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FULL TEXT ARTICLE

Implementing School-Based Policies to Prevent Obesity: Cluster Randomized Trial

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Introduction

Healthier school environments can benefit students, and school wellness policies may result in meaningful enhancements. Schools participating in federal child nutrition programs must implement wellness policies as mandated by law. The primary study objective is to assess effectiveness of implementing school-based nutrition and physical activity policies on student BMI trajectories.

Study design

Cluster randomized trial using 2×2 factorial design.

Setting/participants

Twelve randomly selected schools in an urban district. Students were followed for 3 years through middle school, fifth to eighth grades (2011-2015, n = 595 students, 92.3% participation, 85.2% retention).

Intervention

Specific to randomized condition, support was provided for implementation of nutrition policies (e.g., alternatives to food-based rewards/celebrations) and physical activity policies (e.g., opportunities for physical activity during/after school).

Main outcome measures

Sex-/age-adjusted BMI percentile and BMI z -score; behavioral indicators. Data collected via standardized protocols.

Results

Analyses followed intention-to-treat principles, with planned secondary analyses (conducted 2016–2018). Students at schools randomized to receive support for nutrition policy implementation had healthier BMI trajectories over time (F = 3.20, p = 0.02), with a greater magnitude over time and cumulatively significant effects 3 years post-intervention ($\beta = -2.40$, p = 0.04). Overall, students at schools randomized to receive the nutrition intervention had an increase in BMI percentile of <1%, compared with students in other conditions, whereas BMI percentile increased 3%–4%. There was no difference in student BMI between those in schools with and without physical activity policy implementation. Examining behavioral correlates in eighth grade, students at schools randomized to the nutrition condition consumed fewer unhealthy foods and sugar-sweetened beverages, and ate less frequently at fast-food restaurants (all p < 0.03).

Conclusions

This cluster randomized trial demonstrated effectiveness of providing support for implementation of school-based nutrition policies, but not physical activity policies, to limit BMI increases among middle school students. Results can guide future school interventions.

Trial registration

This study is registered at www.clinicaltrials.gov (http://www.clinicaltrials.gov) NCT02043626.

INTRODUCTION

Schools have figured prominently in national discourse about policy approaches to prevent childhood obesity because they afford concentrated contact, teach health education, provide meals, and can model health-promoting environments. 1 2 3 In 2004, all school districts participating in the U.S.'s federal meal programs were required to create a committee of stakeholders and write a school wellness policy. ⁴ School wellness policies required schools to set goals for physical education and nutrition education, as well as set nutrition standards for meals and snacks served. Several years later (in 2010, and prior to this study), the scope of school wellness policies was expanded by The Healthy, Hunger-Free Kids Act to include policies on physical activity and food marketing in schools; in addition, school districts must measure policy implementation and share findings publicly. ⁵

There is a robust body of empirical literature that documents that healthier school environments benefit students. For example, quality physical education predicts higher levels of physical activity in school. ⁶ School wellness policies that promote increased access to healthier foods and limit access to unhealthy foods have been linked to lower caloric intake ⁷ and improved student dietary quality 8 9 at school.

There is emerging evidence that stronger state-level competitive food policies are associated with a healthier weight trajectory among middle school students. ¹⁰

The rationale behind requiring school wellness policies is that, when implemented, they will lead to meaningful improvements in the school environment. Although nearly every school district in the country has a written policy, several studies have found that strong written policies do not necessarily predict thorough implementation. 11 12 13 School districts face multiple demands and have been expected to implement new policies with little to no additional financial support. One strategy has been to collaborate with local organizations, such as universities, health systems, and community-based organizations, to assist in implementation and evaluation of school wellness policies after they have been written and approved. 14 15 The objective of this cluster randomized trial is to assess whether implementation of specific nutrition and physical activity components of the written school wellness policies lead to healthier student outcomes, including BMI trajectories and behavioral correlates. In addition, the study seeks to determine whether these policy interventions are more or less effective for girls or boys and for differences on baseline BMI (i.e., prevention/treatment) based on prior research that has demonstrated these subgroup effects. 16 17

METHODS

This study was conducted in New Haven, Connecticut, an urban district with >21,000 students. Using a quantitative coding system to evaluate written school wellness policies in all Connecticut districts, New Haven's policy scored higher than any other district. 18 19 Therefore, it was an ideal setting to assess implementation of a strongly written school wellness policy.

