

PEDIATRIC HIGHLIGHT

Successful overweight prevention in adolescents by increasing physical activity: a 4-year randomized controlled intervention

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Background: Population-based studies directed at promoting physical activity in youth have shown limited success in obesity prevention.

Objective: To assess whether an intervention integrating environmental changes to induce sustained changes in physical activity, prevents overweight in adolescents.

Design: Four-year randomized trial started in 2002 in eight middle schools of Eastern France. The intervention, randomized at school level, was designed to promote physical activity by changing attitudes through debates and attractive activities, and by providing social support and environmental changes encouraging physical activity.

Subjects: Nine hundred and fifty four 12-year-old six-graders.

Measurements: Body mass index (BMI), body composition, physical activity by questionnaire, plasma lipids and glucose, insulin resistance.

Results: Intervention students had a lower increase in BMI ($P=0.01$) and age- and gender-adjusted BMI ($P<0.02$) over time than controls. The differences across groups of the age- and gender-adjusted BMI changes (95% confidence interval (CI)) were -0.29 (-0.51 ; -0.07) kg/m^2 at 3 years, -0.25 (-0.51 ; 0.01) kg/m^2 at 4 years. An interaction with baseline weight status was noted. The intervention had a significant effect throughout the study in initially non-overweight adolescents (-0.36 (-0.60 ; -0.11) kg/m^2 for adjusted BMI at 4 years), corresponding to a lower increase in fat mass index ($P<0.001$). In initially overweight adolescents, the differences observed across groups at 2 years (-0.40 (-0.94 ; 0.13) kg/m^2 for adjusted BMI) did not persist over time. At 4 years, 4.2% of the initially non-overweight adolescents were overweight in the intervention schools, 9.8% in the controls (odds ratio = 0.41 (0.22; 0.75); $P<0.01$). Independent of initial weight status, compared with controls, intervention adolescents had an increase in supervised physical activity ($P<0.0001$), a decrease of TV/video viewing ($P<0.01$) and an increase of high-density cholesterol concentrations ($P<0.0001$).

Conclusion: Enhancing physical activity with a multilevel program prevents excessive weight gain in non-overweight adolescents. Our study provides evidence that prevention of obesity in youth is feasible.

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Keywords: adolescent; physical activity; cardiovascular risk; randomized controlled program

Introduction

The prevalence of childhood overweight has dramatically increased in the USA over the last three decades.¹ Similar trends are observed in European countries^{2,3} and worldwide. Overweight in childhood is associated with an increased risk of overweight and obesity in adulthood,^{4,5} with several comorbidities and increased early mortality rates.^{6–8} These observations emphasize the urgent need for effective prevention strategies.

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Physical activity, which is inversely related to overweight in youth^{9–12} and to the associated metabolic and cardiovascular risk,^{9,11,13,14} is thought to be a key element in preventing the obesity epidemic.^{15,16} Although a few studies targeting physical activity have shown significant trends toward a reduction in adiposity after short-term (6–12 months) interventions, convincing effective long-lasting population-based prevention programs are still lacking.^{17,18}

Several reasons may explain the so far reported limited effect of physical activity programs on obesity prevention in the youth. Health education used alone has shown its limits.^{17–20} On the other hand, school-based physical education programs show consistent increases of in-school physical activity but their effectiveness on out-of-school physical activity and weight status has been questioned.^{17,20} Also the academic form of physical activity in these programs may limit their impact on unfit or overweight students. Recently, the importance of taking into account the environment in which the students live has been emphasized.²¹ In this regard, interventions integrating environmental changes that reduce the barriers to adopting an active lifestyle have a higher potential for changing physical activity habits.^{22,23} Such approach, partially used in a recent 6-month intervention study, indeed demonstrated a significant effect, although moderate, of recreational exercise on adiposity in girls.²⁴

The 'Intervention Centered on Adolescents' Physical activity and Sedentary behavior' (ICAPS), a 4-year randomized trial, was developed on the basis of the above-described socioecological perspective. ICAPS emphasizes the dynamic interplay among personal factors, behaviors and social or physical environmental influences. It postulates that interventions on physical activity should be most effective when targeting each level. The program was designed to enhance in- and out-of-school physical activity by motivating and enabling adolescents through debates and attractive activities, and by providing social support and an environment that encourage physical activity. In this study, we present scientific evidence for the beneficial effect of ICAPS, so far unmatched for its 4-year duration, on body mass index (BMI) as primary outcome.

Methods

Design overview

The study rationale, research design, intervention program and process evaluation have been described in detail elsewhere.^{25,26} Briefly, the study, a 4-year cluster-randomized controlled intervention study, started in fall 2002, is based on a randomization of the intervention status at school level, with stratification on sociogeographical criteria. The intervention program was designed to increase physical activity in six-graders. The design, implementation and reporting conform to the recommendations of the

CONSORT statement for cluster randomized trials.²⁷ Trial registration is ClinicalTrials.gov NCT00498459. The analyses follow the intention-to-treat principle. The relevant local ethics committee approved the research protocol, which is consistent with the principles of the Declaration of Helsinki. All participants and parents gave their written informed consent.

