

# Association Between a School-Based Intervention and Adiposity Outcomes in Adolescents: The Italian “EAT” Project

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**Objective:** To evaluate whether a school-based multicomponent educational program could improve adiposity measures in middle-school adolescents.

**Methods:** A non-randomized controlled pilot study was conducted in six state middle schools (487 adolescents, 11-15 years) in townships in an urban area around Milan, three schools ( $n = 262$  adolescents) being assigned to the intervention group and three schools ( $n = 225$  adolescents) to the control group. The two-school-year intervention included changes in the school environment (alternative healthy vending machines, educational posters) and individual reinforcement tools (school lessons, textbook, text messages, pedometers, re-usable water bottles). The main outcome measure was change in BMI z-score. The secondary outcomes were changes in waist-to-height ratio (WHtR) and behavioral habits.

**Results:** The intervention was associated with a significant difference in BMI z-score ( $-0.18 \pm 0.03$ ,  $P < 0.01$ ) and in WHtR ( $-0.04 \pm 0.002$ ,  $P < 0.001$ ), after controlling for baseline covariates. Subgroup analysis showed the maximum association between the intervention and the difference in BMI z-score for girls with overweight/obesity. Physical activity increased and consumption of sugar-sweetened beverages and high-energy snacks decreased in adolescents after the intervention.

**Conclusions:** A school-based multicomponent intervention conducted at both environmental and individual levels may be effective for reducing adiposity measures mainly in adolescents with overweight/obesity.

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## Introduction

Childhood overweight and obesity are a global public health concern associated with an increased risk of chronic non-communicable diseases, disability, and social problems (1-3). The prevalence of childhood obesity is increasing worldwide, with local differences (4-6), and the prevention and treatment of obesity still constitute a challenge. School-based childhood obesity prevention interventions showed promising results. Additional research is needed in adolescence, a stage of life where obesity is more predictive of obesity during adulthood than obesity in younger children. Moreover, few obesity prevention studies in adolescents have been demonstrated to be effective as well as feasible (7,8).

The school environment has been identified as a player in the development and maintenance of obesity. In many schools, adolescents can easily purchase unhealthy foods or beverages from vending

machines or in a snack bar (9,10), and time and space for physical activity during school time are often limited. In this scenario, we hypothesized that an obesity prevention intervention should include both changes in the school environment and multiple individual reinforcement tools focused on healthy eating and exercise.

To date, body mass index (BMI) is the most common adiposity measure used as a measure of effectiveness in childhood obesity prevention studies (7). Waist-to-height ratio (WHtR), a marker of central adiposity, is a useful indicator of cardiometabolic risk in children (11). We previously suggested that in addition to BMI, quantifying the distribution of adipose tissue with simple measures such as the WHtR could improve assessments of the effectiveness of childhood obesity prevention interventions (12).

This pilot study was aimed to evaluate whether a school-based multicomponent educational program of the duration of two school

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years could improve adiposity measures, mainly BMI *z*-score and WHtR, in middle-school adolescents.

## Methods

### Study design and participants

The “EAT” Project (the Italian acronym for *Educazione Alimentare Teenagers*—Teenagers Nutritional Education) was designed as a non-randomized controlled (quasi-experimental) pilot study monitored by the Italian Ministry of Education, University and Research, to consider later implementation in Italian schools.

From 2009 to 2011, 487 adolescents from six state middle schools in townships in an urban area around Milan were involved in a non-randomized controlled study of the duration of two school years. Three schools (262 adolescents) were chosen as the intervention schools because of previous collaboration with educational initiatives of our Institute, not related to nutrition and carried out with different pupils. Three other socio-demographically matched schools (225 adolescents) were chosen as a comparison group. Exclusion criteria were applied only for individuals with conditions interfering with anthropometric measurements, such as severe malformation.

The characteristics of the schools of the intervention and the control groups were sufficiently homogeneous, on the basis of previous reports of the Italian National Institute of Statistics. The schools were all in a limited area of about 20 square kilometers with a high degree of urbanization and about 10% of public green areas. The access to green areas as well as to fast food outlets and food stores was similar for all the schools. Before the intervention started, all the schools had installed vending machines containing food of scant nutritional value, high in fats, sugar, salt, and calories, accessible to the students. Nutritional education was not usually included in the school curriculum. Exercise opportunities during school time before the intervention were limited to 2 hours a week (physical education). Most of the pupils attending the schools were Caucasian, with less than 5% of ethnic minorities including Asians, Arabs, and South Americans. The annual average income of the households was about 35,000 euros (about 38,000 dollars). The parental educational levels included mainly middle-school and high-school certificates. Consent to participate in the study was obtained from the representatives of the schools during a meeting organized before the study. All students and their parents gave informed consent to participation. The study protocol was approved by the local Ethics Committee (ASL Milano 2, protocol number 2516).

