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PEDIATRIC ORIGINAL ARTICLE

Assessment of an after-school physical activity program to prevent obesity among 9- to 10-year-old children: a cluster randomized trial

V Martínez Vizcaíno[1], F Salcedo Aguilar[2], R Franquelo Gutiérrez[3], M Solera Martínez[1], M Sánchez López[1], S Serrano Martínez[3], E López García[4,5] and F Rodríguez Artalejo[4,5]

[1]*Health and Social Research Centre, Universidad de Castilla-La Mancha, Cuenca, Spain;* [2]*Family and Community Medicine Teaching Unit, Servicio de Salud de Castilla-La Mancha, Cuenca, Spain;* [3]*Clinical Analysis Laboratory, Hospital Virgen de la Luz, Cuenca, Spain;* [4]*Department of Preventive Medicine and Public Health, School of Medicine, Universidad Autónoma de Madrid, Madrid, Spain and* [5]*CIBER de Epidemiología y Salud Pública (CIBERESP), Instituto de Salud Carlos III, Madrid, Spain*

Objective: To assess the impact of a physical activity program on obesity in primary school children.
Design: Cluster-randomized controlled trial with 10 intervention and 10 control schools.
Participants: A total of 1044 children, mean age 9.4 years (s.d. = 0.7) at baseline, of the Province of Cuenca, Spain.
Intervention: Recreational, non-competitive physical activity program conducted after school hours on school premises. The program consisted of three 90-min sessions per week, for 24 weeks.
Main outcome measures: Body mass index (BMI), triceps skin-fold thickness (TST) and percentage body fat. Secondary measures were blood lipids and blood pressure. Measurements were made at the beginning (September 2004) and at the end of the program (June 2005). Since schools rather than children were randomized, mixed regression models were used to adjust for individual-level covariates under cluster randomization.
Results: There were no differences in BMI between the intervention and control groups. Compared with controls, intervention children showed a decrease in TST in both boys (−1.14 mm; 95% confidence interval (CI) −1.71 to −057; $P<0.001$) and girls (−1.55 mm; 95% CI −2.38 to −0.73; $P<0.001$), as well as a reduction in the percentage of body fat in girls (−0.58%; 95% CI −1.04 to −0.11; $P=0.02$). Furthermore, the intervention boys exhibited a decrease in apolipoprotein (apo) B levels (−4.59; 95% CI −8.81 to −0.37; $P=0.03$) and an increase in apo A-I levels (13.57; 95% CI 7.95–19.20; $P<0.001$). Blood lipid results in girls were very similar. No changes in total cholesterol, triglycerides or blood pressure were associated with the intervention in either sex, except for an increase in diastolic blood pressure (1.55 mm Hg; 95% CI 0.19–2.91; $P=0.03$) in the intervention versus control boys.
Conclusion: An after-school program of recreational physical activity reduced adiposity, increased apo A-I and decreased apo B in primary school children.
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Keywords: physical activity; adiposity; children; blood lipids; blood pressure; randomized controlled trials

Introduction

The prevalence of overweight and obesity is increasing among children in many countries around the world.[1,2] In the case of Spain, the prevalence of childhood obesity is high and rising rapidly.[3,4] Using the Cole *et al.* criteria,[5] the prevalence of overweight and obesity rose from 24% in 1992 to 31% in 2004 among children aged 9–10 years in the city of Cuenca.[6]

The high rate of childhood obesity, its health impact and the modest effectiveness of treatment[7] configure a problem that urgently requires preventive interventions. Nevertheless, a recent Cochrane review underlined the dearth of research on childhood obesity prevention and the methodologic limitations of many earlier studies.[8] Furthermore, most interventions assessed in higher-quality studies were ineffective,[9–11] although a moderate reduction in obesity was

Correspondence: Dr VM Vizcaíno, Centro de Estudios Sociosanitarios, Universidad de Castilla-La Mancha, Edificio Melchor Cano, Calle Santa Teresa Jornet s/n, Cuenca-16071, Spain.
E-mail: vicente.martinez@uclm.es
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reported by one long-term trial (18 months) in girls,[12] and by another short-term trial (6 months) in both sexes.[13] In both studies, the key success factor was a reduction in sedentariness by reducing television viewing time.

Simple programs designed to increase physical activity and reduce sedentariness seem to be the most promising option for preventing obesity.[14] Among the explanations postulated for why these programs have not achieved full prevention potential are insufficient physical activity[15,16] and the fact that programs aimed to change children's lifestyle habits without substantially altering the environment in a way conducive to such changes.[8,14] This may also explain the null or only moderate impact of school-based physical activity programs on obesity-related cardiovascular risk factors, such as blood lipids[17,18] and blood pressure.[17,19]

This study assessed the impact of a physical activity program on obesity, blood lipids and blood pressure in fourth- and fifth-grade schoolchildren. The program included three 90-min sessions of moderate physical activity per week, involving more activity than most previous studies.[20] Moreover, the program endeavored to create optimal conditions for the children's participation. Specifically, activities were held after school hours at school sports facilities located near the children's homes. The program was recreational and access was free of charge.