Twelve schools (kindergarten through eighth grade [K-8]) were randomly selected from among the 50 K-8 district schools. All agreed to participate. Schools served as clusters, and were randomized to receive support for school wellness policy implementation via standard 2×2 factorial design ($\underline{\text{Figure 1 (fig0001)}}$), such that policy interventions related to nutrition and physical activity were implemented and evaluated, leading to four conditions: nutrition only, physical activity only, nutrition and physical activity (dual), or delayed. Schools randomized to the delayed condition received other health-relevant training (e.g., oral health, cold/influenza prevention) during the study period, with obesity-related materials delivered after data collection was completed. To minimize selection bias, all schools were recruited before randomization. Randomization was achieved using a computer-generated sequence. Enrollment was conducted in 2011, with annual data collection and implementation through 2015.

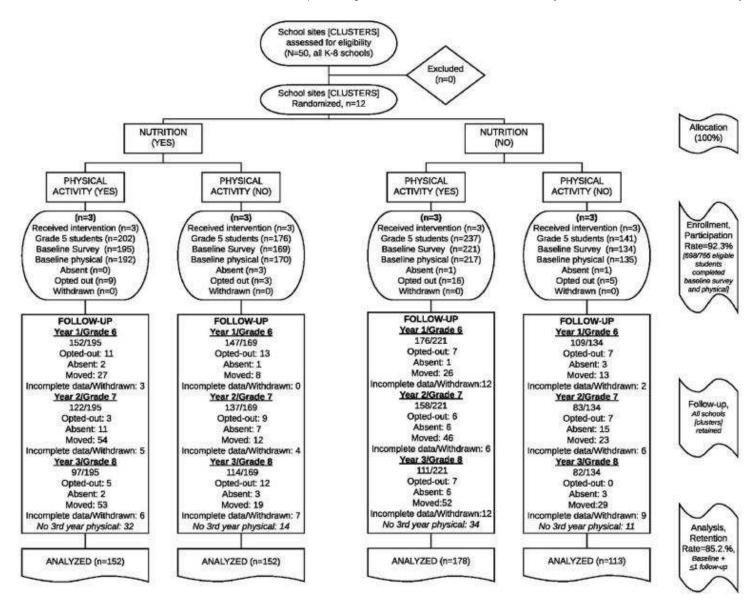


Figure 1
CONSORT diagram.

All procedures were approved by Yale University IRB, the New Haven Board of Education, and participating schools, including permission to collect identifying information and track the same students over time. Regulations as established by the Family Educational Rights and Privacy Act ²⁰ and the Health Insurance Portability and Accountability Act ²¹ were followed. Parental consent and student assent were

obtained, and participation was entirely voluntary and noncoercive. Throughout the entire trial, there were no adverse effects to report. CONSORT with extension to cluster randomized trials guide this report. ²²

Study Population

Because randomization was conducted by school, all students in these school enrolled in the requisite grades were invited to participate. Of 756 students enrolled in study schools, 698 completed baseline surveys and physical assessments (92.3% participation rate). This high participation rate was achieved working in close partnership with the school district. To minimize participant burden and maximize participation, all data were collected during school. There were no differences in sociodemographic or health indicators between students who completed baseline assessments and those who did not. To be included in the final analytic sample, students were enrolled in fifth grade when the study began (n = 533) or began attending a target school in sixth grade (n = 62). All had one or more follow-up sessions over the study period (through eighth grade, 2014–2015 academic year), resulting in a final sample of 595 students (85.2% retention; CONSORT diagram in Figure 1 (fig0001).) The majority of loss to follow-up was due to movement out of study schools or the district as a whole. Sample size was based on the primary study endpoint: student BMI. With power at 0.80, α set to 0.05, and interclass correlation assumed at 0.001, a total of 12 schools and 588 students were needed to detect small/medium effect (Δ =0.30; software Optimal Design, version 3.0).

