# School-based mindfulness intervention for stress reduction in adolescents: Design and methodology of an open-label, parallel group, randomized controlled trial

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ABSTRACT

Adolescents are in a high-risk period developmentally, in terms of susceptibility to stress. A mindfulness intervention represents a potentially useful strategy for developing cognitive and emotion regulation skills associated with successful stress coping. Mindfulness strategies have been used successfully for emotional coping in adults, but are not as well studied in youth. This article details a novel proposal for the design of an 8-week randomized study to evaluate a high school-based mindfulness curriculum delivered as part of a two semester health class. A wellness education intervention is proposed as an active control, along with a waitlist control condition. All students enrolled in a sophomore (10th grade) health class at a private suburban high school will be invited to participate ($n = 300$). Pre-test assessments will be obtained by youth report, parent ratings, and on-site behavioral testing. The assessments will evaluate baseline stress, mood, emotional coping, controlled attention, and working memory. Participants, divided into 13 classrooms, will be randomized into one of three conditions, by classroom: A mindfulness intervention, an active control (wellness education), and a passive control (waitlist). Waitlisted participants will receive one of the interventions in the following term. Intervention groups will meet weekly for 8 weeks during regularly scheduled health classes. Immediate post-tests will be conducted, followed by a 60-day post-test. It is hypothesized that the mindfulness intervention will outperform the other conditions with regard to the adolescents' mood, attention and response to stress.

## 1. Introduction

Stress is a common experience among adolescents [8] with potentially significant health impacts and risk. Yet its impact on mental and physical health within this population is often minimized and misunderstood [8,27]. In 2013, more than thirty percent of adolescents surveyed reported feeling overwhelmed, depressed or sad due to stress [1]. Furthermore, lifetime criteria for a diagnosable mental health problem was reported in nearly half (49.5%) of a nationally representative sample of more than 10,000 adolescents in the United States, and 40% of these individuals met criteria for more than one disorder [30]. Unmanageable stress in adolescence can come from myriad sources including rapid

socioemotional changes [25], identity development and autonomy of choices [11], as well as the mounting pressure of school performance and responsibilities [23].

Chronic or unmanaged stress can cause difficulties in development [23], and lead to long-term setbacks in physical and mental health [8,15]. Distressed teens are at higher risk for anxiety disorders [8], depression [25], behavioral problems and suicide [27]. Adolescent stress levels have been associated with risky sexual behavior [27], smoking, substance abuse, self-harm [6,19], and poor eating habits [7].

Mindfulness interventions represent a potential strategy for developing the skills and insights associated with the ability to cope with stress. Psychoeducational training approaches for mindfulness have shown success addressing the mental health in people with chronic physical health problems such as diabetes [21], and the stress associated with having cancer [28]. Mindfulness interventions have also been helpful in improving the mental

health of adults with chronic disease [3]. Researchers have also found moderate symptom improvement for anxiety and depression symptoms using mindfulness approaches [20]. In a feasibility study of an 8-week mindfulness intervention for adults and adolescents with ADHD [38], mindfulness improved attention, mood, and self-management skills, while reducing stress. A pilot trial of a mind-fulness curriculum, delivered in a classroom setting to 120 high school seniors, found participants reported decreased negative affect and increased feelings of relaxation and self-acceptance after completing the class [5]. In a meta-analysis of healthy adults, Mindfulness-Based Stress Reduction (MBSR) reduced ruminative thinking and increased empathy and self-compassion [9].

The current study described here will include a large number of students in an open-label randomized controlled trial. The study will evaluate the feasibility of embedding a mindfulness curriculum into a two semester high school health class to reduce student stress, and to improve mood and attention. The study intervention will focus on teaching mindfulness skills through the integration of mindful thinking, mindful movement and meditation, with specific the curriculum components explained below. The rationale is that teaching adolescents stress-coping skills during this important developmental period may reduce the frequency and severity of stress-related mental and physical health issues [2,33]. Addition-ally, adolescents may learn techniques to help them effectively interact with peers, teachers and parents, thus increasing their social and emotional abilities, with potential benefit to academic outcomes [18]. This article details the methodology and design of this novel trial of mindfulness compared to two controls, delivered within a high school health curriculum.