Settings and participants

We calculated the number of students to detect a difference in BMI changes between groups of 0.4 kg/m², with a power of 80% at a significance of $P = 0.05$ (two-sided), using methods taking into account the cluster randomization.²⁸ Based on a study conducted on six-graders from the same region,² an intracluster correlation of 0.007 was used. Assuming a 4-year dropout rate of 30%, 960 students from eight schools had to be randomized. To ensure a broad socioeconomic representation, school randomization was stratified on geographical location, city size and location (or not) in a low economic neighborhood. Four pairs of matched schools (Figure 1) were randomly selected out of the 77 public middle schools of the Department of Bas-Rhin (Eastern France). Intervention status of the schools was randomized in each pair of schools. Ninety-one percent of the 1048 six-graders of the randomized schools (479 controls and 475 intervention students) accepted to participate in the surveys. Among these, 73% agreed to provide a blood sample. Due to concerns about fasting status, data of 326 controls and 304 intervention students were available for blood analysis at baseline. Results of a short survey showed that nonparticipating students were somewhat older (11.9 (0.7) vs 11.7 (0.6) years; $P < 0.02$) and more often boys (61.7 vs 49.1%; $P < 0.03$) than participating students but prevalence of overweight did not differ across groups (23.7 vs 23.2%).

Intervention

All the six-graders of the intervention schools were exposed to the program that began during the first school year and lasted until the end of the fourth school year. The intervention program came in addition to the standard school curriculum (which, in France, includes three 50-min physical education classes per week). The controls followed their usual school curriculum without any intervention. The theory-based multilevel intervention, open and free of charge, involved not only the school settings but numerous partnerships with three objectives: (1) changing attitudes toward physical activity, (2) promoting social support by parents and educators (3) providing environmental and institutional conditions encouraging the adolescents to use the knowledge and physical activity skills they have acquired.²⁶ The program included an educational component focusing on physical activity and sedentary behaviors. New opportunities for physical activity were offered at lunchtime, during breaks and afterschool hours, taking into

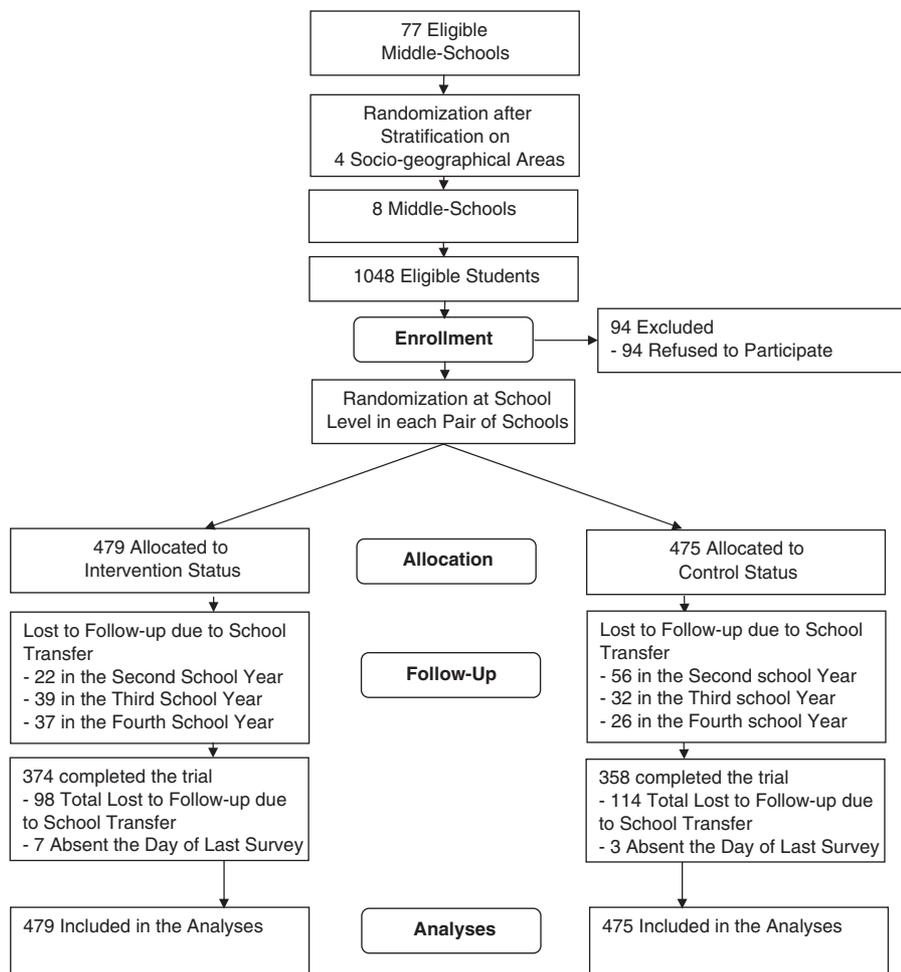


Figure 1 Flow diagram.

account the obstacles to being active. The activities, academic or less formal during breaks, were organized by physical educators without any restrictive competitive aspect. Enjoyment of participation was highlighted to help the less confident children to develop the competences needed to adopt an active lifestyle. Sporting events and ‘cycling to school’ days were organized. Parents and educators were encouraged to provide support to enhance the adolescents’ physical activity level through regular meetings.

Outcomes and follow-up

The primary outcome was changes in BMI. Prespecified secondary end points included changes in body composition, physical activity, attitudes toward physical activity and various cardiovascular risk factors.

Surveys took place at baseline before initiation of the intervention program (between September and October), and annually at the end of each of the four school years of intervention (between May and June). Fasting blood was

sampled at baseline and every 2 years. The procedures were standardized between schools. Physical examinations were performed by qualified professionals and questionnaires administered by trained interviewers to small groups (3–6 children). Each annual survey, which lasted half a day for each group of 50–60 pupils, was performed within 1 month.