Measures

Research staff provided technical assistance and support to schools to implement components of the district's written school wellness policy (

Table 1 (tbl0001)), as well as basic and advanced workshops on building a school culture of health for administrators, teachers, and parents twice annually. All schools received \$500/year to support a member of the school community (most often teachers) to establish and lead a School Wellness Team. The focus was on different elements of written policy implementation depending on the schools' randomized study condition. Each school was assigned one research staff member who visited the school one to two times per month. Visits typically included meeting with the School Wellness Team, principal, all teachers for the target grade, school cafeteria manager (nutrition condition), and physical education teachers (physical activity condition). Newsletters were distributed triennially to reinforce targeted health messages (e.g., Rethink Your Drink campaign). Additionally, nutrition interventions included cafeteria-based nutrition promotion to encourage healthy food choices, taste-testing new foods, and providing alternatives for use of food during celebrations. Physical activity interventions included promotion of active transport (walk/bike) to school, integrating physical activity into classroom lessons, and fitness challenges. Table 1 (tbl0001) provides a list of interventions to support school wellness policy implementation.

Table 1

Policies and Study Interventions to Support School Wellness Policy Implementation

Intervention group	Policies	Implementation support by research staff
District- wide in all schools	 Meals served through the National School Breakfast Program and National School Lunch Program will be appealing and attractive to students; will be served in clean and pleasant settings; will include no fried vegetables at K-8 schools; will offer a variety of fruits and vegetables; and will offer only low-fat milk (no flavored milk). All cereals are whole grain. Competitive foods will not be sold. Students will have physical education class at least 90 minutes per week 	 Create School Wellness Teams each year at each school. Recruit an in-school team leader and pay a stipend to the leader of \$500 per year. Attend School Wellness Team meetings and assist in setting annual goals to support the implementation of wellness policies. Meet annually with teachers and principals to support the implementation of wellness policies. Provide gift cards for principals to use to incentivize teachers to implement policies in the classroom.

Intervention group	Policies	Implementation support by research staff
Nutrition intervention schools	 Schools will not use food or beverages as rewards for academic performance or good behavior. Schools will not withhold food or beverages as punishment. Schools should limit celebrations that involve food during the school day to no more than one party per class per month. Each party should include no more than one food or beverage that does not meet nutrition standards for food and beverages sold individually. The district will disseminate a list of healthy party ideas to parents and teachers. Schools will provide nutrition education to foster lifelong habits of healthy eating. Nutrition education will also extend to the students' homes via workshops for parents, materials given to students and directly sent to parent/guardians such a school menus and other bulletins. Schools should engage students and parents, through taste tests of new entrées and surveys, in selecting foods sold through the school meal programs in order to identify new, healthful, and appealing food choices. 	 Meet with teachers each year and provide materials to support the nutrition education curriculum in the classroom. Provide school with materials that contain messages about healthy beverage choices. Meet with food service director and staff regularly to support professional development and ensure that all meals meet federal nutritional criteria, specifically increasing whole grain products and lowering sodium. Ensure all competitive foods meet state standards. Meet with principals and teachers each year to ensure that food is not used for celebrations or as a reward in class. Provide alternative strategies to the principals and teachers to reward students. Work with cafeteria staff to provide nutrition education activities in the cafeteria, including tastetesting. Work with School Wellness Teams to conduct school-wide campaigns to limit sugary drinks and promote water. Provide newsletters to be sent home with students with nutrition tips and ideas for healthy snacking.