Methods

Study design and participants

We conducted a randomized controlled trial to prevent contamination between intervention and control participants. The design, implementation and reporting of the study followed recommendations from the CONSORT statement on cluster-randomized trials.[21]

We selected 20 schools in 20 towns in the Province of Cuenca, Spain. Except for the provincial capital (population 48 000), all the towns were small (population 1800–6500) and their main economic activities were farming, food processing and mechanical industries. All participating schools were public and had at least one complete fourth-grade class and one complete fifth-grade class. In towns with two or more schools, only one was chosen at random to avoid contamination of the intervention. Using a computer-generated procedure, 10 schools were randomized to the intervention group, and 10 to the control group. Randomization was not stratified by town size, because all were of similar size, aside from the provincial capital. Schools were informed of the result of randomization after they agreed to participate in the study.

The Boards of Governors (community participatory organ in each school) and the children's parents were informed of the study's aims and methods, and consented to their children's participation in writing. Similarly, the study was presented classroom-by-classroom to the children and their oral consent was obtained. Participating children were free of serious learning difficulties or physical or mental disorders that could impede participation in scheduled physical activities. The study was approved by the Cuenca Clinical Research Ethics Committee and an insurance policy was contracted to cover injuries during the physical activity program.

Intervention

The intervention is described in detail elsewhere (www. movidavida. org). Briefly, it consisted of a non-competitive recreational physical activity program (Movi) adapted to the children's age and held after school at the school's athletic facilities. In most cases, children went home after class and then returned to the school premises to participate in the program.

The program was implemented during the 2004–2005 academic year and consisted of three 90-min sessions per week for 24 weeks. The physical activity sessions were planned by two qualified physical education teachers and were supervised by sports instructors. The sessions included sports with alternative equipment (pogo sticks, frisbees, jumping balls, parachutes, and so on), cooperative games, dance and recreational athletics. The sports instructors underwent a 2-day training program and a written plan of activities for each session was developed to ensure program standardization in all 10 intervention schools. Each 90-min session included 15 min of stretching, 60 min of aerobic resistance and 15 min of muscular strength/resistance exercises. On average, these exercises required physical activity of moderate intensity throughout the 90 min of each session. Use of an RT3 Tri-axial accelerometer (Stayhealthy, Monrovia, CA, USA)[22] on 75 randomly selected children found a mean count per minute (c.p.m.) per session of 1345.48 (s.d. = 1023) and 33.5% of time dedicated to >1700 c.p.m. activity during each session. In contrast, the accelerometer c.p.m. was 527.38 (s.d. = 741.28) at the same time on days with no program session. To facilitate generalizability, program cost was kept relatively low (28 euros per child per month). As the program cost was wholly subsidized by the research grant, participation in the program was free of charge.

The standard physical education curriculum (3 h per week of physical activity at low-to-moderate intensity) continued to be taught in both the control and intervention schools, because it is compulsory for all primary school pupils in Spain.

Participation in the Movi program was promoted by presenting it separately to physical education teachers, the children's parents and the Board of Governors of each intervention school. All were informed: (a) about the importance of obesity and other cardiovascular risk factors in childhood as predictors of cardiovascular disease in adulthood; (b) that the Movi program would be implemented by instructors trained by the research team; and that instructors would receive training by an expert in developmental psychology that would specifically address work with pubertal children; (c) that the Movi program was designed to be compatible with the children's other leisure activities; (d) that the Movi program was supported by the Castilla-La Mancha Regional Health Department and (e) that the equipment used in the physical activities was funded by the research grant and would be donated to the participating schools at the end of the research project.

Good adherence to the Movi program was encouraged with a system of rewards (T-shirts, caps, board games, and so on, with the program logo) for the children and their parents. We assessed satisfaction with Movi using anonymous questionnaires. Program instructors administered the questionnaires to children; questionnaires were mailed to parents. Finally, children's parents were invited to call about any complaint, suggestion or question they had about the Movi program. The research staff remained available during working hours to field calls for the duration of the intervention.

Outcome variables

The variables of interest were measured in the intervention and control participants at the start (September 2004) and at the end (June 2005) of the physical activity program. Specifically, children were weighed twice to the nearest 0.1 kg in light clothing using a portable electronic scale (Seca 770). Height was measured twice to the nearest 0.1 cm without shoes using a wall-mounted stadiometer (Seca 222). Using the mean of these measurements, body mass index (BMI) was calculated as weight in kilograms divided by height in square meters ($kg\,m^{-2}$). Children were classified as normal weight, overweight and obese according to the BMI cutoff values proposed by Cole *et al*.[5] Triceps skin-fold thickness (TST) was the mean of three measurements to 0.1 mm with a Holtain skin-fold caliper. Percentage body fat was estimated with an eight-electrode BC-418 MA bioimpedance analysis system (Tanita Corp. Tokyo, Japan)[23] using the mean of two readings made under controlled temperature and humidity conditions. Measurements were made in children without shoes, under fasting conditions and after urinating and a 15-min rest. The reliability of the BMI, TST and % body fat measurements was very high (intraclass correlation coefficient 0.99 for BMI and 0.97 for both TST and % body fat).