After the end of the first two school years, the schools assigned to the control group refused to participate further and disrupted their data collection. In agreement with the representatives of the other schools, the educational program was continued in the schools assigned to the intervention group as a health promotion activity. The intervention schools agreed to continue with the measurements of adolescents, so anthropometric data were collected for another three two-school-year periods on different pupils only in the intervention schools (2010-2012 *n* = 303, 2011-2013 *n* = 298, 2012-2014 *n* = 348).

### Intervention

All the pupils from the intervention and control schools had anthropometric measurements taken, and a questionnaire related to dietary

and physical activity habits was administered. The three schools in the intervention group received the same multicomponent health promotion intervention: adolescents underwent a two-school-year educational program including changes in the school environment and individual reinforcement tools.

*Changes in the school environment.* In the intervention group schools, all traditional vending machines were replaced with machines containing healthy foods and beverages, including fresh fruit and vegetables, dried fruit, fruit juices, smoothies without added sugar, and drinkable yogurt, all from local farms, carefully evaluated by our expert nutritionist team. On the basis of a comparative analysis of nutritional facts, the products selected for the alternative healthy vending machines contained per 100 g an average of 60 less kilocalories, 14 g less added sugars, 0.1 g less salt, 1 g less saturated fats, and 1.4 g higher fiber, compared with the traditional vending machines. An agreement was reached with the vending machine supplier to keep prices as low as possible and to dedicate part of the proceeds to childhood health promotion initiatives. No other food and drink sources were available inside the schools, except for tap water. Students were free to bring food or drinks from home. Educational posters adapted from The Healthy Eating Plate (13) conveying messages promoting healthy diet, water consumption, and daily exercise were posted in schools. The schools were asked to create more opportunities for exercise during breaks. Pupils were allowed to leave their classrooms and walk in the corridors or outdoor play areas, for a total of one additional hour a week of movement.

*Reinforcement tools.* Sixteen health-promoting group lessons by expert nutritionists over two-school-years were included in the curriculum. Students were given an easy textbook developed by our nutritionist team as a support to school lessons and as a tool for involving parents. Automated text messages promoting a healthy diet and daily exercise were sent to the students and their parents three times a week throughout the two school years including school vacations. Text messages were sent close to meal times to encourage constructive debate in each family. Students were given a pedometer (PE320-BL, Oregon Scientific Italia Srl) to encourage them to be physically active. A re-usable BPA-free TRITAN™ water bottle was supplied to encourage water consumption.

### Outcome measures

Since the primary aim was the change in adiposity measures in adolescents after two school years of intervention, the primary end point was the change in BMI *z*-score (BMI standardized on age and sex). The secondary end points were the WHtR and some behavioral habits after the two-school-year intervention. We employed a questionnaire to collect several physical activity-related and diet-related indicators. As an additional indicator of physical activity, daily walking was objectively measured using the pedometer: students in the intervention group were required to record their daily steps for one consecutive week at the beginning and at the end of the first and the second school year. The pedometer was given only to the adolescents of the intervention group since it was a tool of the intervention.

We recorded anthropometric measurements for all students in both groups and a questionnaire was completed at the beginning and at the end of the first and the second school year. Demographic data were collected, including ethnic group. Students were measured in light

clothing and without shoes by trained operators, using the same instrument. Weight and height were measured using respectively a calibrated scale and stadiometer with accuracy 0.1 kg and 1 mm. BMI was calculated and expressed as *z*-scores using CDC growth charts as reference (14). Pupils were stratified as subjects with normal weight, overweight, and obesity according to the International Obesity Task Force (IOTF) age- and sex-specific BMI cut-offs (15). All pupils in the intervention group received the same degree of intervention irrespective of their weight. Adolescents with overweight or obesity were considered together for subsequent analysis. Waist circumference was measured at the umbilicus with a flexible tape, with an accuracy of 0.5 cm (16), and the WHtR was calculated.

