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Design and methods for "Commit to Get Fit" – A pilot study of a school-based mindfulness intervention to promote healthy diet and physical activity among adolescents

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Abstract

Introduction—Cardiovascular prevention is more effective if started early in life, but available interventions to promote healthy lifestyle habits among youth have been ineffective. Impulsivity in particular has proven to be an important barrier to the adoption of healthy behaviors in youth. Observational evidence suggests that mindfulness interventions may reduce impulsivity and improve diet and physical activity. We hypothesize that mindfulness training in adjunct to traditional health education will improve dietary habits and physical activity among teenagers by reducing impulsive behavior and improving planning skills.

Methods/Design—The Commit to Get Fit study is a pilot cluster randomized controlled trial examining the feasibility, acceptability and preliminary efficacy of school-based mindfulness training in adjunct to traditional health education for promotion of a healthy diet and physical activity among adolescents. Two schools in central Massachusetts (30 students per school) will be randomized to receive mindfulness training plus standard health education (HE-M) or an attention-control intervention plus standard health education (HE-AC). Assessments will be conducted at baseline, intervention completion (2 months), and 8 months. Primary outcomes are feasibility and acceptability. Secondary outcomes include physical activity, diet, impulsivity, mood, body mass index, and quality of life.

Conclusions—This study will provide important information about feasibility and preliminary estimates of efficacy of a school-delivered mindfulness and health education intervention to

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Conflicts of interest

None.

promote healthy dietary and physical activity behaviors among adolescents. Our findings will provide important insights about the possible mechanisms by which mindfulness training may contribute to behavioral change and inform future research in this important area.

Keywords

Mindfulness; diet; physical activity; school-based interventions; adolescents

1. INTRODUCTION

Unhealthy dietary habits and physical inactivity are important modifiable risk factors for the development of cardiovascular disease, the leading cause of death in the United States and worldwide. (1) Both habits are often established during adolescence and are highly prevalent among teenagers. (2) There is mounting evidence that poor diet and sedentary lifestyle early in life lead to the premature development of the metabolic syndrome (3) and contribute to the early development of atherosclerosis. (4, 5) Conversely, the establishment of healthy dietary and physical activity habits in youth leads to significant health benefits in adulthood, thus highlighting the need to develop programs aimed at improving dietary and physical activity habits early in life. (6) Such programs, however, have had modest effects, and there is limited knowledge on how to maintain positive changes over time. (7–9) A possible reason is that adolescents underestimate the long-term consequences of unhealthy behaviors (10) and are thus not motivated to adopt a healthy lifestyle. In addition, adolescence is a time of expanding freedom and boundaries testing, often resulting in impulsive behaviors that undermine efforts at engaging in health-supporting behaviors. Unhealthy behaviors (including poor diet and lack of exercise) in adolescents have been in fact associated with impulsivity and poor planning skills. (11, 12)

Mindfulness training is a behavioral intervention aimed at developing an increased awareness of the moment-to-moment experience of mental events and physical sensations. (13) There is preliminary evidence suggesting a role of mindfulness training in promoting healthy behaviors in youth, possibly through a reduction in impulsiveness. Observational studies conducted among college students have linked higher mindfulness levels with healthier dietary and exercise behaviors (14, 15) and with lower impulsiveness. (16, 17) The role of mindfulness training in promoting healthy behaviors among younger teens, however, has been so far fairly unexplored.

This pilot study proposes to evaluate the feasibility, acceptability, and preliminary efficacy of a novel approach using mindfulness training to promote and maintain healthy dietary and physical activity behaviors among adolescents. The primary outcomes of this study are feasibility and acceptability. We hypothesize that 1) we will be able to meet our recruitment goals within the specified time frame, 2) no more than 20% of participants will drop out of the study, and 3) at least 80% of participants will indicate high acceptability ratings in program evaluations. Secondary aims include preliminary assessments of efficacy on physical activity, dietary behaviors, impulsivity, mood, sedentary behaviors and quality of life. We posit that the addition of mindfulness training to a health education program, compared to a health education program alone, will improve diet and physical activity, and these changes will be maintained over time. In addition, we expect to observe a decrease in

impulsivity, indicating impulsivity may serve as a potential mediator of the effect of the intervention on diet and physical activity.

2. MATERIALS AND METHODS

2.1. Study design

The "Commit to Get Fit" study (Clinicaltrials.gov NCT01975896) is a pilot cluster randomized clinical trial designed to evaluate the feasibility, acceptability, and preliminary estimates of efficacy of health education plus mindfulness training compared to health education plus attention control for the promotion of physical activity and healthy dietary behavior among adolescents.