After a 5-min rest, three blood pressure readings were taken at 2-min intervals. Children were seated in a quiet, restful environment with the right arm semiflexed and raised to heart level. Blood pressure was obtained with an OMRON M5-I automatic sphygmomanometer[24] using three cuffs sized for arm circumference (17–22, 22–32 and 32–42 cm). The mean of the three blood pressure readings was used in the analyses. Two certified, trained nurses, who were unblinded to school allocation made the anthropometric and blood pressure measurements.

Twelve-hour-fasting blood samples were obtained under standardized conditions from the cubital vein in Vacutainer serum-gel-separator tubes. Samples were processed within 60 min of drawing at the Virgen de la Luz Hospital Laboratory in Cuenca. The following parameters were determined: total cholesterol (enzymatic CHOD-PAP (cholesterol-esterase, cholesterol-oxidase, peroxidase) method[25]); triglycerides (enzymatic GPO-PAP (glycerolphosphate oxidase, peroxidase) method[26]) and apolipoprotein B (apo B) and apolipoprotein A-I (apo A-I) (Tina-quant immunoturbidimetric version 2 assay, Roche/Hitachi Modular Analytics[27]). The laboratory analysts who determined blood lipids were blinded to school allocation.

Sexual maturity ratings are recommended for interpreting and control interindividual differences in obesity, lipid profile and blood pressure.[28,29] However, due to cultural constraints and the limited privacy of school-based physical examinations, information on sexual maturity was not obtained.

Calculation of sample size

Using methods that took cluster randomization into account,[30] we estimated that approximately 400 boys and 400 girls from 20 schools would be needed to show differences of $0.5\,kg\,m^{-2}$ (s.d. $= 2\,kg\,m^{-2}$) in BMI between the intervention and control group with a two-tailed $\alpha = 5$ and 80% power. Based on information from children of the same age at schools in Cuenca,[6]calculations assumed that the mean BMI would be $18\,kg\,m^{-2}$ for boys and girls, that each cluster (school) would have a mean size of 55 pupils, and that the intracluster correlation coefficient for BMI would be 0.009.

Statistical analysis

The principal level of inference corresponded to comparison of changes between baseline (September 2004) and end of follow-up (May 2005) between intervention and control schoolchildren. Primary end points were BMI and adiposity measures (TST and % body fat), and secondary end points were blood pressure and blood lipids.

We analyzed the data with mixed regression models, where the dependent variable was each end point at the end of follow-up.[31] Models were adjusted for the baseline values of each end point by age and cluster (random effect). The intervention was included in the model as a fixed effect using an independent dummy variable with a value of 1 for intervention schools, and 0 for control schools. Results were expressed as the absolute difference in the changes in end points between baseline and end of follow-up between intervention and control schoolchildren, with 95% confidence interval (CI). However, when the dependent variable was the prevalence of excess weight (overweight or obesity), odds ratios (OR) with 95% CI were estimated.

We constructed separate models for boys and girls because of their different growth, height, skin-fold and body-fat patterns.[28,32] We also tested whether the effect of the intervention was different in boys and girls using interaction terms that were the product of intervention by sex.

Analyses were performed according to the intention-to-treat, with children analyzed in their original randomized allocation, regardless of the number of scheduled physical activity sessions attended.[33] Lastly, we examined whether the results were sensitive to the school situated in the provincial capital, Cuenca, a city 10 times larger than the towns where the other schools were located. For this purpose, we repeated the analyses after excluding the school in the provincial capital.

Statistical significance was set at $P<0.05$. SAS package version 9.1 was used for analyses.[34] PROC GENMOD was used to construct generalized mixed linear models where the dependent variable was dichotomous and PROC MIXED where the dependent variable was continuous. Additionally, results were validated against those of comparable models using the PROC PHREG and PROC GLM procedures, respectively; similar results were obtained.[35]

Results

Figure 1 shows the flow of schools and participating children across the study. All invited schools agreed to participate. The 10 schools allocated to intervention included 691 fourth-grade and fifth-grade pupils versus 718 in the 10 schools allocated as controls. Among the children in the intervention schools, 513 (74.2%) agreed to participate and provided baseline data. Measurements were obtained in 465 (90.6%) of these children at the 9-month follow-up and were included in the analyses. The respective figures for the control group were 606 (84.4%) and 579 (95.5%). In the intervention and control groups, baseline and 9-month follow-up participation rates were similar in boys and girls.

