

## ORIGINAL ARTICLE

# A Randomized Trial of Sugar-Sweetened Beverages and Adolescent Body Weight

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## ABSTRACT

**BACKGROUND**

Consumption of sugar-sweetened beverages may cause excessive weight gain. We aimed to assess the effect on weight gain of an intervention that included the provision of noncaloric beverages at home for overweight and obese adolescents.

**METHODS**

We randomly assigned 224 overweight and obese adolescents who regularly consumed sugar-sweetened beverages to experimental and control groups. The experimental group received a 1-year intervention designed to decrease consumption of sugar-sweetened beverages, with follow-up for an additional year without intervention. We hypothesized that the experimental group would gain weight at a slower rate than the control group.

**RESULTS**

Retention rates were 97% at 1 year and 93% at 2 years. Reported consumption of sugar-sweetened beverages was similar at baseline in the experimental and control groups (1.7 servings per day), declined to nearly 0 in the experimental group at 1 year, and remained lower in the experimental group than in the control group at 2 years. The primary outcome, the change in mean body-mass index (BMI, the weight in kilograms divided by the square of the height in meters) at 2 years, did not differ significantly between the two groups (change in experimental group minus change in control group,  $-0.3$ ;  $P=0.46$ ). At 1 year, however, there were significant between-group differences for changes in BMI ( $-0.57$ ,  $P=0.045$ ) and weight ( $-1.9$  kg,  $P=0.04$ ). We found evidence of effect modification according to ethnic group at 1 year ( $P=0.04$ ) and 2 years ( $P=0.01$ ). In a prespecified analysis according to ethnic group, among Hispanic participants (27 in the experimental group and 19 in the control group), there was a significant between-group difference in the change in BMI at 1 year ( $-1.79$ ,  $P=0.007$ ) and 2 years ( $-2.35$ ,  $P=0.01$ ), but not among non-Hispanic participants ( $P>0.35$  at years 1 and 2). The change in body fat as a percentage of total weight did not differ significantly between groups at 2 years ( $-0.5\%$ ,  $P=0.40$ ). There were no adverse events related to study participation.

**CONCLUSIONS**

Among overweight and obese adolescents, the increase in BMI was smaller in the experimental group than in the control group after a 1-year intervention designed to reduce consumption of sugar-sweetened beverages, but not at the 2-year follow-up (the prespecified primary outcome). (Funded by the National Institute of Diabetes and Digestive and Kidney Diseases and others; ClinicalTrials.gov number, NCT00381160.)

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**T**HE CONSUMPTION OF SUGAR-SWEETENED beverages among adolescents<sup>1</sup> has increased in tandem with the prevalence of pediatric obesity in the United States,<sup>2</sup> suggesting a causal relationship. At present, a substantial proportion of high-school students habitually consume sugar-sweetened beverages, including carbonated soda, sports drinks, energy drinks, and highly sweetened coffees and teas.<sup>3</sup> Sugar-sweetened beverages are the leading source of added sugar in the diet of a wide range of racial and ethnic groups.<sup>4</sup> According to nationally representative data, overweight and obese adolescents obtain more than 300 kcal per day from these products, amounting to an average of 15% of their total daily energy intake.<sup>5</sup>

Short-term feeding studies show greater energy intake and weight gain with the consumption of sugar-sweetened beverages than with beverages containing artificial sweeteners,<sup>6</sup> and prospective observational studies show positive associations with the risk of obesity and related complications.<sup>7</sup> However, the findings from the relatively few randomized, controlled trials designed to examine the effects of sugar-sweetened beverages on body weight have not been conclusive,<sup>8-10</sup> and the use of public health measures to reduce the consumption of sugar-sweetened beverages remains controversial.<sup>11,12</sup>

We previously conducted a 6-month pilot study<sup>10</sup> involving normal-weight, overweight, and obese adolescents who consumed sugar-sweetened beverages habitually. The experimental group received home delivery of noncaloric beverages, and the control group did not. The mean body-mass index (BMI, the weight in kilograms divided by the square of the height in meters) decreased significantly in the experimental group, as compared with the control group, only among the overweight and obese adolescents. The current study, which is a follow-up to the pilot study,<sup>10</sup> was designed to test the hypothesis that overweight and obese adolescents who received an intervention to reduce the consumption of sugar-sweetened beverages would gain weight at a slower rate than those who did not receive the intervention. We examined prespecified covariates as potential effect modifiers and mediators. In addition, we reanalyzed data from an observational study<sup>13</sup> involving 548 middle-school students to corroborate the findings of the current study.

