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Randomized Control Trials

Impact of school-based nutrition and physical activity intervention on body mass index eight years after cessation of randomized controlled trial (AVall study)

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SUMMARY

Background & aims: The prevalence of obesity and overweight among children is increasing, representing a new and pressing societal problem. Excess weight in childhood is an independent risk factor for adult obesity. Although school-based interventions are generally considered effective in the short term, few studies analyze their longterm impact. The aim of study was to assess if the effect of the intervention on body mass Index (BMI) immediately after the intervention remained eight years later (AVall Study).
Methods: In 2006–2008, an intervention for primary school children promoted healthy eating habits and physical activity in the school setting using the Investigation, Vision, Action and Change (IVAC) educational methodology, which involves children as active participants in healthy change. At baseline, parents reported their weight, height and educational level by questionnaire. Children's weight and height were measured in situ in 2006, 2008, 2010, 2012 and 2016, and levels of physical activity were assessed by questionnaire. Multilevel mixed effects linear regression was used to assess changes in BMI over time.
Results: Increases in BMI from 2006 to 2016 were 0.68 kg/m^2 (95% CI, 0.02, 1.34; P = 0.045) higher in the control group than in the intervention group. The prevalence of obesity and overweight combined in 2006 and 2016 was 22.2% and 27.9%, respectively, in the control group and 25.6% and 21.2% respectively, in the intervention group. Changes in BMI in the intervention group were maintained from 2006 on: at the end of the intervention in 2008, −0.4 kg/m^2 (P = 0.001); in 2010, −0.23 g/m^2 (P = 0.012); in 2012, −0.63 kg/m^2 (P < 0.001) and in 2016, −0.27 kg/m^2 (P = 0.025). The child's BMI increased by 0.52 kg/m^2 (P = 0.046) if the father was obese, by 1.26 kg/m^2 (p = 0.011) if the mother was obese, and by 2.37 kg/m^2 (P < 0.001) if both parents were obese. Parental education levels were not associated with childhood obesity.
Conclusions: A school-based healthy eating habits and physical activity intervention using IVAC methodology contributed to lower increases in BMI among children in primary school. Although parental BMI also influenced children's BMI, the intervention was effective.
Trial registration: ClinicalTrials.gov NCT01156805.
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1. Introduction

The prevalence of childhood obesity is increasing dramatically, constituting an important global public health problem [1,2]. A recent study analyzed 25-year trends in the prevalence of overweight and obesity among children and adults and quantified the burden of disease related to high body mass index (BMI) [3]. The study concluded that the rapid increase in the prevalence of high BMI and associated disease burden highlight the need to identify, implement and evaluate evidence-based interventions.

Spain has the third highest prevalence of childhood obesity in Europe [4]. The Aladino study showed that 45.2% of Spanish schoolchildren between six and nine years of age were overweight or obese [5]. The treatment of obesity is difficult, with low success rates [1]. Thus, it is of great interest to identify effective preventive measures to reduce childhood obesity.

A number of meta-analyses and systematic reviews have demonstrated that school-based interventions may be an effective way of preventing childhood obesity [6–8] and may help prevent future adulthood obesity. However, most studies are evaluated at the end of the intervention; the effect of childhood interventions over the long term remains largely unknown. A few studies over the medium term have demonstrated positive results in terms of changes in BMI, but the included interventions required changes in the school curriculum [9,10].

The 2006–2008 AVall study consisted of a school-based intervention during the first two years of primary school. The effect of the intervention was evaluated immediately after it ended, and the intervention group showed smaller gains in BMI than did the control group [11]. Observations two and four years after the intervention ended [12,13] revealed that the control of weight gain was sustained. The current study investigates whether the effect of the intervention on BMI was maintained eight years after it ended.

2. Materials and methods

2.1. Study population

The Avall project (ClinicalTrials.gov NCT01156805) was approved in 2006 by the Clinical Research Ethical Committee of Granollers General Hospital and conducted with the support of the Education and Health Departments of the Catalan government and all headmasters/headmistresses of involved schools. The participants were schoolchildren born in 2000; they started their first year of primary education in 2006 and attended one of the 16 schools in the city of Granollers (Barcelona).

In 2006, informed consent was obtained from 598 (84.9%) parents of 704 children invited to participate in the study. We obtained baseline data on 509 children. In 2008, at the end of the two-year intervention, anthropometric measurements were obtained on 237 children in the control group and 272 children in the intervention group. In 2012, information was obtained from 397 children: 181 from the control group and 216 from the intervention group (Fig. 1).