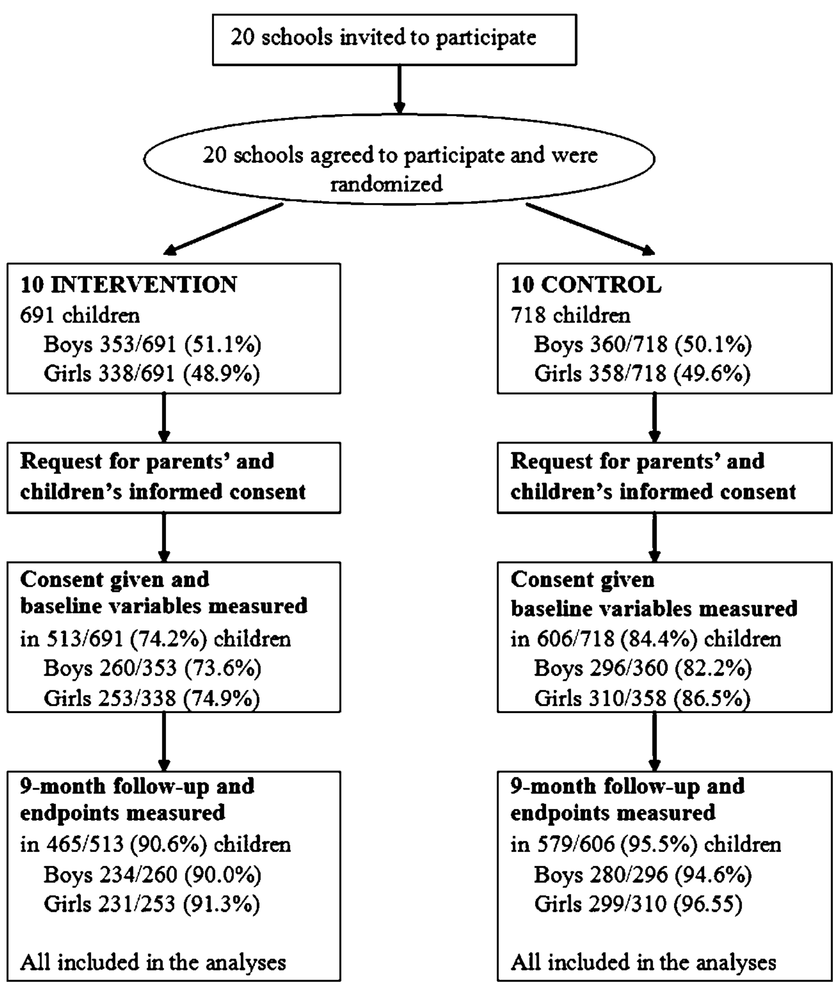

Figure 1 Flow chart depicting the progress of clusters and individuals across the trial.

Table 1 Baseline end point values among intervention and control schoolchildren, by sex

	Boys			Girls		
	Intervention n = *260*	*Control* n = *296*	P-*value*[a]	*Intervention* n = *253*	*Control* n = *310*	P-*value*[a]
Age	9.4 (0.7)	9.5 (0.7)	0.18	9.4 (0.7)	9.4 (0.6)	0.52
% Overweight or obesity	30.9	33.9	0.38	33.9	29.1	0.38
Body mass index (kg m^{-2})	18.4 (3.6)	18.8 (3.4)	0.70	18.7 (3.5)	18.5 (3.6)	0.39
Triceps skinfold thickness (mm)	15.5 (7.8)	15.33 (6.65)	0.53	18.5 (6.5)	17.3 (6.4)	0.07
% Body fat	22.2 (6.7)	23.3 (6.8)	0.35	25.9 (6.3)	26.2 (6.2)	0.60
Systolic blood pressure (mm Hg)	106.0 (8.11)	109.4 (9.7)	0.001	104.2 (9.5)	107.6 (9.5)	0.08
Diastolic blood pressure (mm Hg)	62.9 (6.8)	65.6 (7.6)	0.007	64.4 (6.8)	66.6 (7.4)	0.001
Total cholesterol (mg dl^{-1})	167.6 (26.5)	171.0 (29.7)	0.48	169.8 (27.6)	169.1 (26.0)	0.83
Apolipoprotein B (mg dl^{-1})	63.7 (13.7)	65.6 (16.5)	0.50	67.7 (15.1)	65.8 (14.2)	0.18
Apolipoprotein A-I (mg dl^{-1})	148.0 (19.3)	149.3 (20.4)	0.49	140.1 (18.8)	146.2 (20.9)	0.007
Triglycerides (mg dl^{-1})	57.5 (30.3)	57.4 (27.1)	0.95	65.0 (30.0)	64.0 (29.8)	0.88

Values are means (s.d.) unless otherwise stated. [a]Calculated from generalized mixed linear models.

The baseline data in September 2004 are summarized in Table 1. The intervention and control participants, stratified by sex, had similar ages, anthropometric variables and blood lipids, except for apo A-I, which was lower among the intervention girls. Furthermore, blood pressure was significantly lower among intervention schoolchildren of both sexes. Among boys, the prevalence of excess weight was 30.9% in the intervention and 33.9% in the control schools; among girls, the respective figures were 33.9 and 29.1%.