## METHODS

### STUDY DESIGN

We randomly assigned participants to an experimental group or a control group for 2 years. The study included a 1-year intervention and a 1-year follow-up, with assessment of study outcomes at the end of each period. The institutional review board at Boston Children's Hospital approved the study protocol (available with the full text of this article at NEJM.org). Parents provided written informed consent, and participants provided written assent. Beverages for the intervention group were purchased from an online delivery service (Peapod) affiliated with a supermarket chain. The study was conducted between October 2007 and December 2011. The first two authors and the last author vouch for the accuracy and completeness of the data and analysis and the fidelity of the study to the protocol.

### PARTICIPANTS

We enrolled 224 adolescents (124 boys and 100 girls) who reported consuming at least one serving (12 oz) per day of sugar-sweetened beverages or 100% fruit juice. Additional inclusion criteria were enrollment in grade 9 or 10 and a BMI at or above the 85th percentile for sex and age.<sup>14</sup> During telephone conversations with parents, we collected demographic information, including sex, date of birth, race (white, black, Asian, multiple, or other), ethnic group (Hispanic or non-Hispanic), parents' level of education, and total annual household income.

### INTERVENTION

We used a multicomponent intervention designed to reduce the consumption of sugar-sweetened beverages in the experimental group. The emphasis was on displacing sugar-sweetened beverages with noncaloric beverages in the home as a strategy to decrease consumption.<sup>5</sup> The 1-year intervention consisted of home delivery of noncaloric beverages (e.g., bottled water and "diet" beverages) every 2 weeks, monthly motivational telephone calls with parents (30 minutes per call), and three check-in visits with participants (20 minutes per visit). Written intervention messages with instructions to drink the delivered beverages and not to buy or drink sugar-sweetened beverages were mailed to participants. Unsweetened water was recommended over artifi-

cially sweetened beverages. Discussions during telephone calls and check-in visits focused exclusively on beverage consumption, with no attention to other dietary behaviors or to physical activity. We mailed \$50 supermarket gift cards to participants in the control group at 4 and 8 months as a retention strategy but did not provide instructions on what to purchase with the cards.

#### OUTCOMES

All personnel who assessed study outcomes were unaware of the group assignments. The primary outcome was the change in BMI at 2 years. To calculate BMI, trained personnel measured weight and height using calibrated scales and stadiometers, respectively. We used data from bioelectrical impedance analysis (BIA) and the equation of Sun et al.<sup>15</sup> to calculate body fat as a percentage of total body weight. In three telephone interviews conducted at each assessment (baseline, 1 year, and 2 years), participants were asked to recall their dietary intake and physical activity during the preceding 24 hours. Dietary intake data were collected with Nutrition Data System for Research (NDSR) software, versions 2006 through 2011, developed by the Nutrition Coordinating Center, University of Minnesota, Minneapolis. Final calculations were completed with NDSR, version 2011. Variables used to assess dietary quality included reported daily servings of sugar-sweetened, artificially sweetened, and unsweetened beverages; servings of 100% fruit juices; total energy and sugar intakes; and energy intake from sugar-sweetened beverages and 100% fruit juices. The interviewer also asked each participant to recall the activity performed most often during each 15-minute block throughout the previous day.<sup>16,17</sup> We calculated a daily physical-activity factor, using metabolic equivalent (MET) levels for each reported activity,<sup>18</sup> and hours of television viewing.

#### ADVERSE EVENTS

An adverse event was defined as any symptom or safety concern requiring medical attention that was reported by an adolescent or a parent during participation in the study.