## 2. Study aims

The primary aims of this study are to evaluate the feasibility of providing an 8-week mindfulness intervention delivered by a psychologist resident as part of the high school curriculum, and to examine the effectiveness of mindfulness, in comparison to an active control and a waitlist, in helping adolescents cope effectively with stress. These aims will be examined in relation to student- and parent-reports of intervention credibility, as well as mood, stress and attention levels pre- and post-intervention. Mood and stress will be measured by student-reports on the Depression Anxiety and Stress Scale-21 (DASS-21) [29,34], and the Perceived Stress Scale (PSS) [12]; attention, by self- and parent-reports on the Conners 3 [13]. The effect of the mindfulness intervention will be compared to the wellness intervention, and the waitlist control, which is the usual health class curriculum. Based on previous findings, we anticipate that mindfulness will improve mood, attention and stress levels in comparison to the other two conditions.

Secondary aims are to test whether the mindfulness or wellness interventions lead to relative improvements in attention and stress reactivity as measured by behavioral tasks of attention and physi-ological measures of stress response.

## 3. Study design

This single-site parallel group, randomized controlled trial, with waitlist, will deliver an 8-week school-based mindfulness or well-ness intervention to a convenience sample of high school students enrolled in a two semester sophomore (10th grade) health class at a private suburban high school. While the participants will not be blinded to the intervention, deliberate steps will be taken to retain the study's internal validity. This will be accomplished by mini-mizing the focus on mindfulness as the hypothesized 'active' intervention and by presenting the 'control' intervention, called "wellness" as a logical and equal alternative. The study materials

will advertise "stress reduction" as the intention. Instructors will maintain equipoise for the two interventions. After parental con-sent and student assent is received, participants will be randomized into one of the three experimental conditions according to their health class: (1) the mindfulness intervention, (2) the wellness intervention, or (3) the waitlist. Participants who are on the waitlist will receive one of the active conditions in the subsequent term. Both intervention conditions will be comprised of standardized 8-week group sessions, delivered once-per-week at the high school as part of the regular health curriculum. All groups will receive a pre-intervention evaluation consisting of baseline ratings for mood, anxiety and stress, plus behavioral tests of controlled attention, and working memory. One parent will complete a baseline measure of their child's attention. After the intervention is completed, post-tests consisting of the same measures will be completed, fol-lowed by a 60 day post-test. The Institutional Review Board at Oregon Health & Science University (OHSU) has approved all study procedures. This trial is registered with clinicaltrials.gov.

### 3.1. Participants and enrollment

Participation will be open to all sophomore (10th grade) students, age range: 14–16 years, enrolled in one of the 13 health classes ($n = 300$ students). In addition, each participating student will have one parent complete questionnaires pre- and post-intervention. Parents will be notified about the study by an email from the high school principal, and health teachers will tell students about the study in class. Parents or students may opt not to participate in the data collection, but the student will remain in the class during the intervention, and participate as part of the group, as the intervention will be considered a regular class offering for the students. Parents who wish to have their student participate in the study will com-plete an online consent and questionnaires programed in the REDCap environment, a secure online data repository system. Stu-dents wishing to participate will sign an online assent form.

Participants will not be compensated for their study involve-ment, but within each of the thirteen classes, students who enroll and complete the pre- and post-intervention questionnaires will be entered in a drawing for a $20 gift certificate. The ten study sessions will involve the students spending one class period completing pre-intervention questionnaires followed by attending eight, once-per-week intervention classes, or receiving their regular health class instruction, and one class period completing post-intervention questionnaires.

### 3.2. Eligibility requirements

Inclusion criteria: (1) Students will be eligible for this study if they are enrolled in a sophomore (10th grade) health class at the participating high school, (2) have access to an iPad, cell phone or computer, (3) accept participation in the study, including willing-ness to abide by the randomization process, (4) have parent permission.

Exclusion criteria: Any student who does not choose to partic-ipate will be excluded from data collection, but not from class.

