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A School-Based Intervention for Diabetes Risk Reduction

The HEALTHY Study Group*

Abstract

BACKGROUND—We examined the effects of a multicomponent, school-based program addressing risk factors for diabetes among children whose race or ethnic group and socioeconomic status placed them at high risk for obesity and type 2 diabetes.

METHODS—Using a cluster design, we randomly assigned 42 schools to either a multicomponent school-based intervention (21 schools) or assessment only (control, 21 schools). A total of 4603 students participated (mean [±SD] age, 11.3±0.6 years; 54.2% Hispanic and 18.0% black; 52.7% girls). At the beginning of 6th grade and the end of 8th grade, students underwent measurements of body-mass index (BMI), waist circumference, and fasting glucose and insulin levels.

RESULTS—There was a decrease in the primary outcome — the combined prevalence of overweight and obesity — in both the intervention and control schools, with no significant difference between the school groups. The intervention schools had greater reductions in the secondary outcomes of BMI z score, percentage of students with waist circumference at or above the 90th percentile, fasting insulin levels (P = 0.04 for all comparisons), and prevalence of obesity (P = 0.05). Similar findings were observed among students who were at or above the 85th percentile for BMI at baseline. Less than 3% of the students who were screened had an adverse event; the proportions were nearly equivalent in the intervention and control schools.

CONCLUSIONS—Our comprehensive school-based program did not result in greater decreases in the combined prevalence of overweight and obesity than those that occurred in control schools. However, the intervention did result in significantly greater reductions in various indexes of adiposity. These changes may reduce the risk of childhood-onset type 2 diabetes. (Funded by the National Institutes of Health and the American Diabetes Association; ClinicalTrials.gov number, NCT00458029.)

Recent data indicate that 16% of children 6 to 19 years of age in the United States are overweight, and 19% are obese.[1] Rates are even higher in economically disadvantaged ethnic minority groups.[2] Of all the consequences of childhood obesity,[3–5] the most serious is the development of type 2 diabetes. Children in whom type 2 diabetes develops are at risk for complications from the disease, including retinopathy, neuropathy, and cardiovascular and renal disease, that can be manifested when they are adults, if not earlier. Schools present opportunities for reducing the risk of diabetes, since no other institution has as much contact time with children.[6] Moreover, schools can implement environmental changes that affect available foods, physical education, class curricula, and the acceptability of healthy behaviors. Although some school-based interventions have had effects on overweight or obesity,[7–9] most, particularly those involving large cohorts,[10,11] have not.[12] However,

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

several short-term, school-based programs favorably altered glucose levels, insulin levels, or both,[13,14] even though they had no effect on the body-mass index (BMI).

The purpose of the HEALTHY study was to evaluate the effects of a 3-year, multicomponent, school-based program on risk factors for type 2 diabetes. In this article, we describe the major outcomes among more than 4600 children who were followed from 6th grade through 8th grade.

METHODS

STUDY DESIGN

We conducted a randomized, cluster-design study in 42 schools at 7 field sites. Schools were the unit for randomization, intervention, and analysis. For a school to be included in the study, at least 50% of the children in the school had to be eligible for federally subsidized, free or reduced-price meals or at least 50% of its students had to be black or Hispanic. Black and Hispanic children of lower socioeconomic status were oversampled, given the fact that these children are at a high risk for both obesity and type 2 diabetes.[1,15] Previous reports have described the baseline characteristics of the schools and the children,[2] the study design,[16] and the methods.[17–22] The study was conducted in accordance with the protocol and the statistical analysis plan, which are available with the full text of this article at NEJM.org.

Students enrolled in 6th grade in the fall of 2006 were eligible for participation if their height, weight, sex, and age were recorded at baseline and if they did not have diabetes or any condition that would preclude regular participation in physical education. Although all the children in the intervention schools and grades were exposed to the intervention program, written consent from parents and assent from children were required for any data collection. The study was approved by the institutional review board at each participating university. Recruitment procedures[22] were identical for the intervention and control schools.