2.2. Setting

The study will be conducted at two high schools located in central Massachusetts that offer health education classes as part of their 9th grade school curriculum. We selected schools with similar key characteristics, i.e. socioeconomic level and ethnic diversity of their student body (more than 40% of students belong to non-white minorities). We chose a school setting for a number of reasons. First, the majority of adolescents (over 95%) attend school, (18) making a school-based program easily accessible to adolescents. Second, health education classes are taught in 9th grade in more than 60% of schools in Massachusetts and throughout the US, thus providing a natural venue for delivering information regarding healthy diet and physical activity and providing training in mindfulness. (19) Third, a program conducted within the school setting and integrated with the academic curriculum does not place additional time or transportation burdens on the students and their families. Developing and testing mindfulness training within existing health education programs in schools provides a model with high dissemination potential.

2.3. Population

We will recruit a convenience sample of 9th grade students (n = 30 per school) from health education classes. We chose this particular age group because this is an emerging adult population, transitioning from the parental control typical of childhood to a phase in which teens begin to make their own independent choices, including dietary and physical activity choices. (20) Another reason for targeting adolescents is that unhealthy dietary and physical activity habits are often established during adolescence. (2) Currently available educational programs have had only modest effects on dietary and physical activity behaviors, and mixed results on weight and body-mass index. (7–9) The combination of the increasing prevalence of unhealthy dietary and physical activity behaviors and the limitations of currently available interventions suggest a critical need for interventions targeting these unhealthy behaviors in this population.

The study sample will likely reflect the gender and ethnicity distribution of students at the selected high schools, where minorities are well represented (40% of students). Students will be considered eligible for the study under the following conditions: 1) Enrolled in 9th grade; 2) No prior mindfulness training; and 3) English speaking with at least one English speaking parent/guardian. Students will be excluded if any of the following conditions is present: 1)

Planning to move out of the area within the next 8 months; 2) Unable or unwilling to provide informed assent (adolescent) and consent (parent); 3) A diagnosis of a serious psychiatric illness during the past 5 years; and 4) Developmental delay that would prevent study participation.

2.4. Recruitment

Schools will serve as the primary vehicle for reaching parents or guardians of potentially eligible students. A letter will be sent to school principals and health education teachers explaining the purpose and benefits of the project, and requirements for student participation. Investigators and research staff will meet with the school principals and health education teachers to explain the purpose and significance of the study. Recruitment packets containing an informational brochure, eligibility criteria, and parental informed consent and adolescent assent forms will be mailed to parents or given to students to take home. For logistical reasons and to avoid singling out students participating in the study, all students will receive the study interventions as part of their health education curriculum, while only those consenting/assenting will complete study assessments and receive study stipends. Enrollment in the study will be on a “first come, first served” basis; namely, students returning consent/assent forms first will be enrolled until we reach our planned sample size.

2.5. Screening and consent/assent procedures

Interested students who returned a signed parental consent form will be invited to a screening visit with the Project Director in the school nurse’s office, similar to the approach successfully used by the investigators in prior school-based trials. (21, 22) Assent will be explained such that students understand they have a right to refuse to participate and that their school evaluations will not be affected by whether or not they decide to enroll in the study. The informed consent and assent process will not identify the condition in which the students will be enrolled so that students will not have prior knowledge of which condition they may be assigned, thereby reducing the potential for selection bias. The proposed study will be explained in detail, along with the participant’s role in it and the confidentiality of all collected information, including the digital recording of the intervention sessions for treatment fidelity assessments. The Project Director will be responsible for obtaining assent and consent and will address any question the adolescent may have. Assent and consent will be requested from and signed by the adolescent and parent. Once student assent and parental consent are obtained and eligibility is confirmed, the student will be enrolled in the study and follow the protocol for their school condition.

2.6. Randomization

To avoid intra-school contamination between the two interventions, we will use a cluster design where each school is the unit of randomization, rather than randomizing individual students. Schools will be randomized to one of two conditions: Health Education plus Attention Control (HE-AC) or Health Education plus Mindfulness training (HE-M).

2.7. Retention plan

We will collect address, phone, and email information from participants as well as from three contacts to ensure we will be able to reach participants for follow-up study assessments at the end of intervention (2 months post-baseline) and at 8 months follow-up (end of academic year). Tracking procedures will be implemented for those not attending a scheduled study visit or not accessible by phone or e-mail. In addition, students will receive a $20 incentive at each data collection completion and an additional $20 for their participation in the final focus group. The Committee for the Protection of Human Subjects at the University of Massachusetts Medical School approved the study protocol and all study materials (Docket H-00002904).