### 3.3. Randomization

Randomization will be by classroom, using an Excel random number generator. Due to the nature of the intervention, group assignment cannot be hidden from participants, but careful wording of intervention materials will de-emphasize the hypoth-esized "active" versus "control" conditions to minimize expectation effects on the part of students, parents, or teachers. "Stress reduc-tion" will be the emphasized aspect of the study.

## 4. Interventions

The intervention phases will occur during an eight-week period. Participants in both conditions will attend a 50—55 min, group-based session, delivered as part of the regular health class. Treatment fidelity will be assessed by a rater who will report on the components delivered in each session using a fidelity questionnaire designed to capture the unique, as well as any potentially overlapping, components or features of the two interventions.

### 4.1. Mindfulness

Delivered during the students' regular health class, once per week, the mindfulness intervention will be provided by a psychologist resident and licensed marriage and family therapist with more than 10 years of psychology background, including 3 years of mindfulness training. The intervention will be based on Mindfulness Based Stress Reduction (MBSR) [24] and include elements of Acceptance and Commitment Therapy (ACT) [10], and MindUP [35], a curriculum designed to teach mindfulness in the classroom. MindUP will be used specifically to teach the brain science behind mindfulness at a level appropriate to this sample. An average of 10—15 min of guided mindfulness meditation practice will be provided during each class session, in addition to the psychologist-delivered didactic material and group exercises and discussion. Students will also be provided with Headspace©, an application that will be downloaded to their iPad. This application will guide the student through 10 min of daily mindfulness practice, teaching the student how to pay attention in the present moment, with intention, and without judgment. Group discussion and activities will focus on incorporating mindfulness concepts, and their practice, into everyday life. Frequency of use data will be evaluated at the end of the intervention period through distinct codes provided to the students.

### 4.2. Wellness

A wellness control intervention will be provided over the same 8-week period, by the same instructor, in the same school during regular health class. It is a group-based intervention that introduces a number of health-promoting concepts including emotional and physical wellness. In contrast to the mindfulness material, the wellness content will focus on the "doing" aspects of stress relief including smart goal setting and planning ahead, as well as sleep hygiene and effective conflict resolution. Concepts from the 7 Habits of Highly Effective Teens will be taught including: Begin with the End in Mind; First Things First; Think Win, Win; and Sharpen the Saw [14]. Group discussion and activities will focus on incorporating the wellness concepts into everyday life. To control for the daily meditation time assigned to the mindfulness group, the students in the wellness condition will be assigned 10 min daily of TED talks or YouTube videos, on content relating to the material presented in class. The pre-selected videos are designed to improve students' skills in coping with stress. Video viewing will be monitored through self-report and discussion of videos during weekly group time.

### 4.3. Waitlist

Students in waitlisted classes will receive their regular health class curriculum, taught by their usual health teacher, for the eight weeks. Topics include personality types, learning styles, teenage brain development and the effects of drug use, among other topics.

## 5. Assessments and measures

Student assessments will be completed at their high school.

Students will complete self-report measures during regular health class, using OHSU's REDCap online questionnaire system on their iPads. Parent ratings of their student will also be completed remotely online using the REDCap system. Four domains comprise the areas assessed with primary measures: credibility, mood, stress and attention.

### 5.1. Feasibility/credibility

Students will complete a pre-intervention expectations scale, the Attitudes Towards Study Questionnaire, to measure the participants' attitudes about how logical both of the interventions seem. After the study, participants will assess the intervention's credibility with the Intervention Credibility Questionnaire. These primary measures will be used to compare treatment expectancy to credibility. Finally, the students will complete the Instructor Credibility Questionnaire, an assessment of the participant's beliefs about the credibility of the clinician who facilitated the group, given post-intervention.