INTERVENTION

The intervention consisted of four integrated components: nutrition, physical activity, behavioral knowledge and skills, and communications and social marketing. The rationale, techniques, and pilot testing of each component were described previously[16–22] and are summarized in the Supplementary Appendix, available at NEJM.org. The intervention materials are available at www.healthystudy.org. The nutrition component targeted the quantity and nutritional quality of foods and beverages that were served throughout the school environment (cafeteria, vending machines, a la carte options, snack bars, school stores, fundraisers, and classroom celebrations).[18] The physical-education component was designed to increase the amount of time students spent in moderate-to-vigorous physical activity, defined as activity sufficient to raise the heart rate to 130 beats or more per minute.[17] Behavioral knowledge and skills were communicated with the use of a classroom-based program, FLASH (Fun Learning Activities for Student Health),[19] which targeted self-awareness, knowledge, behavioral skills (e.g., self-monitoring and goal setting), and peer involvement for behavioral change. Communication strategies and social marketing integrated and supported the intervention.[20]

OUTCOMES

Fasting measurements of weight, height, waist circumference, blood pressure, glucose level, and insulin level were obtained as described previously[16] (see also the Supplementary Appendix). The primary outcome was the combined prevalence of overweight and obesity (BMI ≥85th percentile). Secondary outcomes included obesity (BMI ≥95th percentile), BMI z score, and continuous and categorical measurements of waist circumference, fasting

glucose level, and fasting insulin level. All measurements were performed at the schools in the fall of 2006, when the students were in 6th grade and in the spring of 2009, when the students were in 8th grade. Measurements were performed by specially trained study staff members who were not involved in the intervention. During the course of each semester, structured observations were conducted on a random and unannounced basis to assess the extent to which the intervention was being implemented as planned.[21] Adverse events were defined as any untoward event that occurred at the time blood was drawn or as a result of blood being drawn for health screening and that required on-site attention (see the Supplementary Appendix).

STATISTICAL ANALYSIS

Descriptive data are presented as means ±SD or percentages. General linear mixed models were used to analyze differences between the intervention and control schools,[23,24] with the covariance structure appropriately adjusting for variability both between clusters (schools) and within a cluster (students within the same school).[25,26] We estimated that with a sample of 36 schools, the study would have 90% power to detect a difference of 5 percentage points between the intervention and control schools with respect to the primary outcome (combined prevalence of overweight and obesity), at a two-sided significance level of 0.05. The number of schools was increased to 42 to allow each of the 7 field centers to recruit the same number of schools and to compensate for any attrition of schools.

Analyses were performed on data from the cohort of students who underwent measurements at baseline, when they were in 6th grade, and at the end of the study, when they were in 8th grade. Baseline values were included in the models as covariates. Prespecified secondary outcomes included obesity (BMI ≥95th percentile), other measures of adiposity (e.g., BMI z score and waist circumference), and glucose and insulin levels.

Students who were overweight or obese (BMI ≥85th percentile) at baseline were defined as a high-risk subgroup; approximately 50% of the participating students were in this category (Table 1). During the planning of the study, we considered limiting the intervention to the high-risk subgroup but decided against this because we wanted to support a public health approach and to avoid stigmatization of overweight and obese children. Nonetheless, examining outcomes in the high-risk subgroup is important, with appropriate caution in interpreting the results of subgroup analyses.[27]

To evaluate the need to adjust for site, sex, or race or ethnic group as covariates, models included a term for the interaction with study group (intervention or control). A P value of less than 0.10 was considered to indicate a significant interaction. Since all the P values were greater than 0.15, the analyses were not adjusted for site, sex, or race or ethnic group.