2.8. Study interventions

Both interventions will be delivered during the time allocated for health education classes at each school. This choice has the advantage of integrating the interventions into the students' regular school day. Furthermore, health education classes are taught in 9th grade in more than 60% of schools in Massachusetts and throughout the US, (19) thus providing a wide platform for dissemination should efficacy be demonstrated in a future phase III efficacy trial.

Students in both conditions will receive the same dose and content of health education (one session each week for 8 weeks). In addition to health education classes, students in the school allocated to the HE-M condition will receive one 35-minute session of mindfulness training per week for 8 weeks, while students in the school allocated to the HE-AC condition will receive one 35-minute "attention control" session for 8 weeks, with no active component delivered.

Health Education—The health education intervention will be delivered by existing health education teachers, one at each school (total of 2 teachers). Prior to the start of the health education classes we will hold regular meetings with the two health education teachers to produce a manualized version of the intervention. The health education curriculum will be informed by materials developed as part of a previous study conducted by our group to improve diet and physical activity among adolescents. The curriculum will be based on the Diabetes Prevention Program (DPP) lifestyle intervention (22, 23) as well as on standard curricula for school-based health education programs with particular attention to the unique needs of adolescents. (24) (25) Topics will include increasing the intake of fruits and vegetables, reducing sugar sweetened drinks, and decreasing the intake of foods high in fat, unhealthy carbohydrates, and calories. Additional topics will include managing hunger and appetite, structuring meals to include a healthy breakfast, portion sizes, and eating out in a healthy way. The physical activity curriculum will be based on current recommendations about physical activity in youth (26), such as engaging in at least 1 hour of moderate-to-vigorous physical activity most days of the week, importance of building physical activity into the teen's lifestyle, (27) and reducing sedentary behavior. Prior to the beginning of the study, the health education intervention will be standardized and manualized in collaboration with the health education teachers at both schools. The health education

curriculum and materials will include a detailed, standardized lesson plan as well as a student booklet.

Mindfulness Training—The mindfulness instructor will be a graduate of the Center for Mindfulness professional training program with significant experience in teaching mindfulness among teenagers as well as with a current personal mindfulness practice. Only one instructor will deliver the mindfulness intervention for the HE-M condition throughout the study. The instructor will receive three hours of training including review and discussion of the intervention script and of treatment fidelity procedures.

The mindfulness intervention is aimed at developing and increasing mindfulness skills among teenagers. The curriculum of the intervention is based on an adaptation of the traditional Mindfulness Based Stress Reduction Program (13) to a school setting and to an in-class delivery format. The intervention will focus on two main practices:

1. Practice of attention focusing techniques such as the awareness of breath exercise and body scan exercise. To avoid jargon, these techniques will be called “awareness of breath” (AOB) and “awareness of sensations” (AOS) exercises. These exercises will be the focus of the first 1–4 sessions/weeks of training;
2. Practice of techniques aiming at widening the focus of attention from one single object of attention (the breath or physical sensations in the body) to different objects. This will be the focus of the second part of the training (session/weeks 5–8). Whenever possible, practical and every day life examples will be used to illustrate and clarify a particular technique within a context that is meaningful for teen-agers.

Briefly, the mindfulness intervention’s curriculum will include the following components: 1) the AOS exercise, a technique based on the cultivation of attention to bodily sensations that normally go unnoticed; 2) training in the awareness of the sensations of breathing; 3) training in directing the attention to simple activities of daily life: sounds, visual objects, thoughts and emotions, and in recognizing when the attention is no longer focused on that specific object of attention; 4) practice of ‘open awareness’ in which students will be instructed to just notice which events (physical sensation, sound, visual object, thought) their attention is spontaneously drawn to from moment to moment; and 5) mindful movement (standing and walking exercises).

An outline of the mindfulness intervention with a description of the content of each session is provided in Table 1. The instructor will follow the intervention outline in regard to topics introduced at each session as well as their sequence. Q&A sessions are deliberately left open.

In addition to the weekly training session with the mindfulness instructor, students will practice mindfulness with the guidance of a 15 minute digitally recorded guided mindfulness practice CD or MP3, consistent with the techniques learned during each session with the instructor. Students will practice daily in class for 15 minutes and will be instructed to practice for an additional 15 minutes at home.

Attention Control—The attention control intervention (HE-AC condition) is designed to control for the non-specific components associated with the mindfulness intervention (i.e., attention received by the instructor, additional time spent in discussion and interaction with classmates). The attention control intervention will match the mindfulness intervention for duration and frequency. Its content will not include any active component of either health education (i.e., diet and physical activity) or mindfulness training and will include topics chosen by the health educators as feasible for the health education classroom setting. These include discussions and classroom activities regarding the 5 components of wellness (mental, spiritual, physical, emotional, energetic), health risk factors identified by the CDC, strategies for increasing one's health literacy, improving one's self-confidence, self-esteem, and resiliency, and mental and emotional health.

