# 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 seek 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 to explore moderators of intervention experience. 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). 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 (Chiappetta et al, 2020).

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 help to build resilience may help students deal 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. Education online 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 spaces, university mental health centers seek effective behavior change tools that help students with coping and mental health.

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). 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 provided for them, easy to access and utilize, etc. 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 demonstrate that shorter, i.e., 4-6 week mindfulness-based interventions can also be helpful (Jain et al., 2007; Mackenzie et al., 2006; Demarzo et al., 2017). A 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 explore 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 Muse neurofeedback tool provides additional benefits beyond the meditation app alone, for any outcome.

Hypotheses to test 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.

**Method**

***Location***

The study will take place at the Storrs campus of the University of Connecticut, a large, public research university in a rural section of southern New England. The orientation will take place in the meditation room that is located on the main floor of the University’s Counseling and Mental Health Services (CMHS). Participants will be asked to meditate every day, using this room at least twice a week during the intervention. EEG measurements, saliva drop off and debriefings will take place in a private research office space in the Psychology Building, located adjacent to CMHS.

***Participants***

We anticipate enrolling a total of 140 university students to participate in the study who are interested in developing a meditation practice to self-manage stress. We base this estimate on power analysis that assumes a medium effect size will result on the primary measures (and power=0.80, alpha=0.05), then n=136 is reasonably powered. Note that we may need to screen upwards of 500 subjects in order to enroll these numbers. We will run multiple study waves during a single semester and conduct the study over two semesters.

Participants will be 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 will respond via email if interested in the study. Participants will then receive two emails, one to obtain informed consent electronically and one to determine inclusion/exclusion criteria. Participants will be excluded if they are under the age of 18 years, have difficulties understanding English, or if they had engaged in previous meditation practice.

***Random assignment.*** Random assignment will be accomplished by using a random number generator (e.g., RAND function in Excel, which returns an evenly distributed random real number greater than or equal to 0 and less than 1) for each participant, then participants will be sorted and split into the two treatment groups based on the random number.

***Procedure***

Eligible participants will be asked to complete the baseline questionnaires and sign up for an orientation time slot via email. All questionnaires are conducted through REDCap. Table 1 contains the schedule of enrolment, interventions, and assessments, using SPIRIT template (SPIRIT, 2020). Figure 1 illustrates the study timeline.

***Orientation.*** A one-hour group orientation will take place at the start of the intervention, located in a meditation room in Counseling and Mental Health. Orientation groups will be small (e.g., 5-10 participants) and will be led by the study coordinator (a meditation instructor with 15 years teaching experience); the sessions include an introduction to mindfulness meditation, guided meditation, and group discussion about establishing a daily meditation practice. The guided meditation will include instructions to mindfully place and return attention to a single point of focus (e.g., breath, sensation, color visualization, or mantra). All anchor points will be practiced as a group, and participants will be asked to select which anchor worked best for them. Instruction is provided on the fundamental elements of mindfulness, along with tips for helping to integrate the habit of meditation and mindfulness into daily life. Instructions are provided at orientation for the remaining portion of the study, which includes returning to the meditation room during business hours at least twice a week during the one-month intervention period, to practice meditating with assigned tools. After orientation, participants are asked to make individual appointments with the study coordinator to collect baseline EEG measures while meditating for five minutes.

***Saliva collection procedures***. During orientation, procedures and materials are provided for collecting saliva for biomarker assays. Participants are instructed to collect saliva at home at three points throughout the day; immediately upon waking, one a half hour later, and one in the late evening. Specific instructions are provided to reduce risk of contamination (e.g., avoiding alcohol). To facilitate saliva collection, participants will be given three disposable ‘straws’ that insert into the vial, and three labeled vials with color-coded caps that are labeled with the participant ID and collection times for the saliva sample. The participants are then instructed to freeze the saliva and return it to a cooler on ice within the lab, where the experimenters will transfer the samples to the freezer for storage.