On average, a total of 69 90-min sessions were held at each school. Children attended 78.4% of sessions. A total of 85.3% of children participating in Movi reported enjoying the program activities always or almost always; 92.4% of parents reported that their children enjoyed such activities. The changes in end points between baseline and 9 months of follow-up are shown in Table 2. Among boys, prevalence of excess weight fell by 3% in the intervention and 2% in the control groups. After controlling for baseline variables, however, the reduction in the prevalence of excess weight in the intervention versus control boys was not statistically significant (OR 0.72; 95% CI 0.39–1.31; $P = 0.28$). Similarly, there were no statistically significant differences in BMI between the intervention and control boys. Results were similar for girls. Nevertheless, the intervention children registered a reduction in TST compared to controls in both boys (−1.14 mm; 95% CI −1.71 to −057; $P < 0.001$) and girls (−1.55 mm; 95% CI −2.38 to −0.73; $P < 0.001$), and a reduction in % body fat in girls (−0.58%; 95% CI −1.04 to −0.11; $P = 0.02$).

Compared with controls, intervention boys had lower apo B levels (−4.59; 95% CI −8.81 to −0.37; $P = 0.03$) and higher apo A-I levels (13.57; 95% 7.95–19.20; $P < 0.001$). Results were similar in girls. Intervention was not associated with any statistically significant changes in total cholesterol, triglycerides or blood pressure in either sex, with the exception of diastolic blood pressure, which rose by 1.55 mm Hg (95% CI 0.19–2.91; $P = 0.03$) in the intervention versus control boys (Table 2).

None of the interaction terms testing whether intervention effects varied with sex attained statistical significance, except for systolic blood pressure ($P = 0.02$).

As some previous interventions in schoolchildren have been associated with an increase in the prevalence of low weight,[36] we examined the changes in end points before and after the intervention in three strata, defined by percentiles (P) of baseline BMI in the whole study sample. After adjustment for baseline end points, the intervention was associated with a modest rise in BMI in children with BMI $< P_{25}$ and a reduction in TST and % body fat in children with BMI P_{25}–P_{75} and BMI $> P_{75}$ (Table 3). Apo B levels fell and apo A-I levels rose in children across all three BMI strata. Among children with BMI $< P_{25}$, there was a rise in systolic blood pressure associated with the intervention.

The results did not vary materially when the school situated in the provincial capital was excluded from the analysis.

Discussion

An after-school physical activity program targeting primary school pupils showed modest reductions in TST in both sexes and in % body fat in girls. Furthermore, lower apo B and higher apo A-I concentrations were found.

It is known that BMI does not measure body fat directly and that changes in BMI may reflect lean body mass rather than fatness, particularly among young people engaging in physical activity.[28] Therefore, an especially positive result of our intervention was the reduction of adiposity, measured by TST and % body fat, in the absence of any reduction in BMI, because this indicates that the physical activity program maintained or slightly increased lean body mass. These results coincide with previous studies that increased physical activity in schoolchildren and succeeded in reducing skin folds but not BMI or other weight-to-height measures.[37–41] However, our study adds to the evidence on effective

Table 2 Changes in obesity, blood pressure and blood lipids from baseline to the end of follow-up among intervention versus control schoolchildren, by sex

