Contemporary Clinical Trials 58 (2017) 40–46

Contents lists available at ScienceDirect

Contemporary Clinical Trials

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

The Fit Study: Design and rationale for a cluster randomized trial of school-based BMI screening and reporting

Kristine A. Madsen[a,*], Jennifer Linchey[a], Lorrene Ritchie[b], Hannah R. Thompson[a]

[a] UC Berkeley School of Public Health, University Hall, Box 7360, Berkeley, CA 94720-7369, United States
[b] Nutrition Policy Institute, University of California, Division of Agriculture and Natural Resources, 1111 Franklin Street #10123, Oakland, CA 94607, United States

ABSTRACT

Background: In the U.S., 25 states conduct body mass index (BMI) screening in schools, just under half of which report results to parents. While some experts recommend the practice, evidence demonstrating its efficacy to reduce obesity is lacking, and concerns about weight-related stigma have been raised.
Methods/design: The Fit Study is a 3-arm cluster-randomized trial assessing the effectiveness of school-based BMI screening and reporting in reducing pediatric obesity and identifying unintended consequences. Seventy-nine elementary and middle schools across California were randomized to 1 of 3 Arms: 1) BMI screening and reporting; 2) BMI screening only; or 3) no BMI screening or reporting. In Arm 1 schools, students were further randomized to receive reports with BMI results alone or both BMI and fitness test results. Over 3 consecutive years, staff in schools in Arms 1 and 2 will measure students' BMI (grades 3–8) and additional aspects of fitness (grades 5–8), and students in grades 4–8 in all Arms will complete surveys to assess weight-based stigmatization. Change in BMI z-score will be compared between Arm 1 and Arm 2 to determine the impact of BMI reporting on weight status, with sub-analyses stratified by report type (BMI results alone versus BMI plus fitness results) and by race/ethnicity. The potential for BMI reports to lead to weight-based stigma will be assessed by comparing student survey results among the 3 study Arms.
Discussion: This study will provide evidence on both the benefit and potential unintended harms of school-based BMI screening and reporting.

1. Introduction

The prevalence of childhood obesity remains alarmingly high [1] and disparities by race/ethnicity are widening [2]. The National Academy of Medicine recommends school-based body mass index (BMI) screening and reporting, noting that while schools are not the ideal setting for such assessments, many children do not have BMI assessed regularly by health care providers [3]. Reporting a child's BMI to parents is a minimal-dose intervention, but its broad reach makes it a potentially valuable public health tool for addressing obesity. As of 2015, 25 states had legislation requiring BMI screening or surveillance in schools and 11 states required reporting results to parents [4].

Theoretically, BMI reports can inform parents that their child's weight places her or him at increased risk for negative health outcomes, thereby motivating parents to take action to improve their child's weight status. Some evidence suggests that school-based BMI reporting could change parents' perceptions of and behaviors related to their child's weight status [5–10]. Importantly, while African-American and Latino families are less likely to accurately classify their child's weight status than white parents [5,11], when exposed to BMI reports, they have shown greater increases in accuracy of weight perceptions [5] and greater likelihood to make changes in their child's diet and physical activity [9] than white parents. Thus, BMI reports could have a greater impact for youth most at risk of obesity. However, the few studies that have examined school-based BMI screening and reporting have demonstrated no impact on weight status, although all have had limitations that preclude drawing definitive conclusions [12–16].

There are also gaps in the evidence surrounding BMI reports with respect to the context in which BMI assessments are conducted and the potential for unintended consequences. BMI is frequently measured in schools as part of a comprehensive fitness assessment (including measuring aerobic capacity, strength, and flexibility); thus, BMI results may be reported to parents along with other fitness results [17], which may decrease the salience of the BMI results. However, no studies have explored the relative benefits of reporting BMI alone versus including fitness results. Additionally, concerns have been raised that school-

Abbreviations: BMI, Body mass index; FRPM, Free or reduced-price meals; IDR, Interquartile range

* Corresponding author.
E-mail addresses: madsenk@berkeley.edu (K.A. Madsen), jlinchey@berkeley.edu (J. Linchey), lritchie@ucanr.edu (L. Ritchie), thompsonh@berkeley.edu (H.R. Thompson).

http://dx.doi.org/10.1016/j.cct.2017.05.005
Received 8 November 2016; Received in revised form 24 April 2017; Accepted 3 May 2017
Available online 04 May 2017

based BMI screening and reporting can increase weight-based stigmatization, such as teasing and negative comments by peers and families [18–20], which may increase body dissatisfaction and disordered eating [21–23].

Given the widespread use of BMI reporting, the lack of evidence as to its benefits, and the concerns for potential unintended consequences, rigorous evidence is needed to allow for a truly informed discussion of risks versus benefits. The Fit Study is a National, Heart, Lung, and Blood Institute (NHLBI)-sponsored cluster-randomized controlled trial that will address pressing questions related to school-based BMI screening and reporting. The goals of the Fit Study are to: 1) determine the impact of BMI reporting on pediatric obesity and identify effect modification by race/ethnicity; 2) compare the effectiveness of BMI-only reports versus BMI plus fitness reports in reducing obesity; and 3) examine the potential for unintended consequences. This manuscript describes the rationale and design for the 3-year study, as well as participant characteristics at baseline.