#### STATISTICAL ANALYSIS

The trial was designed to have 80% power at a type I error rate of 5% to detect a net intervention effect with respect to the primary outcome BMI of 0.49, as attained with a shorter intervention in

our pilot study.<sup>10</sup> All analyses followed the intention-to-treat principle. Baseline demographic characteristics, dietary intake, and obesity-related behavioral variables were compared between the experimental and control groups with the use of Student's t-test and Fisher's exact test for continuous and categorical variables, respectively. Changes in BMI and other anthropometric outcomes were compared between groups with a general linear model, adjusted for baseline covariates that could affect body weight. We performed identical but separate analyses for the change from baseline after 1 year (intervention period) and the change from baseline after 2 years (follow-up period without further intervention). Dietary intakes and obesity-related behavioral outcomes were analyzed similarly, without adjustment for covariates. Residual analysis confirmed that the assumption of normal error was satisfied. The net intervention effect (the mean change in the experimental group minus the mean change in the control group) was calculated from the parameters of the fitted model.

We tested each covariate for interaction and, finding Hispanic ethnic group to be the sole significant effect modifier for between-group differences in the change in BMI, we constructed additional ethnicity-specific summary statistics for the anthropometric and behavioral outcomes from a model that included an interaction term for study group and ethnic group. Testing 14 covariates for effect modification with a critical value of  $P < 0.05$  gave us an expected number of 0.7, or less than 1, type I error for each time point. Missing values for BMI were conservatively imputed by assuming that the participant's BMI z score was unchanged from baseline and calculating BMI at the appropriate later age from national norms.<sup>14</sup> Other methods for treating missing data, including use of the immediately preceding BMI z score, produced similar results.

We also reanalyzed data from a 19-month prospective observational study of 548 ethnically diverse middle-school students<sup>13</sup> to test for effect modification by ethnic group in the association of a change in the consumption of sugar-sweetened beverages with a change in BMI. We added an interaction term for ethnic group and change in consumption of sugar-sweetened beverages to the fully adjusted model. This regression included covariates related to diet (change in consumption of sugar-sweetened beverages,

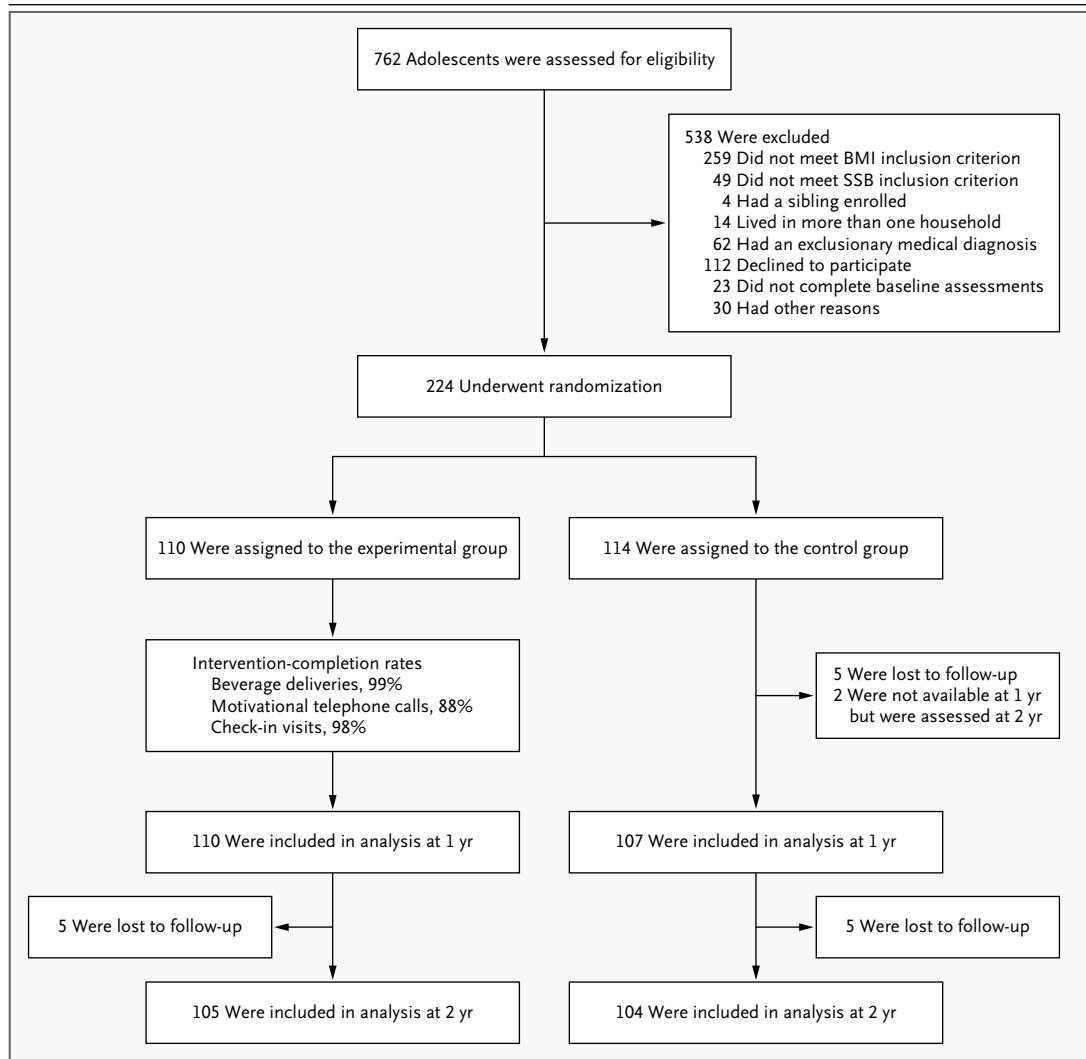
adjusted for total energy intake and controlled for baseline consumption; baseline fat and change in fat, expressed as a percentage of total energy intake; and baseline energy-adjusted intake of fruit juice and change in fruit-juice intake), demographic characteristics (age, sex, ethnic group, and race, with indicator variables for schools), anthropometric variables (BMI and triceps skin-fold thickness), physical activity (exercising to lose weight at baseline [yes or no], number of physical-education classes per week at baseline, and baseline physical activity [ $<3$  METs vs.  $\geq 3.5$  METs] and change in physical activity), and hours of daily television viewing (baseline and change).