	Boys					*Girls*				
	Baseline[a]	*End of follow-up*[a]	*Crude change*	*Adjusted difference of intervention versus control*[b] *(95% CI)*	P-*value*	*Baseline*[a]	*End of follow-up*[a]	*Crude change*	*Adjusted difference of intervention versus control*[b] *(95% CI)*	P-*value*
% Overweight or obesity										
Control (*n* = 579)	33	31	−2	0.72 [c] (0.39; 1.31)	0.28	29	28	−1	0.83 [c] (0.36; 1.92)	0.66
Intervention (*n* = 465)	30	27	−3			33	31	−2		
Body mass index (kg m^{-2})										
Control	18.6 (3.4)	19.0 (3.4)	0.4	0.07 (−0.12; 0.27)	0.45	18.5 (3.6)	18.8 (3.6)	0.3	−0.12 (−0.32; 0.07)	0.22
Intervention	18.4 (3.6)	18.8 (3.7)	0.4			18.7 (3.7)	18.9 (3.4)	0.2		
Triceps skinfold thickness (mm)										
Control	15.2 (6.7)	15.8 (7.1)	0.6	−1.14 (−1.71; −0.57)	<0.001	17.2 (6.4)	17.4 (6.5)	0.2	−1.55 (−2.38; −0.73)	<0.001
Intervention	15.5 (7.7)	14.8 (6.9)	−0.7			18.3 (6.6)	16.9 (6.2)	−1.4		
% Body fat										
Control	23.1 (6.8)	23.2 (6.6)	0.1	−0.37 (−0.86; 0.13)	0.15	26.1 (6.2)	26.1 (6.2)	0	−0.58 (−1.04; −0.11)	0.02
Intervention	22.2 (6.8)	21.8 (6.4)	−0.4			25.9 (6.3)	25.3 (5.9)	−0.6		
Systolic blood pressure (mm Hg)										
Control	109.5 (9.7)	105.6 (9.0)	−3.9	1.03 (−0.61; 2.67)	0.22	107.4 (9.4)	103.1 (8.9)	−4.3	0.05 (−1.68; 1.77)	0.96
Intervention	106.0 (8.3)	105.0 (8.6)	−1			104.4 (9.6)	101.7 (8.1)	−2.7		
Diastolic blood pressure (mm Hg)										
Control	65.5 (7.7)	62.5 (6.6)	−3	1.55 (0.19; 2.91)	0.03	66.6 (7.4)	63.9 (6.7)	−2.7	0.13 (−1.44; 1.18)	0.85
Intervention	63.2 (7.1)	63.0 (6.5)	−0.2			64.5 (6.9)	62.8 (6.2)	−1.7		
Total cholesterol (mg dl^{-1})										
Control	170.6 (30.0)	164.5 (24.2)	−1.8	0.89 (−1.96; 3.75)	0.54	169.0 (26.2)	163.2 (25.4)	−5.8	0.62 (−2.64; 3.94)	0.71
Intervention	168.8 (27.4)	163.2 (24.0)	−5.6			169.4 (37.3)	164.5 (25.1)	−4.9		
Apolipoprotein B (mg dl^{-1})										
Control	65.3 (16.3)	70.8 (14.6)	5.5	−4.59 (−8.81; −0.37)	0.03	65.8 (14.1)	71.9 (14.5)	6.1	−4.90 (−9.49; −0.30)	0.04
Intervention	64.3 (14.1)	66.1 (13.1)	1.8			67.8 (15.3)	68.5 (14.0)	0.7		
Apolipoprotein A-I (mg dl^{-1})										
Control	149.4 (20.9)	144.3 (21.0)	−5.1	13.57 (7.95; 19.20)	<0.001	145.9 (21.1)	138.4 (19.6)	−7.5	13.64 (8.21; 19.07)	<0.001
Intervention	148.2 (19.8)	156.0 (20.5)	7.8			138.9 (18.6)	148.5 (19.1)	9.6		
Triglycerides (mg dl^{-1})										
Control	57.3 (26.9)	61.4 (32.3)	4.1	−2.17 (−8.74; 4.39)	0.51	63.9 (29.7)	67.4 (28.9)	3.5	−2.95 (−9.19; 3.29)	0.35
Intervention	57.5 (30.2)	57.5 (27.5)	0			64.2 (29.6)	65.3 (27.7)	1.1		

Abbreviation: CI, confidence interval. [a]Figures at baseline and end of follow-up correspond to crude data. [b]Differences adjusted for baseline value, age and cluster (random effect) using generalized mixed linear models. [c]Odds ratio of overweight or obesity among intervention versus control children.

Table 3 Changes in obesity, blood pressure and blood lipids from baseline to end of follow-up among intervention versus control schoolchildren, by baseline BMI

