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EdAl-2 (*Educació en Alimentació*) program: reproducibility of a randomized, interventional, primary-school-based study to induce healthier lifestyle activities in children

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ABSTRACT

Objectives: To assess the reproducibility of the EdAl program in "Terres de l'Ebre" (Spain), EdAL-2, an educational intervention to improve lifestyles, including diet and physical activity recommendations; over a period of 22 months.

Design*:* reproduction of a randomized controlled trial

Setting: primary-secondary care, two school clusters were randomly assigned to intervention (5 schools in Amposta) or control group (11 schools in surroundings towns of Amposta)

Participants: 690 pupils (320 in the intervention group and 370 in the control group); 78% were of Western European ethnicity. Mean age (±SD) was 8.04 ± 0.6 years (47.7% females) at baseline. Inclusion criteria were name, gender, date and place of birth, and written informed consent from the parent or guardian.

Intervention: The interventions focused on 8 lifestyle topics covered in 12 activities (1h/activity/session) implemented by health promoting agents (HPAs) in the primary-school over 3 school academic years.

Primary and secondary outcomes: the primary outcome was obesity prevalence and the secondary outcomes were body mass index (BMI) collected every year, and dietary habits and lifestyles collected by questionnaires were filled-in by the parents at baseline and end-of-study.

Results*:* At 22-months of the EdAl-2 program reproducing the original EdAl protocol, showed that there was an increase of 15% (p=0.027) in boys performing ≥4 after-school physical activity (PA) h/week, while watching TV was reduced to ≤2h/day. TV watching decreased by 23.1% (p=0.009) in intervention compared to control group. The obesity prevalence was similar in intervention and control groups over the period of the program. Multivariate statistical analysis indicated that the performance of ≥4 after-school PA h/week was a protective factor against childhood OB (OR: -0.511; p=0.032).

Conclusions: Our school-based intervention program is feasible, reproducible and adaptable to any school environment. It can lead to an increased percentage of children (mainly boys) performing ≥4 after-school PA h/week.

Words: 299/300

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ARTICLE SUMMARY

Strengths and limitations of the study

- Strengths: Reproducibility of studies is rare because of the huge complexity of trying to replicate a program. However, studies in OB prevention as EdAl need to be reproducible, especially those improving healthy lifestyle such as after-school PA, to confirm best childhood practices.
- Strengths: Statistical methods controlling for confounders and taking clustering of data
- Limitations: Assessment of treatment adherence in order to evaluate reproducibility and feasibility
- Limitations: Dietary habits were observed via a questionnaire that did not take into account the quantities of the different types of food items consumed

BACKGROUND

Obesity (OB) has become a disease of epidemic proportions [1]. However, this increasing tendency towards excess weight in childhood and adulthood [2] observed in some countries (United Kingdom, France, Korea, United States and Spain) is stable despite the absolute rates being a cause for concern [1]. OB prevalence in children and adolescents is higher in southern regions of Europe [3-4].

Accumulation of fat tissue in childhood constitutes an increased disease risk in childhood, as well as in adulthood [5]. This disease risk has a multifactorial etiology such as an unhealthy diet and sedentary lifestyle [6-7].

The Organization for Economic Co-operation and Development (OECD), an international body, has predicted an increase of 7% in excess weight prevalence in adulthood over the period spanning 2010 to 2020 [8]. The WHO proposes the prevention and control of OB prevalence as key in the updated "Action Plan 2008-2013" in which effective health promotion is considered the principal strategy [9].

Since excess weight status in adulthood is almost invariably predicated on childhood and adolescent weight, OB prevention should start early in life [10]. The optimum age to commence an intervention is between the ages of 7 and 8 years because children are more receptive to guidance [11]. As such the school is an ideal place for promotion of healthy nutrition and lifestyle habits [12]; the message being received by all schoolchildren irrespective of ethnic and socioeconomic differences [9]. The effectiveness of an intervention is when educational strategies and environmental factors such as healthy nutrition and physical activity habits coincide since both aspects are essential in preventing childhood OB [13]. Currently, European children spend more of their leisure time in sedentary activities such as watching television (TV), video games or on the Internet. These activities represent a decrease in physical movement and lowering energy expenditure and, as such, are risk factors for OB [14].

We had designed the EdAl (*Educació en Alimentació*) program as a randomized, controlled, parallel study applied in primary schools, and implemented by university students acting as Health Promoter Agents (HPAs) [15]. This intervention was deployed in Reus (as intervention

group) with the neighboring towns of Salou, Cambrils and Vilaseca as control group. The interventions focused on 8 lifestyle topics covered in 12 activities (1h/activity/session) in 7-8 year old children, and implemented by HPAs over 3 school academic years. We found that the EdAl program successfully reduced childhood OB prevalence in boys by 4.39% and increased the percentage of boys who practice ≥5 after-school physical activity (PA) h/week [16]. The EdAl program needed to be reproduced in other localities and with other children to demonstrate the effectiveness of this intervention program [17].

The outcomes of the EdAl program support the feasibility of improving PA in childhood. However, an educational intervention such as our EdAl program implemented by HPAs also tests complex components such as healthy lifestyles including diet and physical activity recommendations. Due to the complexity, such interventions are difficult to rationalize, standardize, reproduce, and administer consistently to all participants [17].

There has been one study in the literature that has reproduced its programs in other locations. Described as the Kiel Obesity Prevention Study (KOPS), it demonstrated the efficacy and feasibility of implementing new nutritional concepts [18]. We tested the reproducibility of the EdAl program in a geographical area (Terres de l'Ebre) about 80 km away from where the original EdAl program was designed and implemented. We describe, here, the primary-school-based study to reduce the prevalence of childhood OB (The EdAl-2 study) which remains an intervention to induce healthy lifestyles, including diet and physical activity recommendations, in 7-8 year old school children over 3 academic years (22 months active school time).

METHODS

The original protocol, rationale, randomization, techniques and results of the initial EdAl program have been published in Trials [15-16]. The current study (EdAl-2) was conducted in exactly the same way so as to examine whether comparable results could be achieved. The EdAl-2 study was approved by the Clinical Research Ethical Committee of the Hospital Sant Joan of Reus, Universitat Rovira i Virgili (Catalan ethical committee registry ref 11-04-28/4proj8). This study was registered in Clinical Trials *NCT01362023*. The protocol conformed

to the Helsinki Declaration and Good Clinical Practice guides of the International Conference of Harmonization (ICHGCP). This study followed the CONSORT criteria [see Additional file 1]. For logistics reasons, the EdAl-2 program was reduced by 6 months, from 28 months to 22 months.

Study population

The coordinating Center (in Reus) developed a randomization scheme to have a study sample in which the schools in Amposta were designated as Group A (intervention) and 9 towns around Amposta (Sant Jaume d'Enveja, Els Muntells, l'Ametlla de Mar, El Perelló, l'Ampolla, Deltebre, l'Aldea, Lligalló del Gànguil and Camarles) as Group B (control).

The socio-demographic indicators in all towns were similar to that of the original EdAl Program in Reus. Children attending the schools in both groups (intervention and control) lived in close proximity within each school's catchment area. Intervention institutions were 5 schools involving 18 classrooms and 457 pupils in Amposta. Control institutions consisted of 11 schools involving 23 classrooms and 531 pupils in the 9 towns of around Amposta. Children of this study are in the 2nd and 3rd grade of primary education (7-8 year olds). Schoolchildren were enrolled since 25th May 2011 (children born in 2002–2003) and followed-up for 3 school academic years (2012–2013) and it was completed 30th March 2013.

To be representative of the child population, the schools selected needed to have at least 50% of the children in the classrooms volunteer to participate. We offered the program to all schools, whether public (funded by the government and termed "charter" schools) or private which included fee-paying and/or faith schools. Inclusion criteria were: name, gender, date and place of birth, and written informed consent from the parent or guardian.

Intervention program

The original EdAl Reus protocol was followed [15-16]. The educational intervention activities focused on eight lifestyle topics based on scientific evidence [19] to improve nutritional food item choices (and avoidance of some foods), healthy habits such as teeth-brushing and hand-

washing and, overall, adoption of activities that encourage physical activity (walking to school, playground games), and to avoid sedentary behavior [19].

Each of the eight topics was integrated within educational intervention activities of 1 hour/activity, prepared and standardized by the HPAs, and implemented in the children's classrooms. In the first school academic year, we focused on four topics: 1) to improve healthy lifestyle; 2) to encourage healthy drinks intake (and avoidance of unhealthy carbonated/sugared beverages); 3) to increase the consumption of vegetables and legumes; and 4) to decrease the consumption of candies and pastries while increasing the intake of fresh fruits and nuts. These corresponded to four standardized activities (1 hour/ activity). In the second year, the remaining four of the eight selected lifestyle topics were addressed: 5) to improve healthy habits within a set timetable (home meals, teeth-brushing, hand-washing) and physical activity participation; 6) to increase fruit intake; 7) to improve dairy product consumption; and 8) to increase fish consumption. These corresponded to four standardized activities. Finally, in the third school academic year, four standardized activities were introduced that reinforced the eight lifestyle topics implemented in the previous 2 academic years. Thus, the intervention program was based on eight lifestyle topics incorporated in 12 activities which were disseminated over 12 sessions (1 hour/activity/session), and prepared, standardized and implemented as four activities per school academic year by the HPAs in the school classrooms.

Process evaluation

The measurements were performed in each school academic year, as was the original EdAl program [15-16].

Outcomes

Assessment of the reproducibility of the EdAl program was based on primary outcomes such as prevalence of OB (overall as well as segregated by gender), according to the International Obesity Task Force (IOTF) [20] recommendations for better international comparisons of data. Secondary outcomes included: changes in measures of adiposity (overall as well as segregated

by gender) such as BMI z-score and waist circumference, incidence and remission of excess weight (OW and OB), as well as changes in lifestyles (eating habits and physical activity h/week). Weight, height, and waist circumference values were obtained as described previously [15]. Prevalence of underweight was analyzed according to Cole et al [21] using 17 Kg/m^2 as cut-off point. BMI z-score was analyzed according to the WHO Global InfoBase [22]. To identify the risk factors of OB, the OB category was determined according to WHO criteria since this is based on data from countries which have a low OB prevalence [22] and, as such, provide an understanding of the protective (or risk factors) for OB in our own population.

