to freeze the saliva and return it to a cooler on ice within the lab, where the experimenters then transferred the samples to the freezer for storage.

*2.3 Intervention*

The intervention consisted of a four-week practice of self-guided meditation in which participants were asked to meditate for 10 minutes every day. Adherence was monitored through emailed self-report surveys every 2-3 days to ensure compliance with the intervention as well as ensuring that participants were not having any issues with the Muse headband and apps.

Both groups were asked to use the meditation app, 10% Happier, at least twice a week; 10% Happier contains guided meditations typically five to ten minutes in length, written and delivered by a variety of reputable meditation instructors. Participants in the Muse group were also asked to use the Muse at least twice a week, in addition to 10% Happier. In both groups, participants were encouraged to use whichever tools worked best for them during the remaining days of the week in order to meditate every day for one month.

*2.4 Measures*

*Personality:* **Big Five** personality traits (Costa & McCrae, 1992), which are openness, conscientiousness, extraversion, agreeableness, and neuroticism. These factors have been used to understand the relationship between personality and various academic behaviors. Respondents rate each item on a five-point scale from *strongly disagree* to *strongly agree*. This scale has been used extensively in psychology research and has demonstrated good internal consistency, test–retest reliability, and validity ([Costa & McCrae, 1992](http://www.sciencedirect.com/science/article/pii/S000579670500104X#bib11)). In our sample, the Cronbach’s alpha for the total score and each subscale (openness to experiences, 0.5321; conscientiousness, 0.6019; extraversion, 0.7566; agreeableness, 0.3169; emotional stability, 0.7241) was **excellent/poor**.

*Stress:* The Perceived Stress Scale–4 (**PSS4**) is an abbreviated, 4-item Likert format scale designed to measure the degree to which situations in one’s life are appraised as stressful (Cohen et al., 1983). The PSS is a validated, publicly available, and widely used psychological instrument for measuring stress. Each item asks the participant to appraise his or her feelings and thoughts using a 5-point Likert scale (0 =*never*, 4 = *very often*). The Cronbach’s alpha for our sample was 0.8707.

*Distress:* Depression, Anxiety, and Stress Scales-21 (**DASS-21**; Lovibond & Lovibond, [1995](https://link.springer.com/article/10.1007/s12671-013-0247-1#CR26)): an abbreviated, 21-item, Likert-style scale to assess levels of distress on three subscales: depression, anxiety, and stress, based on how one felt over the past week. The DASS-21 has been used in prior studies assessing the benefits of mindfulness in undergraduate students (Gallego et al., 2014). It consists of 21 items with seven items per subscale, scored on a four-point scale ranging from 0 = *did not apply to me at all* to 3 = *applied to me very much* *or most of the time*.The total score sums all items. In our sample, Cronbach's alpha for the total score and each subscale (overall Cronbach’s α = 0.9274; depression, 0.9153; anxiety, 0.79, stress, 0.8132).Higher scores indicate higher levels of distress.

*Resilience (coping):*Connor–Davidson Resilience Scale (**CD-RISC**; [Connor & Davidson, 2003](http://www.sciencedirect.com/science/article/pii/S000579670500104X#bib9)): The CD-RISC is a 25-item scale that measures the ability to cope with stress and adversity. Items include: “I am able to adapt when changes occur,” “I tend to bounce back after illness, injury, or other hardships,” and “I am able to handle unpleasant or painful feelings like sadness, fear, and anger.” Respondents rate items on a scale from 0 (*not true at all*) to 4 (*true nearly all the time*). A preliminary study of the psychometric properties of the CD-RISC in general population and patient samples showed it to have adequate internal consistency, test-retest reliability, and convergent and divergent validity ([Connor & Davidson, 2003](http://www.sciencedirect.com/science/article/pii/S000579670500104X#bib9)). In the current sample that held true as well with the Cronbach’s α = 0.9273. This measure has been used in studies that assess resilience across the lifespan (Campbell-Sills et al., 2006).