Intervention group	Policies	Implementation support by research staff
Physical activity intervention schools	Schools will provide a quality physical education program that will foster a life-long appreciation for physical fitness through participation in fitness activities. Students will acquire the knowledge to lead a healthy and productive lifestyle. Teachers and other school and community personnel will not use physical activity (e.g., running laps, pushups) or withhold opportunities for physical activity (e.g., recess, physical education) as punishment.	 Support physical education curriculum; provide resources for equipment; focus on exposing students to a variety of activities to enhance lifetime fitness. Work with teachers to support the integration of physical activity into the classroom. Work with principals and teachers to ensure that there are no punitive uses of physical activity and promote positive physical activity-focused fundraising and celebrations. Provide support for physical activity outside of school, including walking/running clubs, use of school building for physical activity after school hours, and participation in community physical activity events. Promote school-wide campaigns to increase physical activity, including distribution of individual activity monitors and online tracking program. Provide newsletters to be sent home with students with fun family physical activity resources.

K–8, kindergarten through eighth grade.

To control for time and attention, time with schools receiving support for both nutrition and physical activity policies was adjusted to be equivalent to the other conditions. As described, for delayed-intervention schools, health-focused messages not related to obesity prevention were implemented, with obesity prevention delivered at the end of the trial.

Data were collected from multiple sources each fall (September–November) and linked via school-assigned identification numbers to protect privacy. ²⁴ Student-level demographic data were obtained from the school district administrative database: birthdate, sex, race/ethnicity. Student surveys (English or Spanish) were administered in school computer labs (Surveymonkey.com). To address literacy concerns, all

questions and responses were read aloud while students completed surveys online. Research assistants helped students with technical or content-related questions. Surveys took $\cong 30$ minutes, and participants received small gifts after each survey.

Physical measurements were obtained by trained research assistants according to WHO Expanded STEPS protocol. ²⁵ Height was measured to nearest half-centimeter using a stadiometer. Weight was measured to nearest 0.10 pound using an electronic flat scale. Primary outcome was BMI, measured annually, from baseline through end of study (fifth to eighth grades). BMI percentile was calculated based on Centers for Disease Control and Prevention age-adjusted and sex-adjusted growth charts. ²⁶ Age- and sex-specific BMI percentile is the most commonly used indicator to measure growth and chart overweight/obesity among adolescents. ²⁷ Moreover, many students are overweight and obese, and BMI percentile is a better indicator of adiposity, particularly for children with high BMI. ²⁸ Outcomes were specified a priori during clinical trial registration (www.ClinicalTrials.gov (http://www.ClinicalTrials.gov), NCTO2043626).

An additional focus was concurrent changes of obesogenic behaviors. Nutritional habits were obtained from self-reported student surveys based on nutrition items from the Youth Risk Behavior Survey ²⁹ and School-Based Nutrition Monitoring Questionnare. ³⁰ Students were asked about foods and drinks consumed yesterday in school, at home, or elsewhere. Surveys were only administered on days when students had school the prior day. Indices were created for consumption of healthy foods (fruit, vegetables, green salad, potatoes-not fried), unhealthy foods (french fries, chips, candy, ice cream, other sweets), healthy drinks (water, milk, 100% juice), and unhealthy drinks (flavored milk; soda; sweetened coffee; and sport, energy, and flavored drinks). Participants also were asked about number of days within past 7 days that they ate at fast-food restaurants and drank sugar-sweetened beverages. Physical activity behaviors were measured based on U.S. Centers for Disease Control and Prevention physical activity recommendations for children (≥60 minutes/day). ³¹

Statistical Analysis

Data analyses were conducted using prespecified hypotheses and intention-to-treat principles, whereby students were assigned to an intervention group based on school of enrollment in fifth grade. Students who transferred from a nonstudy school to a study schools in sixth grade (n = 62) were assigned to an intervention group based on sixth grade school. Maximum likelihood approach was used to handle missing observations, with the assumption that any data missing were missing completely at random or missing at random. ³² Basic statistics describe students by intervention condition. Differences in categorical variables were compared using the Rao–Scott chi-square test.