### 5.2. Self-reported mood and stress

Used as a primary self-report measure, the Depression Anxiety and Stress Scale − 21 (DASS-21) [29,34], is a 21-item measure containing three scales. This 21-item version of the DASS is a reliable and valid measure of depression, anxiety and physical tension/stress in clinical and non-clinical populations of adolescents and adults [22,34]. Students are asked to use a 4-point severity or frequency scale: 0 (*Did not apply to me at all*) to 3 (*Applied to me very much, or most of the time*) to rate the extent to which they have experienced each state *over the past week*. Scores for depression, anxiety and stress are calculated by summing the scores for the relevant items. Scores offer a quantitative measure of distress along the three axes, though they are not categorical measures of clinical diagnoses of depression or anxiety. The 21-item version was developed by selecting the highest loading items from each scale of the original 42-item version of the DASS, while also aiming to retain coverage of the full symptom content of each of the three affective scales [29]. The factor structure of the DASS-21 is stable, and its scales possess good convergent and discriminant validity and high internal consistency in clinical and in non-clinical samples with a Cronbach's alpha range = 0.82—-0.93 for the three subscales and the total score [22,34].

The 10-item Perceived Stress Scale (PSS) [12] will assess students' perceived levels of stress in the previous week, as measured by self-reported thoughts and feelings. Since its inception, the PSS has demonstrated adequate reliability and validity [12]. More recent reviews of the scale with multiple sclerosis patients found the Cronbach's alpha range = 0.87—0.91 for the two subscales and total score [37].

### 5.3. Attention

Students will rate themselves on their attention and concentration levels and parents will rate their students' attention using the Conners 3. Two versions of the Conners 3 Short Form will be used: Self-Report the Parent Form [13].

### 5.4. Behavioral tasks

As secondary measures, three behavioral tasks of attention will be completed by up to five participating students from each class. Among the enrolled students, names will be drawn from those in class the day of the assessment and these students will be administered the Digit Span [36], and two subtests from the Delis-Kaplan Executive Function System (DKEFS) [17]. The Digit Span is a brief test of working memory with a score derived from the maximum

number of digits recalled. To shorten the test battery, only the backwards condition will be given. DKEFS Trail Making Test is a task of visual attention and task switching. Two conditions will be given. In condition 2, students are instructed to connect a set of dots in alphabetical order, as fast as possible while still maintaining accuracy. In condition 3, students are given the same instructions, but this time the dots must be connected by switching between a number and a letter, then back to a number, in numerical then alphabetical order. In addition to attention, these two tasks provide information about visual search speed, scanning, speed of processing, mental flexibility, as well as executive functioning. Three conditions of the DKEFS Color Word Interference will be given. Condition 2 requires students to read patches of color as quickly as possible without making any mistakes. Condition 3 requires saying the ink color the word is printed in, rather than reading the word itself, and Condition 4 requires the student to switch between saying the ink color, or, reading the word if it is in a box.

### 5.5. Physiological stress response

The randomly drawn students who complete the behavioral attention tasks and physiological measures will be administered the Portland Arithmetic Stress Task, which is a shortened version of the Montreal Imaging Stress Task [16], which itself is derived from the Trier Mental Challenge Test [26]. The task consists of a series of computerized mental arithmetic challenges, along with evaluative components and is designed to evoke temporary physiological and emotional stress by manipulating the task to be just beyond the individual's mental capacity. Upon completion of each task, the program presents a performance evaluation to further increase the social evaluative threat of the situation. Student heart rate and blood pressure will be recorded using the Omron Healthcare Wrist Blood Pressure Monitor, at three time points: prior to beginning the tasks; after completing the DKEFS tasks, just before the computerized arithmetic task; and finally, after completing all the tasks. At the same three time points, students will be asked to rate their current stress level on a Likert scale from 0 to 10.

### 6. Statistical analyses

Univariate analyses will be used to examine the data for distribution, missing values, and outliers. Bivariate analyses and scale reliability will be used to finalize the summary variables for each construct, based on planned measures. Missing data will be handled via full information maximum likelihood estimation. Because the students are nested within classrooms, to test the hypothesis that a mindfulness intervention will improve students' mood, attention and stress response relative to two control conditions, the students' responses will be compared within and between classes. This can be handled in two ways: using the CLUSTER command in MPLUS, which focuses on student-level effects adjusted for classroom level effects, or, more appropriate for most of the analyses here, will be to model class and student effects together via a hierarchical linear model, also called a multi-level model. Multilevel modeling (MLM) [32] was specifically designed for educational research, to use with nested data such as students within classes. That is, some of the variance in outcomes will be associated with variance in the students, within the class, and some of the variance will be associated with differences between the classes. Unlike Ordinary Least-Squares (OLS) regression models, which require independent error terms in predictors, MLM allows researchers to take advantage of the correlated errors of the students by including these in the model without violating OLS assumptions, enabling between- and within-variance modeling at the same time.