	Baseline[a]	*End of follow-up*[a]	*Crude change*	*Adjusted difference of intervention versus control*[b]	*95% CI*	P-*value*
BMI $<P_{25}$ (n = 253)						
Body mass index (kg m^{-2})						
Control	14.8 (0.8)	15.1 (0.9)	0.3	0.20	0.05; 0.35	0.008
Intervention	14.8 (0.9)	15.2 (0.9)	0.4			
Triceps skinfold thickness (mm)						
Control	10.0 (2.7)	10.2 (2.9)	0.2	−0.25	−0.85; 0.35	0.41
Intervention	9.8 (3.2)	9.7 (3.0)	−0.1			
% Body fat						
Control	18.3 (3.0)	18.5 (3.1)	0.2	−0.11	−0.62; 0.40	0.67
Intervention	17.3 (2.7)	17.5 (2.5)	0.2			
Systolic blood pressure (mm Hg)						
Control	106.9 (8.9)	102.8 (9.2)	−4.1	2.55	0.10; 4.99	0.04
Intervention	102.1 (8.0)	102.5 (8.3)	0.4			
Diastolic blood pressure (mm Hg)						
Control	63.5 (7.1)	60.9 (6.5)	−2.6	0.34	−1.57; 2.23	0.73
Intervention	61.5 (7.2)	60.9 (6.0)	−0.6			
Total cholesterol (mg dl^{-1})						
Control	169.4 (27.1)	164.2 (26.0)	−5.2	−0.71	−4.99; 3.57	0.74
Intervention	168.7 (28.4)	162.7 (23.9)	−6.0			
Apolipoprotein B (mg dl^{-1})						
Control	63.5 (14.5)	70.3 (14.5)	6.8	−6.35	−9.91; −2.80	<0.001
Intervention	64.6 (14.7)	64.7 (12.0)	0.1			
Apolipoprotein A-I (mg dl^{-1})						
Control	150.5 (21.5)	143.5 (20.2)	−7.0	15.67	9.42; 21.93	<0.001
Intervention	149.8 (21.1)	159.2 (20.0)	9.4			
Triglycerides (mg dl^{-1})						
Control	50.2 (18.2)	56.2 (20.7)	6.0	−0.61	−8.22; 6.99	0.87
Intervention	50.1 (19.3)	54.4 (22.9)	4.3			
$P_{25} \geqslant$ *BMI* $\leqslant P_{75}$ (n = 522)						
Body mass index (kg m^{-2})						
Control	17.9 (1.4)	18.2 (1.6)	0.3	−0.08	−0.30; 0.13	0.44
Intervention	18.0 (1.5)	18.2 (1.6)	0.2			
Triceps skinfold thickness (mm)						
Control	15.3 (4.6)	15.6 (4.6)	0.3	−1.25	−1.82; −0.67	<0.001
Intervention	15.8 (4.7)	14.9 (4.4)	−0.9			
% Body fat						
Control	23.6 (4.2)	23.6 (4.2)	0	−0.59	−1.03; −0.16	0.008
Intervention	23.2 (4.0)	22.7 (3.9)	−0.5			
Systolic blood pressure (mm Hg)						
Control	108.2 (9.5)	103.8 (8.5)	−4.4	0.09	−1.64; 1.82	0.92
Intervention	105.6 (9.1)	102.8 (8.3)	−2.8			
Diastolic blood pressure (mm Hg)						
Control	65.6 (6.9)	62.6 (6.4)	−3.0	1.00	−0.16; 2.16	0.09
Intervention	63.7 (6.8)	62.8 (6.0)	−0.9			
Total cholesterol (mg dl^{-1})						
Control	169.1 (28.5)	163.3 (24.1)	−5.8	1.30	−1.86; 4.46	0.42
Intervention	168.4 (27.1)	164.2 (23.6)	−4.2			
Apolipoprotein B (mg dl^{-1})						
Control	64.5 (14.9)	69.9 (14.1)	5.4	−3.98	−8.61; 0.65	0.09
Intervention	64.7 (14.0)	66.5 (12.7)	1.8			

Table 3 (continued)

	Baseline[a]	*End of follow-up*[a]	*Crude change*	*Adjusted difference of intervention versus control*[b]	*95% CI*	P-*value*
Apolipoprotein A-I (mg dl^{-1})						
Control	149.3 (20.8)	143.8 (19.7)	−5.5	12.68	6.48; 18.89	<0.001
Intervention	145.3 (19.6)	153.8 (19.3)	8.5			
Triglycerides (mg dl^{-1})						
Control	55.5 (20.6)	60.2 (26.2)	4.7	−3.84	−7.54; −0.14	0.04
Intervention	58.1 (28.5)	57.7 (22.3)	−0.4			
BMI $>P_{75}$ (n = 264)						
Body mass index (kg m^{-2})						
Control	23.5 (2.5)	23.7 (2.5)	0.2	−0.13	−0.41; 0.16	0.38
Intervention	23.6 (2.8)	23.5 (2.6)	−0.1			
Triceps skinfold thickness (mm)						
Control	24.3 (4.6)	24.9 (4.8)	0.6	−1.87	−3.43; −0.32	0.01
Intervention	25.9 (4.7)	23.8 (4.8)	−2.1			
% Body fat						
Control	33.0 (4.8)	32.6 (4.9)	−0.4	−0.67	−1.32; −0.01	0.05
Intervention	32.4 (5.2)	31.2 (5.2)	−0.1			
Systolic blood pressure (mm Hg)						
Control	110.3 (10.2)	106.8 (9.4)	−3.5	0.14	−2.80; 2.52	0.92
Intervention	107.4 (8.9)	105.3 (8.8)	−2.1			
Diastolic blood pressure (mm Hg)						
Control	69.8 (7.9)	66.5 (6.3)	−3.4	0.005	−2.05; 2.06	0.99
Intervention	66.4 (6.5)	65.0 (6.5)	−1.4			
Total cholesterol (mg dl^{-1})						
Control	171.5 (28.3)	164.6 (25.4)	−6.9	1.04	−4.27; 6.36	0.70
Intervention	170.8 (26.9)	164.5 (27.0)	−6.3			
Apolipoprotein B (mg dl^{-1})						
Control	69.8 (15.9)	75.4 (14.9)	5.6	−4.93	−10.58; 0.72	0.09
Intervention	70.0 (15.7)	71.4 (15.6)	1.4			
Apolipoprotein A-I (mg dl^{-1})						
Control	141.3 (19.8)	133.8 (20.5)	−7.5	14.31	8.21; 20.40	<0.001
Intervention	134.6 (15.3)	142.6 (18.6)	8			
Triglycerides (mg dl^{-1})						
Control	81.6 (38.5)	81.0 (39.8)	−0.6	−2.93	−12.67; 6.82	0.55
Intervention	76.6 (35.3)	75.3 (36.0)	−1.6			