RESULTS

ENROLLMENT

A total of 42 schools participated in the study. The 21 intervention and 21 control schools were similar with respect to the mean number of students (873 and 863, respectively), the mean number of 6th graders (265 and 266), the percentage of students eligible for free or reduced-price meals (77% and 74%), and the percentage of black or Hispanic students (77% and 70%).[16]

The rate of parental consent and child assent was 58.9%. There was little difference between those who consented and assented and those who did not with respect to mean (±SD) BMI (the weight in kilograms divided by the square of the height in meters) (22.6±8.7 and 21.8±5.3, respectively), mean age (11.3±0.6 and 11.3±0.7 years), race or ethnic group

(70.5% and 72.9% black or Hispanic), or sex (47.7% and 53.0% boys). There were no significant differences between students in the intervention schools and those in the control schools on any baseline measure.[16] The baseline characteristics of the study cohort are presented in Table 1.

ATTRITION

None of the 42 schools left the study. Figure 1 shows the recruitment and retention of students in the intervention and control schools. Among the 6358 students assessed at the beginning of 6th grade, 4603 (72.4%) were reassessed when they were in 8th grade and valid measurements were obtained; these students constituted the HEALTHY cohort. Among the 1755 students who were not included in the cohort, 1706 (97.2%) had transferred to a nonstudy school, 42 (2.4%) were still in school but were not assessed, and 7 (0.4%) were assessed but the data could not be used (e.g., because the student was pregnant or was wearing a cast). There were 53 students in control schools and 71 students in intervention schools who transferred to one of the other 41 study schools during the study. These students attended an end-of-study screening at the school to which they had transferred, but were assigned to the condition (intervention or control) of their original school for data analysis.

The baseline characteristics were similar between the HEALTHY study cohort of 4603 students and the 1755 students who were not reassessed in 8th grade, with respect to age (11.3 and 11.5 years, respectively), sex (47.3% and 48.4% boys), race or ethnic group (72.2% and 74.5% black or Hispanic), the highest level of education attained by the head of the household (51.7% and 54.2% high school or less), family history of diabetes (17.6% and 18.5%), BMI (22.3 and 22.4), fasting glucose level (93.5 and 93.1 mg per deciliter [5.19 and 5.17 mmol per liter]), and fasting insulin level (13.3 μU per milliliter [92.4 pmol per liter] in both groups) (Table 1). Student attrition was identical (27.5%) in the intervention and control schools.

PROCESS EVALUATION

A total of 1101 structured observations of physical-education components of the study, 210 cafeteria observations, 449 FLASH-class observations, and 105 social-marketing observations were made over the course of the study. Strategies regarding nutrition were implemented approximately 90±5.6% of the time. Physical-education class activities were implemented as planned 87±4.9% of the time, and FLASH activities 97±4.8% of the time. The adherence rate for hanging the required number of posters as part of the communications campaign was 84±9.1%.

WEIGHT-RELATED OUTCOMES

Data on outcomes are presented in Table 2. Both intervention and control schools had reductions in the primary outcome, the prevalence of overweight and obesity (BMI ≥85th percentile), with no significant difference between the groups. However, there was a nearly significant reduction in the prevalence of obesity (BMI ≥95th percentile) in the intervention schools, as compared with the control schools; children in the intervention schools had 19% lower odds of being obese at the end of the study than did those in the control schools (odds ratio, 0.81; 95% confidence interval [CI], 0.66 to 1.00; P = 0.05). The mean BMI z score and the percentage of students with waist circumference in the 90th percentile or higher at the end of the study were significantly lower in the intervention schools than in the control schools (P = 0.04 for both comparisons).

Among the 2292 students who were overweight or obese in 6th grade (approximately 50% of the sample), there were significant and nearly identical decreases in the prevalence of

overweight and obesity in the intervention and control schools (15.9% in the control schools and 16.5% in the intervention schools). There was a greater reduction in the prevalence of obesity in the intervention schools than in the control schools. Students in intervention schools who were overweight or obese in 6th grade had 21% lower odds of being obese at the end of 8th grade (odds ratio, 0.79; 95% CI, 0.63 to 0.98; P = 0.04). Among students who were overweight or obese in 6th grade, there was a trend toward greater reductions in the BMI z score in the intervention schools than in the control schools (P = 0.06). In addition, intervention schools had a significantly lower percentage of students with waist circumferences at or above the 90th percentile at the end of the study (P=0.03).