2.2. Design

The design and short- and medium-term effects have been published previously [11]. Briefly, AVall is a cluster randomized longitudinal trial with two parallel intervention arms and ten-year follow-up. In 2006, all schools in Granollers city were invited to participate in the trial; they comprised ten public schools fully supported by the government and six semiprivate schools with partial government support. Schools were randomly distributed to intervention and control groups, and the distribution was stratified by schools' public or semiprivate status, the number of first-year classrooms and the socioeconomic status of the local neighborhood.

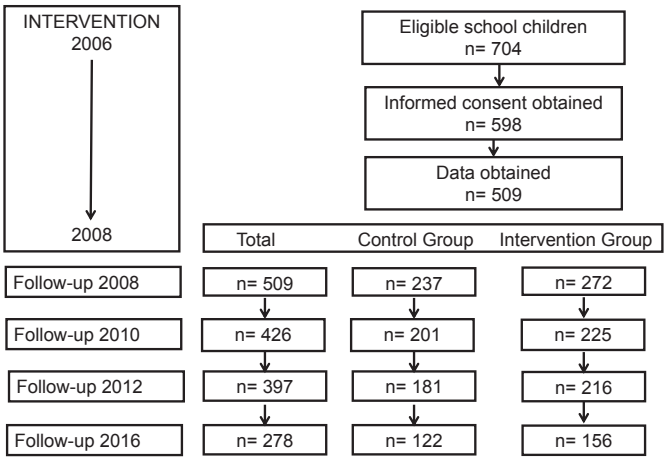

Fig. 1. Flow chart of the study.

In June 2016, the same trained AVall project nurses who had collected all previous anthropometric and questionnaire data returned to each school.

Children were weighed using a portable digital scale with a precision of 100 g (Oregon model BWR101, Oregon Scientific, Hong Kong), and height was recorded using a portable stadiometer (MZ10017). On the same day that nurses measured anthropometric parameters, schoolchildren completed questionnaires soliciting data on daily hours spent watching television, playing video or screen games and engaging in physical activity. Data collected in 2012 on eating in school and parental height, weight and level of education were used.

2.3. Intervention

The aim of the intervention was to promote healthy eating habits and physical activity in the school setting, using the investigation, vision, action and change (IVAC) educational methodology during two school years. In the IVAC methodology, children investigated and reflected on how conditions in their environment and in society affected their health and lifestyle and developed actions for change [14,15]. The teacher helped them develop skills and competencies to change the conditions in their environment. At the beginning of the project, the intervention group in each school was offered necessary equipment to promote physical activity during break time (balls, ropes, elastic bands and handkerchiefs to practice traditional games) and educational material on healthy food consisting of a nutritional and physical activity pyramid prepared by the research team, complementary material from public institutions or approved material prepared by food companies.

Every classroom used three hours a week for activities related to healthy food habits and/or physical activity. The teachers in each classroom developed activities related to healthy habits that were integrated into regular content (e.g., math, science, language, knowledge of the environment) through means such as posters, food tables, games, crafts, cooking workshops or games on the school playground. Each activity was designed to ensure that children participated. Over the two-year intervention period, six meetings between the research team, teachers and educators took place to monitor activities and plan subsequent actions. The purpose of the meetings was to attempt to standardize the intervention across classes and collect ideas that could be implemented in other schools. The methodology was not rigid;

individual classroom teachers adapted the concepts to discuss with students in the different thematic areas. This educational method allowed the inclusion of activities related to healthy eating habits and physical activity in any subject in the curriculum. In addition, an extracurricular intervention that relied on collaboration between schools and participating families was designed.

2.4. Variables

The main outcome variable was change in BMI over time. The secondary outcome variable was physical activity and sedentary activity. Weight, height and BMI were measured as previously described. BMI status was based on the age (15, 15.5 and 16 years) and sex of each child and categorized using cut-point values from the International Obesity Task Force [16]. Garrow's criteria were used to classify parents' weight status, with BMI categorized into low weight (<18.5 kg/m^2), normal weight (18.5–24.9 kg/m^2), overweight (25–29.9 kg/m^2), and obesity (≥30 kg/m^2). Two additional variables were measured: daily time spent watching television, videos or DVDs, dichotomized as less than two hours and more than two hours, and after-school physical activity, categorized as yes or no.