Prior to using MLM, its appropriateness will be evaluated by examining the extent to which variance is explained within- and between-classes by calculating the intra-class correlation coefficient (ICC) [31]. The ICC is an estimate of the ratio of between-group (or individual) variance to the total variance [31]. For example, an ICC of 0.5 would suggest there is equal variance between- and within-groups, thus conducting MLM analyses would be appropriate. If the ICC is sufficient for each outcome, a two-level MLM will be conducted with students nested within classes. While models use either maximum likelihood or restricted maximum likelihood as appropriate for each model, we expect that, barring unexpected data distributions, we will use grand mean centering and maximum likelihood models.

### 7. Discussion

This article describes the design and methodology of an open-label, parallel group, randomized controlled trial of a mindfulness intervention versus an active control, wellness education, and a passive control, waitlist, for stress reduction in adolescents. The primary aim of this study is to evaluate the feasibility and effectiveness of providing an onsite mindfulness intervention as part of the school health curriculum, to help high school-attended adolescents cope with stress.

Previous meta-analyses suggest that mindfulness mediation programs have moderate evidence for improving anxiety, depression, and pain [20], but have not published the effect sizes. Stronger study designs are needed to determine the effect size of mediation programs in improving the positive dimensions of mental health and stress related behaviors. The current study expects enrollment of at least 300 participants, which will help build off previous research of smaller sample sizes, and will publish the findings. Other research has suggested that ease of access to the mindfulness program as well as schedule flexibility is important when offering training to adolescents [38]. Addressing this need, the proposed study will offer the mindfulness curriculum as an integrated part of the regular school day, thus avoiding schedule conflicts and the potential stigma associated with seeking treatment for mental health issues. In addition, the study will offer the idea of stress prevention, as well as teach skills to help students navigate the turbulent waters of the adolescent period, using mindful thinking, mindful movement, and meditation. We anticipate that this study will contribute valuable experimentally-driven evidence to evaluate the feasibility and effectiveness of integrating mindfulness in adolescents' regular school day.

This study has several other strengths. Furthering the work of previous researchers, this study will randomize a large sample of students, by classroom, to two active control conditions as well as a waitlist. Outcome measures will be validated instruments for all participants, enabling comparisons between interventions.

This study will also extend the research by offering a holistic approach to research collection by including parent/guardian reports of attention, as well as behavioral tasks and physiological measures of attention and stress, and in addition to the usual self-reports. Typically, mindfulness studies rely on single-sources reports [4].

Despite many strong points, this study will have limitations. The participants all attend a private, college-preparatory Catholic high school, so the outcomes may not generalize to public schools, schools with a greater percentage of students from a lower socioeconomic status or schools without a religious affiliation. These students may represent a more highly motivated, but also more stressed population than students who attend public high schools. Many students and their families choose to attend this high school due to its academic rigor, strong sports and arts programs, and the school's focus on serving others. These foci of interest likely attract a unique type of student who may not represent other high school students.

Although the researchers and teachers will hold equipoise in presenting the two interventions and will attempt to downplay the exact nature of the two interventions through carefully worded materials, it is likely that participants will determine the exact intervention or that of the control group, making the participants unblinded. In addition, the potential exists for cross-contamination between the two interventions, as both will be implemented at the high school. However, the test administrators for the behavioral tasks and physiological measures of attention and stress will be blinded to the students' intervention during testing. The weekly intervention sessions will be 50—55 min in length, whereas typical MBSR studies offer longer sessions and include a day-long silent retreat.

In conclusion, this paper describes the rationale, study design and methodology of a parallel-group, randomized controlled trial aimed at comparing two active conditions, taught over eight weeks as part of a two semester health class, to help students reduce and cope with stress. This study will contribute to the growing body of literature on the potential benefits of mindfulness-based programs while addressing the feasibility of providing a high school-based intervention.