A summary of all study–related activities, including schedule for intervention delivery in each school is shown in Table 2.

2. 9. Safety considerations

While we do not anticipate serious adverse events or side effects given the educational nature of the health education curriculum, the behavioral nature of the mindfulness intervention and the lack of report of severe side effects with mindfulness training, we will actively monitor the possible occurrence of adverse events. Potential untoward events include muscle soreness, pain, and musculoskeletal injuries as a result of the mindful movement practiced during sessions and emotional discomfort during mindfulness practice. Mindful movement includes simple stretching exercises and walking meditation that are safely practiced by older age groups with minimal risk. Students will be instructed to wear comfortable clothes and shoes during classes; and the mindfulness instructor will actively supervise the students during these exercises. Psychological distress during mindfulness practice rarely occurs in the absence of ongoing serious psychiatric conditions. The mindfulness instructor will actively inquire at the beginning and during each class about psychological side effects, and the students will be instructed to inform the mindfulness instructor should any discomfort arise during the training. Mindfulness instructors are experienced and trained on how to help individuals presenting with such issues. If a student presents signs of psychological discomfort during or between sessions, the student will be excused from participating in the mindfulness component of the health education class.

2.10. Primary outcomes

All assessments will be performed at baseline, at the end of the intervention (2 months post-baseline), and at 8 months of follow-up (6 months after intervention completion and also the end of the academic year). A chart of the study assessments is presented in Table 2.

Feasibility—We will measure recruitment rates, retention rates, and intervention adherence. Recruitment metrics will include number of screened and eligible participants, number of eligible students who refused to participate, and reasons for refusal. Retention measures will be the number of subjects who dropped out or were lost to follow-up and reason(s) for dropping out. As for adherence, we will collect information on class attendance and on the number of times the adolescent listened to the study MP3 recording on their own

by means of a self-reported mindfulness log that students will receive at enrollment and which will be collected by the health education teacher each week.

Acceptability—At the end of the intervention we will conduct a focus group with participants in the HE-M condition to obtain feedback on the interventions and on their participation in the study. Topics will include the students' opinions regarding the health education and mindfulness training sessions and materials; instructor-led mindfulness sessions and individual and in-class mindfulness practice; the effectiveness of the mindfulness instructor and health education teachers; perceived barriers to participating in the in-class mindfulness sessions on and individual mindfulness practice; and feedback and recommendations for study recruitment strategies. On a survey following the intervention, each teen will also complete a form rating the overall satisfaction with the program on a scale ranging from 1 (not at all) to 5 (very much). A debriefing session will be conducted with the two heath education teachers to assess the teachers' overall opinion about the study and obtain feedback about recruitment strategies, study assessments, the health education curriculum, barriers to implementation, and incentives recommended for the involvement of health education teachers in a future larger study.

2.11. Secondary outcomes

Physical activity—Physical activity will be measured using accelerometry (Actigraph, LLC, Fort Walton Beach, FL) Model GT1M(28). Accelerometry has been recommended for the assessment of physical activity among teens and children, (28) has high reliability, (29) and has shown good correlations with measured oxygen uptake (30, 31). Students will receive an accelerometer at each study visit and will be instructed to wear the accelerometer for the next 7 days, and then to return it to the health education teacher for study staff to collect. For adolescents, wearing an accelerometer for longer periods of time is problematic, as we repeatedly experienced in our previous studies involving teenagers. We thus decided to compromise on a 7-day period. There is very limited information on accelerometer reactivity effects among children and adolescents, with a recent manuscript reporting higher activity on the first day the accelerometer is worn. (32) The extent of reactivity, however, was much larger in younger (pre-school) children than that in adolescents (such as those enrolled in our study). (32) Furthermore, since both HE and M-HE students will wear accelerometers in our study, we expect reactivity effects to be similar in both groups. The following metrics will be considered: number of valid days, wearing time, average counts/min, average counts/day, average minutes of moderate-to-vigorous physical activity /day, and average minutes of moderate-to-vigorous physical activity bouts per day. The Physical Activity Recall Questionnaire (33) will also be collected and used as a backup for accelerometer failure or missing data.

Diet—We will use 24-hour dietary recalls (validated with adolescents and children) to assess total calorie intake, saturated fat, and fruit/vegetables intake. The prevalence of teens meeting current recommendations (34) for diet and physical activity will also be assessed.