Sample size

We calculated that, with a sample of more than 300 pupils per group, the study would have 85% power to detect a difference of 5 percentage points between the intervention and control schools in relation to the primary outcome (prevalence of OB).

Statistical analyses

Descriptive variables were presented as means and confidence intervals (95%CI). General linear mixed models (GLM) were used to analyze differences between the intervention and control pupils with respect to prevalence of OB. Repeated measures of GLM were used to analyze the trend of BMI z-score between baseline and end-of-study. The McNemar test was used to analyze change-over-time of food habits, after-school PA h/week and hours TV/day categories, in intervention and control group. The continuous outcomes studied in each group were compared using ANOVA.

To evaluate risk and protective factors involved in childhood OB, logistic regression analyses were performed at baseline, with no distinction between intervention and control group. The odds ratios (OR) and 95%CI were calculated for dietary patterns and lifestyles, based on the Krece Plus Questionnaire [23] and the AVall Questionnaire [24], respectively. The main analyses were performed with the modified intention-to-treat (mITT) population i.e. subjects with baseline and end-of-study data on weight, height, and date of birth, and written inform

consent. The analyses did not use any imputation missing method; the implication being that missing data were random. Statistical significance was defined by a $P<0.05$. The statistical analyses were performed with the SPSS 20.0 for Windows (SPSS Inc., Chicago, IL, USA).

RESULTS

Enrollment

Figure 1 shows the recruitment and flow diagram of pupils in the intervention and control groups over the course of the study. The mITT population in the intervention group and control group were 320 and 370 pupils, respectively.

The characteristics of the study group are shown in Table 1. At baseline, the intervention and control group were homogeneous in BMI status. The ethnicity of the population was predominantly Western European in intervention and control group (77.5% *vs.* 78.9%, respectively) while 7.5% *vs.* 10.8% was Eastern European; 10.3% *vs.* 3.5% was Latin American; 3.4% *vs.* 6.2% was North African Arab.

Table 1. Anthropometric characteristics of pupils at baseline: Intervention *versus* Control group

	Intervention group (n=320)			Control group (n=370)			Intervention *vs.* control; P value	Intervention *vs.* control; P value	Intervention *vs.* control; P value
	Mean (95%CI)			Mean (95%CI)					
	Boys	Girls	Total	Boys	Girls	Total	Boys	Girls	Total
Weight; Kg	30.35 (29.22; 31.48)	29.86 (28.81; 30.91)	30.11 (29.34; 30.88)	31.29 (30.26; 32.33)	31.35 (30.36; 32.34)	31.32 (30.60; 32.04)	0.226	0.043	0.024
BMI; Kg/m^2	17.40 (16.93; 17.86)	17.42 (16.97; 17.88)	17.41 (17.09; 17.73)	17.70 (17.28; 18.13)	17.94 (17.51; 18.37)	17.82 (17.51; 18.12)	0.340	0.104	0.073
Height; m	1.32 (1.30; 1.33)	1.30 (1.29; 1.31)	1.31 (1.30; 1.32)	1.32 (1.31; 1.33)	1.32 (1.31; 1.33)	1.32 (1.31; 1.33)	0.242	0.045	0.027
Fat mass; Kg	6.71 (5.99; 7.42)	7.11 (6.50; 7.72)	6.90 (6.42; 7.38)	6.44 (5.78; 7.09)	7.70 (7.12; 8.27)	7.03 (6.59; 7.47)	0.584	0.167	0.698
Lean mass; Kg	23.99 (23.34; 24.64)	22.86 (22.32; 23.39)	23.44 (23.02; 23.87)	24.88 (24.28; 25.47)	23.71 (23.21; 24.22)	24.33 (23.93; 24.73)	0.049	0.022	0.003
Waist circumference; cm	60.97 (59.68; 62.27)	59.91 (58.67; 61.15)	60.46 (59.56; 61.36)	64.37 (63.18; 65.56)	65.17 (64.00; 66.34)	64.75 (63.91; 65.58)	<0.001	<0.001	<0.001

Notes to Table 1:

The results are expressed as Mean (95%CI)

[1]p value: general linear model (GLM) statistics

Attrition rate

Figure 1 shows the recruitment and retention of pupils in intervention and control schools. Among the 916 pupils assessed at the beginning of the study, 690 (75.3%) pupils (73.6% of those allocated to the control group and 77.5% of those allocated to the intervention group) were reassessed three academic courses later, and valid measurements were obtained. The rate of parental consent was 95.7%. Drop-outs in both groups are understood to be missing at random.

Primary outcome: Prevalence of OB

At 22 months of the study, OB prevalence assessed by IOTF criteria, was similar in intervention and control group (p=0.628) (Table 2).

Table 2. Baseline and end-of-intervention measurements of categorized BMI in Intervention and Control group

Criteria/Category		Group		Baseline % (n)	End of study % (n)	Change %	Baseline to study end p- value[1]	Intervention vs. Control p-value[2]
IOTF criteria	OW	Intervention	Boys	18.2 (30)	24.2 (40)	6	0.087	0.629
			Girls	16.2 (25)	23.2 (36)	7	0.043	0.066
			Total	17.2 (55)	23.8 (76)	6.6	0.005	0.086
		Control	Boys	25.5 (50)	27.0 (53)	1.5	0.690	
			Girls	28.2 (49)	32.8 (57)	4.6	0.185	
			Total	26.8 (99)	29.7 (110)	2.9	0.169	
	OB	Intervention	Boys	9.7 (16)	11.5 (19)	-1.8	0.453	0.735
			Girls	13.6 (21)	12.3 (19)	-1.3	0.754	0.732
			Total	11.6 (37)	11.9 (38)	0.3	1.000	0.628
		Control	Boys	10.7 (21)	10.2 (20)	-0.5	1.000	
			Girls	12.1 (21)	10.9 (19)	-1.2	0.687	
			Total	11.4 (42)	10.5 (39)	-0.93	0.607	

Notes to Table 2

IOTF: International Obesity Task Force

The results are expressed as % (n)

[1]p value: McNemar's Test

[2]p value: Fisher's Exact Test

Secondary outcomes

At 22 months of the study, the progress of OW prevalence (according to IOTF criteria) was similar between groups (p=0.086).

There were no significant differences in BMI z-score differences between intervention and control group (p=0.512) (Table 3). The remission, and incidence, of OB was similar in the overall intervention and control group, as well as segregated with respect to gender.

Table 3. BMI z-score at baseline and at the end of intervention in Intervention and Control group

			Baseline Mean (95%CI)	End of study Mean (95%CI)	Change Mean (95%CI)	Baseline to Study end P-value[1]	Intervention vs. Control P-value[2]
BMI z-score	Intervention	Boys	0.73 (0.53; 0.94)	0.74 (0.54; 0.93)	0.00 (-0.07; 0.08)	0.973	0.985
		Girls	0.71 (0.50; 0.91)	0.89 (0.68; 1.10)	0.18 (0.10; 0.26)	<0.001	0.376
		Total	0.72 (0.58; 0.86)	0.81 (0.67; 0.95)	0.09 (0.03; 0.14)	0.002	0.512
	Control	Boys	0.83 (0.64; 1.01)	0.81 (0.63; 1.00)	-0.12 (-0.08; 0.06)	0.726	
		Girls	0.52 (0.33; 0.71)	0.63 (0.44; 0.83)	0.11 (0.02; 0.20)	0.013	
		Total	0.68 (0.55; 0.82)	0.73 (0.60; 0.86)	0.05 (-0.01; 0.10)	0.100	

Notes to Table 3:

[1]p-value: Mixed Models Repeated Measures

[2]p-value: Fisher's Exact Test

Differences between intervention and control pre-post intervention

Lifestyles evaluation

At 22 months, food habits changes showed that control group had significantly decreased (p<0.001) breakfast consumption by 7.1% (from 98.1% to 92.9%) compared to the change in intervention group (98.4% to 98.8%).

The control boys had a reduction of 14% compared to intervention boys with respect to consumption of pastry (p=0.005). The intervention girls had an increase of 8.1% in the consumption of fast-food, compared to the change in control girls (p=0.014).

The once/day consumption of vegetables was higher in intervention group compared to control, while vegetables once/day increased by 16.2% in girls of intervention group compared to girls of control group (p=0.008). The intake of a second vegetable/day increased by 13.8% in boys of intervention group compared to boys of control group (0.024).

Table 4 summarizes the time spent doing after-school PA, watching TV, playing video games, and other leisure-time activities. At 22 months, the percentage of boys who performed ≥4h after-school PA/week was increased by 15% (p=0.027) while watching TV daily was reduced to ≤2h/day. This was equivalent to a change in TV watching of 23.1% (p=0.009) in intervention compared to control group.

Table 4. Lifestyles assessed at baseline and at the end of study in Intervention and Control

		Intervention			Control			Intervention vs. Control
		Baseline %(n)	End of study %(n)	p-value[1]	Baseline %(n)	End of study %(n)	p-value[1]	p-value[2]
TV and/or video games								
0-2h/day	Boys	49.2 (62)	45.2 (57)	0.268	32.5 (51)	27.0 (43)	0.627	0.009
	Girls	48.4 (60)	51.2 (63)	1.000	44.0 (66)	49.7 (71)	0.430	1.000
	Total	48.8 (122)	48.2 (120)	0.464	38.1 (117)	37.7 (114)	0.910	0.062
3-4h/day	Boys	46.0 (58)	50.0 (63)	0.542	62.4 (98)	63.5 (101)	1.000	0.049
	Girls	43.5 (54)	44.7 (55)	0.860	54.0 (81)	47.6 (68)	0.349	0.693
	Total	44.8 (112)	47.4 (118)	0.489	58.3 (179)	56.0 (169)	0.606	0.080
>4h/day	Boys	4.8 (6)	4.8 (6)	0.375	5.1 (8)	9.4 (15)	0.607	0.301
	Girls	8.1 (10)	4.1 (5)	0.453	2.0 (3)	2.8 (4)	1.000	0.253
	Total	6.4 (16)	4.4 (11)	1.000	3.6 (11)	6.3 (19)	0.481	1.000
After-school PA								
0-2h/week	Boys	26.2 (34)	14.5 (18)	0.013	21.5 (34)	19.0 (31)	0.286	0.483
	Girls	35.2 (43)	33.6 (41)	0.701	34.5 (50)	36.6 (52)	1.000	1.000
	Total	30.6 (77)	24.0 (59)	0.049	27.7 (84)	27.2 (83)	0.435	0.744
2-4h/week	Boys	29.2 (38)	24.2 (30)	0.418	38.0 (60)	3.1 (54)	0.780	0.067
	Girls	36.9 (45)	32.0 (39)	0.377	32.4 (47)	31.0 (44)	1.000	1.000
	Total	32.9 (83)	28.0 (69)	0.188	35.3 (107)	32.1 (98)	0.764	0.193
>4h/week	Boys	44.6 (58)	61.3 (76)	0.006	40.5 (64)	47.9 (78)	0.243	0.027
	Girls	27.9 (34)	34.4 (42)	0.136	33.1 (48)	32.4 (46)	0.868	1.000
	Total	36.5 (92)	48.0 (118)	0.002	37.0 (112)	40.7 (124)	0.272	0.068

Notes to Table 4

[1]p-value: McNemar's Test

[2]p-value: Fisher's Exact Test.