***Intervention.*** Upon completing the orientation session, the one month self-guided meditation program will commence. Both groups will be asked to use the meditation app, 10% Happier (<https://www.tenpercent.com/>), at least twice a week. Participants in the Muse group are also asked to use the Muse at least twice a week, in addition to 10% Happier. In both groups, participants are 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. Prior to starting the intervention, participants are asked to schedule an appointment with the primary researcher to acquire a baseline EEG reading using the Muse (see below). The intervention consists of a four-week practice of self-guided meditation in which participants are asked to meditate for 10 minutes every day. Adherence is encouraged via email reminders that included a brief survey sent every other day and is also monitored by asking participants to produce screenshots of the apps at the debriefing. Upon completing the intervention, participants fill out post-questionnaires online and schedule a follow-up meeting with the research coordinator, where post-EEG data is collected using the same procedure as baseline using the Muse app and device; at the follow-up meeting, participants are asked to show their app usage times from their phone and confirm how much they meditated each week on average. They are then debriefed, thanked, and compensated with a $20 Amazon Gift Card for taking part in the study.

***Muse group.*** Participants assigned to the Muse Group will be provided access to eight Muse devices for the duration of the study month, which they can sign out using their student ID at the main office of Counseling and Mental Health. 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 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). Participants in the Muse group are asked to use the Muse at least twice a week, and also try using the 10% Happier app at least twice a week. During the remaining days, they are encouraged to use whichever tools worked best for them (e.g., 10% Happier, Muse, or any of the self-guided techniques taught in the orientation).

***App group.*** 10% Happier is an app that contains guided meditations typically five to ten minutes in length, written and delivered by a variety of reputable meditation instructors. All students will be provided with a code for full access to the app for free, for 6 months. The app group is asked to use the meditation app, 10% Happier, at least twice a week. During the remaining days, they can continue using the app, or use any of the self-guided techniques taught in the orientation.

***EEG Recording Procedure***

To evaluate if Muse’s EEG outcomes serve as a proxy for mindfulness meditation progress, EEG recording of baseline and follow-up brain wave activity during a five-minute meditation was collected in individual sessions with the research coordinator and were held in a small private office space, which lasted approximately 10 minutes. During the individual sessions, participants were asked to wear the Muse headband, which was connected to the research team’s mobile device via Bluetooth. Participants were told that they were going to be asked to meditate for five minutes while their brain waves were recorded and that they should meditate using their own preferred anchor point (e.g., breath, sound/mantra, bodily sensations), which was based on what worked best for them during orientation (at baseline) or in their daily practice (at follow-up). Next, the researcher ensured that the participant was comfortable with the instructions, which included sitting still and upright in a chair, feet flat, eyes closed, taking a few deep breaths to relax, and preparing to meditate. Then, the researcher offered to exit the room to allow the participant to meditate in privacy or to remain in the room and meditate alongside the participant during the five-minute session. All participants chose to have the researcher remain in the room. Participants followed the instructions played out loud from the Muse app for calibration. Following calibration and instructions from Muse to begin meditating, the researcher turned off the volume so the participants could begin meditating on their own in silence (with no aural feedback). After five minutes, the researcher notified the participant that the meditation session ended. Participants were able to look at their outcome measures displayed on the Muse app after their meditation session.

***Instruments***

Table 2 presents an overview of the measures to be used at each assessment point for the current study.

**Primary mental health outcomes:**

*Distress:* The 21-item Depression, Anxiety, Stress Scale (DASS-21; Henry & Crawford, 2005; Lovibond & Lovibond, 1995) is a self-report measure in which participants rate the frequency and severity of experiencing negative emotions over the past week and is translated into the severity of stress, anxiety, and depression. The measure can be used to assess the current state or change in the state of the severity of stress, anxiety, and depression. Frequency and severity are translated to a 4-point Likert Scale (*0 = did not apply to me at all - NEVER, 1 = applied to me to some degree or some of the time - SOMETIMES, 2 = applied to me to a considerable degree or a good part of the time - OFTEN, 3 = applied to me very much or most of the time - ALMOST ALWAYS*). In this study, stress, anxiety, and depression will be measured by calculating the summation of scores for the items relevant to each given category, with higher scores indicating increased severity. These scores will then be combined to create a DASS-21 total score, which we refer to as mental health throughout the study, with lower scores on DASS-21 marking higher levels of mental health. As such, the direction of the effect size was set to use positive values to represent improvements.