GLUCOSE LEVELS

There were no significant differences between the intervention and control schools in mean plasma glucose levels or in the percentage of students who had glucose levels of 100 mg per deciliter (5.55 mmol per liter) or higher, in the full sample or in the subgroup of students who were overweight or obese at baseline. Among all students — both those in the intervention group and those in the control group — 30% of those who were in the 95% percentile or higher of BMI in 8th grade had glucose levels of 100 mg per deciliter or higher, as compared with 21% of those in the 85th to 94th percentile of BMI and 19% of those under the 85th percentile.

INSULIN LEVELS

Students in both the intervention and control schools had increases in fasting insulin levels between the beginning of 6th grade and the end of 8th grade, a finding that is consistent with a peak in plasma insulin levels at Tanner stage 3 or 4.[28] In the full sample and in the subgroup of students who were overweight or obese at baseline, students in the intervention schools had significantly lower mean insulin levels in 8th grade than did students in the control schools (P=0.04). There were no significant differences between the intervention and control schools in the percentage of students with insulin levels that were 30 μU per milliliter (208.4 pmol per liter) or higher (Table 2), either in the full sample or in the subgroup of students who were overweight or obese at baseline. Among all students — both those in the intervention group and those in the control group — 35% of those who were in the 95% percentile or higher of BMI in 8th grade had insulin values of 30 μU per milliliter or higher, as compared with just 6% of those in the 85th to 94th percentile of BMI and 2% of those under the 85th percentile.

ADVERSE EVENTS

A total of 2.4% of the students at baseline and 1.7% at the end of the study reported at least one adverse event that occurred during the health screening, with no significant differences between the intervention and control schools. The most frequent adverse event was dizziness (Table 3). One 8th-grade girl in a control school committed suicide. The site investigators, the investigators from the National Institute of Diabetes and Digestive and Kidney Diseases, and the data and safety monitoring board determined that the event was unrelated to the study.

DISCUSSION

We did not observe a significant effect of the intervention on the primary outcome — the combined prevalence of overweight and obesity. However, the intervention, as compared with assessment only, was associated with significantly greater reductions in various indexes of adiposity. Specifically, the intervention was associated with a decrease in the prevalence of obesity — a decrease that was significant in the subgroup of students who were overweight or obese at the beginning of the study and approached significance in the full

sample. There were also significantly greater reductions in the intervention schools than in the control schools in the BMI z score, the percentage of students with waist circumference in the 90th percentile or higher, and the mean insulin level in the overall sample.

Although some previous school-based interventions have been associated with a decrease in the number of overweight participants,[8,9] only one study showed an effect of a school-based intervention on obesity, and the effect was limited to girls.[7] Intensive, clinic-based, behavioral-treatment programs have had only a modest effect.[29] Thus, the reduction in obesity in the present study is notable, given the sociodemographic characteristics of the sample and the numerous challenges that these youth and their families face. The outcomes of the intervention in our study were observed in comparison with outcomes in control schools, in which there were also decreases in the prevalence of obesity. The results in the control schools are in contrast to those of previous studies, in which control schools had increased rates of obesity.[7–9] The observed efficacy of our intervention with respect to most of the weight-related outcomes may be due to a comprehensive approach that targeted energy balance specifically rather than nutritional quality alone (e.g., increasing the intake of fruits and vegetables), the intervention's duration of almost 3 years, the high degree of fidelity with which the intervention was delivered, or some combination of these factors.