Differences between intervention and control pre-post intervention program

At 22 months, subjects who were normal weight at baseline increased after-school PA to ≥4h/week. This reflects a rise to 32.7% in boys (p=0.002) but, in girls, the changes were not statistically different (p=0.134). No statistically significant differences were observed in the control group.

Impact of certain additional factors on obesity

The ORs of OB, using BMI z-score criteria, were related to some of the more relevant dietary habits and lifestyles. Thus, breakfast dairy product consumption (OR: -1.092; p=0.004) and ≥4 after-school PA h/week (OR: -0.511; p=0.032) were protective factors against OB. Conversely, doing <4 h/week PA (OR: 0.594; p=0.018) increased the risk of childhood OB.

DISCUSSION

The EdAl-2 program, a reproducibility study, in Terres de l'Ebre, shows that intervention is useful for improving weekly after-school PA. However, the OB prevalence remained unchanged at 22 months, as has been shown in the data on stability of OB prevalence observed in some European countries [8].

The EdAl-2 program confirmed that after-school PA (in terms of h/week) can be stimulated in primary school as part of a healthy lifestyle. As we had observed in the original EdAL program [16] at 28 months of intervention, there was an increase of up to 19.7% of children dedicating >5 hours/week to extra-curricular physical activities [16]. Further, the after-school PA was maintained despite cessation of the intervention program [25]. The effect of EdAl program during its implementation and after the official cessation indicated an impact on PA, whereas modification towards healthy food-choices occurred according to the site of the program's implementation, and was not consistent.

Interventions to prevent OB in the school setting have shown dramatic improvements [26]. However, successful studies in OB prevention need to be reproducible, especially those improving healthy lifestyle such as after-school PA, to confirm best childhood practices.

Reproducibility of studies is rare because of the huge complexity of trying to replicate a program. For the standardization of any method it is essential to be able to reproduce appropriate levels of an intervention study, especially one that involves behavioral changes. Feasibility of our intervention was confirmed in two different towns and over two different time-courses (the first in Reus over 28 months, and the second in Amposta over 22 months).

It is also important to assess treatment adherence in order to evaluate reproducibility and feasibility [17]. For example, the KOPS study [18] demonstrated that nutritional knowledge was increased as a result of their intervention in the two cohort studies (KOPS 1 and KOPS 2) [18]. However, the study was unable to show whether there were differences in overweight outcomes, weight categories or lifestyles between the two cohorts. Some multi-centered studies have attempted to reproduce methodological aspects in interventions conducted in different countries or different populations. However, while multi-centered studies are usually implemented concurrently, reproducibility involves the applicability of the intervention in different sites and/or different times in order to validate the initial findings. One example of this is the Pro Children Study [27] which, as a multi-centered study, had been applied in different countries simultaneously and had demonstrated its efficacy and feasibility.

The ALADINO study presented the obesity status prevalence in Spain which, according to the IOTF is about 11.4% in children of around 9 years of age [28]. In the EdAl-2 study, the OB prevalence was similar, but lower in the intervention group than the equivalent in the ALADINO study, as well as in the EDAL-2 control group.

The EdAl-2 study showed a significant improvement of 16.7% in the young boys in the intervention group who participated in ≥4 h/week after-school PA. Further, the increased numbers of children in the intervention group who performed ≥4 h/week after-school PA who were normal-weight at baseline, suggested that the intervention was effective not only in the primary-school healthy population but also effective in preventing OB over the longer-term due to the PA being maintained.

In the dietary habits aspect of the EdAl-2 study, we observed that there was an increase in breakfast consumption. A recent study [29] showed that frequent breakfast eaters had

significantly lower levels of body-weight, BMI, z-score BMI, and waist circumference compared to those who partook of breakfast infrequently. In the EdAl-2 study we observed that consumption of dairy products at breakfast was a protective factor against obesity.

Several studies have shown that participating in PA was a protective factor against OB and that spending >2h watching TV was a risk factor for childhood OB. A recent Spanish study showed that leisure-time PA was a protective factor against OB (as with our present study) and that performing >4 h/week is a protective factor while watching TV for this amount of time was, according to Ochoa et al [30], associated with OB.

A limitation of our study is that it only observed dietary habits via a questionnaire that did not take into account the quantities of the different types of food items consumed. These data would be important in contributing to the quantity *versus* quality debate in OB or OW prevalence. Furthermore, EdAl-2 demonstrated that performing >4h/week after-school PA, plus having dairy product at breakfast are protective factors. Hence, we believe that a participating in >4h/week after-school PA, and continuing with a healthy breakfast, are key points in preventing childhood OB.

CONCLUSION

Our school-based intervention program is feasible, reproducible and adaptable to any school environment. It can lead to an increased percentage of children (mainly boys) performing ≥4 after-school PA h/week. This suggests that our intervention program induces beneficial effects, such as after-school PA h/week, which could exert an anti-obesity health-benefit in children.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

LIST OF ABBREVIATIONS

OB: Obesity

OW: Overweight

PA: Physical Activity

mITT: modified Intention to Treat

HPAs: Health Promoter Agents

WHO: World Health Organization

BMI: Body Mass Index

OR: Odds Ratio

Authors' contributions

MG, EL, LT, RS designed the study (project, conception, development of overall research plan, and study oversight)

MG, EL, LT, RQ, RS conducted research (hands-on conduct of the experiments and data collection)

EL, LT, MG, RS provided essential materials (applies to authors who contributed by providing constructs, database, etc. necessary for the research)

DM, EL, LT analyzed data or performed statistical analysis

RS, MG, LT, DM, EL drafted and revised the manuscript (authors who made a major contribution). The final manuscript was read and approved by all co-authors

RS, MG take primary responsibility for the study, and manuscript content

REFERENCES

1. Organización para la Cooperación y el Desarrollo Económicos (OCDE): *Obesity update.* 2012.

2. World Health Organization. The Challenge of Obesity in the WHO European Region and the strategies for response. Denmark; 2007.

3. Ahrens W, Bammann K, Siani A, et al. The IDEFICS cohort: design, characteristics and participation in the baseline survey. *Int J Obes* 2011;35(Suppl 1:)S3-15. doi:10.1038/ijo.2011.30

4. Brug J, van Stralen MM, Te Velde SJ, et al. Differences in weight status and energy-balance related behaviors among schoolchildren across Europe: the ENERGY-project. *PLoS One* 2012;7(4):e34742. doi: 10.1371/journal.pone.0034742. [Published Online First: 25 April 2012]

5. Martos-Moreno GA, Argente J. Paediatric obesities: from childhood to adolescence. *An Pediatr (Barc)* 2011;75(1):63e1-23. doi:10.1016/j.anpedi.2011.03.018. [Published Online First: 23 May 2011]

6. Manco M, Dallapiccola B. Genetics of pediatric obesity. *Pediatrics* 2012;130(1):123-133. doi:10.1542/peds.2011-2717. [Published Online First: 4 June 2012]

7. Vos MB, Welsh J. Childhood obesity: update on predisposing factors and prevention strategies. *Curr Gastroenterol Rep* 2010;12(4):280-287. doi:10.1007/s11894-010-0116-1.

8. The Organisation for Economic Co-operation and Development (OECD): Obesity Update 2012. [http://www.oecd.org/health/49716427.pdf]

9. Van Cauwenberghe E, Maes L, Spittaels H. Effectiveness of school-based interventions in Europe to promote healthy nutrition in children and adolescents: systematic review of published and 'grey' literature. *Br J Nutr* 2010;103(6):781-797. doi:10.1017/S0007114509993370. [Published Online First: 14 January 2010]

10. Reinehr T, Wabitsch M. Childhood obesity. *Curr Opin Lipidol* 2011;22:21-5.

11. Guia de práctica clínica (GPC). *AATRM* 2007.

12. Verbestel V, De Henauw S, Maes L, et al. Using the intervention mapping protocol to develop a community-based intervention for the prevention of childhood obesity in a multi-

centre European project: the IDEFICS intervention. *Int J Behav Nutr Phys Act* 2011;8:82. doi:10.1186/1479-5868-8-82.

13. De Bourdeaudhuij I, Van Cauwenberghe E, Spittaels H, et al. School-based interventions promoting both physical activity and healthy eating in Europe: a systematic review within the HOPE project. *Obes Rev* 2011;12(3):205-216. doi:10.1111/j.1467-789X.2009.00711.x.

14. Papandreou D, Malindretos P, Rousso I. Risk factors for childhood obesity in a Greek paediatric population. *Public Health Nutr* 2010;13(10):1535-1539. doi:10.1017/S1368980009993156. [Published Online First: 15 January 2010]

15. Giralt M, Albaladejo R, Tarro L, et al. A primary-school-based study to reduce prevalence of childhood obesity in Catalunya (Spain)--EDAL-Educacio en alimentacio: study protocol for a randomised controlled trial. *Trials* 2011;12:54-62. doi:10.1186/1745-6215-12-54.