The reliability and validity of DASS-21 are considered adequate with data applied to non-clinical populations (Henry & Crawford, 2005); internal consistency on the DASS-21 is high in our sample, with a Cronbach’s α of 0.92. Decreases in the severity of elements of the DASS-21 correlates with the practice of mindfulness meditation (Myint et al., 2011; Schreiner & Malcolm, 2008; van der Zwan et al., 2015).

**Secondary mental health outcomes:**

*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*).

*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).

**Physiological Outcomes:**

We plan to capture physiological outcomes through saliva samples for a sub-sample of participants in our study.

*Physiological stress:* Salivary cortisol levels, collected at 3 timepoints in a 24-hour period both before and after the intervention, will be immediately frozen, stored and later shipped and processed at Salimetrics. Many studies document immediate changes in salivary cortisol in response to stress inducing or reducing activities (e.g., yoga, animal therapy; Sullivan et al., 2019; Pendry & Vandagriff, 2019), but less is known about long term changes in cortisol levels of adolescent and young adults following a month-long intervention.

*Inflammation:* Salivary c-reactive protein levels, collected 30 minutes after waking, before and after the intervention, will be immediately frozen, stored and later shipped and processed at Salimetrics. Studies show C-reactive protein may be implicated in the relationship between inflammation and depression (e.g., Vogelzangs et al., 2012), and CRP levels are higher in young adults with depression compared to controls (Sawyer, 2016).

**Health Behaviors:**

*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.

*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).

**Target Mechanisms for examining moderators:**

### *Mindfulness:* The MINDSENS (Soler et al., 2014) is a self-report composite index of mindfulness comprised of ten questions from the Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2006) and nine from Experiences Questionnaire (EQ; Fresco et al., 2007) that displayed the strongest response to mindfulness meditation practice. The questionnaire focuses on the facets of observing (e.g., “I pay attention to how my emotions affect my thoughts and behavior”), non-reactivity (e.g., “When I have distressing thoughts or images, I just notice them and let them go”), and decentering (e.g., “I can separate myself from my thoughts and feelings”) (Soler et al., 2014). A total score on the MINDSENS is calculated by averaging all 19 items together; higher scores indicate greater levels of mindfulness. The MINDSENS has successfully distinguished daily meditators from non-meditators in 82.3% of cases (Soler et al., 2014).

*Interoception*: 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).

*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 (Spaapen et al., 2014).

*Decentering:* 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).

**Student Characteristics:**

*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.

*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)).

*Motivation Survey:* Before the intervention took place, participants were asked to fill out an optional survey regarding their motivation to complete the study.

**Student Experience:**

*Post-Intervention Interview:* During the debriefing, participants were asked about their meditation practice, the meditation room, how they felt about the tools they used. They were also asked to rate how motivated they were to continue meditating, and if they would be interested in attending more group sessions. They were asked to pull up the Muse and 10% Happier apps on their phones to show how much they used each.

*Student Adherence:* Participants will be assigned an adherence score based on the amount of time/days spent meditating over the course of the intervention, using data from a combination of sources: 1) amount of time spent meditating per week, as reported by participants on the satisfaction survey, 2) amount of time spent meditating per week, as reported by participants in person when asked by the research coordinator during the debriefing meeting, 3) number of sessions using Muse and 10% Happier app, according to the app profile display on participants’ phones, which was displayed to the research coordinator during the debriefing, and 4) self-report surveys that are distributed electronically every two days during the intervention. Adherence scores will be developed *a priori* to the primary analysis, based on the range as follows: 1) high: meditated over 160 minutes total (16+ sessions; 4+ times per week, 2) medium: meditated 120-160 minutes total (12-16 sessions; 3-4 times per week, or 3) low: meditated less than 120 minutes total (less than 12 sessions; less than 3 times per week). If there are discrepancies between self-reported meditation adherence and app minutes, objective data collected from the app profile display will be used to generate the adherence score.

