Contemporary Clinical Trials Communications 4 (2016) 99–104

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

# 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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ARTICLE INFO

*Article history:*
Received 17 March 2016
Received in revised form
28 June 2016
Accepted 18 July 2016
Available online 20 July 2016

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

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http://dx.doi.org/10.1016/j.conctc.2016.07.001

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 mindfulness 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]. Additionally, 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 physiological 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 wellness 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 minimizing 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 consent 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, followed 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 complete an online consent and questionnaires programed in the REDCap environment, a secure online data repository system. Students wishing to participate will sign an online assent form.

Participants will not be compensated for their study involvement, 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 willingness to abide by the randomization process, (4) have parent permission.

Exclusion criteria: Any student who does not choose to participate 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 hypothesized "active" versus "control" conditions to minimize expectation effects on the part of students, parents, or teachers. "Stress reduction" will be the emphasized aspect of the study.