The reason for the significant reduction in obesity among the 50% of the students who were overweight or obese at the beginning of the study is unclear. It may be that the same intervention (e.g., increased moderate-to-vigorous physical activity and decreased energy content of a la carte items) given to both nonoverweight and overweight or obese children resulted in a greater energy deficit in the overweight and obese children because they probably had higher energy intakes, lower levels of physical activity, and higher basal energy requirements at baseline than did the children who were not overweight. We speculate that it might be less stigmatizing for overweight and obese children to make healthy changes when they are actively supported by changes in the schoolwide environment than it would be if the intervention targeted these children without addressing the environmental factors that promote obesity. We also speculate that the higher rate of a family history of diabetes among overweight and obese children may have caused the parents of these children to be more responsive to intervention messages than the parents of nonoverweight children might have been. Although the present results are encouraging, they should be interpreted conservatively, because they are based on a subgroup analysis (approximately 50% of the entire sample).[27]

Decreasing the number of children in the 95th percentile or higher of BMI may have profound effects on the population risk of diabetes, since obese children in this study were at highest risk for elevated levels of both glucose and insulin. The observed reduction in the percentage of students with waist circumference at or above the 90th percentile is also likely to decrease the risk of diabetes, given that waist circumference is a risk factor for insulin resistance in children, independently of BMI.[30] Although the difference in mean insulin levels between groups was statistically significant, the small difference makes the clinical significance difficult to assess.

There were significant decreases in adiposity in the overall cohort, irrespective of the study group, during the study period. Even in control schools, both the combined prevalence of overweight and obesity and the prevalence of obesity decreased by approximately 4%. Among the 49.3% of children in the control schools who were overweight or obese at the beginning of the study, the combined prevalence of overweight and obesity fell by 15.9%, and the prevalence of obesity by 8.5%.

Cross-sectional data from the 2008 National Health and Nutrition Examination Survey (NHANES) suggested that childhood obesity in the United States may have reached a plateau.[1] Our current longitudinal data set from the fall of 2006 to the spring of 2009 indicated a decrease in childhood obesity among children whose race or ethnic group and family income placed them at high risk for obesity. It is possible that the assessment of children in the control schools and the feedback to parents (see the Supplementary Appendix for sample letter) were responsible for the decreased rates of obesity in these schools. Although previous school-based studies have not shown reductions in obesity among control schools, the measurement effect may be enhanced now that there is greater public concern about obesity, as was suggested by the recent experience in Arkansas with the reporting of children's BMI to parents.[31]

It is also possible that adolescence is not a stage of life that is associated with an increasing prevalence of obesity.[32] We found no difference in the prevalence of obesity between our current sample in 6th grade[2] and more than 1700 8th graders of similar race or ethnic group and socioeconomic status,[33] although this finding is limited by its cross-sectional nature. Our large, longitudinal data set strongly indicated a decrease, rather than a flattening, of the prevalence of obesity from 6th to 8th grade, a finding that has great public health importance, given the evidence that obesity in adolescence persists into adulthood.[3] Exploration of similar longitudinal data sets can help clarify the nature of changes in the prevalence of obesity at various ages.

This study had limitations. Because we intentionally oversampled low-income black and Hispanic students, the sample is not nationally representative. The intervention was facilitated by staff and funds provided by the study. Such an efficacy study cannot assess the feasibility, effectiveness, or sustainability of an intervention program outside a study setting. Effectiveness studies are needed to determine whether these results can be generalized.