***Satisfaction Survey.***

To enable comparison of satisfaction with Muse and 10% Happier App, and to evaluate aims of the study as promoted in the recruitment material that stated “Do you want to learn skills to self-manage stress?”, participants will complete an online survey following the four-week mediation intervention which asks the following questions: “*Did you feel the [devices] were helpful for learning how to meditate*?” and “*Do you feel like your meditation practice is helping to provide you with skills to self-manage stress*?”

***Monitoring for Adverse Experiences.***

Participants will be monitored by the research team for adverse events through the self-report surveys that are distributed electronically every two days during the intervention and through the satisfaction survey. As the study was located at and co-hosted by the University Counseling and Mental Health Center (CMHS), participants will be instructed to contact the office at CMHS if a major adverse experience occurs.

**EEG-measurements.**

### *Percent Time Calm and Bird Count:* While participants meditated with the Muse device on in “silent” mode, two EEG measurements were obtained from the Muse app: 1) percent time calm and 2) bird count (each bird is meant to represent an extended period of time in the calm zone). These are the two main measures that the Muse app provides to the user as feedback through a summary report, following the meditation session. There is no existing research on the reliability or validity of either of these measurements as measuring successful mediation practice.

**Statistical Analysis**

Paired *t*-tests will be conducted to compare within-group changes in each outcome measure at baseline and post-intervention. A probability value of less than 0.05 (*p <* .05) will be considered significant. Becker’s (1988) *d* values will be calculated and reported as a measure of within-group effect size (Becker's *d* is similar to Cohen’s *d*, but performs better than for within-group standardized mean differences (Johnson & Huedo-Medina, 2013). Becker’s norms will be used to determine if effect sizes are small (≥ 0.20), medium (≥ 0.50), or large (≥ 0.80). Ninety-five percent confidence intervals of the effect sizes will be calculated. Improvements will be coded as positive for both effect size and confidence interval.

To determine if there are differences in performance on any measures between the two treatment groups, analyses of covariance (ANCOVAs) will be used. The dependent variables are the outcome measures at post-test (e.g., mental health outcomes), the independent variables are the conditions and the covariates are the pre-test (baseline) measurements of the outcome measures. The effect of potential categorical and continuous moderators on the effectiveness of the mindfulness intervention on the primary and secondary outcomes will be examined by adding the moderators to the ANCOVAs. Data will be de-identified and imported from an online server software (i.e., REDCap) and will be securely stored at the server at the University of Connecticut where data back-ups will be performed regularly. Data analysis will be performed in Excel and Stata.

**Discussion**

This study protocol introduces the design of a registered RCT investigating the effectiveness of two self-guided mindfulness-based interventions for university students. One intervention uses a meditation app, and the other uses the meditation app plus an EEG neurofeedback tool designed to assist people in learning how to meditate. The purpose of these interventions is to assist universities in selecting tools to teach students how to mediate to improve mental well-being. The study will also help determine if such programs can also assist with improving important physiological markers of health, and health behaviors. We will use a sufficiently large sample size that was established based on power analysis, to allow investigation of differences between groups.

Recruiting a diverse sample of students is a priority of this work, as many previous mindfulness studies consist of mostly white and female participants. To attract males and students with diverse races and ethnicities, specific wording was selected and images were used in recruitment flyers to target diverse demographics. The study will be advertised through the Cultural Centers at the University of Connecticut, and through other groups that have higher numbers of males and/or students of diverse backgrounds.