SAS software (version 9.2) was used for all computations. A two-sided P value of 0.05 or less was interpreted as a statistically significant result.

## RESULTS

### STUDY POPULATION

At baseline, there were no significant differences between the experimental and control groups with regard to demographic characteristics (Table 1) or other variables (Tables 2 and 3). The retention rate for study participants was 97% at 1 year and 93% at 2 years (Fig. 1), with no significant difference between groups in the percentage



**Figure 1. Screening, Randomization, and Follow-up of the Study Participants.**

Among the 538 adolescents who were excluded, 15 of the 49 who did not meet the sugar-sweetened-beverage (SSB) criterion also had other reasons and are included in the counts for those reasons. The weight and height of all available participants were measured at each time point in order to calculate BMI.

**Table 1. Baseline Characteristics of the Study Participants.\***

Characteristic	Experimental Group (N=110)	Control Group (N=114)	P Value
Sex — no. (%)			
Male	58 (53)	66 (58)	0.50
Female	52 (47)	48 (42)	
Race or ethnic group — no. (%)†			
Race			
White	60 (55)	64 (56)	0.99
Black	26 (24)	27 (24)	
Asian	4 (4)	4 (4)	
Multiple or other	20 (18)	19 (17)	
Ethnic group			
Hispanic	27 (25)	19 (17)	0.19
Non-Hispanic	83 (75)	95 (83)	
Age — yr	15.3±0.7	15.2±0.7	0.50
Weight — kg	85.2±16.8	86.1±17.0	0.70
Height — cm	167.4±8.8	168.9±9.1	0.21
BMI	30.4±5.2	30.1±4.7	0.64
Weight status‡			
Overweight	40 (36)	44 (39)	0.78
Obese	70 (64)	70 (61)	
Body fat — % of total weight	31.9±8.3	31.2±8.2	0.55
Annual household income — no. (%)			
<\$30,000	30 (27)	31 (27)	0.71
\$30,000–\$59,999	38 (35)	34 (30)	
≥\$60,000	42 (38)	49 (43)	
Parental educational level — no. (%)§			
Some high school	2 (2)	5 (4)	0.56
High-school diploma or GED certificate	23 (21)	20 (18)	
Some college or vocational school	28 (25)	24 (21)	
Associate's degree	7 (6)	14 (12)	
Bachelor's degree	33 (30)	33 (29)	
Some graduate school or graduate degree	17 (15)	18 (16)	
Daily physical activity level — MET	1.53±0.18	1.54±0.18	0.85
Television viewing — hr/day	3.0±1.8	2.8±1.4	0.46

\* Plus-minus values are means ±SD. Means were compared with the use of the Student's t-test and proportions compared with the use of Fisher's exact test. Percentages may not sum to 100 owing to rounding. GED denotes General Educational Development, and MET metabolic equivalent.