A simple self-completion questionnaire designed by the Italian National Institute of Health, adapted from a validated international standard questionnaire targeting adolescents (17), was administered in the classroom in the presence of trained operators, who remained available to the students for any explanations. Questions concerned the following: 1) weekly fruit and vegetable consumption, 2) weekly consumption of sugar-sweetened beverages (SSB) including soft drinks and fruit juices, 3) weekly consumption of high-energy snacks (savory and sweet), 4) daily time spent in front of a screen (screen time), and 5) weekly physical activity. Students were asked how many hours of moderate-to-vigorous exercise they usually did during the week. A list of examples of typical light, moderate, or vigorous activity was provided.

### Statistical analysis

The primary analysis involved data from the two-school-year controlled pilot study performed from 2009 to 2011. The variables used for the analysis are derived from measurements at the beginning of the first school year and at the end of the second school year (pre- and post-intervention). Data were expressed as mean  $\pm$  standard deviation (SD) or percentage. Differences in mean baseline variables were determined by unpaired *t*-tests or chi-square tests, as appropriate. A multiple regression analysis was conducted using the value of BMI *z*-score after the two-school-year intervention, as a function of the baseline variable (ANCOVA), the group (intervention vs. control), gender, age, and weight status stratified according to IOTF cut-offs (15) (subjects with overweight/obesity were considered together). The same analysis reported above was performed for the WHtR after the two-school-year intervention. Subsequently, subgroup analysis was conducted through interaction analysis (group by sex and group by weight status) to observe possible effect modification by sex and weight status. To account for the intra-class correlation, the analyses were performed with clustering at school level, since the intervention involved school environment changes. Considering the small number of clusters included in the study, a methodology used in community research was adopted (18). In particular, the procedures used in survey methodology were used (svy regression). Such procedures allow estimation of robust standard errors accounting for the clustering effect even when a small number of clusters is present. Such a situation is typical of community research where only two or three large communities are studied (18). In this case, the use of mixed effects models or generalized estimating equations would have produced optimistic *P* values. The other secondary end points were analyzed simply by comparing how behavioral habits changed after two school years in the intervention with respect to control groups (unpaired *t*-tests). Subjects with normal weight and with overweight/obesity were analyzed separately. Statis-

tical analyses were done using Stata<sup>®</sup> 12 statistical software (Stata Corporation, College Station, TX). A *P* value less than 0.05 was considered statistically significant.

The change through time of BMI *z*-score and WHtR using all four measurements available was inspected graphically but without a formal multilevel analysis considering the small number of clusters available. In the schools assigned to the intervention group, data were collected from 2009 to 2014 for a total of four two-school-year data collections. Anthropometric variables were used to show the longitudinal changes in BMI *z*-score over the intervention period graphically.

## Results

### Study population

Figure 1 shows the flow of participants throughout the study. Table 1 shows the main demographic, anthropometric, and behavioral measures and the frequency of overweight and obesity for the intervention and the control groups at baseline.

### Adiposity measures

The observed adiposity outcomes after two school years of intervention are described below. We found that the intervention was associated with a significant difference in BMI *z*-score between the intervention and control groups ( $-0.18 \pm 0.03$ ,  $P < 0.01$ ), after controlling for baseline covariates. The results of the ANCOVA analysis are reported in Table 2. The analysis on WHtR showed a similar result (Table 3): the intervention was associated with a significant difference in WHtR ( $-0.04 \pm 0.002$ ,  $P < 0.001$ ) after controlling for baseline covariates.

The interaction between group and sex resulted not significant ( $P = 0.07$ ), while a significant interaction between group and weight status was found ( $P = 0.02$ ). Table 4 reports differences in BMI *z*-score and WHtR between the intervention and control groups in subgroups divided by sex and weight status, after adjusting for baseline covariates. Subgroup analysis showed the maximum association between the intervention and the difference in BMI *z*-score for girls with overweight/obesity, while no evidence for an association was found for boys with normal weight. The intervention was significantly associated with differences in WHtR in all the subgroups. Figure 2 shows mean BMI *z*-score values of subjects of the intervention and the control groups during the two-school-year study.

Anthropometric data of pupils of the intervention schools were continued to be collected after the schools of the comparison group refused to further participate in the study, as described above. Figure 3 shows the mean BMI *z*-score values of adolescents of the intervention schools from 2009 to 2014 for a total of four consecutive two-school-year series (2009-2011; 2010-2012; 2011-2013; 2012-2014), stratified for sex and weight status.

### Behavioral measures

Table 5 reports the differences in changes in behavioral parameters after two school years of intervention between the intervention and control groups stratified for weight status.