*Self-esteem:* The Rosenberg (1965) self-esteem scale (**RSES**), is a self-esteem measure widely used in social-science research, with a scale of 0 (*low*) to 30 (*high*). It is a ten-item Likert-type scale with items answered on a four-point scale—from strongly agree to strongly disagree. It has been used extensively in research and has demonstrated good internal consistency, test–retest reliability, and validity. In the sample, Cronbach's α = 0.9181.

*Mindfulness:* Improvement in mindfulness has been associated with better health outcomes in both medicine and psychology, but mindfulness can be problematic to measure, because practicing mindfulness meditation often leads people to become more aware of how easily the mind can become distracted. The **MINDSENS** is a composite index consisting of selected items from two other mindfulness questionnaires (**The Five Facet Mindfulness Questionnaire and Experiences Questionnaire**) that showed the strongest response to practice. The MINDSENS index was able to correctly discriminate daily meditators from non-meditators in 82.3% of cases (Soler et al., 2014). Decentering, a specific component of mindfulness related to learning how to separate from one’s own thoughts and emotions, will be assessed with the **Experiences Questionnaire** (Fresco 2007).

Due to the length of the FFMQ, this measure has been abbreviated to 10 questions (Nos 1, 19, 20, 21, 24, 26, 29, 31, 33, 36), the ones required to calculate the MINDSENS Index.

The current sample demonstrated **good/bad** internal consistency with a Cronbach’s α = 0.8129. Higher scores indicate increased mindfulness.

Interoceptive self-awareness: Interoception refers to the signaling and perception of internal bodily sensations, which we will assess using the validated Multidimensional Assessment of Interoceptive Awareness (MAIA) (Mehling et. al., 2009 and 2012). The MAIA is a relatively new scale, with good validity and reliability in studies to date (Mehling et. al., 2009 and 2012; Bornemann et. Al., 2014). In our sample, the Cronbach’s alpha for each subscale (Noticing, 0.7194; Not Distracting, 0.6096; Not Worrying, 0.5125; Attention Regulation, 0.8727; Emotional Awareness, 0.8719; Self Regulation, 0.8026; Body Listening, 0.8304; Trusting, 0.8889) was **excellent/poor.**

*Emotion regulation:* Emotion Regulation Questionnaire (**ERQ**) (Gross & John, 2003). The ERQ assesses two specific emotion regulation strategies, suppression and reappraisal. The ERQ comprises 10 items (5 for suppression and 5 for reappraisal) rated from 1 (*never do this*) to 7 (*always do this*). The ERQ has demonstrated strong psychometric properties in both (Spaapen et al., 2014) and our current sample (Cronbach’s α for cognitive reappraisal = 0.89, and for expressive suppression = 0.7943).

*Sleep:* Sleep quality will be assessed using the The Pittsburgh Sleep Quality Index **(PSQI) (**Buysse et al, 1989), a commonly used, validated and reliable measure of sleep quality. Higher scores indicate worse sleep dysfunction. The Cronbach’s α in the current sample was 0.5174.

*Self-Regulation of Eating:* The Self-Regulation of Eating Behavior Questionnaire (SREBQ) is a short, Likert format questionnaire comprising of two dichotomous screener questions, one directional question to bring tempting foods to mind, and five Likert-format items assessing respondents’ self-regulation of eating. The five Likert-format items span a five-point scale from *Never* to *Always*. The SREBQ has been shown to be reliable and valid (Kliemann et al., 2016). In the current sample, Cronbach’s α was 0.7785.

*Motivation Survey:* Before the intervention took place, participants were asked to fill out an optional survey regarding their motivation to complete the study (Table \_\_). For the first

*Student Adherence:* Adherence is defined as the degree to which an intervention is exactly followed (Segal et al., 2002) Adherence was assessed utilizing a combination of factors: debriefings between the researchers and participants, self-report surveys that were distributed electronically every two days of the intervention, and the reported minutes per week from the Muse and 10% Happier app, and the Satisfaction Survey. The ranking system went as follows (1) - poor; less than 100 total minutes, (2) - okay; between 100-150 minutes, (3) - good; between 150-225 minutes, (4) - great; between 225-300 minutes, (5) excellent; above 300 total minutes.