2.12. Other secondary outcomes of interest

Body mass index (BMI)—Trained research staff will collect measures of height and weight to calculate BMI using standard methodology. Weight measurements will be taken on digital scales and measured to the nearest $2/10^{th}$ of a pound. Heights will be measured to the nearest $1/8^{th}$ of an inch using portable stadiometers, without shoes. Measures will be converted to the metric scale. BMI will be calculated from weight (kg)/height squared (in meters) and BMI-z score for age/sex determined using CDC growth charts.

Quality of life will be measured using the Pediatric Quality of Life Inventory. (35)

Sedentary behaviors will include self-reported assessments of the average number of hours the teen spent watching TV, at the computer or playing non-active video games.

2.13. Mediators

Impulsivity will be measured using the Barratt impulsivity scale, (36) modified to exclude items not applicable to adolescents (e.g., “I plan for job security”, “I change jobs”) and to adapt some items to make them more relevant for teens (e.g., “I am restless at the theater or lectures” changed to “I am restless at the movie theatre or in class”).

Mindfulness will be evaluated using the Mindful Attention Awareness Scale, (37, 38) an instrument that has been validated in healthy teens. One item that does not apply to this specific age group (“I drive places on ‘automatic pilot’ and then wonder why I went there”) has been deleted.

Knowledge will be assessed through an ad-hoc survey containing specific questions on dietary recommendations, physical activity, and sedentary behavior.

Diet and exercise self-efficacy will be measured using a one-item questionnaire adapted from the Go Girls study (39).

Stress will be evaluated using the Perceived Stress Scale, 4-items measuring the teen’s stress level over the past month. (40)

Depression will be measured by the Children’s Depression Inventory, a 6-item measure that screens for depressive symptoms, assessed over the past month. (41)

Anxiety will be assessed using the State-Trait Anxiety Inventory for Children. (42)

2.14. Covariates

We will collect socio-demographic information (age, gender, ethnicity, socio-economic status), medical history (previous medical and psychiatric health conditions, current medications, smoking); and information about the youth’s perception of the level of parental control on dietary habits, healthy food availability, and exercise choices (modified questionnaire based on Parental Control Index). (43, 44)

2.15. Process measures

The protocols and materials for each intervention will be refined and manualized in order to ensure that the delivery of the interventions is consistent across mindfulness instructors and health education teachers.

Fidelity assessments will be conducted following the guidelines developed by the Treatment Fidelity Workgroup. (45) For the mindfulness curriculum, the mindfulness instructor will digitally record each session and complete the auditor checklist corresponding to that class at the end of each session. A random selection of 10% of all recordings will be reviewed after each weekly session and feedback provided to the instructor before the next scheduled session. Optimal treatment fidelity would be evidenced by 100% of objectives met. If less than 85% of objectives are met, the auditor will provide remediation as needed. For the health education curriculum delivered in both study conditions, clear lesson plans were developed to standardize delivery of the curriculum to the students. To assess fidelity to delivery of the health education intervention, the health education teachers will complete a structured form to record whether or not the planned topics were discussed during each health education session.

2.16. Data collection

Measurements of weight and height and accelerometer fitting will be performed in the school nurse's office; dietary recalls will be conducted over the phone while the student is at home. Study surveys will be completed at school and will be pre-tested to ensure the time burden does not exceed 45 minutes. Research Electronic Data capture (REDCap) technology will be used for direct data entry from study participants during the interviews. (46) REDCap employs automatic checks for values that are out of range or represent errors of logic. Outliers will be corrected with verification from participants.

Data management—We will program the system with validation rules at the time of entry and develop programs to perform comprehensive edits after the data have been submitted to the main database. These edits will check for validity, consistency, and normal range values both within and between forms. Edit queries will be generated and resolved with corrections posted to the database through the REDCap system, which enforces an audit trail for all changes. For analysis, data will be exported from the REDCap system as SAS© data sets and merged within SAS© to create the official analysis files for the study using SAS© statistical software version 9.2. (47). All data analysis personnel will be blinded to group assignment.