16. Tarro L, Llauradó E, Albaladejo R, et al. A primary-school-based study to reduce the prevalence of childhood obesity – The EdAl (Educació en Alimentació) study: a randomized controlled trial. *Trials* 2014;15:58. doi:10.1186/1745-6215-15-58.

17. Boutron I, Moher D, Altman DG, et al. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med* 2008, 148(4):295-309.

18. Danielzik S, Pust S, Muller MJ. School-based interventions to prevent overweight and obesity in prepubertal children: process and 4-years outcome evaluation of the Kiel Obesity Prevention Study (KOPS). *Acta Paediatr Suppl* 2007;96(454):19-25.

19. Gidding SS, Dennison BA, Birch LL, et al. Dietary recommendations for children and adolescents: a guide for practitioners: consensus statement from the American Heart Association. *Circulation* 2006;113(Suppl 23):e857.

20. Cole TJ, Bellizzi MC, Flegal KM, et al. Establishing a standard definition for child overweight and obesity worldwide: international survey. *BMJ* 2000;320(7244):1240-1243.

21. Cole TJ, Flegal KM, Nicholls D, et al. Body mass index cut offs to define thinness in children and adolescents: international survey. *BMJ* 2007, 335(7612):194. [Published Online First: 25 June 2007]

22. World Health Organization. Growth Reference data for 5-19 years. 2007. [http://www.who.int/growthref/en/.] Date accessed: 05/03/2014

23. Serra Majem L, Ribas Barba L, Aranceta Bartrina J, et al. Childhood and adolescent obesity in Spain. Results of EnKid study (1998-2000). *Med Clin (Barc)* 2003;12:725-732.

24. Llargues E, Franco R, Recasens A, et al. Assessment of a school-based intervention in eating habits and physical activity in school children: the AVall study. *J Epidemiol Community Health* 2011;65(10):896-901. doi:10.1136/jech.2009.102319. [Published Online First: 12 March 2011]

25. Tarro L, Llauradó E, Moriña D, et al. Five-year follow-up of a healthy lifestyle education program (the EdAl study): Two years post-cessation of intervention. (Manuscript under review)

26. Brown T, Summerbell C. Systematic review of school-based interventions that focus on changing dietary intake and physical activity levels to prevent childhood obesity: an update to the obesity guidance produced by the National Institute for Health and Clinical Excellence. *Obes Rev* 2009;10(1):110-41. doi:10.1111/j.1467-789X.2008.00515.x. [Published Online First: 30 July 2008]

27. Te Velde SJ, Brug J, Wind M, et al. Effects of a comprehensive fruit- and vegetable-promoting school-based intervention in three European countries: the Pro Children Study. *Br J Nutr* 2008;99(4):893-903. [Published Online First: 22 October 2007]

28. Pérez-Farinós N, López-Sobaler AM, Dal Re MA, et al. The ALADINO Study: A National Study of Prevalence of Overweight and Obesity in Spanish Children in 2011. *Biomed Res Int* 2013;2013:163687. doi: 10.1155/2013/163687. [Published Online First: 8 September 2013]

29. Nurul-Fadhilah A, Sze Teo P, Huybrechts I, et al. Infrequent breakfast Consumption is associated with higher Body Mass Adiposity and Abdominal Obesity in Malaysian School-Aged adolescents. *PLoS One* 2013;8(3):e59297. doi: 10.1371/journal.pone.0059297. [Published Online First: 8 March 2013]

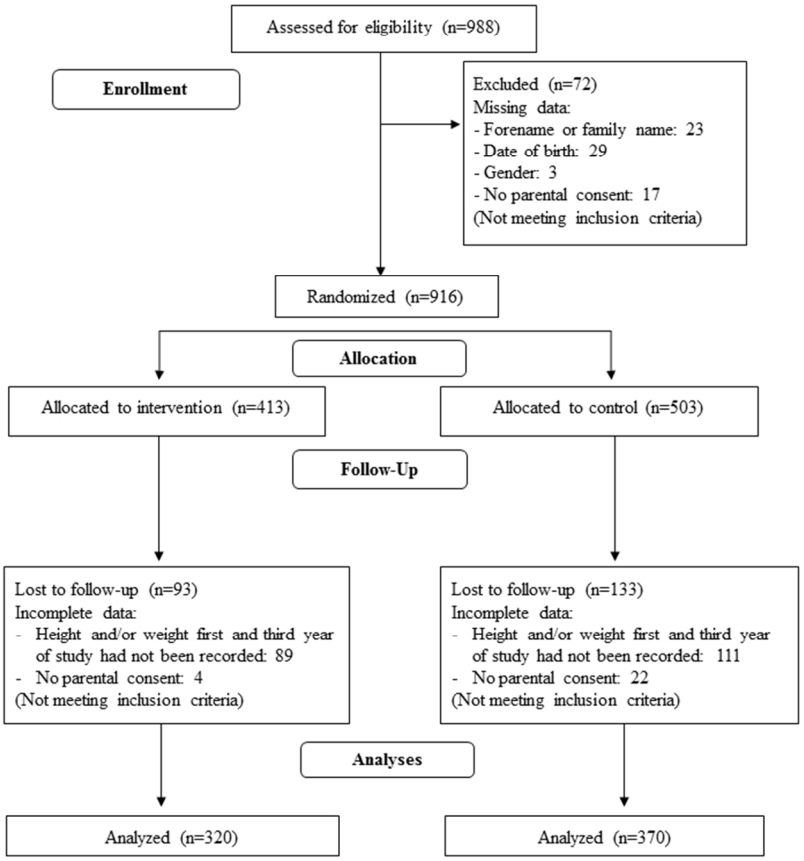
30. Ochoa MC, Moreno-Aliaga MJ, Martinez-Gonzalez MA, et al. Predictor factors for childhood obesity in a Spanish case-control study. *Nutrition* 2007;23(5):379-384. [Published Online First: 3 April 2007]

FIGURE LEGENDS

Figure 1: Flow of subjects through the study.

Incomplete height and/or weight (measures of first and/or third academic year)

No parental consent signed (first, second or third academic year).



190x275mm (96 x 96 DPI)

"Research Checklist"

CONSORT 2010 checklist of information to include when reporting a randomised trial*

EdAl-2 (*Educació en Alimentació*) program: reproducibility of a randomized, interventional, primary-school-based study to induce healthier lifestyle activities in children

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title (abstract)	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio **(described in Giralt M, Albaladejo R, Tarro L, Moriña D, Arija V, Solà R. A primary-school-based study to reduce prevalence of childhood obesity in Catalunya (Spain) – EDAL- Educació en Alimentació: Study protocol for a randomized controlled trial. Trials 2011;12:54.)**	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	-
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:		**described in Trials 2011**	
Sequence	8a	Method used to generate the random allocation sequence	7
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	7

"Research Checklist"

concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	-
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9-10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1 and page 9
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1 and tables
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results (page 10-17) Tables
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Figure 1
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	17-19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	17-19

"Research Checklist"

Other information			
Registration	23	Registration number and name of trial registry	Clinical Trials registration NCT01362023
Protocol	24	Where the full trial protocol can be accessed, if available	Trials 2011
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19-20

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

EdAl-2 (Educació en Alimentació) programme: reproducibility of a randomised, interventional, primary-school-based study to induce healthier lifestyle activities in children

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EdAl-2 (*Educació en Alimentació*) programme: reproducibility of a randomised, interventional, primary-school-based study to induce healthier lifestyle activities in children

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Keywords: feasibility, reproducibility, childhood obesity, physical activity, school-based intervention

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ABSTRACT

Objectives: To assess the reproducibility of the EdAl programme in "Terres de l'Ebre" (Spain), EdAL-2, an educational intervention over a period of 22 months, to improve lifestyles, including diet and physical activity recommendations

Design*:* Reproduction of a randomised controlled trial

Setting: Primary schools, two school clusters were randomly assigned to intervention or control group

Participants: Pupils (n=690; intervention group n=320; control group n= 370) 78% of Western European ethnicity. Mean age (±SD) was 8.04±0.6 years (47.7% females) at baseline. Inclusion criteria were name, gender, date and place of birth, and written informed consent from the parent or guardian.

Intervention: The interventions focused on 8 lifestyle topics covered in 12 activities (1h/activity/session) implemented by health promoting agents (HPAs) in the primary-school over 3 school academic years.

Primary and secondary outcomes: the primary outcome was obesity prevalence and the secondary outcomes were body mass index (BMI) collected every year, and dietary habits and lifestyles collected by questionnaires filled-in by the parents at baseline and end-of-study.

Results: At 22 months, the percentage of boys in the intervention group who performed ≥4h after-school PA h/week was 15% higher (p=0.027), while there was 16.6% more boys in the intervention group watching ≤2hTV/day (p=0.009), compared to controls. The obesity prevalence was similar in intervention and control groups over the period of the program. Multivariate statistical analysis indicated that the performance of ≥4 after-school PA h/week was a protective factor against childhood OB (OR:0.600; p=0.032).

Conclusions: Our school-based intervention is feasible, adaptable to quite different

school environments, and reproducible. The main improvement was after-school PA (≥4h/week) in boys. Further, TV watching decreased to <2 TV h/day. This suggests that our intervention programme induces healthy lifestyle effects (such as more exercise and less sedentary behaviour) which can produce anti-obesity benefits in children.

Words: 294/300

Clinical Trials registration NCT01362023

ARTICLE SUMMARY

Strengths and limitations of the study

- Strengths: Reproducibility of studies is rare because of the complexity of replicating a programme. Studies in OB prevention, such as EdAl, need to be reproducible, especially those improving healthy lifestyle, including after-school PA, to reinforce beneficial practices in childhood
- Strengths: Statistical methods controlling for confounders and taking into account clustering of data
- Limitations: Failure to assess treatment adherence to evaluate reproducibility and feasibility
- Limitations: Dietary habits were noted via a questionnaire that did not take into account the quantities of the different types of food items consumed

BACKGROUND

Obesity (OB) has become a disease of epidemic proportions,[1]. However, this increasing tendency towards excess weight in childhood and adulthood,[2] observed in some countries (United Kingdom, France, South Korea, United States and Spain) has stabilised despite the absolute rates being a cause for concern,[1]. OB prevalence in children and adolescents is higher in southern regions of Europe,[3-4].