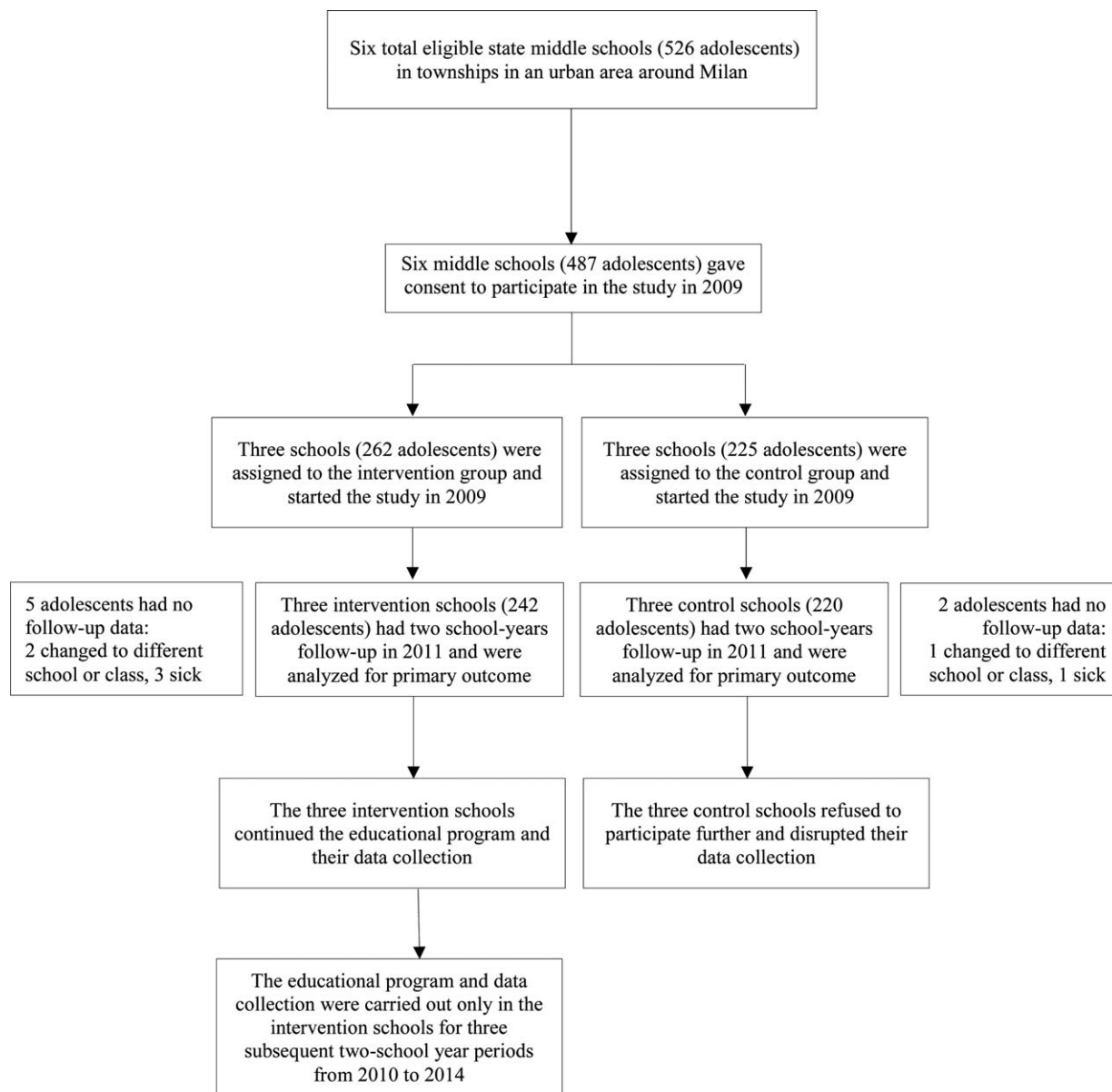


Figure 1 Participant flow over the study.

We observed an increase in physical activity, assessed from the questionnaire (Table 5) and confirmed by the pedometer records (from  $9,475 \pm 2,648$  to  $11,333 \pm 3,863$  daily steps,  $P = 0.01$ ) associated with the intervention in adolescents with normal weight. In these adolescents, a reduction in SSB and high-energy snack consumption, a slight increase in fruit and vegetable consumption, and a reduction in daily screen time were also observed after the intervention (Table 5).