*Experience Score:* Participants were given an experience score upon completion of the study. The methodology of assigning the score was as follows: (0) - was not beneficial whatsoever, (1) - satisfactory/small benefit, (2) - good/multiple aspects of life improved slightly,p85658960tywefc (3) - great/multiple aspects of live improved, (4) - life-changing/dramatic improvement in lifestyle. Scores were based on debriefings between the researchers and participants and the Satisfaction Follow Up questionnaire.

**3. Results**

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# **Table 1. Overview of the variables’ instruments and sources**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **utcome** | **Variable name** | **Instrument Name** | **Abbrev.** | **Subscales** | **Time of measurement** | **Variable type** | **Study** |
| Primary Mental Health | Distress | Depression, Anxiety, and Stress Scales-21 | DASS-21 |  | T1, T2 | Outcome | **EEG** |
|  | Anxiety | Depression, Anxiety, and Stress Scales-21 | DASS-21 | Anxiety | T1, T2 | Outcome | Main |
|  | Stress (perceived) | Depression, Anxiety, and Stress Scales-21 | DASS-21 | Stress (perceived) | T1, T2 | Outcome | Main |
|  | Depressive symptoms | Depression, Anxiety, and Stress Scales-21 | DASS-21 | Depressive symptoms | T1, T2 | Outcome | Main |
| Secondary Mental Health Outcomes | Perceived Stress | Perceived Stress Scale-4 | PSS4 |  | T1, T2 | Outcome | Main |
|  | Resilience | Connor-Davidson Resilience Scale | CD-RISC |  | T1, T2 | Outcome | Main |
| Physiological Outcomes | Physiological stress | Cortisol (salivary) | Cortisol |  | T1 waking, T1 30 min, T1 pm, T2 waking, T2 30 min, T2 pm | Outcome | Main |
|  | Inflammation | C-reactive protein (salivary) | CRP |  | T1, T2 | Outcome | Main |
| Health Behaviors | Sleep | Pittsburgh Sleep Quality Index | PSQI |  | T1, T2 | Outcome | Main |
|  | Eating behavior | Self-Regulation of Eating Behavior Questionnaire | SREBQ |  | T1, T2 | Outcome | Main |
| Target Mechanisms | Mindfulness | MINDSENS Composit Index (FFMQ + EQ) |  |  | T1, T2 | Outcome, moderator | Main |
|  | Interoception | Multidimensional Assessment of Interoceptive Awareness | MAIA |  | T1, T2 | Outcome, moderator | Main |
|  | Emotion Regulation - Suppression | Emotion Regulation Questionnaire | ERQ | suppression | T1, T2 | Outcome, moderator | Main |
|  | Emotion Regulation - Reappraisal | Emotion Regulation Questionnaire | ERQ | reappraisal | T1, T2 | Outcome, moderator | Main |
|  | Decentering | Expereinces Questionnaire | EQ |  | T1, T2 | Outcome, moderator | Main |
| Student characteristics | Self-esteem | Rosenberg (1965) self-esteem scale | RSES |  | T1, T2 | Outcome, moderator | Main |
|  | Personality | Big Five Personality Inventory |  |  | T1, T2 | Outcome, moderator | Main |
|  | Motivation | Developed for this study |  |  | T1 | Outcome, moderator | Main |
| Demographics | Demographics | Developed for this study |  |  | T1 | Outcome, moderator | Both |
| Student experience | Continueing Meditation | Long-term Follow-up Survey |  |  | F1, F2, F3 | Outcome | Main |
|  | Tool Satisfaction | Developed for this study |  |  | T2 | Outcome | Both |
|  | Adherence | Developed for this study |  |  | T2, 48 hr surveys | Outcome | Both |
|  | Adverse experiences/issues | Developed for this study |  |  | T2, 48 hr surveys | Outcome | Both |
|  | Post-meditative state | Developed for this study |  |  | 48 hr surveys | Outcome | Main |
| EEG outcomes | Bird Count | From Muse app |  |  | T1, T2 | Outcome | EEG |
|  | % Time Calm | From Muse app |  |  | T1, T2 | Outcome | EEG |