In conclusion, our comprehensive school-based program did not result in greater decreases in the combined prevalence of overweight and obesity than those that occurred in control schools. However, the intervention did result in significantly greater reductions in various indexes of adiposity. These changes may reduce the risk of childhood-onset type 2 diabetes. The observation that the rates of overweight and obesity declined among the adolescents in the control schools is encouraging. The reasons for this finding are unclear and should be explored with the use of other recently compiled longitudinal data sets.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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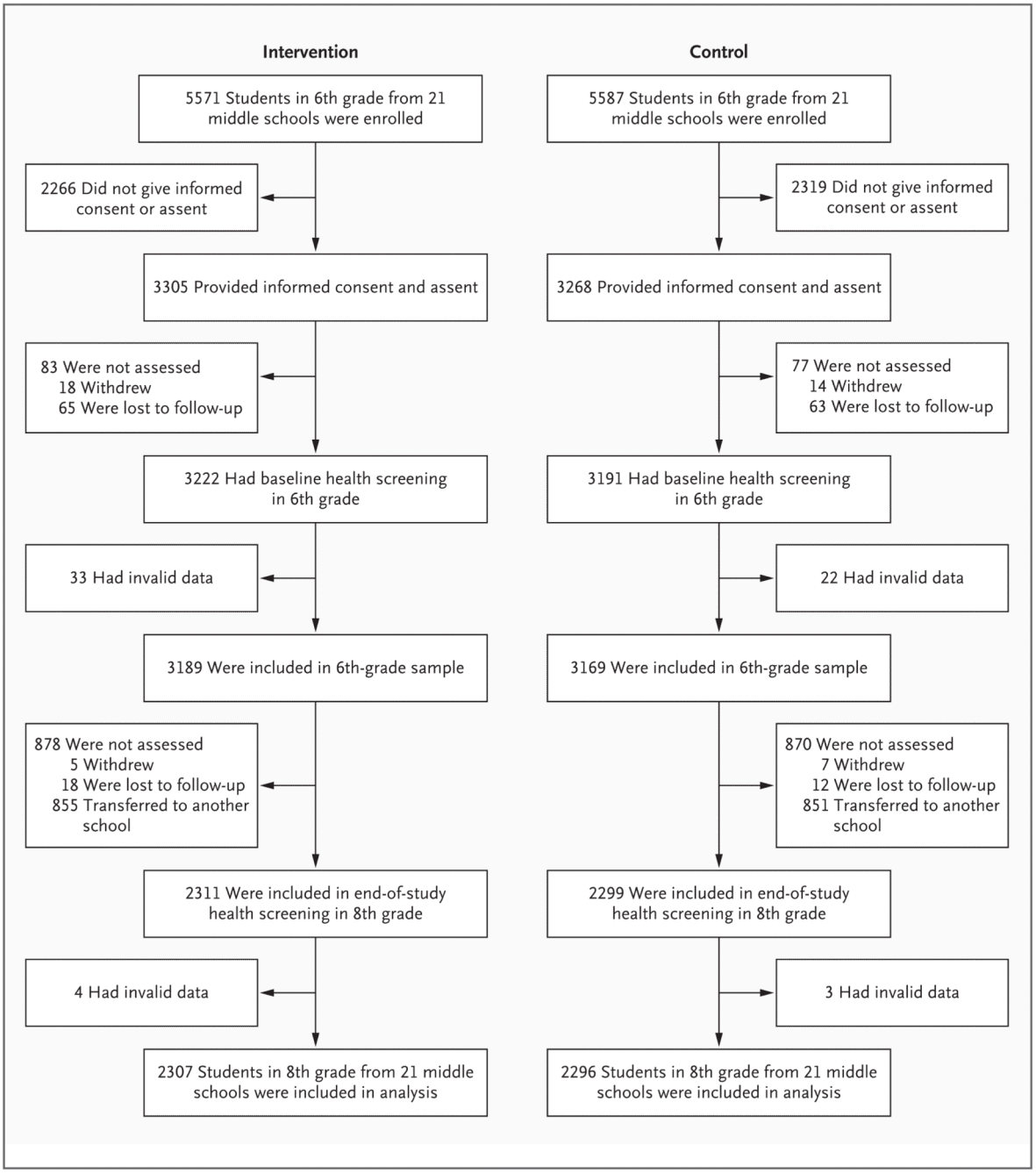

Figure 1.
Recruitment, Assessment, and Retention of Students.