In adolescents with overweight/obesity, there was a relationship between the intervention and the increase in physical activity, judged from the questionnaire (Table 5) and their pedometer records (from  $9,399 \pm 211$  to  $12,268 \pm 4701$  daily steps,  $P = 0.01$ ). There was a significant group difference for SSB and high-energy snack

consumption (Table 5), while no significant association between the intervention and the other behavioral indicators, such as fruit and vegetable consumption and daily screen time, was found (Table 5).

In the overall group of adolescents, no significant differences in changes in behavioral habits were found between boys and girls (data not shown), except for a greater decrease in high-energy snack consumption in girls after the intervention ( $P = 0.045$ ).

## Discussion

This pilot study suggests a possible effectiveness of a two-year broad multicomponent educational program including changes in the



**TABLE 1** Baseline demographic, anthropometric and behavioral characteristics of the study population

	Intervention group (n = 262)	Control group (n = 225)	P value
Female (%)	50	48	0.72
Age (years)	12.5 (0.4)	12.5 (0.4)	0.93
Weight (kg)	48.5 (10.9)	49.0 (11.0)	0.62
Height (cm)	154.0 (7.7)	154.0 (8.0)	0.90
BMI (kg/m <sup>2</sup> )	20.4 (3.6)	20.5 (3.6)	0.59
BMI z-score	0.41 (1.05)	0.48 (0.99)	0.46
Waist circumference (cm)	71.0 (9.2)	70.6 (9.6)	0.66
WHtR	0.461 (0.056)	0.458 (0.059)	0.63
Overweight (%)	23.7	24.4	0.92
Obesity (%)	7.3	6.7	0.86
Fruit consumption (times/week)	5.3 (2.1)	5.1 (2.1)	0.53
Vegetable consumption (times/week)	4.4 (2.3)	4.1 (2.4)	0.26
Snack consumption (times/week)	3.4 (2.2)	3.7 (2.3)	0.25
SSB consumption (times/week)	2.6 (2.2)	2.7 (2.4)	0.81
Physical activity (hours/week)	2.5 (1.6)	2.3 (1.5)	0.24
Screen time (hours/day)	2.1 (1.1)	2.1 (1.5)	0.90

Data are expressed as mean (SD).  
WHtR: waist-to-height ratio; SSB: sugar-sweetened beverages.

school environment and individual reinforcement tools, for reducing adiposity and boosting exercise- and diet-related behaviors in middle-school adolescents. To our knowledge, there is a small number of controlled obesity prevention studies targeting adolescents

**TABLE 2** Adjusted regression coefficients of BMI z-score after two school years of intervention

Variable	Regression coefficients of BMI z-score			
	BMI z-score	SE	P value	95% CI
Intervention (vs. control)	-0.18	0.03	0.003	-0.27 to -0.09
Baseline BMI z-score	0.77	0.05	0.000	0.65 to 0.89
Gender	0.13	0.07	0.12	-0.05 to 0.31
Age	0.07	0.03	0.07	-0.006 to 0.14
Weight status	0.36	0.11	0.02	0.07 to 0.66
Constant	-0.88	0.35	0.06	-1.79 to 0.03

Regression coefficients from a multiple linear regression model adjusted for the variables in the first column plus the clustering effect of the schools.  
SE: standard error; CI: confidence interval.

**TABLE 3** Adjusted regression coefficients of waist-to-height ratio after two school years of intervention

Variable	Regression coefficients of WHtR			
	SE	P value	95% CI	
Intervention (vs. control)	-0.04	0.002	0.000	-0.04 to -0.03
Baseline WHtR	0.81	0.06	0.000	0.66 to 0.96
Gender	0.004	0.004	0.37	-0.007 to 0.02
Age	0.01	0.003	0.03	0.002 to 0.02
Weight status	0.01	0.004	0.03	0.001 to 0.02
Constant	-0.04	0.03	0.26	-0.11 to 0.04