Height was measured with a wall-mounted stadiometer. Weight and body composition (that is, fat and fat-free mass) were determined with the students in light indoor clothing, using periodically calibrated Tanita TBF 310 (Tanita Corporation, Tokyo, Japan) bioelectrical impedance analyzers.²⁹ BMI was calculated as the weight divided by the square of the height. To account for the differences in BMI, according to age and gender, adjusted BMI was further calculated by subtracting the gender–age-specific median BMI³⁰ of the French reference curves.³¹ Age- and gender-adjusted BMI has been shown to be a better measure of adiposity changes in children than BMI z-score or BMI centile.³⁰ Overweight was defined according to the International Obesity Task Force gender–age cutoffs, corresponding to the percentile that pass through a BMI of 25 kg/m² at the age of 18 years.³² Fat mass

index (FMI) and fat-free mass index were calculated as fat mass and fat-free mass, respectively, divided by the square of the height. The highest occupational category of either parent, categorized in three levels, was taken as an indicator of socioeconomic status (SES).

Self-reported leisure physical activity was assessed with the Modifiable Activity Questionnaire for adolescents,³³ whose reliability has been reported for junior high school students.³⁴ The questionnaire, more specifically the physical activity checklist, was adapted to better fit to French physical activity habits. The leisure physical activity level was calculated as the product of the duration and frequency of each activity summed for all the activities performed during the previous year. Supervised physical activities performed during school weeks, excluding physical education classes, are considered here. In the intervention students, participation to the physical activities offered in the intervention program, as recorded by the educators, was added to the other leisure physical activities obtained from the questionnaire, to compute total supervised physical activity during follow-up. Time spent in front of TV/video and in active commuting between home and school (additional questions not present in the original Modifiable Activity Questionnaire) was recorded for a typical week. Self-efficacy and intention toward physical activity (lower scores indicating better outcomes) were assessed with the Stanford Adolescent Heart Health Program's questionnaire.³⁵ The reproducibility of the questionnaires assessed with a 1 month test-retest interval in a sample of 79 adolescents was found reasonably good with intraclass correlations ranging from 0.71 to 0.83.²⁶

Plasma glucose, total and high-density lipoprotein-cholesterol, triacylglycerols and insulin were determined as previously described.²⁶ Insulin resistance was estimated by homeostasis model assessment.³⁶

Statistical analysis

Analyses were performed with the SAS software (version 9.1, SAS Institute Inc., Cary, NC, USA). Two-sided *P*-values are reported. *P*-value of less than 0.05 was considered significant.

Baseline descriptive statistics are expressed as means (s.d.) or percentages. Differences between groups at baseline were compared with *t*-tests and χ^2 tests, as appropriate.

The analysis of outcomes used mixed linear models taking into account the cluster randomization and the repeated individual data over time, by means of PROC MIXED and GLIMMIX (for binary outcomes). Random effects were schools within baseline stratification and individuals within schools. Main effects were intervention, time and intervention-by-time interaction. Fixed effects were baseline stratification, gender, sexual maturity, SES, initial weight status, baseline participation to sports club and their interactions with time. Akaike Information Criterion was used to select the covariance structures for the within-subject

measurements. A spatial power structure was found appropriate for almost all anthropometric variables; compound symmetric or heterogeneous Toeplitz covariance structures were used for the other variables. The Kenward-Roger method for degrees of freedom was used for hypothesis testing. Adjusted least-square means and differences across groups of their within-group changes over time are presented with their 95% confidence intervals (CI). Possible heterogeneity of the intervention's effect was tested. No interaction with gender or SES status was found. Due to an interaction between intervention and initial weight status, we performed analyses stratified on initially weight status (non-overweight or overweight) when testing the effect of the intervention on anthropometric outcomes. The cumulative incidence of overweight in initially non-overweight students was analyzed with the same models.

All available data were used for the analyses, including those from participants lost to follow-up, assuming non-informative dropout. We conducted the same analyses using either the participants with at least one follow-up survey or participants who completed the study. These analyses had little effect on intervention estimates. Therefore, only results from the analyses using all the participants included at baseline are presented.

To detect contamination, 4-year outcomes were further compared to those of 1466 students (94% of the eligible students) of the same grade as students of the ICAPS program. These students, who were not submitted to any intervention or survey in the four previous years, came from 12 middle schools matched according to the baseline stratification (three in each stratum). Examination of this 'comparison' group was performed with the same protocol, at the same time as the last follow-up survey of the ICAPS cohort.

Results

Study cohort characteristics and follow-up

The study participants had an initial mean (s.d.) age of 11.6 (0.6) years (range 9.9–13.8 years) and an overweight prevalence of 23.2%. Baseline characteristics were similar between groups (Table 1), except for some differences in SES (19, 66, 15 and 14, 64, 22% for low, middle and high in control and intervention groups, respectively; $P < 0.01$). Outcomes were obtained for 848 students at the end of the second school year, 778 at 3 years and 732 at 4 years (Figure 1). The main reason for lack of follow-up was school transfer or school absence on the day of the survey. Students lost to follow-up were more frequently boys (60.8 vs 46.7%; $P < 0.01$) and slightly older (11.9 (0.8) vs 11.6 (0.6) years; $P < 0.01$) but their anthropometric and physical activity characteristics did not differ from those of the follow-up students (Table 2) and were comparable between intervention and control groups (data not shown).

Mobilization and implication of the partners increased progressively throughout the first year and were sustained over the 4 years. On average, ninety percent of the study participants attended the educational classes and debates (15 classes organized with teachers' collaboration over the four school years). Regular participation in physical activities offered in the program, defined as a mean participation time of at least 30 min per week, increased from 25% in the first months to 65% during the last 2 years of follow-up.