2.17. Statistical analyses

All analyses will be performed according to the intention to treat approach. (48)

Feasibility—Separately for each treatment group (school), we will estimate rates of retention, adherence, and acceptability scores (dichotomized at 80+%) at 2 and 8 months, accounting for within-class clustering and dependence over time using generalized estimating equation (GEE) logistic regression. (49) Correlates will be identified by including candidate predictors in the logistic regression models. For qualitative analyses we will use

NVivo© qualitative data analysis software, QSR International Pty Ltd. Version 9, 2010 to import transcribed data, conduct thematic analyses, identify common themes in participants' responses, sort responses according to themes and summarize findings. (50, 51)

Diet and physical activity—We expect that the HE-M group, compared to HE-AC, will have greater changes since baseline in healthy diet indicators (total calorie, saturated fat and fruit/vegetable intake), and in physical activity (accelerometer counts) at the end of the intervention; these changes will be maintained over time (at 8 months follow-up). To obtain preliminary estimates of efficacy at key time points HE-M versus HE-AC differences will be estimated for change since baseline diet and using linear mixed models (52) with a random effect for class to account for clustering, with fixed effects treatment group, time point (categorized as 2 and 8 months), and their interaction, adjusting for baseline outcome values to account for possible regression to the mean. (53) Baseline variables predictive of the outcome being modeled will be included as covariates. (54, 55) Similar models will be estimated for the other secondary outcomes (continuous variables).

Exploratory analyses

Mediators: We posit that the HE-M intervention, compared to HE-AC, will increase mindfulness skills; changes in mindfulness skills will be associated with a decrease in impulsivity; and a decrease in impulsivity will be positively associated with changes in diet and physical activity. We will use linear mixed modeling (to incorporate clustering within class) to examine the mediation hypothesized above.

Moderators: We will explore whether the effect of the intervention differs by gender, baseline levels of physical activity and dietary intake of certain nutrients, baseline BMI (under-normal weight, overweight, obese), and categorized levels of perceived parental control on dietary and physical activity choices. Interactions of these characteristics with treatment group will be added one at a time to models for Aim 2.

Sample size considerations—Since pilot studies do not provide meaningful estimates of effect sizes for planning subsequent large randomized controlled trials due to the imprecision inherent in data from small samples, (56, 57) our proposed sample size of 30 students per condition/school was based on practical consideration (costs and duration of funding). Estimates of intra-class correlation from our prior studies of mindfulness interventions for hot flashes (58) range from 0.0105 for within-mindfulness class to 0.027 for within-school (change in BMI from our previous study of obese adolescents)(22); taking a conservative approach and using the 0.027 multiplied by 50% to account for possibly higher intra-class correlation in a class than in an entire school, the resulting design effect is $1+[0.027 \times 1.5 \times (20-1)] = 1.77$, (59) giving an effective sample size of $40/1.77 = 23$ per condition/school. Based on our prior studies with adolescents in school settings, we anticipate at least 80% retention. Thus, a conservatively wide 95% confidence interval for retention rate per condition is 80% ± 15.7%, equal 64.4%, 95.7%. 3.

DISCUSSION

Mindfulness has been defined as the act of “paying attention to the present moment’s experience in an intentional and non-judgmental way”. (60) Studies have shown that mindfulness skills can be improved and refined with training and dedicated practice and such increases in mindfulness in turn result in a variety of beneficial effects on psychological distress, pain, and other important health outcomes. (61, 62)

An area of inquiry that has received limited attention is the possible effect of mindfulness training on health behaviors. In adults, mindfulness training may promote healthier eating habits by increasing awareness of eating and satiety cues. (63) Preliminary studies, however, have shown that overall, mindfulness interventions *alone* have a modest (64) or null effect on the dietary intake of several nutrients. (65, 66) In contrast, *composite* interventions including mindfulness training and a dietary intervention increased vegetable protein and fiber intake and decreased total energy and saturated fat intake. (67, 68) Likewise, mindfulness training delivered together with an exercise and dietary intervention has been shown to significantly increase activity levels. (67)

The literature is likewise relatively silent regarding the possible effect of mindfulness training on health habits among younger populations. Preliminary evidence based on observational studies suggests that mindfulness training may play a role in promoting behavioral change in adolescents. For example, higher dispositional mindfulness (i.e., the capacity that individuals have to be mindful prior to training)(69, 70) has been associated with increased physical activity, reduced binge eating episodes and better sleep quality (14) as well as with healthier dietary habits and greater diet self-efficacy. (15)

There are a number of reasons why mindfulness training could have an effect on promoting healthy behaviors in youth. In this age group, unhealthy behaviors such as poor diet quality, sedentariness, and low physical activity levels appear strongly associated with poor self-regulation and high impulsivity. (11, 12, 71, 72) In addition, high impulsivity has been associated with overweight and obesity and with measures of abdominal adiposity. (12) Mindfulness training typically emphasizes the development of a particular type of attention, namely the intentional and non-judgmental acceptance of thoughts, feelings, and sensations arising in the field of consciousness at any given moment. This particular way of paying attention is the very opposite of impulsivity and in fact, dispositional mindfulness has been associated with lower impulsivity and better self-control in youth (16), which are both important determinants of healthy behaviors in younger populations. (11, 12, 71)

The objective of the present study is to explore whether mindfulness may play a role in promoting behavioral change. Specifically, “Commit To Get Fit” seeks to study the role of mindfulness training in promoting healthy diet and physical activity among adolescents. Our working hypothesis is that mindfulness training will increase mindfulness levels, which in turn will be associated with lower impulsivity, and that improvement in impulsivity will be associated with positive changes in dietary and physical activity habits (Figure 1).