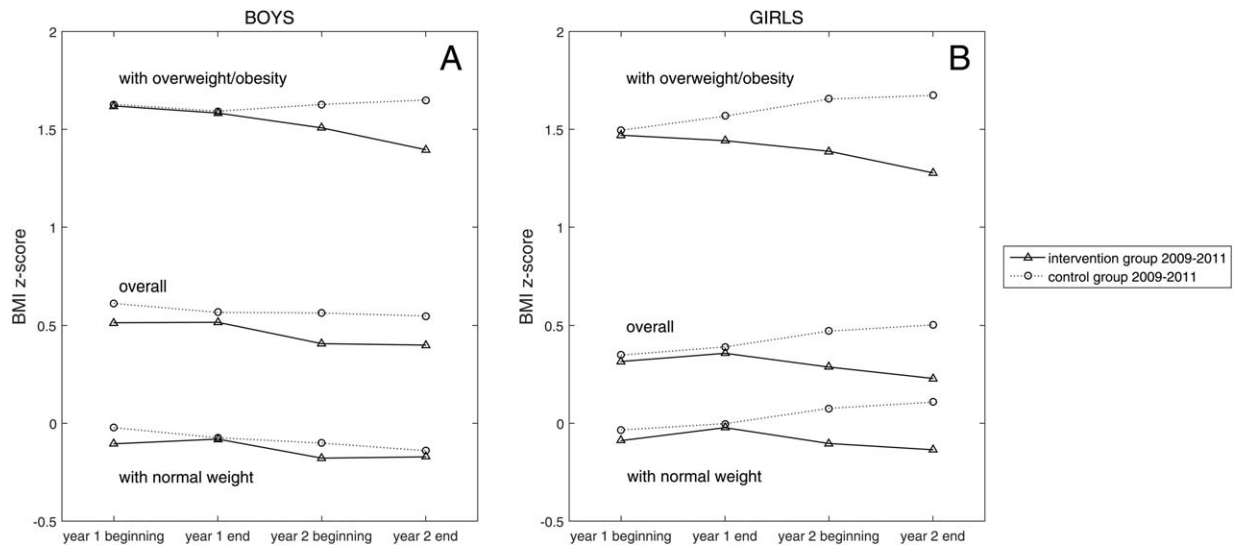
Regression coefficients from a multiple linear regression model adjusted for the variables in the first column plus the clustering effect of the schools.  
WHtR: waist-to-height ratio; SE: standard error; CI: confidence interval.

and only few studies reported significant intervention effects on adiposity measures (7,8,19-21). Although our health promotion intervention addressed all adolescents independently of their weight, a more pronounced difference in BMI z-score was observed in subjects with overweight or obesity. This was particularly true in girls, in line with previous studies (19,22), although a possible confounding effect of differences in the pubertal onset cannot be fully excluded. A difference in BMI z-score associated with the intervention was observed also in girls with normal weight: this seems to derive from an increase in BMI z-score values in the control group over the two school years as compared with relatively constant values in the intervention group, thus suggesting a possible role of the educational program in the prevention of excessive weight gain. The reduction in the WHtR observed after the intervention seems promising since this parameter represents a good correlate of abdominal obesity and obesity-related cardiometabolic diseases (11).

**TABLE 4** Adjusted differences in BMI z-score and waist-to-height ratio between the intervention and control groups after two school years of intervention in subgroups divided by sex and weight status

	BMI z-score		WHtR	
	95% CI	95% CI	95% CI	95% CI
Boys with normal weight	-0.04	-0.23 to 0.15	-0.04	-0.05 to -0.03
Boys with overweight/obesity	-0.22	-0.42 to -0.03	-0.05	-0.06 to -0.04
Girls with normal weight	-0.20	-0.32 to -0.09	-0.03	-0.04 to -0.02
Girls with overweight/obesity	-0.39	-0.56 to -0.22	-0.04	-0.06 to -0.03

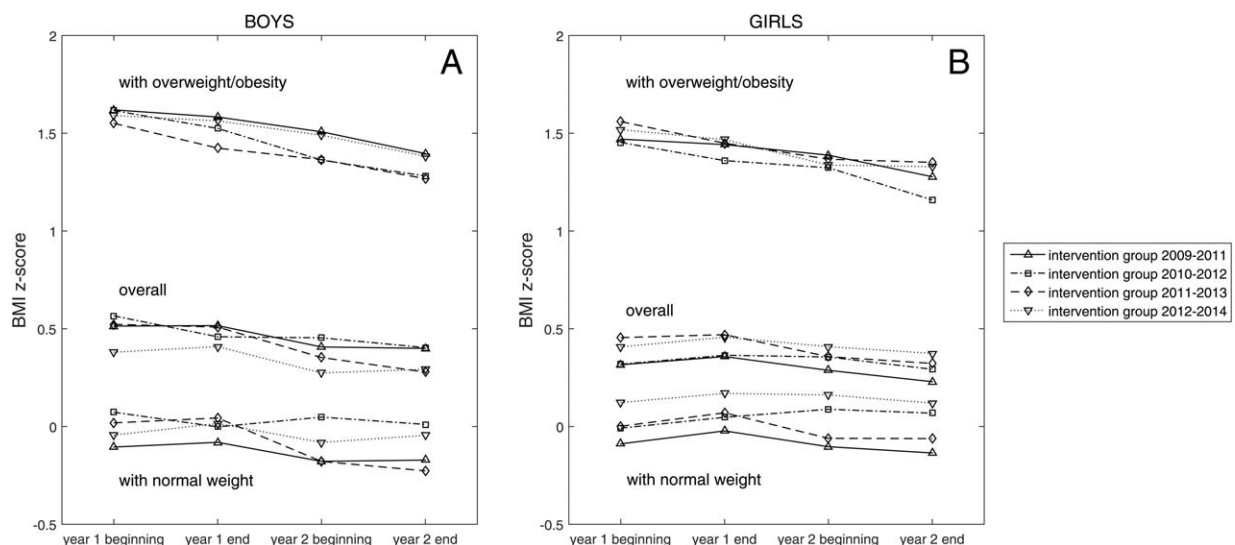
Regression model including the interaction terms group by sex and group by weight status.  
WHtR: waist-to-height ratio; CI: confidence interval.