2.5. Statistical analysis

A per-protocol analysis was used. Categorical variables were expressed as frequencies and percentages and continuous variables were expressed as means and standard deviations (SD).

Between-group (intervention vs. control) comparisons were made using Student's t-test for continuous variables and the Pearson χ [2] test for categorical variables. Multilevel mixed effects linear regression adjusted for clustering within schools and within children was performed to assess the effect of the intervention on changes in BMI over time (BMI × year interaction), adjusted by variables that influenced changes in BMI.

The initial regression model included all variables that were individually associated with the outcome at $P < 0.10$. The final model included variables that were statistically significant at the level of $P < 0.05$; the Akaike information criterion and biological plausibility were also taken into account.

Missing values for BMI at follow-up were imputed using all available variables. The estimation model was based on 10 replications and included the same variables as in the final hierarchical model.

In baseline data, all hypothesis tests were performed by linear or logistic regression analysis, adjusting for clustering within schools. Changes in BMI over time were analyzed using linear regression, adjusted for clustering within schools and within children. Statistical significance was set at $P < 0.05$ (two-tailed). Data were analyzed with SPSS version 23.0. Multiple imputation and multilevel mixed effects linear regression analysis were performed with the Statistical Package StataSE 14.0 for Windows.

3. Results

Of the 509 schoolchildren with complete anthropometric data in 2008, complete data were obtained in 2016 for 122 children (51.5%) from the control group and 156 (57.4%) children from the intervention group (Fig. 1). The Avall study generated 2545 records for 509 schoolchildren in the five data collection waves; 1430 (56.2%) records lacked information on at least one variable (Supplementary Data Table A).

Table 1 indicates average baseline values for all variables and compares participants at baseline and at follow-up with schoolchildren who were not assessed at follow-up. The only difference between children with and without complete follow-up was that children in the intervention arm with complete follow-up more

Table 1
Baseline characteristics of both groups (2006) and analysis of children lost to follow-up vs. those who completed the study (2016).

Group	Complete Follow-up		p-value[a]	Missng Follow-up	p-value[b]		p-value[c]
	Control (n = 122)	Intervention (n = 156)		Control (n = 115)		Intervention (n = 116)	
BMI (mean, SD)	16.4 (2.41)	17.2 (2.45)	0,854	16.4 (2.90)	0.955	16.6 (2.17)	0.035
Female	56 (45.9%)	74 (47.4%)	0.799	52 (45.2%)	0.916	52 (44.8%)	0.67
Immigrant	11 (9.0%)	15 (9.6%)	0.865	38 (33.0%)	<0.001	32 (27.6%)	<0.001
Paternal weight status[d]							
Low weight	1 (1.1%)	1 (0.7%)	0.369	2 (2.8%)	0.039	3 (3.4%)	0.47
Normal weight	37 (39.4%)	54 (38.3%)		18 (25.0%)		30 (34.5%)	
Overweight	51 (54.3%)	69 (48.9%)		40 (55.6%)		43 (49.4%)	
Obese	5 (5.3%)	17 (12.1%)		12 (16.7%)		11 (12.6%)	
Maternal weight status[d]							
Low weight	16 (16.7%)	23 (16.3%)	0.976	11 (14.7%)	0.239	9 (9.7%)	0.048
Normal weight	59 (61.5%)	90 (63.8%)		37 (49.3%)		52 (55.9%)	
Overweight	16 (16.7%)	22 (15.6%)		21 (28.0%)		28 (30.1%)	
Obese	5 (5.2%)	6 (4.3%)		6 (8.0%)		4 (4.3%)	
Paternal education level							
No schooling or primary	29 (33.0%)	26 (20.0%)	0.066	23 (33.8%)	0.857	18 (21.7%)	0.143
Secondary	41 (46.6%)	65 (50.0%)		29 (42.6%)		50 (60.2%)	
University	18 (20.5%)	39 (30.0%)		16 (23.5%)		15 (18.1%)	
Maternal education level							
No schooling or primary	19 (21.6%)	20 (15.0%)	0.176	26 (37.1%)	0.067	24 (27.9%)	0.038
Secondary studies	48 (54.5%)	67 (50.4%)		27 (38.6%)		42 (48.8%)	
University studies	21 (23.9%)	46 (34.6%)		17 (24.3%)		20 (23.3%)	
School lunch	40 (32.8%)	79 (50.6%)	0.003	25 (21.7%)	0.057	41 (35.3%)	0.012
>2 h of TV/day	18 (20.2%)	26 (19.8%)	0.945	25 (35.7%)	0.029	18 (21.2%)	0.813
Physical activity	60 (67.4%)	91 (67.9%)	0.938	54 (77.1%)	0.120	51 (60.0%)	0.147