2. Methods

2.1. Design

The Fit Study is a 3-arm, cluster-randomized controlled trial conducted in public schools in California. This study was approved by the University of California at Berkeley's Committee for the Protection of Human Subjects and by participating school districts.

2.2. School district and school recruitment

California currently mandates that all students in public schools in grades 5, 7 and 9 participate in the Fitnessgram® annually. The Fitnessgram® comprises 6 tests that assess aerobic capacity, strength, flexibility, and body composition. Over 95% of schools assess body composition by measuring student height and weight and calculating BMI (e-mail communication from the California Department of Education [CDE], April 2010). Sending students' Fitnessgram® results home to parents is optional, and as of 2008, 49% of California school districts elected *not* to report results to parents [13]. School districts were eligible for participation in the Fit Study if: 1) the districts' schools had no history of sending home Fitnessgram® results and 2) the district had at least 8 elementary or middle schools with both enrollment of $\geq 15\%$ and $\leq 85\%$ Latino students (to facilitate analysis of ethnicity as an effect modifier) and at least 30 students per grade (to ensure adequate power). We excluded 431 school districts that sent Fitnessgram® results home to parents as of 2008 [13] and an additional 425 school districts that failed to meet the criteria regarding enrollment of Latino students and/or students per grade (based on data from the CDE for the 2014–15 school year). We screened 31 of the 74 remaining districts for study participation based on location (with the goal of including schools in northern, central, and southern California) and size (preferentially selecting districts with the largest number of schools). Of the 31 districts screened, 15 were sending BMI reports to parents and were considered ineligible, 11 declined to participate, and 5 agreed to participate (Fig. 1). Within participating districts, 109 schools met eligibility criteria. We invited 92 schools to participate, preferentially selecting schools to ensure a balance of students across grades; 79 schools (86%) agreed with 38 having grades K-5, 18 having K-6, 13 having K-8, 9 having 6–8, and 1 school having 7–8. Table 1 shows characteristics of study schools compared to all California elementary and middle schools. Participating schools receive an annual stipend of $500 for study participation.

2.3. Student recruitment

Students in grades 3 to 7 with at least one more grade to complete at their school were considered eligible. In one district with 13 participating schools, a subset of classrooms in 9 study schools had participated in a BMI screening and referral program associated with a local clinic in 2011–2015 (representing 5% of enrolled students in that district). Students who were part of that program (n = 275) were excluded from the study (Fig. 1). Eligible students were invited to participate through a letter that schools sent home to parents, which included a participation opt-out form. Parents who did not want their child to participate were asked to return the opt-out form to the school. Students were told that participation was voluntary and could also opt themselves out of the study.

2.4. Parent recruitment

A random sample of 3030 parents/guardians of enrolled students was sent a survey via mail in 2015, with a cover letter explaining the study and inviting participation in the survey. All parents completing the survey will be sent a follow-up survey in 2016 along with additional randomly selected parents/guardians not recruited in 2015 to achieve a similar sample size in 2016.

2.5. Randomization

Prior to inviting students to participate, schools were randomized to one of three study Arms: 1) BMI screening and reporting to parents; 2) BMI screening only; or 3) no BMI screening or reporting. Randomization was stratified by school type to produce a similar distribution of grades in each group. Waivers were obtained from the CDE to allow schools in Arm 3 to refrain from conducting BMI assessments with 5th and 7th grade students as part of the annual Fitnessgram® test (as required by California state education code) during the 2014–15 and 2015–16 school years. In Arm 1 schools, students in grades 5–8 were further randomized to receive one of two types of BMI reports: BMI results alone or BMI plus fitness results.

3. Assessments and measures

3.1. BMI assessments

School staff assess BMI among participating students in study Arms 1 and 2 between February and April in 2015, 2016 and 2017; BMI will be assessed in 2017 among students in Arm 3 (control). Fig. 2 shows the grades assessed each year. Trained school staff have demonstrated reproducibility of height and weight measures equivalent to that of trained researchers [24–26]. Because this study aims to assess potential stigma associated with height and weight assessments at school, it is important to ensure that BMI assessments in the study reflect usual practice. However, as part of the study, all school staff charged with conducting height and weight assessments are asked to register for and attest to having watched a training video (available at www.thefitstudy.org). The measurement protocol stipulates that height be measured to the nearest 0.1 cm twice, and if the two measures are off by > 0.5 cm, a third height should be recorded. Weight is measured to the nearest 0.1 lb. Schools receive research-grade stadiometers (ShorrBoard® Infant/Child/Adult Measuring Board, Weigh and Measure, LLC, Maryland) and scales (Tanita BWB 800S Digital Scale, Weigh and Measure, LLC, Maryland), as well as laminated quick reference cards to be stored with equipment. Teachers who conduct BMI assessments receive $25 gift cards for each class measured.

3.2. Fitness assessments

School staff administer five additional Fitnessgram® tests (assessing aerobic capacity, flexibility, and strength [27]) to students in grades 5 to 8 in Arms 1 and 2, and in grades 5 and 7 in Arm 3. The CDE provides instructions for conducting the Fitnessgram on their website (https://pftdata.org/resources.aspx); fitness test instructions are also available