**Figure 2** Mean BMI z-score values at all measurement points of overall adolescents studied from 2009 to 2011 and of the same subjects divided by weight status. (A) Boys. (B) Girls.

Although some significance about diet-related and physical activity-related habits was found in this pilot study, in line with other studies (19-21,23-26), the use of self-completion questionnaire has some limitations. There is no certainty as to whether self-reported changes correspond to real changes in behaviors. Moreover, the sensitivity of our questionnaire could be limited since weekly frequencies of consumption instead of daily ones were used to better represent local and national consumption levels. However, it seems reasonable that the observed changes in adiposity measures rely on a set of positive behavioral changes.

A key point of our intervention is that it was focused on changes in the school environment as well as individual behavior changes through several reinforcement tools. It has been increasingly recognized the potential impact of the environment on the pathogenesis and treatment of childhood obesity (7,9,10,27-30). In our intervention, high-nutritional-quality foods and beverages were supplied to adolescents from alternative healthy vending machines in schools, at attractive prices. Healthful foods usually cost more than less healthy ones. However, there is evidence that lower prices and greater availability of healthy food do lead to higher consumption and lower BMI,



**Figure 3** Mean BMI z-score values at all measurement points of four distinct series of adolescents who received the two-school-year intervention from 2009 to 2014 and of the same subjects divided by weight status. (A) Boys. (B) Girls.

**TABLE 5** Behavioral outcomes after the intervention and the mean difference in change between the intervention and control groups, in adolescents with normal weight and overweight/obesity

Variable	Baseline	After two school years	Change after two school years	Difference in change between groups after two school years
<b>Subjects with normal weight</b>				
<b>Physical activity (hours/week)</b>				
Intervention group	2.51 (1.56)	3.71 (1.43)	1.20 (1.69)	1.38 [1.01; 1.75]
Control group	2.22 (1.57)	2.04 (1.47)	-0.18 (0.96)	
<b>SSB consumption (times/week)</b>				
Intervention group	2.33 (2.08)	1.39 (1.40)	-0.95 (1.86)	-1.12 [-1.52; -0.72]
Control group	2.70 (2.46)	2.86 (2.45)	0.17 (0.95)	
<b>Snack consumption (times/week)</b>				
Intervention group	3.43 (2.36)	2.62 (1.87)	-0.81 (2.81)	-0.93 [-1.43; -0.43]
Control group	3.92 (2.37)	4.04 (2.32)	0.12 (0.54)	
<b>Fruit consumption (times/week)</b>				
Intervention group	5.72 (1.70)	5.97 (1.46)	0.24 (1.45)	0.48 [0.09; 0.87]
Control group	5.27 (2.06)	5.02 (2.07)	-0.24 (1.18)	
<b>Vegetable consumption (times/week)</b>				
Intervention group	4.74 (1.99)	5.14 (1.94)	0.40 (2.09)	0.45 [0.03; 0.87]
Control group	4.10 (2.39)	4.04 (2.37)	-0.05 (0.85)	
<b>Screen time (hours/day)</b>				
Intervention group	1.90 (1.02)	1.72 (0.93)	-0.17 (0.90)	-0.33 [-0.54; -0.12]
Control group	1.94 (1.33)	2.09 (1.45)	0.16 (0.59)	
<b>Subjects with overweight/obesity</b>				
<b>Physical activity (hours/week)</b>				
Intervention group	2.67 (1.88)	3.48 (1.54)	0.81 (2.04)	0.72 [0.13; 1.31]
Control group	2.38 (1.44)	2.48 (1.57)	0.09 (0.72)	
<b>SSB consumption (times/week)</b>				
Intervention group	2.05 (1.80)	1.24 (1.84)	-0.81 (2.48)	-0.81 [-1.48; -0.14]
Control group	2.58 (2.27)	2.58 (2.15)	0.00 (0.60)	
<b>Snack consumption (times/week)</b>				
Intervention group	2.71 (1.82)	2.05 (1.47)	-0.67 (2.06)	-0.67 [-1.23; -0.11]
Control group	3.13 (2.00)	3.13 (2.00)	0.00 (0.51)	
<b>Fruit consumption (times/week)</b>				
Intervention group	5.19 (2.09)	5.43 (2.20)	0.24 (1.48)	0.30 [-0.17; 0.77]
Control group	4.68 (2.26)	4.61 (2.34)	-0.06 (0.69)	
<b>Vegetable consumption (times/week)</b>				
Intervention group	5.00 (2.37)	5.10 (2.14)	0.10 (2.14)	0.26 [-0.43; 0.95]
Control group	4.20 (2.41)	4.03 (2.48)	-0.16 (0.99)	
<b>Screen time (hours/day)</b>				
Intervention group	2.42 (1.12)	2.05 (0.78)	-0.37 (1.21)	-0.37 [-0.76; 0.02]
Control group	2.45 (1.78)	2.45 (1.82)	0.00 (0.54)	