p-value derived from unpaired *t*-tests for continuous variables and Pearson's chi square test for categorical variables.
BMI: body mass index (kg/m^2).
[a] p-value between control and interventions groups who completed follow up (2006–2010).
[b] p-value in the control group between completed follow up and uncompleted follow up.
[c] p-value in the intervention group between completed follow up and uncompleted follow up.
[d] BMI Weight status was categorized: low weight <18.5; normal weight (18.5–24.9), overweight (25–29.9), and obesity (≥30).

frequently ate at school than did those without complete follow-up (50.6% vs. 32.8%, P = 0.003).

Loss to follow-up over ten years was comparable across groups. More immigrants than native children were lost to follow-up in both groups. In the control group, more children with obese fathers were lost to follow-up, compared to those with non-obese fathers (16.7% vs. 5.3%, P = 0.039), and more children who watched more than two hours of TV a day were lost to follow-up, compared to those who watched less TV (35.7% vs. 20.2%, P = 0.029). In the intervention group, compared to children who completed follow-up at ten years, children who were lost to follow-up had a lower mean BMI (16.6 kg/m^2 vs. 17.2 kg/m^2, P = 0.035), were more likely to have a mother who was overweight (30.1% vs. 15.6%, P = 0.048) or had a lower level of education (27.9% vs. 15.0%, P = 0.038) and less likely to eat lunch at school (35.3% vs. 50.6%, P = 0.012).

Table 2 depicts mean changes in BMI over time. The estimated average BMI from the multilevel mixed-effects linear regression imputation adjusted model showed no between-group differences over time, but the increase in BMI from 2006 to 2016 was higher in the control group at 0.68 kg/m^2 (95% CI, 0.02,1.34; P = 0.045).

Table 3 describes the prevalence of weight states among children with complete follow-up at baseline and eight years after the intervention ended. In the control group, the prevalence of excess weight (obesity and overweight combined) in 2006 and 2016 was 22.2% and 27.9%, respectively; in the intervention group, comparable prevalence was 25.6% and 21.2%, respectively. The prevalence of excess weight increased 5.7% in the control group and decreased 4.4% in the intervention group.

At baseline, the proportion of children who spent more than two hours each day in sedentary activities was similar in both groups: 20.2% in the control group and 19.8% in the intervention group (P = 0.945). In 2016, the proportion of children who spent more than two hours each day in sedentary activities was higher than at baseline in both groups: 64.2% in the control group and 58.3% in the intervention group. The between-group difference in 2016 was not statistically significant (P = 0.325).

The baseline proportion of children with after-school physical activities was similar between groups; 67.4% in the control group and 67.9% in the intervention group (P = 0.945). In 2016, the proportion of children with after-school physical activities in the control group (70.2%) was similar to the baseline value, but the proportion of children with after-school physical activities in the intervention group was slightly higher (75.6%) than at baseline. The between-group difference was not statistically significant (P = 0.340).

Table 4 shows the individual effect of each variable on changes in BMI that could be included in a hierarchical model adjusted for clustering at the levels of school and child, with BMI over time as the dependent variable and the interaction between year and intervention as fixed variables. Of all variables, parental obesity (both mother and father) was directly associated with BMI in children, and the father's educational level was inversely associated with BMI in children. Table 5 shows the results of the intervention model without and with adjustment variables and with missing values imputed.

A multilevel mixed-effects linear regression revealed the need to adjust for clustering within schools and within children. The 'Intervention x Year' interaction indicated an intervention effect that persisted over the course of follow-up, accounting for a variable trend in changes in BMI: −0.42 kg/m^2 in 2008, −0.27 kg/m^2 in 2010, −0.57 kg/m^2 in 2012 and −0.14 kg/m^2 in 2016.

After adjusting for independent variables, the intervention effect was only significant in 2008 (−0.48 kg/m^2, P < 0.001) and 2010 (−0.16 kg/m^2, P = 0.008).