Table 1

Baseline Characteristics of the Students.*

Characteristic	Total	Intervention Group			Control Group		
		Total†	BMI <85th Percentile	BMI ≥85th Percentile	Total†	BMI <85th Percentile	BMI ≥85th Percentile
No. of students (% within group)	4603 (100)	2307 (100)	1147 (49.7)	1160 (50.3)	2296 (100)	1164 (50.7)	1132 (49.3)
Age (yr)	11.3±0.6	11.3±0.5	11.3±0.5	11.2±0.5	11.3±0.6	11.3±0.6	11.3±0.6
Male sex (%)	47.3	47.4	44.2	50.5	47.1	44.0	50.4
Race or ethnic group (%)							
Hispanic	54.2	54.8	51.3	58.4	53.5	50.3	56.7
Black	18.0	20.3	22.2	18.4	15.7	15.3	16.2
White	19.3	17.1	18.6	15.5	21.6	24.4	18.6
Other	8.5	7.8	7.9	7.7	9.2	10.0	8.5
Highest education level attained by head of household (%)							
Less than high school	12.4	13.0	11.7	14.3	11.9	10.7	13.1
Some high school	14.3	14.1	13.7	14.5	14.5	14.9	14.1
High-school diploma	25.0	24.7	24.3	25.1	25.2	22.6	27.7
Some college or specialized training	28.5	29.8	31.4	28.2	27.2	26.9	27.6
College or university degree	13.9	12.6	12.4	12.7	15.2	17.4	13.0
Postgraduate training or degree	5.9	5.8	6.5	5.2	6.0	7.5	4.5
Family history of diabetes (%)	17.6	17.1	13.0	20.9	18.1	12.4	24.2

*Plus–minus values are means ±SD. Sex, date of birth, and race or ethnic group were determined by self-report. Ethnic group (Hispanic or non-Hispanic) and race were asked as two separate questions, with laminated cards showing and defining choices; however, the students themselves did not make such distinctions, and those who identified themselves as Hispanic did not respond to the follow-up question regarding race. The parent or guardian completed a self-report form by mail that included questions about socioeconomic status (highest level of education attained by head of household) and family history of diabetes in first-degree blood relatives. BMI denotes body-mass index.

†All P values for the comparisons between intervention and control schools at baseline were greater than 0.20.[16]

Table 2

Baseline and End-of-Study Assessments of Students in Intervention and Control Schools.*

Measure	All Students (N = 4603)					Students with Baseline BMI ≥85th Percentile (N = 2292)				
	Baseline	End of Study	Change	Odds Ratio for Intervention vs. Control†	P Value	Baseline	End of Study	Change	Odds Ratio for Intervention vs. Control	P Value
BMI ≥85th percentile — % of students				0.99 (0.82–1.19)	0.92				0.96 (0.76–1.21)	0.72
Control	49.3	45.2	−4.1			100.0	84.1	−15.9		
Intervention	50.3	45.8	−4.5			100.0	83.5	−16.5		
BMI ≥95th percentile — % of students				0.81 (0.66–1.00)	0.05				0.79 (0.63–0.98)	0.04
Control	30.4	26.6	−3.8			61.7	53.2	−8.5		
Intervention	30.1	24.6	−5.5			59.8	48.3	−11.5		
BMI z score				—	0.04				—	0.06
Control	0.87±1.12 (0.10–1.80)	0.86±1.05 (0.16–1.70)	−0.01			1.80±0.44 (1.43–2.14)	1.66±0.59 (1.27–2.12)	−0.14		
Intervention	0.90±1.08 (0.12–1.80)	0.85±1.03 (0.12–1.63)	−0.05			1.80±0.44 (1.43–2.15)	1.62±0.61 (1.23–2.09)	−0.17		
Waist circumference ≥90th percentile — % of students				0.80 (0.64–0.99)	0.04				0.78 (0.63–0.97)	0.03
Control	28.6	22.7	−5.9			57.7	45.1	−12.6		
Intervention	29.4	21.3	−8.1			58.3	41.3	−17.0		
Waist circumference — cm				—	0.07				—	0.09
Control	75.7±14.8 (64.0–85.5)	81.0±14.8 (70.0–89.2)	5.3			87.2±12.1 (78.5–94.5)	91.3±14.0 (80.6–99.9)	4.1		