Abbreviation: BMI, body mass index; CI, confidence interval. [a]Figures at baseline and end of follow-up correspond to crude data. [b]Differences adjusted for baseline value, age and cluster (random effect) using generalized mixed linear models.

childhood obesity prevention measures, because previous studies were non-randomized,[40] interventions were of short duration (8,[38,39] 10[40] or 14 weeks[37]), and the study design could not differentiate the effect of physical activity from that of other components of the intervention, such as diet[38,40,41] or classroom educational materials.[38,40,41]

There have been reports of interventions that were effective in either boys[42,43] or girls alone.[12,44] Although our physical activity program reduced the % body fat in girls and increased diastolic blood pressure in boys, in general, it showed no clear pattern of gender-related effectiveness. Tailoring interventions to a specific gender might maximize program benefits, but our results suggest that it is not essential for reducing adiposity and improving lipid profiles in both genders. The almost identical participation and follow-up rates of boys and girls in our program support this conclusion.

Another positive result of the program was the reduction in adiposity of children with BMI $>P_{25}$ without increasing the prevalence of low weight in the children with a lower BMI. Moreover, all the intervention children showed an improvement in apo B and apo A-I, regardless of BMI. This is important for two reasons. First, because very few studies have reported the intervention's impact on the frequency of low weight,[9,36,42] and second, because it suggests that effective and safe interventions targeting all schoolchildren can be conducted without labeling children with excess weight.

To date, school-based interventions have not substantially improved lipoprotein levels,[20] although some have resulted in a slight improvement in cholesterol-high-density lipoprotein[18] and even total cholesterol.[38] Our intervention achieved an important increase in apo A-I and a substantial decrease in apo B. This may be due to its longer duration than in previous studies on schoolchildren.[20] Recent observational studies have shown that moderate physical activity for at least 90 min per day improves a composite cardiovascular risk factor score in schoolchildren aged 9–15 years.[45] Since elevated cardiovascular risk factors in childhood tend to persist into adulthood,[46,47] our results may be relevant to cardiovascular health in the overall population.

There is no clear evidence that physical activity reduces blood pressure in normotensive children.[19] In our study, physical activity was not associated with changes in blood pressure, other than an increase in diastolic pressure in children. Although we do not know why this occurred, it is compatible with regression to the mean, since baseline blood pressure was higher among the control participants.

This study has several limitations. First, it was conducted in rural schools. Thus, the findings must be confirmed in urban settings. Second, although the follow-up (9 months) was longer than in earlier studies, the impact of the intervention should be examined over a more prolonged time. Third, anthropometric and blood pressure determinations were not blinded to intervention allocation. Hence, we cannot exclude a certain error in the assessment of effectiveness. It should be noted, however, that our study included only objective end points with highly reproducible measures, so the intervention was tested more rigorously than in studies using self-reported end points.[48] Moreover, weight, % body fat and blood pressure measurements were made with automatic digital devices, thereby reducing observer errors.

This study also had important strengths. First, the program was standardized through structured training of the sports instructors and a written plan of the activities undertaken in each session. Second, physical activity was recreational and non-competitive. The rate of consent to participate among parents and children was high and attendance of the program sessions was good, even though sessions were held after school and reduced the children's leisure time. Furthermore, program adherence was very high (90.6% at 9 months) despite its high intensity (three sessions per week, 90 min per session). Third, follow-up rates were similar or even better among children in the control schools. This may be because parents knew in advance that blood pressure and blood lipid results would be given shortly after the health examination at the end of the project, together with appropriate advice if any parameter was abnormal. Fourth, only one school in each town entered the study, thereby limiting the spread of intervention to the control schools. This contributed to the internal validity of the study.

The sustainability and generalizability of the program are potentially high. It was a simple and inexpensive intervention, because it used school sports facilities. Moreover, it achieved objective health benefits without requiring parents' time or active participation, factors that can prove an obstacle in obesity-prevention programs that involve the whole family. In addition, there was no change in school curriculum. Such changes would be difficult due to legal regulations in Spain and may encounter obstacles from teachers and parents concerned that additional school physical education might reduce academic performance. Finally, participation in after-school activities is common in Spain. The offer without social distinctions of a low-cost physical activity in the controlled setting of school premises is favorably received by parents and children. In fact 74% of those invited agreed to participate.

However, future research should examine the feasibility of this program in other contexts (for example, private schools) and countries. Implementation may be conditioned by the availability of school athletic facilities, the background level of the children's physical activity and the total time already devoted to extracurricular activities or leisure. However, it is not likely that cost concerns would limit the generalization of the program to other settings, because its cost is reasonably low for most developed countries.

In conclusion, our after-school program of recreational physical activity reduced adiposity, increased apo A-I and decreased apo B among primary school pupils. It was a low-cost program that is easily generalizable to other schools. Our results also suggest that future programs for preventing obesity in schoolchildren should include more intense physical activity than in previous studies.

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