We considered other models to guide the design of this study, for example, the transactional model of stress, which is typically used in mindfulness interventions in adults. (73, 74)

While this model may apply to the smaller subgroup of adolescents with high perceived stress (75, 76) and psychiatric disorders (77–79) it is unlikely that it will be relevant for the majority of adolescents, who have no anxiety and normal levels of stress. We will however collect information about these important outcomes and explore effect modification by stress and anxiety/depression levels.

In conclusion, this is the first experimental study to explore the role of mindfulness training in the promotion and maintenance of healthy physical activity and dietary habits among adolescents. An additional innovation of the study is the delivery of mindfulness training in the context of existing health education classes in the school setting. This is a notable strength of this study, because it ensures the scalability of the intervention to other high schools if a future phase III efficacy RCT yields positive results. If this preliminary study is feasible and gives us preliminary indications that the HE-M intervention is effective, our next step will be to conduct a large, cluster, 2 × 2 factorial RCT that will rigorously evaluate whether mindfulness plus health education, or either alone, compared to an attention control group, can improve diet and physical activity in adolescents. This future study will also have statistical power to include a full mediation analysis to assess the role of change in mindfulness and impulsivity on maintenance of healthy dietary and exercise habits. We will also consider including a functional magnetic resonance component to test possible neuro-physiological mechanisms underlying the effect of the mindfulness intervention.

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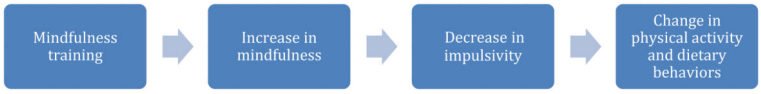

Figure 1.
Conceptual model

Table 1

Mindfulness intervention outline

TOPIC	DURATION (minutes)
Session 1: Introduction to mindfulness training - Awareness of Breath (AOB)	
Instructor to start by introducing herself	
• Why are we doing this? Introduction and discussion	10
• Awareness of Breath (AOB) exercise	5
• Q&A	10
• AOB (let's do it again)	5
• Give MP3s/CDs to students	
• Set up for home practice: How do you do it? How do you set up for success? When is the best time of the day for you?	5
• Students encouraged to practice AOB exercise during the following week with aid of digital recording - track 1 once a day	
Teaching tip: *The following points can be used to initiate/sustain discussion:*	
• Empowering effect of attention training: we are helping them to find this resource to focus and pay attention that they already have –but rarely is one taught HOW to pay attention. Now they are in training (examples from sport/music)	
• Data showing usefulness of mindfulness/attention training for academic success, concentration, learning	
• Practice enables them to choose where they place their attention and consequently, to be aware of their thoughts, emotion, decisions	
Session 2: AOB/daily experience	
• Q&A related to practice in previous week	10
• Awareness of daily experience: exercise of paying attention to everyday activity (raisin exercise). This exercise subtly hints at "dietary habits" and connects students to pay attention to what they "take in"	5
• Q&A/introduce informal practice	10
• AOB exercise	10
• Students encouraged to practice AOB exercise during the following week with aid of digital recording - track 1 once a day	
Session 3: Awareness of Sensations (AOS)	
• Q&A related to practice in previous week	10
• AOS: Students instructed to move awareness to different parts of the body in a systematic way, beginning with the toes and progressing to the top of the head, noticing whatever sensations happen to be present in that part of the body at that moment. Do both sides of the body at once – and do not focus on individual digits. End with short AOB exercise.	15
Teaching tip: *A flashlight with a beam may be a good way to introduce AOS practice. First shifting the light in the room. The beam can be directed to different parts of the body to show shift of attention.*	
• Q&A	10
• Students encouraged to practice AOS exercise during the following week with aid of digital recording - track 2 once a day	
Session 4: Introducing Everyday Practice/Awareness of Body Movement (ABM)	
• Q&A related to practice in previous week	10
• Glass of water or other non-alcoholic drink – exercise of mindful drinking (This exercise subtly hints at "dietary habits" and connects students to pay attention to what they "take in")	
Teaching tip*: Point out to students that we are learning to become aware of activities that occur daily, but are not noticed. For example, when we are very thirsty, we are totally aware of the experience of drinking water. Now, we are learning to pay attention to the entire process of "drinking" …picking up the glass, the first sip, etc.*	5