Primary outcome (BMI)

Intervention students showed a lower increase in BMI ($P=0.01$) and age- and gender-adjusted BMI ($P<0.02$) over time than controls. The differences across groups of the age- and gender-adjusted BMI changes (95% confidence interval (CI)) were -0.26 (-0.43 ; -0.08) kg/m^2 at 2 years, -0.29 (-0.51 ; -0.07) kg/m^2 at 3 years, -0.25 (-0.51 ; 0.01) kg/m^2

at 4 years. At 4 years, BMI was 21.08 (20.66; 21.50) kg/m^2 in the intervention group, 21.32 (20.90; 21.75) kg/m^2 in the control group and 21.68 (21.45; 21.91) kg/m^2 in the comparison group from the 12 matched schools ($P=0.03$). An interaction between intervention and baseline weight status was however noted ($P<0.01$). Table 3 shows the evolution of anthropometric data stratified according to initial weight status (non-overweight or overweight).

In initially non-overweight participants the overall effect of the intervention on mean BMI and age- and gender-adjusted BMI was significant throughout the study and associated with a lower increase in FMI ($P<0.001$). The differences across groups of the adjusted BMI changes were -0.33 (-0.55 ; -0.12) at 3 years and -0.36 (-0.60 ; -0.11) kg/m^2 at 4 years. The differences across groups of the FMI changes were -0.33 (-0.50 ; -0.17) at 3 years and -0.20 (-0.39 ; -0.01) kg/m^2 at 4 years. The cumulative incidence of overweight (Figure 2) was lower in the intervention group than in the controls ($P<0.01$). At 4 years, 4.2% of the initially non-overweight students were overweight in the intervention schools, compared to 9.8% in the control schools (odds ratio (OR) [95% CI] = 0.41 [0.22; 0.75]). These changes were not associated with an unfavorable effect on prevalence of underweight, defined as a BMI lower than the third percentile (2.1 vs 0.9% at 4 years; $P=0.39$).

In initially overweight participants, the differences across groups observed at 2-year for the BMI, age- and gender-adjusted BMI and FMI changes (-0.40 (-0.94 ; 0.13) kg/m^2 , -0.40 (-0.94 ; 0.13) kg/m^2 and -0.23 (-0.70 ; 0.23) kg/m^2 , respectively) did not persist over time.

Socioeconomic status did not interact significantly with intervention ($P=0.82$). Exploratory analyses indicated that the intervention worked as well in students of low SES as in those of higher SES, with a 4-year difference across group in age- and gender-adjusted BMI change of -0.58 (-1.23 ; 0.08) kg/m^2 in low SES students (as compared to -0.18 (-0.50 ; 0.14) kg/m^2 and -0.14 (-0.72 ; 0.2) kg/m^2 in students of middle and high SES, respectively).

Table 1 Baseline characteristics by intervention group^a

Characteristics	Control (n = 479)	Intervention (n = 475)
Age, years	11.7 (0.7)	11.6 (0.6)
Males, %	52.6	47.4
Overweight, % ^b	23.4	23.0
Body mass index, kg/m^2	18.9 (3.7)	18.7 (3.4)
Adjusted body mass index, kg/m^{2c}	1.8 (3.6)	1.7 (3.4)
Body fat, %	18.2 (8.8)	18.1 (8.5)
Fat mass index, kg/m^2	3.8 (2.5)	3.7 (2.3)
Fat-free mass index, kg/m^2	15.1 (1.5)	15.0 (1.5)
Sports club, hours per week	2.5 (3.3)	2.7 (3.3)
TV/video viewing, minutes per day	105.3 (76.2)	109.5 (82.1)
Active commuting between home and school, minutes per day	17.8 (20.2)	15.8 (20.7)

Abbreviation: BMI, body mass index. ^aValues are means (s.d.) unless otherwise noted. ^bOverweight is defined according to the International Obesity Task Force gender-age cutoffs.³² ^cGender-age-adjusted BMI was calculated by subtracting the gender-age-specific median BMI of the French reference curves.³¹

Table 2 Baseline characteristics by follow-up status^a

Characteristics	Completers (n = 732)	Lost to follow-up at 4 years (n = 222)	P-value
Age, years	11.6 (0.6)	11.9 (0.8)	<0.01
Males, %	46.7	60.8	<0.01
Overweight, % ^b	22.1	27.0	0.12
Body mass index, kg/m^2	18.7 (3.4)	19.2 (3.9)	0.33 ^c
Adjusted body mass index, kg/m^{2d}	1.7 (3.4)	2.0 (3.9)	0.17 ^c
Body fat, %	18.2 (8.5)	18.0 (8.9)	0.63 ^c
Fat mass index, kg/m^2	3.7 (2.3)	3.8 (2.6)	0.49 ^c
Fat-free mass index, kg/m^2	15.0 (1.5)	15.4 (1.7)	0.39 ^c
Sports club, hours per week	2.5 (3.0)	2.8 (3.8)	0.22
TV/video viewing, minutes per day	107.0 (79.8)	108.7 (77.3)	0.80
Active commuting between home and school, minutes per day	16.1 (19.78)	19.01 (22.7)	0.08

Abbreviation: BMI, body mass index. ^aValues are means (s.d.) unless otherwise noted. ^bOverweight is defined according to the International Obesity Task Force gender-age cutoffs.³² ^cAdjusted for age and gender. ^dGender-age-adjusted body mass index (BMI) was calculated by subtracting the gender-age-specific median BMI of the French reference curves.³¹