Accumulation of fat tissue in childhood constitutes an increased disease risk in childhood, as well as in adulthood,[5]. This disease risk has a multifactorial aetiology, such as an unhealthy diet and sedentary lifestyle,[6-7].

The Organization for Economic Co-operation and Development (OECD), has predicted an increase of 7% in excess weight prevalence in adulthood over the period spanning 2010 to 2020,[8]. The WHO proposes the prevention and control of OB prevalence as key in the updated "Action Plan 2008-2013" in which effective health promotion is considered the principal strategy,[9].

Since excess weight status in adulthood is almost invariably predicated on childhood and adolescent weight, OB prevention should start early in life,[10]. The optimum age to commence an intervention is between the ages of 7 and 8 years because children are more receptive to guidance,[11]. The school is an ideal place for the promotion of healthy nutrition and lifestyle habits,[12] and, as some studies have shown, such interventions have inspired changes in nutritional habits and BMI status,[13-14]; the message being received by all schoolchildren, irrespective of ethnic and socioeconomic differences,[9]. The effectiveness of an intervention is when educational strategies and environmental factors such as healthy nutrition and physical activity habits coincide since both aspects are essential in preventing childhood OB,[15]. Currently, European children spend more of their leisure time in sedentary activities such as watching

television (TV), video games or on the Internet. These activities represent a decrease in physical movement and lowering energy expenditure and, as such, are risk factors for OB,[16].

We had designed the EdAl (*Educació en Alimentació*) programme as a randomised, controlled, parallel study applied in primary schools, and implemented by university students acting as Health Promoter Agents (HPAs),[17]. This intervention was deployed in Reus (as intervention group) with the neighbouring towns of Salou, Cambrils and Vilaseca as control group. The interventions focused on 8 lifestyle topics covered in 12 activities (1h/activity/session) in 7-8 year old children, and implemented by HPAs over 3 school academic years. We found that the EdAl programme successfully reduced childhood OB prevalence in boys by 4.39% and increased the percentage of boys who practice ≥5 after-school physical activity (PA) h/week,[18]. The EdAl programme needed to be reproduced in other localities, and with other children, to demonstrate the effectiveness of this intervention[19].

The outcomes of the EdAl programme supported the feasibility of improving PA in childhood. However, an educational intervention, such as our EdAl program implemented by HPAs, also tests complex components such as healthy lifestyles including diet and physical activity recommendations. Due to the complexity, such interventions are difficult to rationalise, standardise, reproduce, and administer consistently to all participants,[19].

There has been one study in the literature that has reproduced its programmes in other locations. Described as the Kiel Obesity Prevention Study (KOPS), the results demonstrated the efficacy and feasibility of implementing new nutritional concepts,[20].

We tested the reproducibility of the EdAl programme in a geographical area (Terres de l'Ebre) about 80km away from where the original EdAl programme was designed and

implemented. We describe, here, the primary-school-based study to reduce the prevalence of childhood OB (The EdAl-2 study); the objective remains an intervention to induce healthy lifestyles, including diet and physical activity recommendations. The study was conducted in 7-8 year old school-children over 3 academic years (22 months active school time).

METHODS

The original protocol, rationale, randomisation, techniques and results of the initial EdAl programme have been published in Trials,[17-18]. The current study (EdAl-2) was conducted in exactly the same way so as to assess whether comparable results could be achieved in a different location. The EdAl-2 study was approved by the Clinical Research Ethical Committee of the *Hospital Sant Joan of Reus, Universitat Rovira i Virgili* (Catalan ethical committee registry ref 11-04-28/4proj8). This study was registered in Clinical Trials *NCT01362023*. The protocol conformed to the Helsinki Declaration and Good Clinical Practice guides of the International Conference of Harmonization (ICHGCP). The study followed the CONSORT criteria [see Additional file 1].

For logistics reasons, the EdAl-2 program was reduced by 6 months, from 28 months to 22 months.

Study population

The coordinating Center (in Reus) developed a cluster randomisation scheme to have a study sample in which the schools in Amposta were designated as Group A (intervention) and 9 towns around Amposta (Sant Jaume d'Enveja, Els Muntells,

l'Ametlla de Mar, El Perelló, l'Ampolla, Deltebre, l'Aldea, Lligalló del Gànguil and Camarles) as Group B (control).

The socio-demographic indicators in all towns were similar to that of the original EdAl Program in Reus. Children attending the schools in both groups (intervention and control) lived in close proximity within each school's catchment area. Intervention institutions were 5 schools involving 18 classrooms and 457 pupils in Amposta. Control institutions consisted of 11 schools involving 23 classrooms and 531 pupils in the 9 towns of around Amposta. Children of this study are in the 2nd and 3rd grade of primary education (7-8 year olds). Schoolchildren were enrolled in May 2011 (children born in 2002–2003) and followed-up for 3 school academic years (2012–2013). The study was completed in March 2013.

To be representative of the child population, the schools selected needed to have at least 50% of the children in the classrooms volunteer to participate. We offered the programme to all schools, whether public (funded by the government and termed "charter" schools) or private which included fee-paying and/or faith schools. Inclusion criteria were: name, gender, date and place of birth, and written informed consent from the parent or guardian. A questionnaire on eating habits (Krece Plus) developed by Serra Majem et al,[21], and physical activity, level of parental education and lifestyles developed by Llargues et al,[22] were filled-in by the parents at baseline and at the end of the study.

Intervention program

The original EdAl Reus protocol was followed,[17-18]. The educational intervention activities focused on eight lifestyle topics based on scientific evidence,[23] to improve nutritional food item choices (and avoidance of some foods), healthy habits such as

teeth-brushing and hand-washing and, overall, adoption of activities that encourage physical activity (walking to school, playground games), and to avoid sedentary behaviour,[23].

Each of the eight topics was integrated within educational intervention activities of 1h/activity, prepared and standardized by the HPAs, and implemented in the children's classrooms. In the first school academic year, we focused on four topics: 1) to improve healthy lifestyle; 2) to encourage healthy drinks intake (and avoidance of unhealthy carbonated/sweetened beverages); 3) to increase the consumption of vegetables and legumes; and 4) to decrease the consumption of candies and pastries while increasing the intake of fresh fruits and nuts. These corresponded to four standardised activities (1h/activity). In the second year, the remaining four of the eight selected lifestyle topics were addressed: 5) to improve healthy habits within a set timetable (home meals, teeth-brushing, hand-washing) and physical activity participation; 6) to increase fruit intake; 7) to improve dairy product consumption; and 8) to increase fish consumption. These corresponded to four standardised activities. Finally, in the third school academic year, four standardised activities were introduced that reinforced the eight lifestyle topics implemented in the previous 2 academic years. Thus, the intervention program was based on eight lifestyle topics incorporated within 12 activities which were disseminated over 12 sessions (1h/activity/session), and prepared, standardised and implemented as four activities per school academic year by the HPAs in the school classrooms.

Process evaluation

The measurements were performed in each school academic year, as was the original EdAl program,[17-18].

Outcomes

Assessment of the reproducibility of the EdAl program was based on primary outcomes such as prevalence of OB (overall as well as stratified by gender), according to the International Obesity Task Force (IOTF),[24] recommendations for better international comparisons of data. Secondary outcomes included: changes in measures of adiposity (overall as well as stratified by gender) such as BMI z-score (based on WHO growth charts,[25] and waist circumference, incidence and remission of excess weight (OW and OB), as well as changes in lifestyles (eating habits and physical activity h/week). Weight, height, and waist circumference values were obtained as described previously,[17]. Prevalence of underweight was analysed according to Cole et al,[26] using 17Kg/m^2 as cut-off point. BMI z-score was calculated using the population values of the WHO Global InfoBase,[25]. To identify the risk factors of OB, the OB category was determined according to WHO criteria since this is based on data from countries that have a low OB prevalence,[25] and, as such, provide an understanding of the protective (or risk factors) for OB in our own population. To obtain a measurement of overall improvement in lifestyle we generated variables such as the maintenance of status in each category as well as the status in relation to changes in each category over the 22 month period.

Sample size

We calculated that, with a sample of more than 300 pupils per group, the study would have 85% power to detect a difference of 5 percentage points between the intervention and control schools in relation to the primary outcome (prevalence of OB).

Statistical analyses

Descriptive variables were presented as means and confidence intervals (95%CI). General linear mixed models (GLM) were used to analyse differences between the intervention and control pupils with respect to prevalence of OB. Repeated measures of GLM were used to analyse the trend of BMI z-score between baseline and end-of-study values. The McNemar test was used to analyse change-over-time of food habits, after-school PA h/week and hours TV/day categories, in intervention and control group. The continuous variables studied in each group were compared using ANOVA.

To evaluate risk and protective factors involved in childhood OB, logistic regression analyses were performed at baseline, with no distinction between intervention and control group. The odds ratios (OR) and 95%CI were calculated for dietary patterns and lifestyles, based on the Krece Plus Questionnaire,[21] and the AVall Questionnaire,[22], respectively.

The main analyses were performed with the modified intention-to-treat (mITT) population i.e. subjects with baseline and end-of-study data on weight, height, and date of birth, and written inform consent. The analyses did not use any imputation missing method; the assumption being that missing data were random. Statistical significance was defined by a $P<0.05$. The statistical analyses were performed with the SPSS 20.0 for Windows (SPSS Inc., Chicago, IL, USA).

RESULTS

Enrolment

Figure 1 shows the recruitment and flow diagram of pupils in the intervention and control groups over the course of the study. The mITT population in the intervention group and control group were 320 and 370 pupils, respectively. At 22 months, the mean

age was 9.67 (95%CI: 9.60, 9.73) in the intervention group (9.68 years in boys and 9.65 years in girls) and 9.86 (95%CI: 9.79, 9.91) in the control group (9.85 years in boys and 9.84 years in girls). The differences in age were not significant in relation to gender. The characteristics of the study group are summarised in Table 1. At baseline, the intervention and control group were homogeneous in BMI status. The ethnicity of the population was predominantly Western European in intervention and control group (77.5% *vs.* 78.9%, respectively) while 7.5% *vs.* 10.8% was Eastern European; 10.3% *vs.* 3.5% was Latin American; 3.4% *vs.* 6.2% was North African Arab. At baseline, there was a significant difference in the distribution with respect to Latin American children (10.3% in intervention and 3.5% in control group; $p<0.001$). The distribution was random. Of note is that there were no significant differences in distributions of OB and/or OW. Also, no differences were observed in terms of response to the intervention in relation to ethnicity.