Measure	All Students (N = 4603)					Students with Baseline BMI ≥85th Percentile (N = 2292)				
	Baseline	End of Study	Change	Odds Ratio for Intervention vs. Control†	P Value	Baseline	End of Study	Change	Odds Ratio for Intervention vs. Control	P Value
Intervention	76.0±15.1 (64.3–85.6)	80.6±14.8 (69.3–88.3)	4.6			87.2±12.8 (78.0–94.4)	90.6±14.0 (80.0–99.0)	3.4		
Fasting insulin ≥30 U/ml — % of students				0.91 (0.71–1.17)	0.46				0.87 (0.67–1.14)	0.31
Control	7.3	11.2	3.9			13.7	20.5	6.8		
Intervention	6.3	10.1	3.8			12.2	18.2	6.0		
Fasting insulin — U/ml‡				—	0.04				—	0.04
Control	13.4±12.4 (6.4–15.3)	17.4±13.4 (9.4–20.5)	4.0			18.5±15.0 (9.7–22.8)	22.6±16.1 (12.7–26.9)	4.1		
Intervention	13.1±10.6 (6.8–16.0)	16.9±15.4 (9.2–19.8)	3.8			17.9±12.5 (10.2–21.6)	21.5±18.2 (11.6–25.7)	3.6		
Fasting glucose ≥100 mg/dl — % of students				0.89 (0.63–1.27)	0.52				0.94 (0.67–1.32)	0.70
Control	16.2	23.1	6.9			18.4	25.4	7.0		
Intervention	15.8	20.7	4.9			18.0	23.8	5.8		
Fasting glucose — mg/dl				—	0.33				—	0.23
Control	93.6±6.7 (89.0–98.0)	94.3±7.9 (89.0–99.0)	0.7			94.0±6.9 (90.0–98.0)	94.9±8.2 (90.0–100.0)	0.9		
Intervention	93.5±6.6 (89.0–97.0)	93.5±8.6 (88.0–98.0)	0.0			94.1±6.5 (90.0–98.0)	94.0±7.9 (89.0–99.0)	−0.1		

*Plus–minus values are means ±SD, and data in parentheses are 95% confidence intervals. To convert the values for glucose to millimoles per liter, multiply by 0.05551. To convert the values for insulin to picomoles per liter, multiply by 6.945. BMI denotes body-mass index.

†Odds ratios were not calculated for continuous variables.

‡The distribution of insulin values was skewed; therefore, analyses were performed with log-transformed insulin values.

Table 3

Adverse Events Reported at the Baseline and End-of-Study Health Screenings.*

Variable	Baseline	End of Study
Students reporting an event (% of students screened)†		
Control group	2.4	1.7
Intervention	2.4	1.6
Overall	2.4	1.7
Type of event (% of total events)‡		
Change in skin color	11.7	14.2
Swelling, itching, or rash	2.9	5.7
Bruise or hematoma	6.3	1.4
Dizziness	35.2	43.3
Fainting or loss of consciousness	10.7	9.2
Upset stomach, nausea, or vomiting	23.9	15.6
Other§	9.3	10.6

*The baseline screening was performed in the fall of 6th grade, and the end-of-study screening in the spring of 8th grade.

†Adverse events were reported for all students who were screened, including students who were later determined to be ineligible or whose data were invalid and who were therefore not included in the sample.

‡Adverse events were collected primarily to capture expected side effects of the blood drawing, and one event may have resulted in more than one type of adverse event. At baseline, 205 adverse events were reported in 141 students, and at the end of the study, 141 adverse events were reported in 105 students.

§Included in this category were reports at the baseline screening of excessive crying, headache, arm pain, sensation of feeling very hot, sensation of feeling cold and clammy, difficulty breathing, shaking, weakness, throat dryness, twisted ankle, pain from blood drawing, numbness at the right shoulder extending down to the right leg, cool and sweaty skin and change in lip color, pain in the left eye (perhaps from touching the numbing cream), and of the general statement, “I don’t feel so good.” Reports at the end-of-study screening included shaking, weakness, headache, hot flashes, arm pain, sweating, hyperventilating, nervousness, urinating in pants, bleeding at the site at which the blood was drawn, and the statement, “I can’t feel my right arm and it feels weird but I’m OK.”