The child's BMI increased by (0.64 kg/m^2, P = 0.022) when the father was obese, an effect that was even greater when both parents were obese (2.46 kg/m^2, P = 0.003). The child's BMI decreased when both parents had completed university studies (−0.91 kg/m^2, P = 0.032).

When the model was adjusted for independent variables and missing values were imputed, changes in BMI in the intervention group were sustained over time: −0.40 kg/m^2 in 2008 (P = 0.001); −0.23 kg/m^2 in 2010 (P = 0.012); −0.63 kg/m^2 in 2012 (P < 0.001) and −0.27 kg/m^2 in 2016 (P = 0,025). The child's BMI increased by 0.52 kg/m^2 (P = 0.046) when the father was obese, by 1.26 kg/m^2 (P = 0.011) when the mother was obese and by 2.37 kg/m^2 (P < 0.001) when both parents were obese. However, the association with parents' educational level disappeared.

Table 2
Means changes in BMI[a] over time.

Year	Participants	BMI estimated means (95% CI)[b]	
	Control/Intervention[c]	Control	Intervention
2006	237/272	16.4 (16.1; 16.7)	16.9 (16.6; 17.2)
2008	236/272	18.1 (17.7; 18.5)	17.7 (17.4; 18.1)
2010	201/225	19.1 (18.6; 19.7)	18.9 (18.5; 19.3)
2012	205/247	20.4 (19.9; 20.9)	19.8 (19.3; 20.2)
2016	140/177	22.5 (22.0; 23.0)	22.3 (21.7; 22.8)

Year	Means differences in changes in BMI[d]				
	Participants Control/ Intervention	Control	Intervention	Difference (95% CI)	p-value
2016–2006	122/156	6.16 (2.9)	5.48 (2.7)	0.68 (0.02; 1.34)	0.045

p-value derived from multilevel mixed effect lineal regression in the Imputation adjusted model.

[a] BMI; body mass index (kg/m^2).

[b] 95% CI, estimated means and 95% confidence interval obtained from multilevel mixed effect lineal regression in the Imputation adjusted model.

[c] Number school children those in which variables were obtained at all time points.

[d] Mean differences in changes in BMI between 2016 and 2006 among the control and intervention groups in children who have followed up completely.

4. Discussion

The study analyzed the effect on BMI of a two-year, school-based educational intervention eight years after it ended, finding that the effect of the intervention was sustained. The AVall intervention used the IVAC methodology to promote healthy eating habits and physical activity in children during the first two years of primary school. This methodology was selected because it facilitates authentic dialog and empowerment and actively involves pupils in the decision-making process, an approach that is conducive to building social capital in schools [14,15]. Additionally, it had not been evaluated in a randomized study in schoolchildren and did not require modifying the school curriculum or substantial additional resources, facilitating replication.

Recently, multiple interventional studies have been conducted to prevent obesity and overweight in childhood and adolescence, but very few randomized controlled trials have analyzed long-term effects [17]. The Cretan Health and Nutrition Education Program [9] and the Kiel Obesity Prevention Study [10] carried out interventions at age 5.5–6.5 years, with long-term monitoring of six to seven years after the intervention ended. In both projects, the intervention consisted of nutritional and physical activity components incorporated into teaching throughout the academic year. The three-year Cretan intervention was conducted among schoolchildren at the beginning of primary education. In the Kiel Obesity Prevention Study, all first graders at participating schools were exposed to six nutrition units lasting two to three weeks during the second term of the first school year. In the Cretan study, the intervention group showed a lower increase in BMI than the control

Table 3
Weight status of the students at baseline and six years after cessation intervention in both groups[a].

Weight status[b]	2006			2016		
	Control (n = 122)	Intervention (n = 156)	p-value	Control (n = 122)	Intervention (n = 156)	p-value
Low weight	19 (15.6%)	8 (5.1%)	0.035	5 (4.1%)	5 (3.2%)	0. 551
Normal weight	76 (62.3%)	108 (69.2%)		83 (68.0%)	118 (75.6%)	
Overweight	18 (14.8%)	28 (17.9%)		26 (21.3%)	24 (15.4%)	
Obese	9 (7.4%)	12 (7.7%)		8 (6.6%)	9 (5.8%)	

p-value derived from Pearson's Chi Square test.
[a] Children's with complete follow-up those in which variables were obtained at all time points.
[b] Weight status was calculated based on the age and sex of each child and categorized using the cut-points values proposed by the International Obesity Task Force.

Table 4
Individual effect or each variable on BMI[a].