Table 1. Anthropometric characteristics of pupils at baseline: Intervention *versus* Control group

	Intervention group			Control group					
	Mean (95%CI)			Mean (95%CI)			Intervention *vs.* control; P-value	Intervention *vs.* control; P-value	Intervention *vs.* control; P-value
	Boys (n=165)	Girls (n=155)	Total (n=320)	Boys (n=196)	Girls (n=174)	Total (n=370)	Boys	Girls	Total
Age; years	8.01 (7.91;8.12)	7.97 (7.88;8.07)	7.99 (7.92;8.06)	8.11 (8.03;8.19)	8.06 (7.97;8.15)	8.09 (8.03;8.15)	0.105	0.153	0.967
Weight; Kg	30.35 (29.22; 31.48)	29.86 (28.81; 30.91)	30.11 (29.34; 30.88)	31.29 (30.26; 32.33)	31.35 (30.36; 32.34)	31.32 (30.60; 32.04)	0.226	0.043	0.024
BMI; Kg/m^2	17.40 (16.93; 17.86)	17.42 (16.97; 17.88)	17.41 (17.09; 17.73)	17.70 (17.28; 18.13)	17.94 (17.51; 18.37)	17.82 (17.51; 18.12)	0.340	0.104	0.073
Height; m	1.32 (1.30; 1.33)	1.30 (1.29; 1.31)	1.31 (1.30; 1.32)	1.32 (1.31; 1.33)	1.32 (1.31; 1.33)	1.32 (1.31; 1.33)	0.242	0.045	0.027
Fat mass; Kg	6.71 (5.99; 7.42)	7.11 (6.50; 7.72)	6.90 (6.42; 7.38)	6.44 (5.78; 7.09)	7.70 (7.12; 8.27)	7.03 (6.59; 7.47)	0.584	0.167	0.698
Lean mass; Kg	23.99 (23.34; 24.64)	22.86 (22.32; 23.39)	23.44 (23.02; 23.87)	24.88 (24.28; 25.47)	23.71 (23.21; 24.22)	24.33 (23.93; 24.73)	0.049	0.022	0.003
Waist circumference; cm	60.97 (59.68; 62.27)	59.91 (58.67; 61.15)	60.46 (59.56; 61.36)	64.37 (63.18; 65.56)	65.17 (64.00; 66.34)	64.75 (63.91; 65.58)	<0.001	<0.001	<0.001

Notes to Table 1:

The results are expressed as Mean (95%CI)

[1]p value: general linear model (GLM) statistic

Attrition rate

Figure 1 shows the recruitment and retention of pupils in intervention and control schools. Among the 916 pupils assessed at the beginning of the study, 690 (75.3%) pupils (73.6% of those allocated to the control group and 77.5% of those allocated to the intervention group) were reassessed three academic courses later, and valid measurements were obtained. The rate of parental consent was 95.7%. Drop-outs in both groups are assumed to be missing at random.

Primary outcome: Prevalence of OB

At 22 months of the study, OB prevalence assessed by IOTF criteria, was similar in intervention and control group (p=0.628) (Table 2).

Criteria/Category		Group		Baseline % (n)	End of study % (n)	Change %	Baseline to study end P-value[1]	Intervention vs. Control P-value[2]
IOTF criteria	OW	Intervention	Boys	18.2 (30)	24.2 (40)	6	0.087	0.629
			Girls	16.2 (25)	23.2 (36)	7	0.043	0.066
			Total	17.2 (55)	23.8 (76)	6.6	0.005	0.086
		Control	Boys	25.5 (50)	27.0 (53)	1.5	0.690	
			Girls	28.2 (49)	32.8 (57)	4.6	0.185	
			Total	26.8 (99)	29.7 (110)	2.9	0.169	
	OB	Intervention	Boys	9.7 (16)	11.5 (19)	-1.8	0.453	0.735
			Girls	13.6 (21)	12.3 (19)	-1.3	0.754	0.732
			Total	11.6 (37)	11.9 (38)	0.3	1.000	0.628
		Control	Boys	10.7 (21)	10.2 (20)	-0.5	1.000	
			Girls	12.1 (21)	10.9 (19)	-1.2	0.687	
			Total	11.4 (42)	10.5 (39)	-0.93	0.607	

Table 2. Baseline and end-of-intervention measurements of categorised BMI in Intervention and Control group

Notes to Table 2

IOTF: International Obesity Task Force

The results are expressed as % (n)

[1]p value: McNemar's Test

[2]p value: Fisher's Exact Test

Secondary outcomes

At 22 months of the study, the status of OW prevalence (according to IOTF criteria) was similar between groups (p=0.086).

There were no significant differences in BMI z-score between intervention and control group (p=0.400) (Table 3). Despite no differences in BMI z-score, the boys of intervention group did not have an increase in percentage fat mass (19.96% to 20.02%: p=0.896), whereas intervention girls (22.06% to 23.55%; p<0.001), together with boys (19.18% to 20.64%, p<0.001) and girls (23.26% to 24.98%) of control group had a significant increase.

The remission, and incidence, of OB was similar in the overall intervention and control group, as well as when stratified with respect to gender.

Table 3. BMI z-score at baseline and at the end of intervention in Intervention and Control group

			Baseline Mean (95%CI)	End of study Mean (95%CI)	Change Mean (95%CI)	Baseline to Study end P-value[1]	Intervention *vs.* Control P-value[2]
BMI z-score	Intervention	Boys	0.73 (0.53; 0.94)	0.74 (0.54; 0.93)	0.00 (-0.07; 0.08)	0.973	0.381
		Girls	0.71 (0.50; 0.91)	0.89 (0.68; 1.10)	0.18 (0.10; 0.26)	<0.001	0.030
		Total	0.72 (0.58; 0.86)	0.81 (0.67; 0.95)	0.09 (0.03; 0.14)	0.002	0.400
	Control	Boys	0.83 (0.64; 1.01)	0.81 (0.63; 1.00)	-0.12 (-0.08; 0.06)	0.726	
		Girls	0.52 (0.33; 0.71)	0.63 (0.44; 0.83)	0.11 (0.02; 0.20)	0.013	
		Total	0.68 (0.55; 0.82)	0.73 (0.60; 0.86)	0.05 (-0.01; 0.10)	0.100	

Notes to Table 3:

[1]p-value: Mixed Models Repeated Measures

[2]p-value: ANOVA model

Differences between intervention and control pre- *vs.* post-intervention

Lifestyles evaluation

After 22 months of the study, there were 19.7%, 11.2% and 8.2% more girls in the intervention group who consumed a second fruit per day, one vegetable per day and fast-food weekly than the girls of control group ($p<0.001$, $p=0.017$ and $p=0.013$; respectively). However, there were 17.9% and 17.8% more boys in the intervention group who consumed pastry at breakfast and more than one vegetable a day, compared to boys of control group ($p=0.002$, $p= 0.001$; respectively). Conversely, there were 12.9% and 12.2% more girls in the control group who consumed legumes and cereal breakfast than girls of intervention group ($p=0.013$, $p=0.032$; respectively) (Table 4).

297 **Table 4.** Foods habits assessed at baseline and at the end of the study in the Intervention and

298 Control groups

		Intervention group			Control group			Intervention *vs.* Control
		Baseline %(n)	End of study %(n)	P Value	Baseline %(n)	End of study %(n)	P Value	P-value
Krece plus questionnaire								
Breakfast	Boys	98.4 (125)	98.3 (119)	1	97.5 (154)	92.2 (153)	0.092	0.635
	Girls	98.4 (123)	99.2 (120)	1	98.7 (148)	93.8 (135)	**0.016**	0.453
	Total	98.4 (248)	98.8 (239)	1	98.1 (302)	92.9 (288)	**0.003**	1
Dairy product	Boys	94.5 (121)	93.5 (116)	1	93.6 (147)	92.3 (155)	1	1
at breakfast	Girls	94.3 (116)	93.4 (113)	0.508	94.0 (141)	89.7 (131)	**0.039**	0.325
	Total	94.4 (237)	93.5 (229)	0.481	93.8 (288)	91.1 (286)	0.167	0.574
Cereals at	Boys	65.6 (82)	66.4 (81)	0.864	59.1 (88)	54.6 (89)	0.743	0.706
breakfast	Girls	61.5 (75)	49.6 (58)	**0.036**	59.7 (86)	60.0 (87)	0.880	**0.031**
	Total	63.6 (157)	58.2 (139)	0.098	59.4 (174)	57.1 (176)	1	0.225
Pastry at	Boys	15.8 (19)	23.5 (28)	**0.027**	22.5 (33)	12.3 (20)	**0.001**	**0.002**
breakfast	Girls	20.5 (24)	15.5 (18)	0.383	15.9 (22)	12.4 (18)	0.210	0.260
	Total	18.1 (43)	19.6 (46)	0.441	19.1 (55)	12.3 (38)	**<0.001**	**0.002**
Daily fruit or	Boys	73.4 (94)	76.2 (93)	0.523	74.8 (116)	76.0 (127)	1	0.535
natural juice	Girls	66.7 (82)	70.0 (84)	0.690	79.9 (119)	73.5 (108)	0.243	0.549
	Total	70.1 (176)	13.1 (177)	0.382	77.3 (235)	74.8 (235)	0.443	0.472
Fruit, 2nd per	Boys	39.7 (50)	41.2 (49)	0.581	44.5 (69)	34.1 (56)	**0.006**	0.141
day	Girls	26.4 (32)	47.5 (56)	**0.000**	44.8 (64)	39.0 (57)	0.281	**<0.001**
	Total	33.2 (82)	44.3 (105)	**0.001**	44.6 (133)	36.5 (113)	**0.004**	**<0.001**
Dairy product,	Boys	87.2 (109)	78.5 (95)	**0.029**	80.0 (124)	69.5 (116)	0.174	0.194
2nd per day	Girls	80.5 (99)	79.8 (95)	1	71.6 (106)	75.5 (111)	0.749	0.460
	Total	83.9 (208)	79.2 (190)	0.161	75.9 (230)	72.3 (227)	0.51	0.384
Vegetables,	Boys	65.6 (84)	74.4 (90)	**0.043**	71.1 (113)	70.8 (119)	1	0.473
daily	Girls	71.7 (86)	77.5 (93)	0.169	68.7 (101)	63.3 (93)	0.152	**0.017**
	Total	68.5 (170)	75.9 (183)	**0.011**	69.9 (214)	67.3 (212)	0.374	**0.028**
Vegetables, >1	Boys	19.3 (23)	29.1 (34)	**0.017**	28.7 (43)	20.7 (34)	**0.009**	**0.001**
per day	Girls	25.4 (31)	34.5 (40)	0.052	30.3 (43)	23.1 (33)	0.110	0.149
	Total	22.4 (54)	31.8 (74)	**0.001**	29.5 (86)	21.8 (67)	**0.002**	**0.001**
Fish, regularly	Boys	73.2 (93)	76.6 (95)	0.608	70.0 (112)	70.1 (115)	0.851	0.058