Hierarchical linear modeling was conducted to test effects of study condition on outcomes over time. For continuous outcomes—including primary outcomes models using BMI percentile—hierarchical linear mixed models were used; for categorical variables, hierarchical generalized linear mixed models Poisson regression was used. ³⁴

Models include baseline BMI, sex, nutrition intervention, physical activity intervention, time, and two- and three-way interactions between the intervention conditions X time. In longitudinal data, change in response depends on baseline values (e.g., individuals with high baseline BMI might still have higher BMI at the end of the study simply because of higher starting values).

Because the goal is to understand whether there is differential change to BMI in response to interventions, and whether there is an interaction with time, the authors accounted for baseline BMI using the constrained longitudinal data analysis full likelihood approach ³⁵ in which the baseline values, as well as post-randomization values, are modeled as dependent variables. In these models and because of randomization, baseline mean responses for treatment groups were assumed equal following standard methodologic approaches. 36 37

Multivariable analyses accounted for multilevel nature of data, adjusting for intra-cluster correlation (ICC) among repeated measures within students and schools, and allowed use of all study timepoints. A random intercept model with no predictors was fit to calculate ICC. A three-level hierarchical model was initially tested; however, the ICC for students within schools was o (exactly o), and ICC for time within students was 0.917. Therefore, the two-level hierarchical model (Time=level 1, Students=level 2) was more parsimonious, producing a better model fit. Models with the lowest Akaike Information Criteria were deemed to have best fit. Compound symmetry covariance structures were best fit for between-individual random effect and within-individuals random error. Time and intercept were included as random effects in the statistical models.

All statistical analyses were conducted using SAS, version 9.4. Final analyses for this paper were conducted upon completion of the trial, with details of student behavior at final year and post-hoc analyses more recently (2016–2018).

RESULTS

Mean age of students at study entry was 10.9 years (SD=0.6). Racial/ethnic categorization generally reflected distribution of students in the district: 47.2% Hispanic, 35.0% black, and 17.8% white/other. Students in study conditions did not differ by age or race. Girls accounted for 54% of participants. The physical activity—only condition had significantly more girls; the largest study school, randomized to this condition, was a school where two thirds of students were female. Mean age- and sex-adjusted BMI percentile did not differ at study entry by intervention (mean=73.1, SD=29.5). Although average BMI could be categorized as healthy weight, more than one half of students were overweight (85th to 95th percentile) or obese (95th percentile): 22.5% and 29.2%, respectively ($\frac{7}{100002}$).

Table 2
Baseline Characteristics by Intervention Condition (n = 595)

Characteristics	n	Overall	Nutrition (yes)	Nutrition (no)
		(<i>n</i> =595)		

Characteristics	n	Overall (<i>n</i> =595)	RAttrition (yels/A-		RA#rition (ndP)A—	
			Dual (PA+152)	Nutrition only PA=152)	PA only (PA+178)	Delayed PA=113)
			Dual (<i>n</i> =152)	Nutrition only $(n = 152)$	PA only (<i>n</i> =178)	Delayed (<i>n</i> =113)
Age, years, M±SD	595	10.9±0.62	10.9±0.70	10.7±0.55	10.9±0.62	10.9±0.59
Race/ethnicity, %						
Hispanic	281	47.2	49.3	66.5	42.1	26.6
Non-Hispanic black	208	35.0	42.1	11.2	33.7	59.3
Non-Hispanic white	106	17.8	8.6	22.4	24.2	14.2
Sex, %						
Male	275	46.2	50.0	50.0	37.6	49.6
Female	320	53.8	50.0	50.0	62.4	50.4
BMI percentile, M±SD	595	73.1±29.5	73.8±27.9	73.8±28.1	73.0±31.5	71.4±30.3
BMI z -score, M±SD	595	0.89±1.15	0.89±1.10	0.90±1.06	0.90±1.24	0.86±1.19
BMI category, %						
Underweight	13	2.2	2.0	0.7	3.4	2.7
Normal	270	45.4	48.0	48.0	39.3	47.8
Overweight	134	22.5	24.3	23.0	23.6	17.7
Obese	178	29.9	25.7	28.3	33.7	31.9
Nutrition behaviors						
Healthy food total/day, M±SD	554	2.20±1.3	2.5±1.3	2.1±1.4	2.1±1.2	2.2±1.3