Table 3 Anthropometric outcomes according to initial weight-status^a

Outcome	Outcomes (95% CI)					P ^b	Difference in outcome changes across groups (intervention—controls)								
	Baseline	First year	Second year	Third year	Fourth year		First year—baseline difference		Second year—baseline difference		Third year—baseline difference		Fourth year—baseline difference		
	(n = 954)	(n = 944)	(n = 848)	(n = 778)	(n = 732)		Mean (95% CI)	P	Mean (95% CI)	P	Mean (95% CI)	P	Mean (95% CI)	P	
Initially non-overweight students															
BMI, kg/m ²	C	17.33 (17.02; 17.63)	17.84 (17.53; 18.14)	18.71 (18.40; 19.01)	19.48 (19.18; 19.79)	20.16 (19.86; 20.46)	0.03	-0.04 (-0.16; 0.08)	0.50	-0.18 (-0.36; -0.01)	0.03	-0.34 (-0.55; -0.13)	0.001	-0.33 (-0.57; -0.08)	<0.01
	I	17.20 (16.89; 17.52)	17.67 (17.36; 17.98)	18.40 (18.09; 18.71)	19.02 (18.71; 19.33)	19.71 (19.41; 20.02)									
Adjusted BMI, kg/m ^{2c}	C	0.20 (-0.01; 0.41)	0.36 (0.15; 0.58)	0.58 (0.37; 0.80)	0.68 (0.47; 0.90)	0.73 (0.51; 0.96)	0.03	-0.05 (-0.17; 0.07)	0.39	-0.19 (-0.36; -0.02)	0.03	-0.33 (-0.55; -0.12)	<0.01	-0.36 (-0.60; -0.11)	<0.01
	I	0.17 (-0.04; 0.38)	0.28 (0.07; 0.50)	0.37 (0.15; 0.58)	0.32 (0.11; 0.54)	0.35 (0.13; 0.57)									
Body fat, %	C	15.08 (14.01; 16.15)	14.83 (13.77; 15.89)	16.45 (15.39; 17.51)	17.41 (16.36; 18.46)	17.88 (16.83; 18.93)	<0.01	-0.38 (-0.80; 0.04)	0.07	-0.75 (-1.34; -0.16)	0.01	-1.19 (-1.91; -0.46)	<0.01	-0.55 (-1.38; 0.29)	0.19
	I	14.87 (13.79; 15.94)	14.24 (13.16; 15.31)	15.49 (14.41; 16.56)	16.01 (14.94; 17.08)	17.12 (16.06; 18.18)									
Fat mass Index, kg/m ²	C	2.70 (2.44; 2.97)	2.74 (2.48; 3.00)	3.20 (2.94; 3.46)	3.53 (3.28; 3.79)	3.74 (3.48; 3.99)	<0.001	-0.08 (-0.17; 0.02)	0.12	-0.19 (-0.32; -0.05)	<0.01	-0.33 (-0.50; -0.17)	<0.001	-0.20 (-0.39; -0.01)	<0.05
	I	2.65 (2.39; 2.92)	2.61 (2.35; 2.88)	2.96 (2.70; 3.23)	3.15 (2.89; 3.41)	3.49 (3.23; 3.75)									
Fat-free mass index, kg/m ²	C	14.62 (14.42; 14.83)	15.09 (14.89; 15.29)	15.51 (15.31; 15.71)	15.96 (15.76; 16.16)	16.42 (16.23; 16.62)	0.16	0.04 (-0.04; 0.12)	0.36	0.00 (-0.11; 0.11)	0.95	-0.01 (-0.15; 0.12)	0.86	-0.12 (-0.28; 0.04)	0.14
	I	14.55 (14.35; 14.76)	15.06 (14.85; 15.26)	15.44 (15.23; 15.64)	15.87 (15.67; 16.08)	16.23 (16.03; 16.44)									
Initially overweight students															
BMI, kg/m ²	C	23.94 (23.25; 24.63)	24.51 (23.80; 25.21)	25.57 (24.87; 26.27)	26.00 (25.29; 26.71)	26.33 (25.60; 27.05)	0.06	0.13 (-0.25; 0.51)	0.51	-0.40 (-0.94; 0.13)	0.13	-0.06 (-0.73; 0.61)	0.85	0.20 (-0.58; 0.98)	0.62
	I	23.82 (23.12; 24.52)	24.51 (23.81; 25.21)	25.04 (24.34; 25.75)	25.82 (25.10; 26.53)	26.40 (25.67; 27.13)									
Adjusted BMI, kg/m ^{2c}	C	6.80 (6.12; 7.48)	7.02 (6.33; 7.70)	7.42 (6.74; 8.11)	7.19 (6.50; 7.89)	6.89 (6.18; 7.60)	0.07	0.12 (-0.26; 0.50)	0.53	-0.40 (-0.94; 0.13)	0.14	-0.06 (-0.73; 0.61)	0.86	0.16 (-0.62; 0.95)	0.68
	I	6.76 (6.08; 7.45)	7.10 (6.41; 7.79)	6.98 (6.29; 7.67)	7.10 (6.39; 7.80)	7.01 (6.29; 7.73)									
Body fat, %	C	28.95 (27.71; 30.20)	27.80 (26.52; 29.08)	28.73 (27.45; 30.00)	27.82 (26.51; 29.14)	27.12 (25.74; 28.49)	0.27	-0.35 (-1.35; 0.65)	0.49	-0.46 (-1.84; 0.91)	0.51	0.32 (-1.36; 2.01)	0.70	1.33 (-0.61; 3.28)	0.18
	I	28.15 (26.89; 29.40)	26.64 (25.37; 27.91)	27.46 (26.17; 28.74)	27.34 (26.02; 28.66)	27.64 (26.27; 29.01)									
Fat mass index, kg/m ²	C	7.04 (6.60; 7.49)	6.91 (6.46; 7.36)	7.52 (7.06; 7.97)	7.49 (7.01; 7.96)	7.39 (6.90; 7.89)	0.25	-0.03 (-0.37; 0.30)	0.84	-0.23 (-0.70; 0.23)	0.33	0.02 (-0.56; 0.60)	0.95	0.37 (-0.32; 1.05)	0.29
	I	6.83 (6.41; 7.24)	6.66 (6.25; 7.08)	7.06 (6.65; 7.48)	7.29 (6.86; 7.71)	7.54 (7.10; 7.98)									
Fat-free mass index, kg/m ²	C	16.85 (16.56; 17.13)	17.54 (17.24; 17.83)	17.97 (17.68; 18.26)	18.38 (18.08; 18.69)	18.70 (18.38; 19.01)	0.21	0.16 (-0.08; 0.40)	0.18	-0.13 (-0.45; 0.20)	0.45	0.00 (-0.40; 0.40)	0.99	0.02 (-0.44; 0.48)	0.92
	I	17.03 (16.74; 17.32)	17.88 (17.59; 18.18)	18.03 (17.73; 18.32)	18.57 (18.26; 18.87)	18.90 (18.59; 19.22)									