† Race and ethnic group were reported by the parents of the participants. "Multiple" included white-black (8 participants), white-Asian (3), white-black-Asian (1), and white-Arabic (1). "Other" included Latino or Latina (8 participants), Hispanic (7), Brazilian (2), Cape Verdean (2), Puerto Rican (4), Latino or Latina-Brazilian (1), Spanish (1), and American (1). Comparisons of baseline characteristics according to ethnic group are provided in Table S1 in the Supplementary Appendix.

‡ Participants at or above the 85th percentile for BMI but below the 95th percentile were classified as overweight, and participants at or above the 95th percentile were classified as obese. The BMI range was 23.2 to 28.8 for overweight participants and 26.7 to 50.7 for obese participants.

§ The educational level listed is for the father or mother, depending on which parent had the higher level of education.

Table 2. Dietary Intake.*							
Intake	Unadjusted Data			Change from Baseline			
	Baseline	1 Yr	2 Yr	1 Yr	P Value†	2 Yr	P Value‡
Beverages (servings/day)							
Sugar-sweetened							
Experimental group	1.7±0.9	0.2±0.4	0.4±0.5	-1.5±0.1	<0.001	-1.3±0.1	<0.001
Control group	1.7±1.1	0.9±1.1	0.8±0.8	-0.8±0.1	<0.001	-0.9±0.1	<0.001
Difference				-0.7±0.1	<0.001	-0.4±0.1	0.005
Fruit juices							
Experimental group	0.4±0.5	0.1±0.2	0.2±0.3	-0.3±0.0	<0.001	-0.2±0.1	0.002
Control group	0.3±0.4	0.2±0.3	0.2±0.3	-0.1±0.0	0.02	-0.1±0.1	0.03
Difference				-0.2±0.1	0.01	-0.1±0.1	0.48
Artificially sweetened							
Experimental group	0.1±0.3	0.9±1.0	0.4±0.8	0.8±0.1	<0.001	0.3±0.1	<0.001
Control group	0.1±0.2	0.3±0.5	0.3±0.6	0.2±0.1	0.01	0.2±0.1	<0.001
Difference				0.6±0.1	<0.001	0.1±0.1	0.32
Unsweetened							
Experimental group	0.9±1.0	1.9±1.5	1.8±1.4	1.0±0.1	<0.001	0.9±0.1	<0.001
Control group	1.1±1.0	1.2±1.1	1.4±1.2	0.2±0.1	0.18	0.2±0.1	0.04
Difference				0.8±0.2	<0.001	0.6±0.2	<0.001
Energy intake (kcal/day)							
Total							
Experimental group	1967±553	1513±509	1619±444	-454±48	<0.001	-361±54	<0.001
Control group	1901±510	1720±420	1726±467	-176±48	<0.001	-178±54	0.001
Difference				-278±69	<0.001	-183±76	0.02
Sugar-sweetened beverages							
Experimental group	242±140	29±58	52±70	-213±14	<0.001	-188±15	<0.001
Control group	242±155	134±159	109±112	-108±14	<0.001	-130±15	<0.001
Difference				-105±20	<0.001	-58±21	0.007
Fruit juices							
Experimental group	94±112	30±44	59±84	-63±11	<0.001	-37±12	0.003
Control group	82±92	65±86	58±76	-18±11	0.12	-23±12	0.05
Difference				-45±16	0.005	-13±17	0.44
Sugar (g/day)							
Experimental group	133±42	57±34	71±32	-76±4	<0.001	-63±5	<0.001
Control group	132±48	96±49	89±36	-37±4	<0.001	-44±5	<0.001
Difference				-39±6	<0.001	-19±7	0.005

\* Plus-minus values for unadjusted data are means ±SD, and plus-minus values for changes from baseline are means ±SE. Changes were calculated at 1 year and 2 years from the general linear model, without adjustment for covariates.

† The P values for changes from baseline in each study group are based on tests of the hypothesis that the mean change was zero.

‡ The P values for the between-group differences in changes from baseline are based on tests of the hypothesis that the mean change was the same in the two groups. There were no significant ethnic group-study group interactions for any of the dietary variables.