## Funding
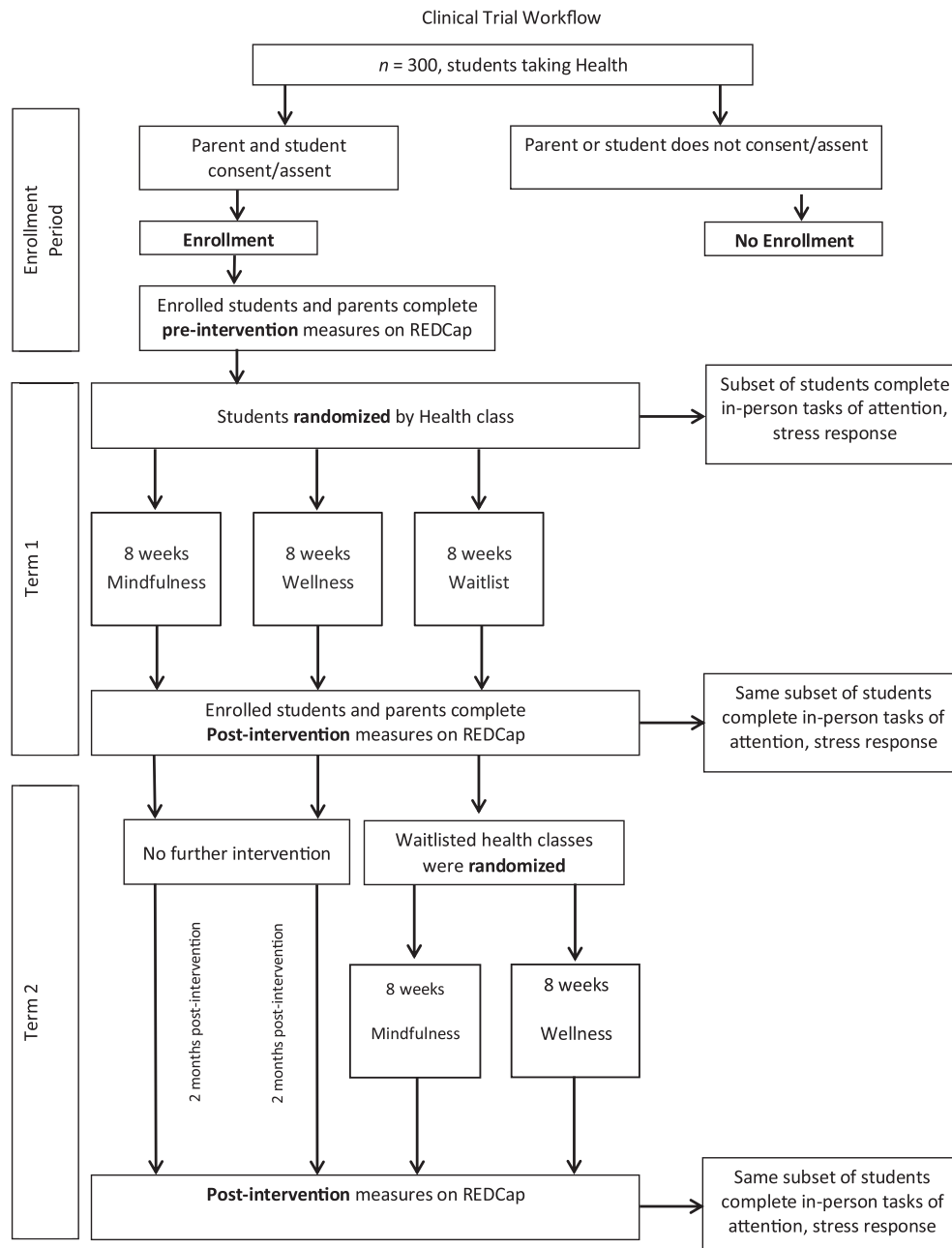
Fig. 1. Flow diagram of study enrollment, assessment and intervention phases.

## Acknowledgements

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