Abbreviations: BMI, body mass index; C, control group; CI, confidence interval; I, intervention group. ^aAdjusted least-square means and differences across groups of their within-group changes over time (95% CI) calculated with linear mixed models adjusted for gender, sexual maturity, socioeconomic status, initial weight status, baseline participation to sports club, baseline stratification and their interactions with time. ^bP are given for intervention by time interaction. ^cGender-age-adjusted BMI was calculated by subtracting the gender-age-specific median BMI of the French reference curves.³¹

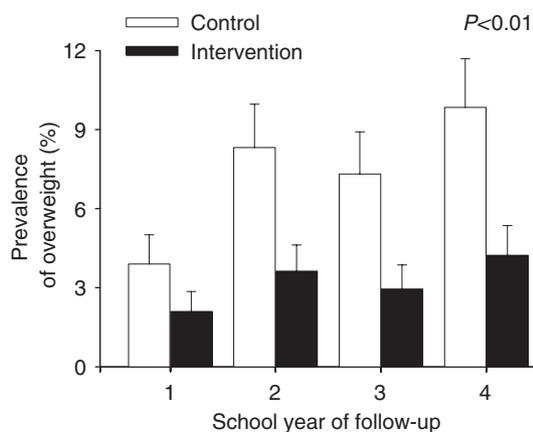


Figure 2 Prevalence of overweight (defined according to the International Obesity Task Force,³¹ taking into account the cluster randomization design, adjusted for gender, sexual maturity, socioeconomic status, baseline participation to sports-club, baseline stratification and their interactions with time. The number of initially normal-weight students was 731 at baseline, 653 at 2 years, 605 at 3 years, and 571 at 4 years. *P*-value is given for intervention effect.

Secondary outcomes

At 4 years, 79% of the intervention students practiced at least one supervised physical activity outside school physical education classes (either in a sports club or through ICAPS activities), as compared with 47% of the controls (OR (95% CI)=2.34 (1.66;3.31); $P < 0.001$). Table 4 illustrates the evolution of physical activity and sedentary behaviors during typical school weeks. Supervised leisure physical activity increased in intervention students, whereas it slightly decreased in the controls, with a difference across groups of the 4-year within-group changes of 66 min (95% CI, 34; 98) per week ($P < 0.0001$). There was no interaction with gender, initial weight status, SES or sports clubs participation at baseline. Intervention students also had a greater reduction over time of TV/video viewing than controls ($P < 0.01$), with a difference in the 4-year changes of -16 min (95% CI, -29; -2) per day. The slight increase observed for active commuting to and from school was similar for both groups. The intervention was associated with an increase of self-efficacy during the first 2 years ($P < 0.0001$ and 0.01 at 1 and 2 years, respectively) and a sustained improvement of intention toward physical activity ($P < 0.05$).

Irrespective of their initial weight status and independently of their body fat, compared to controls, intervention participants had a higher increase of high-density lipoprotein-cholesterol concentrations at 4 years (+3.43 (1.73; 5.13) mg per 100 ml; $P < 0.001$), and a slight decrease of blood pressure at 2 years, but exhibited similar evolutions of the other biological cardiovascular risk factors (Table 5).

Discussion

This 4-year randomized controlled study indicates that a multilevel physical activity intervention program targeting

adolescents induces an increase in supervised leisure physical activity of about 1 h weekly and a reduction in TV/video viewing time. Furthermore, the program had a sustained preventive effect on excessive weight gain in non-overweight adolescents with a 50% reduction in 4-year overweight incidence, but was not sufficient to produce a long-term weight loss in initially overweight students. In addition, a beneficial increase of high-density lipoprotein-cholesterol concentrations was observed, independent of initial weight status and body fat mass.

Our intervention was associated with a significant prevention of excessive fat and weight gain in initially non-overweight students. Interestingly, this one was not associated with an unfavorable increase of underweight. In comparison, the few previous randomized, well-designed population-based prevention studies in youth focusing on physical activity solely have shown inconstant results on body weight.^{15,18,19} So far only two short-term studies of 6 months found benefits of the interventions. The first one is a recent study using an after-school recreational and non-competitive physical activity program conducted in 20 schools.²⁴ The second one was directed at reducing TV watching.³⁷

In contrast, the short-term BMI effects in overweight students did not remain, which is in agreement with clinical studies showing that the effects of obesity treatment diminish over time.³⁸ This was observed despite a favorable modification of high-density lipoprotein-cholesterol, indicating that the physical activity level necessary for weight loss may be higher than for other health-related benefits.³⁹ This may be the result of a smaller effect on everyday physical activity, which was not accurately measured here. It also suggests that long-term weight loss requires more physical activity than weight gain prevention with specific complementary strategies, including dietary counseling and substantial investment of therapists.^{4,40} It further supports the idea that prevention of excessive weight in those who are not yet overweight may be a more cost-effective approach⁴ to weight control in children.