**Table 3. Study Outcomes.\***

Variable	Unadjusted Data			Change from Baseline			
	Baseline	1 Yr	2 Yr	1 Yr	P Value†	2 Yr	P Value‡
<b>BMI</b>							
All participants							
Experimental group	30.36±5.24	30.50±5.55	31.10±5.94	0.06±0.20	0.75	0.71±0.28	0.01
Control group	30.05±4.66	30.61±5.37	31.03±5.51	0.63±0.20	0.001	1.00±0.28	<0.001
Difference				-0.57±0.28	0.045	-0.30±0.40	0.46
Non-Hispanic participants							
Experimental group	30.14±5.20	30.41±5.49	31.16±5.81	0.19±0.23	0.41	0.95±0.33	0.005
Control group	29.96±4.63	30.41±5.25	30.78±5.38	0.48±0.22	0.03	0.77±0.30	0.01
Difference				-0.29±0.31	0.36	0.18±0.44	0.68
Hispanic participants							
Experimental group	31.06±5.39	30.79±5.82	30.90±6.41	-0.36±0.45	0.42	-0.08±0.64	0.89
Control group	30.52±4.90	31.60±6.01	32.29±6.14	1.43±0.52	0.006	2.27±0.73	0.002
Difference				-1.79±0.65	0.007	-2.35±0.92	0.01
<b>Weight (kg)</b>							
All participants							
Experimental group	85.2±16.8	87.0±18.0	90.1±19.4	1.6±0.6	0.01	4.3±1.0	<0.001
Control group	86.1±17.0	90.2±19.8	92.3±20.7	3.5±0.6	<0.001	5.1±1.0	<0.001
Difference				-1.9±0.9	0.04	-0.8±1.4	0.55
Non-Hispanic participants							
Experimental group	86.1±17.4	88.5±18.6	92.5±20.0	2.2±0.7	0.003	5.5±1.1	<0.001
Control group	85.8±16.9	89.3±19.1	91.3±19.9	3.0±0.7	<0.001	4.4±1.0	<0.001
Difference				-0.8±1.0	0.42	1.1±1.5	0.48
Hispanic participants							
Experimental group	82.7±15.1	82.6±15.6	83.2±16.2	-0.5±1.4	0.74	0.3±2.1	0.88
Control group	87.8±18.2	95.4±23.4	98.2±24.6	6.0±1.7	<0.001	9.2±2.5	<0.001
Difference				-6.4±2.1	0.003	-8.8±3.1	0.005
<b>Height (cm)</b>							
All participants							
Experimental group	167.4±8.8	168.8±9.2	169.7±9.4	1.4±0.2	<0.001	2.3±0.2	<0.001
Control group	168.9±9.1	170.7±9.8	171.5±10.0	1.6±0.2	<0.001	2.1±0.3	<0.001
Difference				-0.2±0.2	0.49	0.2±0.4	0.67
Non-Hispanic participants							
Experimental group	168.8±8.4	170.3±8.6	171.5±8.7	1.6±0.2	<0.001	2.6±0.3	<0.001
Control group	168.8±9.0	170.5±9.6	171.3±9.8	1.7±0.2	<0.001	2.2±0.3	<0.001
Difference				-0.1±0.3	0.80	0.4±0.4	0.29
Hispanic participants							
Experimental group	163.2±8.6	164.0±9.3	164.4±9.8	0.8±0.4	0.05	1.1±0.6	0.05
Control group	169.4±10.0	171.7±11.1	172.4±11.6	1.4±0.5	0.004	2.1±0.7	0.002
Difference				-0.6±0.6	0.30	-1.0±0.8	0.24

\* Plus–minus values for unadjusted data are means ±SD, and plus–minus values for changes from baseline are means ±SE. Changes were calculated at 1 year and 2 years from the general linear model, and were adjusted for sex, race, ethnic group, household income, parental education, baseline BMI, baseline beverage consumption (energy from sugar-sweetened beverages and fruit juices and servings of artificially sweetened beverages and unsweetened beverages), baseline total energy intake, baseline sugar intake, and baseline obesity-related behavioral measures (physical activity and hours of television viewing). Results specific to ethnic group are from a model that included an interaction term for study group and ethnic group. For the change during the 2 years, before imputation, BMI data were available for 166 non-Hispanic participants (78 in the experimental group and 88 in the control group) and 43 Hispanic participants (27 in the experimental group and 16 in the control group).