• Q&A	10
• AOB exercise, short AOS exercise - introduce ABM through guided standing or walking practice	10
• Students encouraged to practice AOS exercise during the following week with aid of digital recording - track 2 once a day	
Session 5: AOB/AOS/ABM/Awareness of Sounds	
• Q&A related to practice in previous week	10
• Short AOB, short AOS + ABM, followed by awareness of sounds exercise	15
Teaching tip*: Possible to introduce awareness of sounds with a few musical instruments, then open to ambient sounds. Explain what observing means: the sound itself (qualities like loud, soft, sudden…); the "naming"; the reaction to the sound (memories, associations, emotions…)*	
• Q&A	10
• Students instructed to practice this way of relating to their experience throughout the day and particularly to their experience of sounds. Students encouraged to practice with aid of digital –recording – track 3 once a day.	
Teaching tip*: Give examples. They can do this by stopping and listening, and opening to the sounds that are present in the environment at a given moment. They can try listening to a whole song this way.*	
Session 6: AOB/AOS/Awareness of Emotions	
• Q&A related to practice in previous week	10
• Short AOB, short AOS, followed by awareness of emotions exercise (*observing the physical sensations, memories… associated with the emotion)*	15
• Q&A	
Teaching tip*: A range of emotions needs to be included here. Those that are easy, those that are difficult. Familiar emotions, and the possibility of exploring a wider range of emotions that you have, but don't notice.*	10
• Students instructed to practice this mindful way of relating to their experience throughout the day and particularly to their experience of emotions. Students encouraged to practice with aid of study CD – track 3 once a day.	
Session 7: AOB/AOS/Thoughts	
• Q&A related to practice in previous week	10
• Short AOB, short AOS, followed by awareness of thoughts exercise (observing the physical sensations, memories, emotions… associated with the thought)	
Teaching tip*: Offering the power of different thoughts— The thoughts of not being good enough, popular, or thoughts of being a caring, kind person. How do thoughts affect you? Get to know them more closely. They are not all true, but beginning to become familiar with them, is a source of great power in your life. You can see more clearly that you are more than your thoughts!*	15
• Q&A	10
• Students instructed to practice this mindful way of relating to their experience throughout the day and particularly to their experience of thoughts. Students encouraged to practice with aid of study CD– track 3 once a day.	
Session 8: Open Awareness	
• Q&A related to practice in previous week	10
• Short AOB, short AOS, sounds, emotions, thoughts, open awareness. Students instructed to notice where the attention goes when it is not directed with open awareness.	
Teaching tip*: Metaphor of ocean and waves may be helpful. Like the ocean -- knowing the waves of sensation, thoughts, emotions, but also being the large, deep water. Allowing yourself to be still and know yourself despite all the coming and going, wanting and being satisfied…despite all the changes, we have the ability to attend, to know what is happening as it is happening.*	15
• Q&A	10
• Students asked to practice this mindful way of relating to their experience during the day, and to bring this resource to all their experiences (pleasant and unpleasant ones). Instruct student to keep practicing with or without recording once a day.	

Table 2

Study-related activities

	Baseline	Weekly (week 1–8)	Week 9	6 months of follow-up
Study Interventions				
45 minute Health Education (both HE-M and HE-AC)		x		
35 minute mindfulness session in class (HE-M only)		x		
Listening to mindfulness recording in class (HE-M only)		x		
Listening to mindfulness recording at home (HE-M only)		x		
35 minute AC intervention (HE-AC only)		x		
Feasibility and Acceptability (primary outcome)				
Recruitment metrics	x			
Retention			x	x
Session attendance		x		
Mindfulness practice logs		x		
Program satisfaction scale			x	
Focus groups (students)			x	
Debriefing session (HE teachers)				x
Secondary Outcomes				
24 hours dietary recalls	x		x	x
Accelerometry	x		x	x
7-Days PAR	x		x	x
Weight, height, BMI	x		x	x
Quality of life	x		x	x
Sedentary behaviors	x		x	x
Mediators				
Impulsivity	x		x	x
Mindfulness	x		x	x
Knowledge	x		x	x
Self-efficacy	x		x	x
Stress	x		x	x
Mood & anxiety	x		x	x
Covariates/Moderators				
Socio-demographics	x			
Medical history	x			
Parental control on dietary and exercise choices	x			
Quality Control				
Audit of 10% tapes of mindfulness training (HE-M only)		x		
Health education checklist (HE-M and HE-AC)		x		