Characteristics		Overall (<i>n</i> =595)	Nutrition (yes)		Nutrition (no)	
			PA+	PA-	PA+	PA-
			Dual (<i>n</i> =152)	Nutrition only (<i>n</i> =152)	PA only (<i>n</i> =178)	Delayed (<i>n</i> =113)
Unhealthy food total/day, M±SD	553	2.38±1.7	2.5±1.9	2.4±1.6	2.3±1.7	2.2±1.4
Healthy drink total/day, M±SD	556	2.67±1.3	3.0±1.5	2.6±1.3	2.6±1.3	2.6±1.1
Unhealthy drink total/day, M±SD	540	2.3±2.1	2.6±2.2	2.4±2.2	2.1±1.9	2.1±1.9
Ate fast food last week, %	_	69.1	73.0	73.0	66.3	62.8
PA behavior						
Meets PA guideline (≥60 minutes/7 days per week), %	_	20.8	22.4	19.1	24.2	15.9
Days/week ≥60 minutes of PA, M±SD	505	4.0±2.3	4.1±2.2	3.8±2.3	4.2±2.3	3.5±2.4

PA, physical activity.

There were no notable school-level differences in size or relevant socioeconomic characteristics. Specifically, school size ranged from 465 to 580 students (mean=492), with mean class size constant (20–23 students). Free lunch is available to all students in the district because eligibility is high overall, exceeding 60% in all schools (mean=71.4%).

There was a significant interaction between the nutrition intervention X time (F = 3.20, p = 0.02): students in schools randomized to receive support for nutrition policies had healthier BMI percentile trajectories ($\underline{\text{Figure 2A (fig0002)}}$, described in more detail below). There was no significant interaction between the physical activity intervention X time (p = 0.94; $\underline{\text{Figure 2B (fig0002)}}$). Further, there was no significant interaction between the two interventions (p = 0.33), and no three-way interaction between nutrition intervention X physical activity intervention X time (p = 0.35).

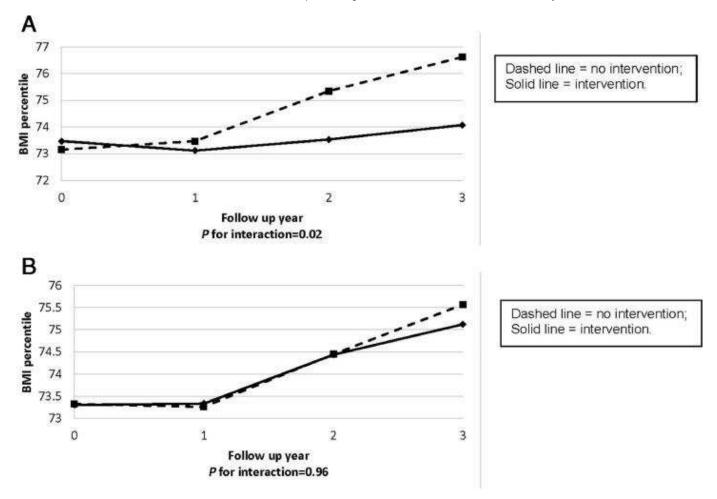


Figure 2

(A) BMI percentile over time by nutrition intervention status. (B) BMI percentile over time by physical activity intervention status.