	β coefficient (95% CI)[b]	p-value
Female sex	−0.14 (−0.67; 0.38)	0.590
Immigrant	0.05 (−0.64; 0.73)	0.890
Father obesity	0.77 (0.31; 1.24)	0.001
Mother obesity	1.06 (0.43; 1.69)	0.001
Father university education	−0.98 (1.72; −0.24)	0.010
Mother university education	−0.58 (1.27; 0.12)	0.102
>2 h TV per day	0.08 (−0.14; 0.30)	0.471
School lunch	−0.10 (−0.34; 0.14)	0.419
Physical activity	−0.15 (−0.37; 0.07)	0.181

p-value derived Multilevel Mixed-Effects linear regression adjusted by school and child, with BMI as the dependent variable, and the interaction between year and intervention as fixed variables.
[a] BMI; body mass index (kg/m^2).
[b] 95% CI; 95% confidence interval.

group (3.68 vs. 4.28 kg/m^2, P < 0.05). In the Kiel study, increases in BMI were similar in control and intervention groups, and the incidence of cumulative overweight during eight years of follow-up increased by 5.9% in the intervention group and 7.1% in the control group. The intervention had a positive effect only among children of high socioeconomic status.

In the AVall study, the increase in BMI from 2006 to 2016 was higher in the control group than in the intervention group (6.16 vs. 5.48 kg/m^2, P = 0.045). At baseline, the prevalence of excess weight was similar in both groups. In 2016, the prevalence of excess weight in the control group increased, overweight increased and obesity decreased, while the prevalence of both overweight and obesity decreased in the intervention group.

Time spent in sedentary activities increased from 2006 to 2016 by 31.7% in the control group and 21% in the intervention group. Although time spent in sedentary activities in 2016 in the control group was higher than in the intervention group, it did not significantly affect changes in BMI. In the intervention group in 2016, the proportion of schoolchildren who performed physical exercise after school increased by 11% from baseline and was slightly higher than that of the control group. However, the multilevel linear regression did not detect a significant influence on BMI. The dichotomous categorization of the amount of time dedicated to sedentary activities and exercise could explain the lack of observed effect on changes in BMI. Another potential explanation is that small changes in activity may have a cumulative effect contributing to the observed results.

Long-term studies have been conducted among schoolchildren with overweight and obesity [18,19] with resulting reductions in

Table 5
Multilevel linear regression analysis on 8-year changes in BMI with random-effects by school and child Intervention.

	Intervention Model[a,b]	p-Value	Adjusted Model[b,c]	p-Value	Adjusted Model[b,d] Imputation Model	p-Value
Constant	16.434		16.563		16.290	
year						
2008	1.75 (1.47; 2.03)	<0.001	1.77 (1.39; 2.14)	<0.001	1.71 (1.34; 2.09)	<0.001
2010	2.71 (2.41; 3.00)	<0.001	2.61 (2.21; 3.01)	<0.001	2.69 (2.27; 3.11)	<0.001
2012	3.84 (3.55; 4.13)	<0.001	3.20 (2.37; 4.03)	<0.001	3.97 (3.56; 4.37)	<0.001
2016	6.15 (5.82; 6.49)	<0.001	5.95 (5.44; 6.46)	<0.001	6.09 (5.66; 6.52)	<0.001
Intervention	0.48 (−0.17; 1.12)	<0.001	0.55 (−0.20; 1.29)	0.150	0.48 (−0.18; 1.15)	0.152
2008*Intervention	−0.90 (−1.28; −0.52)	<0.001	−1.03 (−1.52; −0.54)	<0.001	−0.88 (−1.39; −0.37)	0.001
2010*Intervention	−0.75 (−1.15; −0.34)	<0.001	−0.71 (−1.23; −0.18)	0.008	−0.71 (−1.26; −0.15)	0.012
2012*Intervention	−1.05 (−1.45; −0.65)	<0.001	−0.56 (−1.55; 0.43)	0.269	−1.11 (−1.68; −0.53)	<0.001
2016*Intervention	−0.62 (−1.07; −0.17)	<0.001	−0.27 (−0.93; 0.38)	0.415	−0.75 (−1.40; −0.10)	0.025
Parents obesity						
Paternal obesity			0.64 (0.09; 1.19)	0.022	0.52 (0.01; 1.02)	0.046
Maternal obesity			0.46 (−0.52; 1.45)	0.356	1.26 (0.31; 2.20)	0.011
Paternal and maternal obesity			2.46 (0.83; 4.09)	0.003	2.37 (1.40; 3.33)	<0.001
Parents university level						
Father only			−0.92 (−1.98; 0.14)	0.088		
Mother only			−0.18 (−1.07; 0.70)	0.687		
Both			−0.91 (−1.73; −0.08)	0.032		
Adjusted random-effects						
By school	0.27 (0.02; 4.26)		0.34 (0.03; 3.53)		0.30 (0.03; 2.94)	
By child	2.90 (2.71; 3.11)		2.58 (2.36; 2.82)		2.47 (2.28; 2.67)	