† The P values for changes from baseline in each study group are based on tests of the hypothesis that the mean change was zero.

‡ The P values for the between-group differences in changes from baseline are based on tests of the hypothesis that the mean change was the same in the two groups.

of participants available at 2 years for assessment of the primary outcome ( $P=0.29$ ).

#### CHANGES IN DIETARY INTAKE

Changes in reported dietary intake are shown in Table 2. At 1 year, the change in consumption of sugar-sweetened beverages was significantly different between the groups ( $P<0.001$ ), declining almost to 0 in the experimental group. Concomitantly, consumption of artificially sweetened and unsweetened beverages increased significantly in the experimental group as compared with the control group ( $P<0.001$ ). At 2 years, the consumption of sugar-sweetened beverages remained lower and the consumption of unsweetened beverages remained higher in the experimental group ( $P=0.005$  and  $P<0.001$ , respectively), whereas the consumption of artificially sweetened beverages did not differ significantly between the groups ( $P=0.32$ ). Total energy intake and sugar intake decreased in the experimental group as compared with the control group at 1 year ( $P<0.001$  for both comparisons), with group differences persisting at 2 years ( $P=0.02$  for total energy intake and  $P=0.005$  for sugar intake).

#### OUTCOMES

Study outcomes are presented in Table 3 and in the Supplementary Appendix (available at [NEJM.org](http://NEJM.org)). The prespecified primary outcome, the net intervention effect on BMI at 2 years (the change in the experimental group minus the change in the control group), was not significant ( $-0.30$ ,  $P=0.46$ ). However, the effect on BMI at the end of the 1-year intervention was significant ( $-0.57$ ,  $P=0.045$ ). When sugar intake was added to the model, the intervention effect on BMI was strongly attenuated and no longer significant ( $-0.39$ ,  $P=0.24$ ). The change in the mean ( $\pm$ SE) percentage of body fat in the experimental group as compared with the change in the control group was not significant ( $-0.5\%\pm 0.6$ ,  $P=0.40$ ). Although there was no significant intervention effect for the change in overall reported physical activity ( $0.01\pm 0.04$  METs,  $P=0.86$ ), the experimental group had significant decreases in reported time spent watching television at 1 year ( $-0.6\pm 0.2$  hours per day,  $P=0.002$ ) and at 2 years ( $-0.7\pm 0.2$  hours per day,  $P=0.001$ ), whereas the control group had no significant change. The difference between the two groups (change in experimental group minus change in control group) was sig-

nificant at 1 year ( $-0.7\pm 0.3$  hours per day,  $P=0.01$ ) and at 2 years ( $-0.6\pm 0.3$  hours per day,  $P=0.04$ ). Neither the change in television viewing ( $P=0.03$  for intervention effect on change in BMI at 1 year with change in television viewing added to the model) nor the change in any covariate other than sugar intake mediated the intervention effect on the change in BMI at 1 year.

#### EFFECTS OF ETHNIC GROUP

In prespecified tests of covariates for interaction with group assignment, we found significant effect modification according to ethnic group for changes in BMI ( $P=0.04$  at 1 year and  $P=0.01$  at 2 years) and body weight ( $P=0.02$  at 1 year and  $P=0.005$  at 2 years). Among Hispanics, there were significant intervention effects on the change in BMI at 1 year ( $-1.79$ ,  $P=0.007$ ) and at 2 years ( $-2.35$ ,  $P=0.01$ ) and on the change in body weight at 1 year ( $-6.4$  kg,  $P=0.003$ ) and at 2 years ( $-8.8$  kg,  $P=0.005$ ) (Table 3). Other covariates were not significant effect modifiers.

Given these results, we reanalyzed data from a 19-month prospective observational study that showed an overall positive association between change in consumption of sugar-sweetened beverages and change in BMI ( $\beta=0.24$ ,  $P=0.03$ ).<sup>13</sup> Here, too, we found effect modification according to ethnic group ( $P=0.007$ ). The association for the 84 Hispanic youths in the study was strong ( $\beta=0.63$ ,  $P=0.007$ ), whereas that for the 464 non-Hispanics (predominantly non-Hispanic whites but also non-Hispanic blacks, Asian Americans, American Indians, and others) was not significant ( $\beta=0.164$ ,  $P=0.11$ ).