The preventive effect toward overweight was obtained with a supplement of about 1 h of supervised physical activity weekly, which may appear quite low considering the current recommendations.⁴¹ The guided instruction and supervised practice by qualified educators was probably important to guarantee that sessions consisted of moderate-to-vigorous-intensity activities.⁴¹ Although active commuting between home and school was not different from the control group, partly due to home-school distance limitations, we can also hypothesize that the program induced an increase in everyday activity. The decrease of TV/video viewing may have contributed to the beneficial results through indirect effects, such as diminution of junk food consumption, as well.⁴² On the other hand, our results are in line with the recent observation that even a moderate amount of exercise is associated with substantial health benefits.⁴³⁻⁴⁵

Table 4 Physical activity and attitude towards physical activity by intervention group^a

Outcome	Outcomes (95% CI)					P ^b	Difference in outcome changes across groups (Intervention—Controls)								
	Baseline	First year	Second year	Third year	Fourth year		First year—baseline difference		Second year—baseline difference		Third year—baseline difference		Fourth year—baseline difference		
	(n = 954)	(n = 944)	(n = 848)	(n = 778)	(n = 732)		Mean (95% CI)	P	Mean (95% CI)	P	Mean (95% CI)	P	Mean (95% CI)	P	
Supervised leisure physical activity, hours per week	C	2.70 (2.05;3.38)	2.63 (1.99;3.30)	2.74 (2.11;3.42)	2.64 (2.00;3.31)	2.55 (1.92;3.22)	<0.0001	0.87 (0.46;1.28)	<0.0001	0.70 (0.24;1.15)	<0.01	1.19 (0.70;1.68)	<0.0001	1.10 (0.56;1.63)	<0.0001
	I	2.50 (1.81;3.14)	3.30 (2.61;3.94)	3.24 (2.56;3.89)	3.63 (2.95;4.26)	3.45 (2.77;4.08)									
TV/video time, minutes per day	C	103.99 (92.74;113.24)	112.04 (100.78;121.29)	121.98 (110.52;131.44)	100.91 (89.32;110.51)	99.43 (87.59;109.26)	<0.01	-11.40 (-20.93;-1.86)	0.02	-22.10 (-32.90;-11.30)	<0.0001	-14.35 (-26.16;-2.54)	0.02	-15.71 (-28.49;-2.92)	0.02
	I	108.18 (98.96;119.40)	104.83 (95.66;116.00)	104.07 (94.81;115.34)	90.76 (81.18;102.33)	87.91 (78.27;99.55)									
Active commuting between home and school, minutes per day	C	17.76 (3.41;32.11)	20.32 (5.97;34.68)	19.28 (4.96;33.61)	24.18 (9.87;38.50)	25.56 (11.29;39.84)	0.10	-1.24 (-3.79;1.31)	0.34	2.29 (-0.51;5.08)	0.11	-0.04 (-2.98;2.89)	0.98	1.03 (-2.16;4.22)	0.53
	I	16.19 (1.83;30.55)	17.52 (3.15;31.88)	20.00 (5.65;34.36)	22.57 (8.24;36.91)	25.03 (10.72;39.33)									
Intention toward physical activity, score ^c	C	6.87 (6.58;7.15)	7.15 (6.84;7.46)	7.16 (6.86;7.46)	7.47 (7.16;7.78)	7.60 (7.28;7.92)	0.02	-0.67 (-1.14;-0.19)	<0.01	-0.71 (-1.18;-0.24)	<0.01	-0.65 (-1.14;-0.17)	<0.01	-0.48 (-0.98;0.01)	0.05
	I	6.71 (6.43;6.98)	6.33 (6.04;6.61)	6.29 (6.01;6.57)	6.66 (6.36;6.95)	6.96 (6.65;7.26)									
Self-efficacy, score ^c	C	22.42 (21.43;23.41)	22.71 (21.71;23.72)	21.76 (20.76;22.76)	22.33 (21.32;23.34)	21.68 (20.65;22.72)	<0.0001	-2.64 (-3.78;-1.51)	<0.0001	-2.01 (-3.23;-0.80)	<0.01	-1.50 (-2.84;-0.16)	0.03	-0.48 (-1.86;0.91)	0.5
	I	22.79 (21.80;23.77)	20.44 (19.45;21.43)	20.12 (19.13;21.11)	21.20 (20.20;22.20)	21.58 (20.56;22.59)									

Abbreviations: C, control group; CI, confidence interval; I, intervention group. ^aLeast-square means and differences across groups of their within-group changes over time (95% CI) obtained from linear mixed models adjusting for gender, sexual maturity, socioeconomic status, initial weight status, baseline participation to sports-club, baseline stratification and their interactions with time. ^bP are given for intervention by time interaction. ^cLower scores indicate better outcomes.