	Girls	71.8 (92)	71.4 (85)	0.307	74.5 (111)	71.0 (103)	1	0.662
	Total	74 (185)	74.1 (180)	0.896	72.2 (223)	70.6 (218)	0.791	0.312
Fast food, >1	Boys	6.3 (8)	7.4 (9)	1	7.1 (11)	4.9 (8)	0.227	0.106
per week	Girls	3.3 (4)	10.1 (12)	0.109	4.2 (6)	2.8 (4)	0.219	**0.013**
	Total	4.8 (12)	8.8 (21)	0.21	5.7 (17)	3.9 (12)	**0.049**	**0.003**
Legumes >1	Boys	70.3 (90)	71.1 (86)	0.648	67.5 (106)	65.9 (110)	1	0.555
per week	Girls	72.8 (91)	73.3 (88)	0.815	62.8 (145)	76.2 (112)	**0.001**	**0.013**
	Total	71.5 (181)	72.2 (174)	1	65.2 (251)	70.7 (222)	**0.025**	**0.027**
Candy > per	Boys	14.3 (18)	12.6 (15)	1	17.2 (27)	18.2 (30)	1	0.367
day	Girls	12.9 (16)	12.0 (14)	1	18.7 (26)	11.1 (16)	0.078	1
	Total	13.6 (34)	12.3 (29)	1	17.9 (53)	14.9 (46)	0.262	0.479
Pasta or rice	Boys	63.8 (81)	67.5 (83)	0.839	69.0 (109)	67.9 (114)	0.871	0.708
daily	Girls	59.2 (74)	64.7 (77)	0.377	68.0 (100)	69.4 (102)	0.618	0.724
	Total	61.5 (155)	66.1 ()	0.35	68.5 (209)	68.6 (216)	0.561	1
Cooking with	Boys	97.7 (126)	98.4 (122)	1	98.1 (157)	98.8 (167)	1	0.636
olive oil at	Girls	98.4 (125)	99.2 (120)	0.623	97.3 (145)	98.0 (145)	1	0.628
home	Total	98 (251)	98.8 (242)	0.5	97.7 (302)	98.4 (312)	0.754	0.476
Avall questionnaire								
Before leaving home								
Dairy	Boys	90 (117)	87.3 (110)	0.065	83.6 (133)	95.3 (139)	1	0.074
products	Girls	87.3 (110)	87.8 (108)	0.503	83 (122)	76.4 (110)	**0.004**	0.235
	Total	90.9 (227)	87.6 (218)	0.071	86.2 (255)	81.1 (249)	**0.044**	0.836
Pastry	Boys	4 (5)	2.4 (3)	1	0.7 (1)	1.4 (2)	1	0.610
	Girls	0.8 (1)	1. 7 (2)	1	0.7 (1)	0 (0)	1	1
	Total	2.5 (6)	2 (5)	1	0.7 (2)	0.7 (2)	1	0.606
Cereals	Boys	33.9 (43)	36.8 (46)	0.711	30.7 (46)	35.0 (55)	0.608	1
	Girls	32.2 (38)	26.2 (32)	0.405	25.2 (37)	26.2 (37)	0.458	0.297
	Total	33.1 (81)	31.6 (78)	0.89	27.9 (83)	30.9 (92)	0.314	0.409
Fresh fruit	Boys	18.4 (23)	24.6 (31)	0.189	17.0 (26)	21.2 (32)	1	0.537
or natural	Girls	14.2 (17)	24.6 (30)	0.064	18.5 (27)	23.6 (33)	0.541	0.332
juice	Total	16.3 (40)	24.6 (61)	**0.016**	17.7 (53)	22.3 (65)	0.560	0.256
	Boys	6.6 (8)	17.7 (22)	0.115	17.3 (26)	21.1 (32)	0.458	1
	Girls	0.3 (12)	19.7 (24)	**0.049**	14.9 (21)	18.4 (26)	0.572	1
Sandwich	Total	8.4 (20)	18.7 (46)	**0.008**	16.2 (47)	19.8 (58)	0.289	0.889
Juice	Boys	6.7 (8)	7.4 (9)	0.754	8.7 (13)	7.1 (11)	1	0.756
package/sof	Girls	7.7 (9)	5.0 (6)	0.508	8.6 (12)	10.8 (15)	1	0.507

t drinks								
	Total	7.2 (17)	6.2 (15)	0.359	8.6 (25)	8.9 (26)	0.845	0.483
Break (Midmorning)								
Dairy	Boys	16.0 (20)	20.0 (24)	0.824	15.3 (22)	14.4 (21)	1	0.819
products	Girls	8.7 (10)	9.6 (11)	0.388	10.7 (15)	8.4 (11)	1	0.595
	Total	12.5 (30)	15 (35)	0.367	13.0 (37)	11.6 (32)	1	0.488
Pastry	Boys	4.1 (5)	0.8 (1)	0.625	4.1 (6)	2.1 (3)	1	1
	Girls	0.9 (1)	0.9 (1)	1	1.5 (2)	2.3 (3)	1	0.480
	Total	2.5 (6)	0.9 (2)	0.687	2.8 (8)	2.2 (6)	0.687	1
Cereals	Boys	3.3 (4)	5.9 (7)	0.727	5.7 (8)	4.9 (7)	1	1
	Girls	3.5 (4)	3.4 (4)	1	4.3 (6)	6.9 (9)	0.180	0.544
	Total	3.4 (8)	4.7 (11)	0.804	5 (14)	5.9 (16)	0.238	0.659
Fresh fruit or	Boys	16.3 (20)	10.1 (12)	0.804	19.5 (30)	14.5 (22)	0.189	0.787
natural juice	Girls	15.5 (18)	16.8 (20)	0.424	20.1 (29)	20.3 (28)	0.815	1
	Total	15.9 (38)	13.4 (32)	0.856	19.8 (59)	17.2 (50)	0.522	0.721
Sandwich	Boys	28.3 (36)	37.7 (46)	0.087	43.2 (67)	41.6 (67)	0.701	0.080
	Girls	24.8 (30)	33.6 (41)	0.064	29.7 (44)	41.1 (58)	**0.016**	0.860
	Total	26.6 (66)	35.7 (87)	**0.008**	36.6 (111)	41.4 (125)	0.185	0.299
Juice	Boys	7.4 (9)	9.1 (11)	0.344	12.2 (18)	12.6 (19)	1	1
package/soft	Girls	7.8 (9)	6.1 (7)	0.727	12.1 (17)	13.2 (18)	1	0.233
drinks	Total	7.6 (18)	7.7 (18)	0.815	12.2 (35)	12.9 (37)	1	0.543

Notes to Table 4:

[1]p-value: McNemar's Test (changes in intervention group)

[2]p-value: McNemar's Test (changes in control group)

[3]p-value: Fisher's Exact Test.

Table 5 summarises the time spent in after-school PA, watching TV, playing video games, and other leisure-time activities. At 22 months, the percentage of boys of the intervention group who performed ≥4h after-school PA/week was increased by 15% (p=0.027) while there was 16.6% more boys in the intervention group watching ≤2hTV/day (p<0.009). The results indicate less sedentary behaviour in intervention than control individuals.

Table 5. Lifestyles assessed at baseline and at the end of study in Intervention and Control

		Intervention			Control			Intervention vs. Control
		Baseline %(n)	End of study %(n)	p-value[1]	Baseline %(n)	End of study %(n)	P-value[2]	P-value[3]
TV and/or video games								
0-2h/day	Boys	49.2 (62)	45.2 (57)	0.268	32.5 (51)	27.0 (43)	0.627	0.71
	Girls	48.4 (60)	51.2 (63)	1	44.0 (66)	49.7 (71)	0.43	0.287
	Total	48.8 (122)	48.2 (120)	0.464	38.1 (117)	37.7 (114)	0.91	0.697
3-4h/day	Boys	46.0 (58)	50.0 (63)	0.542	62.4 (98)	63.5 (101)	1	0.874
	Girls	43.5 (54)	44.7 (55)	0.86	54.0 (81)	47.6 (68)	0.349	0.71
	Total	44.8 (112)	47.4 (118)	0.489	58.3 (179)	56.0 (169)	0.606	0.632
>4h/day	Boys	4.8 (6)	4.8 (6)	0.375	5.1 (8)	9.4 (15)	0.607	0.393
	Girls	8.1 (10)	4.1 (5)	0.453	2.0 (3)	2.8 (4)	1	1
	Total	6.4 (16)	4.4 (11)	1	3.6 (11)	6.3 (19)	0.481	0.462
After-school PA								
0-2h/week	Boys	26.2 (34)	14.5 (18)	0.013	21.5 (34)	19.0 (31)	0.286	0.354
	Girls	35.2 (43)	33.6 (41)	0.701	34.5 (50)	36.6 (52)	1	0.557
	Total	30.6 (77)	24.0 (59)	**0.049**	27.7 (84)	27.2 (83)	0.435	0.254
2-4h/week	Boys	29.2 (38)	24.2 (30)	0.418	38.0 (60)	3.1 (54)	0.78	0.602
	Girls	36.9 (45)	32.0 (39)	0.377	32.4 (47)	31.0 (44)	1	0.155
	Total	32.9 (83)	28.0 (69)	0.188	35.3 (107)	32.1 (98)	0.764	0.135

>4h/week	Boys	44.6 (58)	61.3 (76)	**0.006**	40.5 (64)	47.9 (78)	0.243	0.643	
	Girls	27.9 (34)	34.4 (42)	0.136	33.1 (48)	32.4 (46)	0.868	0.598	
	Total	36.5 (92)	48.0 (118)	**0.002**	37.0 (112)	40.7 (124)	0.272	0.485	

Notes to Table 5

[1]P-value: McNemar's Test (changes in intervention group)

[2]P-value: McNemar's Test (changes in control group)

[3]P-value: Fisher's Exact Test.