There were other challenges to this study, which include a large number of instructions for participants to follow, especially considering that the majority of the intervention is self-guided. To facilitate collecting salivary biomarkers, students will be given the option to opt out of this portion, and still participate in the study. Those participating will be given necessary supplies to take home and return to the lab at times that were convenient for them. A separate email address was established for the study to allow participants to reach the research coordinator directly, if any issues arose with technology or saliva collection. Although this was a self-guided intervention, all participants will participate in a in-person, 1-hour orientation, that will teach them how to meditate and review instructions for the intervention .This orientation will take place in the same meditation room that students will be instructed to use for the intervention period. The orientation was delivered in small groups to help establish understanding, accountability and increase adherence.

One primary analysis challenge is a lack of a non-treatment control group as both groups received some form of an intervention to increase mindfulness. It is possible that results from the two groups may not differ, and both may improve equally. To determine the magnitude of change over time within groups, pre/post effect sizes will be calculated to allow comparison to existing studies. Another challenge will be in our assessment of intervention adherence. Methods here describe multiple strategies will be used to evaluate adherence, and how to handle discrepancies if they arise.

The current protocol describes an intervention that will include two waves of data collection, taken over two semesters, and evaluated with two studies. One study will examine a subset of data collected from wave 1, focusing on the primary outcome and EEG scores. The second study will evaluate the full dataset, minus the EEG scores. Together, the results of these studies will inform university mental health clinics seeking to develop easy to use, scalable programs to build students’ coping skills in order to address the growing concerns around mental health and access to care.

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This project was funded in part through grants received through the University of Connecticut’s Office of Undergraduate Research. The Counseling and Mental Health Department at the University of Connecticut provided space for the study as well as purchased Muse devices. 10% Happier donated promotion codes to the study to allow free access to the full version of the 10% Happier app, for all study participants.

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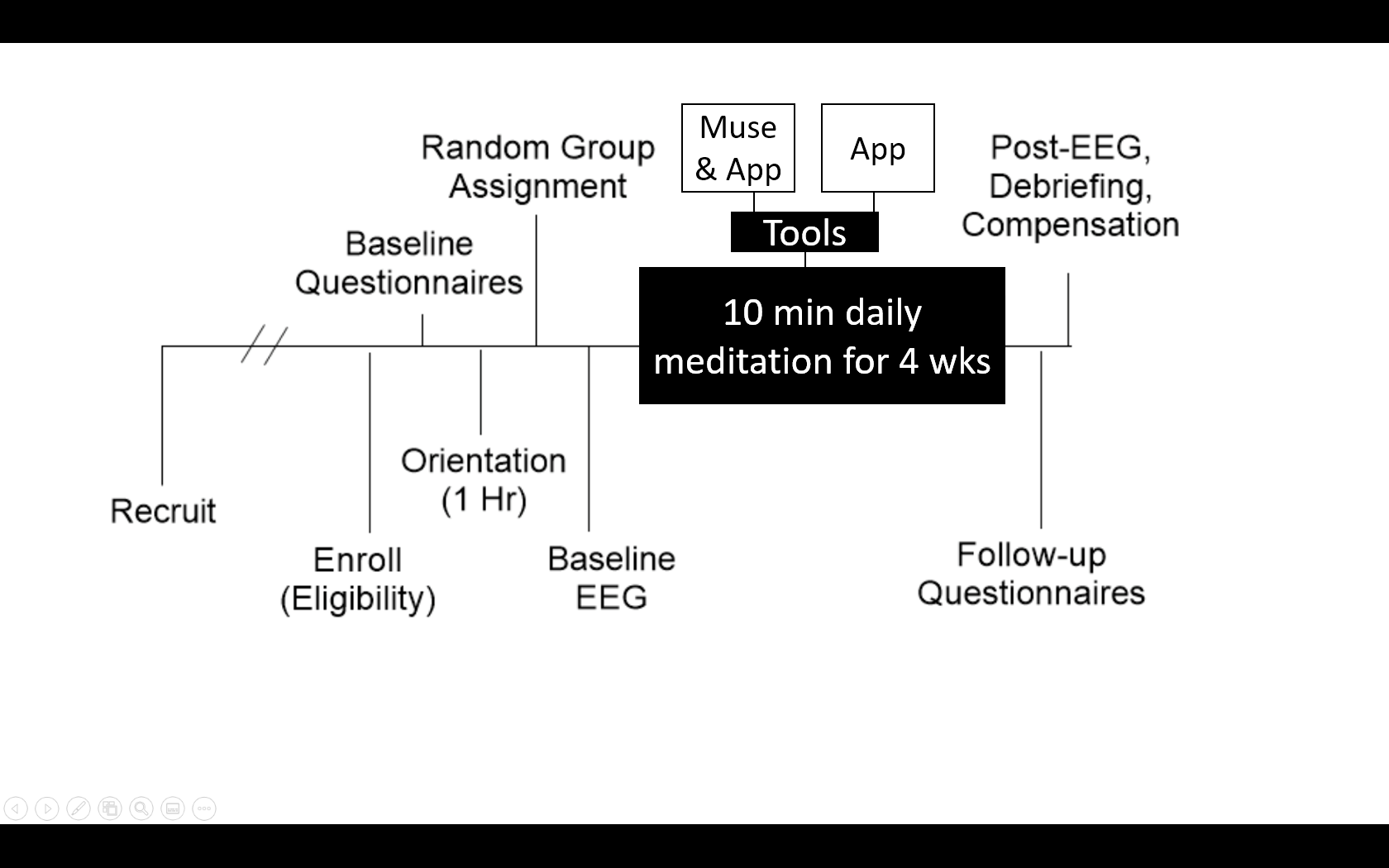
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# **Table 1.** Schedule of enrolment, interventions, and assessments, using SPIRIT template