ESD: estimated standard deviation.
[a] Minimal model to assess the effect of intervention on BMI change over time (BMI*year interaction).
[b] 95% CI: 95% confidence interval.
[c] Model adjusted by variables that influenced changed in BMI.
[d] Adjusted model obtained using multiple imputation.

prevalence, but the intervention methodologies varied from those of the study reported here. Romon et al. [18] carried out the intervention in two five-year phases. The first phase was based on an informative program taught by a dietitian at school or in the community. The object of the second phase was physical activity; sport educators were employed to promote physical activity in primary schools and walking-to-school days and family activities were organized. Reinehr et al. [19] designed an intervention based on behavioral counseling, nutrition education, physical activity and psychological training that was delivered over six months to children and their parents.

At the beginning of the AVall project, the research team presented the study to each school and requested its participation. Subsequently, families received periodic newsletters from the AVall team with news about books and reading recommendations related to diet and physical activity for families, as well as monthly recipes using healthy seasonal foods adapted for the whole family. The Identification and prevention of Dietary- and lifestyle-induced health EFfects In Children and infantS (IDEFICS) intervention was a controlled, non-randomized community-oriented intervention initiated during the school year [20]. Children with baseline overweight or obesity had a significantly greater probability of normal weight status after two years, an effect that was independent of age, sex or survey country and only marginally attenuated by parental education [21]. After imputing missing values, the influence of parental education on children's BMI disappeared. We observed that parental obesity increased BMI in children, a relationship that has been described in other studies [22].

A recent systematic review of interventions to prevent childhood overweight and obesity describes four randomized trials with positive results, only one of which has a longer follow-up period. The authors conclude that the evidence was strongest and most consistently positive for school-based interventions combining diet and physical activity components and a home element. More research is needed to understand the most effective combination of settings and components [17]. In another review of interventions to prevent childhood obesity carried out in Spain, the authors conclude that the most effective strategies lasted longer than one year and were multidisciplinary, including school centers and the family, as in the AVall project [22].

More studies including long term surveillance are needed to understand the effects, cost-effectiveness, feasibility and sustainability of interventions to prevent childhood excess weight [23,24]. It is also important to facilitate replication by describing interventions in detail, leading to advances in the promotion of healthy lifestyles while preventing obesity and overweight children [25].

4.1. Strengths and limitations

A primary strength of this study is its nature as a randomized controlled trial with an eight-year follow-up period. Although the IVAC methodology requires systematic training of teachers in action-oriented and participatory health promotion approaches, it does not affect normal teaching programs. In addition, an extracurricular intervention reflecting collaboration between schools and participating families was designed. All schools in the city of Granollers participated.

The study has several limitations. The number of participating children was relatively small. The intervention group had a higher mean BMI at baseline. We did not assess changes in cardiovascular risk factors or body composition. The overall retention rate (54.8%) was similar in both groups and to that of other school-based intervention studies [10,26]. More immigrant children were lost to follow up in both the intervention and control groups; the design did not allow us to explore reasons for this finding, although the students who dropped out were not registered in any of the schools in the city. Loss to follow-up was also higher among children with fathers who were obese in the control group and among children with mothers who were obese in the intervention group. Although these differences did not reach statistical significance, the reasons for this finding warrant exploration.

In summary, an intervention addressing healthy eating habits and physical activity in primary schoolchildren, carried out using the IVAC methodology and with the involvement of the family, was effective in containing increases in BMI in children after eight years of follow-up.

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Statement of authorship

All persons who meet authorship criteria are listed as authors, and all authors certify that they have participated sufficiently in the work to take public responsibility for the content, including participation in the concept, design, analysis, writing, or revision of the manuscript.

Conflict of interest

None declared.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.clnu.2018.12.029.

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