Contemporary Clinical Trials 41 (2015) 248–258

Contents lists available at ScienceDirect

Contemporary Clinical Trials

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

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

Elena Salmoirago-Blotcher [a,*], Sue Druker [b], Florence Meyer [b], Beth Bock [a], Sybil Crawford [b], Lori Pbert [b]

[a] Centers for Behavioral and Preventive Medicine, The Warren Alpert Medical School of Brown University, One Hoppin Street, Providence, RI 02903, United States
[b] Division of Preventive and Behavioral Medicine, University of Massachusetts Medical School, 55 Lake Avenue North, Worcester, MA 01655, United States

ARTICLE INFO

Article history:
Received 9 December 2014
Received in revised form 9 February 2015
Accepted 10 February 2015
Available online 14 February 2015

Keywords:
Mindfulness
Diet
Physical activity
School-based interventions
Adolescents

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 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.

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

* Corresponding author at: Centers for Behavioral and Preventive Medicine, CORO West, Suite 309, One Hoppin Street, Providence, RI 02903, United States. Tel.: +1 401 793 8325; fax: +1 401 793 8059.
E-mail address: Elena_Salmoirago-Blotcher@brown.edu (E. Salmoirago-Blotcher).

http://dx.doi.org/10.1016/j.cct.2015.02.004
1551-7144/

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 boundary 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 that 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