#### ADVERSE EVENTS

A total of seven events were reported by the parents of participants in the experimental group during motivational telephone calls (diagnosis of Graves' disease, diagnosis of polycystic ovary syndrome, an infected finger, an asthma attack, a mild head injury due to a car accident, the development of a blood clot after knee surgery, and temporary hearing loss due to the buildup of fluid and wax in the ears).

## DISCUSSION

The provision of noncaloric beverages virtually eliminated reported consumption of sugar-sweetened beverages and reduced total reported

energy intake among overweight and obese adolescents after a 1-year intervention, and there were persistent effects on diet through follow-up at 2 years. The change in BMI differed significantly between the experimental and control groups at 1 year but not at 2 years. We also found evidence of effect modification according to ethnic group, with the change in BMI differing between groups in a small sample of Hispanics but not among non-Hispanic participants.

Multicomponent interventions, targeting several aspects of diet and physical activity to promote negative energy balance, constitute a common strategy for treating adolescent obesity.<sup>19,20</sup> However, most intensive interventions have yielded disappointing results. In the present study, education and behavioral counseling focused specifically on decreasing consumption of sugar-sweetened beverages, a single dietary behavior that may be particularly important for controlling body weight. The significant intervention effect for the change in BMI observed at 1 year, together with the findings of de Ruyter et al. involving children 5 to 12 years of age (reported elsewhere in the *Journal*),<sup>21</sup> provides support for public health guidelines that recommend limiting consumption of sugar-sweetened beverages.<sup>22</sup> The lack of effect at 2 years could reflect increasing energy intake from sugar-sweetened beverages or fruit juices in the experimental group on discontinuation of the intervention; decreasing intake of sugar-sweetened beverages or fruit juices in the control group, possibly due to a secular trend resulting from efforts to eliminate these beverages from schools<sup>23</sup>; or both.

We examined several variables that could confound or mediate the effect of the intervention on BMI. We observed a difference in television viewing between the groups, but in our statistical models, this difference did not account for the difference in the change in BMI at 1 year. Similarly, no covariate other than sugar intake attenuated the intervention effect, suggesting that sugar intake had a mediating influence. However, we recognize that the intensity of the intervention, rather than provision of noncaloric beverages per se, may have led to salutary changes in other behaviors, such as decreased television viewing, and that these changes may affect body weight.

We conducted a subgroup analysis after a

prespecified test revealed significant effect modification according to ethnic group, and reanalysis of data from a prospective observational study<sup>13</sup> provided corroborative evidence. However, these data must be interpreted cautiously in view of the small size of the Hispanic subgroup. The reason for effect modification according to ethnic group remains speculative but may involve differences in physiology (e.g., involving insulin secretion in response to the ingestion of sugar<sup>24-26</sup>) or in genetic susceptibility (as reported elsewhere in the *Journal*<sup>27</sup>). Still, even though our statistical models controlled for baseline covariates and no effect modification was detected in our measures of household income and education, we cannot exclude the possibility that effect modification according to ethnic group arose from socioeconomic or behavioral differences between ethnic groups rather than from inherent physiological differences. Additional study is needed to determine whether ethnic group influences the effect of consuming sugar-sweetened beverages on body weight.

The strengths of our trial include a focus on a single dietary behavior in the home environment, a diverse sample, excellent participant-retention rates, collection of data on dietary process measures, and assessment of physical activity and television viewing. The limitations include a small sample as compared with samples in multisite studies, reliance on self-reporting of dietary intake (with the likelihood of underreporting)<sup>28</sup> and physical activity, use of the BIA (a relatively inaccurate method)<sup>29</sup> to estimate body fat, and lack of data on obesity-related risk factors, such as biomarkers of lipid and glucose metabolism.

In conclusion, replacement of sugar-sweetened beverages with noncaloric beverages did not improve body weight over a 2-year period, but group differences in dietary quality and body weight were observed at the end of the 1-year intervention period.

The views expressed in this article are those of the authors and do not necessarily represent the official views of the National Institute of Diabetes and Digestive and Kidney Diseases, the National Center for Research Resources, the National Institute of Child Health and Human Development, the National Institutes of Health, or the Centers for Disease Control and Prevention.

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