Data are expressed as mean (SD) and [95% CI].

SSB: sugar-sweetened beverages.

Plus and minus represent increase or decrease, respectively, after two school years.

particularly BMI among overweight teenagers (31). As the school environment can be an important bearer of health-related messages (32), we suggest that the easy availability of healthy foods and beverages in schools may help adolescents make healthier choices in other life settings too. Educational posters, school lessons, textbooks, and text messages focused strongly on encouraging exercise and healthier eating. Text messages may well be useful in obesity interventions tar-

geting adolescents (33). The text messages and the textbook were designed as an individual reinforcement tool and as a means of involving families as well.

It was almost impossible to prevent cross-contamination of the intervention between schools placed in a geographically limited area. This may limit the differences observed between the groups after

the intervention. However, data collection was continued even after the control schools refused to participate further: it is of interest that from 2009 to 2014 the time trend of BMI  $z$ -score was quite consistent between the different two-year series, suggesting that the results of the educational program may be reproducible when the intervention is performed on different subjects.

The major limit of our study is the absence of randomization, due to the small number of schools available. Although previous collaborations with the schools assigned to the intervention group in the present study were not inherent to nutritional education and were carried out with different students, the possibility of a different motivation between the intervention and control schools cannot be excluded. Randomization is mandatory to overcome a possible selection bias. A randomized trial could serve to confirm or contradict the present results and to establish a causal relationship with the intervention. To this end, we hypothesized to design and implement a school-based cluster randomized controlled trial with randomization at school level. From the pilot study, an intra-class correlation coefficient for the BMI  $z$ -score of 0.005 (95% CI: 0.000-0.026) was estimated. To detect a difference between groups at the end of the intervention of 0.18 in the BMI  $z$ -score using an intra-class correlation coefficient of 0.005 and a standard deviation of 1, assuming an  $\alpha$  of 0.05, 80% power, and a two-sided test, a sample size of 20 clusters (10 clusters per group) with 70 pupils per cluster, for a total of at least 1,400 pupils, was calculated (34). Other Institutes interested in the prevention and treatment of childhood obesity from geographically different areas could be involved. Sources of funding are needed to keep schools through the study, particularly those assigned to the control group, maybe by giving them school equipments. The educational program is relatively inexpensive and easy to implement. We calculated an approximate cost of the intervention of 46 euros (50 dollars) per pupil for the educational materials for two school years. Alternative healthier vending machines did not cost more than the previous ones.

In conclusion, we found that a school-based multicomponent educational program including school environment changes and individual reinforcement tools may be effective for reducing adiposity and improving some physical activity- and diet-related behaviors in middle-school adolescents. Larger and randomized controlled studies are needed to confirm the efficacy of this model. We suggest that changing the school environment could be a basis for population-wide interventions to prevent obesity in children and adolescents. **O**

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