Note: (A) BMI percentile M±SE differences: at baseline (0.32 \pm 0.77, p =0.68), 1-year post-intervention ($-0.35\pm$ 0.29, p =0.65), 2 years post-intervention ($-1.81\pm$ 0.85, p =0.034), and 3 years post-intervention ($-2.55\pm$ 0.90, p =0.005). (B) BMI percentile M±SE differences: at baseline ($-0.02\pm$ 0.77, p =0.98), 1-year post-intervention ($0.07\pm$ 0.79, p =0.93), 2 years post-intervention ($-0.012\pm$ 0.85, p =0.99), and 3 years post-intervention ($-0.45\pm$ 0.90, p =0.62).

Examining effects of the interaction between the nutrition intervention X time, there was no significant difference between BMI percentile of students in schools randomized to receive the nutrition intervention versus those who were not at baseline (β =0.65, p=0.55), Year 1 (β =0.01, p=0.99), and Year 2 post-intervention (β = -1.23, p=0.28). However, significant differences emerged during Year 3 post-intervention (β = -2.40, p=0.04). Notably, the magnitude of intervention effects increased over time (Figure 2A (fig0002)). Overall, students at schools

randomized to the nutrition-only and dual study conditions had an increase in BMI percentile of less than 1 percentile (0.68 and 0.55, respectively), compared with students at schools randomized to physical activity—only and delayed intervention conditions, where increase in BMI percentile was 2.98 and 3.86, respectively.

Post-hoc analyses were conducted to assure that any skewness in BMI percentile did not impact model specification. Although there was some skewness (-1.09), the plot of residuals of the predicted values did not show any systemic trends and residuals were relatively symmetrical (mean=0.0, variance=0.009).

Additional analyses were conducted to determine whether effects are stable using BMI z -score as the outcome. Students in schools randomized to the nutrition condition were less likely to have an increase in BMI z -score, with stronger cumulative effects over time (Year 2: β = -0.01, Year 3: β = -0.03); however, the primary interaction of nutrition intervention X time was not statistically significant (p =0.16). Consistent with BMI percentile, there was no significant difference by BMI z -score between students in schools randomized to physical activity versus those who were not (Year 2: β =0.09, Year 3: β =0.08).

Given significant effects for students in schools randomized to the nutrition intervention, changes in dietary behaviors over time were examined. Specifically, at the end of the study (eighth grade), students in schools randomized to nutrition interventions reported consuming fewer unhealthy foods (mean=1.83 [SD=0.11] vs mean=2.23 [SD=0.12], β = -0.19, p =0.02), and less frequent consumption of sugar-sweetened beverages (37.95% vs 27.18% drank sugar-sweetened beverages on 2 or fewer days in the past 7 days; OR=1.36, p =0.025) compared with those in schools with no targeted nutrition intervention. These students also were less likely to have had any meals at fast-food restaurants in the past 7 days (26.34% vs 35.20%, OR=0.58, p =0.02). There was no difference in healthy foods or healthy beverage consumption. There was no significant improvement in days per week of \geq 60 minutes of physical activity or among the proportion of students who meet physical activity guidelines (\geq 60 minutes, 7 days/week) among students in schools randomized to the physical activity intervention.

To test for interactions between the interventions with sex, based on an a priori analytic plan, a fully saturated model was run. This included all baseline study indicators (BMI, age, sex, race/ethnicity, nutrition intervention, physical activity intervention, time), as well as the two interaction terms (nutrition X sex, physical activity X sex) and interactions between intervention conditions X by time (nutrition X physical activity, nutrition X time, physical activity X time, nutrition X physical activity X time). There were no statistically significant interactions.

Finally, there was interest in determining whether the nutrition intervention was effective for all students across baseline BMI. There was a significant interaction between time X intervention among students in the BMI healthy weight group (fifth to 84.9th percentile, p = 0.04), but not among students underweight, overweight, or obese. Similar to results for the entire study sample, the magnitude of effects increased over time.



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