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **STUDY PERIOD** | | | | | |
|  | **Enrolment** | | **Allocation** | **Post-allocation** | | | **Close-out** |
| **TIMEPOINT\*\*** | ***-t1*** | | **0** | ***1 month*** | ***2 months*** | ***7 months*** | ***13 months*** |
| **ENROLMENT:** |  | |  |  |  |  |  |
| **Eligibility screen** | X | |  |  |  |  |  |
| **Informed consent** | X | |  |  |  |  |  |
| **1 Hour Orientation** | X | |  |  |  |  |  |
| **Allocation** |  | | X |  |  |  |  |
| **INTERVENTIONS:** |  | |  |  |  |  |  |
| ***App group*** |  | |  |  |  |  |  |
| ***Muse group*** |  | |  |  |  |  |  |
| **ASSESSMENTS:** |  | |  |  |  |  |  |
| Demographics, medical history, motivation | X | |  |  |  |  |  |
| Time calm (%) and bird scores during meditation (5 minutes) |  | | X *(n = 52, Wave 1 only)* | X *(n = 52, Wave 1 only)* |  |  |  |
| Salivary biomarkers | X (n = 20) | |  | X (n = 20) |  |  |  |
| Meditation tool use; adverse experiences (every 48 hours) |  | | X | X |  |  |  |
| Distress, anxiety, stress, depressive symptoms, resilience, sleep, eating, mindfulness, emotion regulation, interoception, decentering, self-esteem, personality | X | |  | X |  |  |  |
| Satisfaction |  | |  | X |  |  |  |
| Meditation practice |  | | X | X | X | X | X |



# **Figure 1.** Schematic diagram of the study timeline.

# **Table 2.** Overview of the variables’ instruments and sources

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Outcome** | **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 wake, T1 30min, T1 pm, T2 wake, T2 30min, 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 | Emotion Regulation Questionnaire | ERQ | Suppression, Reappraisal | T1, T2 | Outcome, moderator | Main |
|  | Decentering | Experiences 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 | Continuing 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 |

Note: T1=Baseline, T1=Post intervention, F1=1 month post intervention, F2=6 months post intervention, F3=12 months post intervention