Table 5 Cardiovascular risk factors outcomes by intervention group^a

Outcome	Outcomes (95% CI)				P ^b	Difference in outcome changes across groups (intervention—controls)			
	Baseline	Second year	Fourth year			Second year—baseline difference		Fourth year—baseline difference	
	(n = 630)	(n = 579)	(n = 498)			Mean (95% CI)	P	Mean (95% CI)	P
Plasma glucose, mg per 100 ml	C	0.92 (0.91; 0.92)	0.87 (0.87; 0.88)	0.88 (0.87; 0.89)	0.86	0.00 (-0.01; 0.01)	0.59	0.00 (-0.01; 0.01)	0.81
	I	0.92 (0.91; 0.92)	0.87 (0.86; 0.88)	0.88 (0.87; 0.89)					
Plasma insulin, $\mu\text{U ml}^{-1}$	C	8.61 (8.02; 9.19)	12.62 (11.98; 13.25)	11.03 (10.36; 11.70)	0.85	-0.23 (-1.17; 0.70)	0.63	0.03 (-0.98; 1.04)	0.96
	I	8.57 (7.97; 9.17)	12.35 (11.74; 12.96)	11.02 (10.34; 11.71)					
HOMA	C	1.97 (1.83; 2.11)	2.74 (2.59; 2.89)	2.42 (2.26; 2.57)	0.90	-0.04 (-0.26; 0.18)	0.70	0.01 (-0.23; 0.24)	0.95
	I	1.96 (1.82; 2.10)	2.68 (2.54; 2.83)	2.41 (2.25; 2.57)					
Plasma triglycerides, mg/100 ml	C	70.08 (66.85; 73.31)	56.24 (52.76; 59.72)	65.65 (61.98; 69.32)	0.19	-4.64 (-9.65; 0.38)	0.07	-2.60 (-7.97; 2.78)	0.34
	I	75.20 (71.92; 78.47)	56.72 (53.37; 60.08)	68.17 (64.47; 71.86)					
Plasma total cholesterol, mg per 100 ml	C	152.67 (149.65; 155.68)	157.62 (154.47; 160.77)	160.21 (156.96; 163.45)	0.19	2.82 (-0.58; 6.22)	0.10	2.71 (-0.91; 6.34)	0.15
	I	157.57 (154.44; 160.70)	165.35 (162.19; 168.51)	167.83 (164.53; 171.12)					
Plasma HDL-cholesterol, mg per 100 ml	C	48.23 (44.85; 51.60)	52.98 (49.65; 56.30)	54.88 (51.60; 58.17)	<0.0001	0.44 (-1.16; 2.04)	0.59	3.43 (1.73; 5.13)	<0.0001
	I	47.99 (44.67; 51.32)	53.18 (49.87; 56.50)	58.08 (54.82; 61.35)					
Systolic blood pressure (mm Hg)	C	107.14 (106.10; 108.18)	110.10 (108.96; 111.25)	113.85 (112.63; 115.06)	<0.01	-2.77 (-4.53; -1.00)	<0.01	-0.42 (-2.29; 1.44)	0.66
	I	108.91 (107.86; 109.96)	109.11 (108.03; 110.19)	115.20 (114.02; 116.37)					
Diastolic blood pressure (mm Hg)	C	64.12 (62.27; 65.98)	65.08 (63.25; 66.92)	65.82 (63.99; 67.65)	0.01	-2.31 (-3.91; -0.71)	<0.01	-0.46 (-2.14; 1.23)	0.60
	I	65.38 (63.53; 67.23)	64.03 (62.18; 65.87)	66.61 (64.78; 68.44)					

Abbreviations: C, control group; CI, confidence interval; HDL, high-density lipoprotein; HOMA, homeostasis model assessment; I, intervention group. ^aLeast-square means and differences across groups of their within-group changes over time (95% CI) obtained from linear mixed models adjusted for gender, sexual maturity, socioeconomic status, baseline participation to sports-club, baseline stratification and their interactions with time. ^bP are given for intervention by time interaction.

It is important to point out that the increase of physical activity was similar for students who did not spend time in sports clubs at baseline and for those who did, and that it was not related to gender or initial weight status. Also, participation in ICAPS activities was not related to a displacement of time allocated to sports club but rather to a decrease in TV/video viewing. Increase in intention toward physical activity, associated with the previous observation that physical activity tracks from childhood to adulthood,³⁹ gives hope that the behavior changes will be maintained. We hypothesize that setting the adolescents in motion through attractive convenient activities was crucial for improving their attitudes and skills toward physical activity, which in turn favored their adherence to the activities. Offering supervised enjoyable physical activity opportunities during breaks and immediate afterschool hours in the vicinity of the schools probably contributed to overcoming the usual barriers to physical activity, among which are transportation, time constraints and safety concerns. As previously reported,⁴⁶ the development of strategies adapted to the various environmental contexts, meeting specific needs of participants, was another key point for high participation. In a similar way it appeared important to vary the content of the physical activities offered, as pupils were getting older.

Strengths of our study include the randomized design, long-term follow-up, high participation rate in the surveys and withdrawals explained mainly by school transfer, all of which argue for the representativeness of the study population. If present, a contamination of the control group, suggested by a 4-year BMI in controls lower than the BMI of the matched comparison group, possibly reduces the apparent effect of our intervention, but would give additional confidence in our results. One limitation is the impossibility inherent to the design of determining which program components were effective and whether all components are necessary. Also, as a detailed monitoring of diet could have induced, *per se*, changes in eating patterns, we administered only a few questions on food habits, which precluded energy intake evaluation. On the other hand, the broad sociodemographic range of the targeted population and the absence of interaction between the intervention and SES status suggest that the program may be valid in other contexts.

As the intervention was specifically designed to be integrated into the community environment, we were brought to work with several partners, including community leaders, which should facilitate sustainability at the institutional level. The high participation rates in activities, which increased throughout the study, indicate that the ICAPS program was well accepted by both students and educators. This is further suggested by encouraging initiatives, in- and outside school, to extend some of the ICAPS components to the pupils not concerned by the study and maintain them after the end of the program, even if the ICAPS Team was important for the synergistic implementation of all the intervention components and the coordinated involvement of the different partners. ICAPS gathered existing resources

rather than infusion of new resources. Specific costs concerned mainly the coordination of the different partners by the ICAPS Team and the supervision of the activities provided. The latter, organized in tight collaboration with club educators and community agencies, require only little equipment and can take place in a large number of settings, with limited additional cost. These issues are compatible with large-scale adoption of such a program.

The long-term results of our study show the efficacy of a multilevel physical activity program on excessive weight gain in non-overweight adolescents. These data give hope that prevention of obesity is feasible through multipartner synergistic actions in adolescents.

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