Differences between intervention and control pre-post intervention program

At 22 months, subjects who were normal weight at baseline increased after-school PA to ≥4h/week. This reflects a rise to 32.7% in boys (p=0.002). However, in girls, the changes were not statistically different (p=0.134). No statistically significant differences were observed in the control group.

Impact of certain additional factors on obesity

The ORs of OB, using BMI z-score criteria, were related to some of the more relevant dietary habits and lifestyles. Thus, breakfast dairy product consumption (OR: 0.336; p=0.004) and ≥4 after-school PA h/week (OR: 0.600; p=0.032) were protective factors against OB. Conversely, doing <4 h/week PA (OR: 1.811; p=0.018) increased the risk of childhood OB.

DISCUSSION

The EdAl-2 program, a reproducibility study in Terres de l'Ebre, shows that intervention is useful for improving weekly after-school PA. However, the OB prevalence remained unchanged at 22 months, as has been shown in the data on stability of OB prevalence observed in some European countries,[8]. Despite that OW and OB remained similar between groups, we observed percentage fat mass maintenance in the boys of the intervention group, whereas girls of the intervention and control group had increases.

As proposed by Kain J et al, designing a new school-based intervention study needs to have some critical aspects considered. These include: the random allocation of schools, although methodologically desirable, is not always possible; participation of parents is very limited; obesity is not recognised as a problem; and increasing physical activity

and implementing training programmes for teachers is difficult due to an inflexible curriculum and lack of teachers' time. Unless these barriers are overcome, obesity prevention programmes will not produce positive and lasting outcomes,[27]. As such, our programme of HPA-implemented intervention activities in classrooms is an attractive alternative that circumvents lack-of-teacher-time.

The EdAl-2 program confirmed that after-school PA (in terms of h/week) can be stimulated in primary school as part of a healthy lifestyle. As we had observed in the original EdAL program,[18] at 28 months of intervention, there was an increase of up to 19.7% of children dedicating >5 hours/week to extra-curricular physical activities,[18]. Further, the after-school PA was maintained despite cessation of the intervention program,[28]. The effect of EdAl program during its implementation and after the official cessation indicated an impact on PA, whereas modification towards healthy food choices occurred according to the site of the program's implementation, and was not consistent.

Interventions to prevent OB in the school setting have shown dramatic improvements,[29]. However, successful studies in OB prevention need to be reproducible, especially those improving healthy lifestyle such as after-school PA, to confirm best childhood practices.

Reproducibility of studies is rare because of the complexity of trying to replicate a programme. To standardise a method it is essential to be able to reproduce appropriate levels of an intervention, especially one that involves behavioural changes. Feasibility of our intervention was confirmed in two different towns and over two different time-courses (the first in Reus over 28 months, and the second in Amposta over 22 months). Also, it is important to assess treatment adherence in order to evaluate reproducibility and feasibility,[19]. For example, the KOPS study,[20] demonstrated that nutritional

knowledge was increased as a result of the intervention in the two cohort studies (KOPS 1 and KOPS 2),[20]. However, the study was unable to show whether there were differences in overweight outcomes, weight categories or lifestyles between the two cohorts. Some multi-centred studies have attempted to reproduce methodological aspects in interventions conducted in different countries or different populations. However, while multi-centred studies are usually implemented concurrently, reproducibility involves the applicability of the intervention at different sites and/or different times in order to validate the initial findings. One example of this is the Pro Children Study,[30] which, as a multi-centred study, had been applied in different countries simultaneously and had demonstrated its efficacy and feasibility.

The ALADINO study presented the obesity status prevalence in Spain which, according to the IOTF, is about 11.4% in children of around 9 years of age,[31]. In the EdAl-2 study, the OB prevalence was similar, but lower in the intervention group than the equivalent in the ALADINO study and, as well, in the EDAL-2 control group.

The EdAl-2 study showed a significant improvement of 16.7% in the young boys in the intervention group who participated in ≥4 h/week after-school PA. Further, the increased numbers of children in the intervention group who performed ≥4 h/week after-school PA who were normal-weight at baseline, suggested that the intervention was effective not only in the primary-school healthy population but also effective in preventing OB over the longer-term due to the PA being maintained.

In the dietary habits aspect of EdAl-2 study, we observed that the increase in healthy lifestyle habits such as the increase in fruit and vegetables consumption and increasing PA h/week while maintaining low TV h/d, are promising lifestyle changes that could induce a reduction of OW and OB over the long-term.

In the EdAl-2 study we observed that consumption of dairy products at breakfast was a protective factor against obesity.

Several studies have shown that participating in PA was a protective factor against OB and that spending >2h watching TV was a risk factor for childhood OB. A recent Spanish study showed that leisure-time PA was a protective factor against OB (as with our present study) and that performing >4 h/week is a protective factor while watching TV for this amount of time was, according to Ochoa et al,[32], associated with OB.

There are several limitations to our study. Firstly, we evaluated dietary habits via a questionnaire that did not take into account the quantities of the different types of food items consumed. These data would be important in addressing the quantity *versus* quality debate in OB or OW prevalence. Secondly, assigning control groups according to towns surrounding the intervention town could be a limitation. However, schools of the same town have good relationships and communications with each other and this could entail a possible contamination between schools if assigned to intervention or control status within the same town. This cross-contamination would be minimised if the schools themselves were assigned to intervention or control. Thirdly, the significant difference in Latin American ethnicity between the two groups of the study at baseline could be a limitation. However, there were no significant differences in distributions of OB and/or OW. Also, no differences were observed in terms of response to the intervention study in relation to ethnicity. Fourthly, when asked about fast-food consumption, the participants interpreted this as pertaining only to fast-food outlets such a burger shops, and did consider other concepts such as frozen pizza consumed at home. Finally, another limitation could be the proportion of females who may have started puberty in the course of the study. This implies changes in body composition. However,

both study groups (intervention and control) had a similar proportion of females with a similar age, and this could cancel-out the effect.

Further, EdAl-2 demonstrated that performing >4h/week after-school PA, plus having dairy product at breakfast are protective factors. Hence, we believe that a participating in >4h/week after-school PA, and continuing with a healthy breakfast, are key points in preventing childhood OB.

CONCLUSION

Our school-based intervention is feasible, adaptable to quite different school environments, and reproducible. The main improvement was after-school PA (≥4h/week) in boys. Further, TV watching decreased to <2 TV h/day. This suggests that our intervention programme induces healthy lifestyle effects (such as more exercise and less sedentary behaviour) which can produce anti-obesity benefits in children.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

LIST OF ABBREVIATIONS

OB: Obesity

OW: Overweight

PA: Physical Activity

mITT: modified Intention to Treat

HPAs: Health Promoter Agents

WHO: World Health Organization

BMI: Body Mass Index

OR: Odds Ratio

Authors' contributions

MG, EL, LT, RS designed the study (project conception, development of overall research plan, and study oversight)

MG, EL, LT, RQ, RS conducted research (hands-on conduct of the experiments and data collection)

EL, LT, MG, RS provided essential materials (applies to authors who contributed by providing constructs, database, etc. necessary for the research)

DM, EL, LT analysed data or performed statistical analysis

RS, MG, LT, DM, EL drafted and revised the manuscript (authors who made a major contribution). The final manuscript was read and approved by all co-authors

RS, MG take primary responsibility for the study, and manuscript content

REFERENCES

1. Organización para la Cooperación y el Desarrollo Económicos (OCDE): *Obesity update.* 2012.
2. World Health Organization. The Challenge of Obesity in the WHO European Region and the strategies for response. Denmark; 2007.
3. Ahrens W, Bammann K, Siani A, et al. The IDEFICS cohort: design, characteristics and participation in the baseline survey. *Int J Obes* 2011;35(Suppl 1:)S3-15. doi:10.1038/ijo.2011.30
4. Brug J, van Stralen MM, Te Velde SJ, et al. Differences in weight status and energy-balance related behaviors among schoolchildren across Europe: the ENERGY-project. *PLoS One* 2012;7(4):e34742. doi: 10.1371/journal.pone.0034742. [Published Online First: 25 April 2012]
5. Martos-Moreno GA, Argente J. Paediatric obesities: from childhood to adolescence. *An Pediatr (Barc)* 2011;75(1):63e1-23. doi:10.1016/j.anpedi.2011.03.018. [Published Online First: 23 May 2011]
6. Manco M, Dallapiccola B. Genetics of pediatric obesity. *Pediatrics* 2012;130(1):123-133. doi:10.1542/peds.2011-2717. [Published Online First: 4 June 2012]
7. Vos MB, Welsh J. Childhood obesity: update on predisposing factors and prevention strategies. *Curr Gastroenterol Rep* 2010;12(4):280-287. doi:10.1007/s11894-010-0116-1.
8. The Organisation for Economic Co-operation and Development (OECD): Obesity Update 2012. [http://www.oecd.org/health/49716427.pdf]
9. Van Cauwenberghe E, Maes L, Spittaels H. Effectiveness of school-based interventions in Europe to promote healthy nutrition in children and adolescents:

systematic review of published and 'grey' literature. *Br J Nutr* 2010;103(6):781-797. doi:10.1017/S0007114509993370. [Published Online First: 14 January 2010]

10. Reinehr T, Wabitsch M. Childhood obesity. *Curr Opin Lipidol* 2011;22:21-5.
11. Guia de práctica clínica (GPC). *AATRM* 2007.
12. Verbestel V, De Henauw S, Maes L, et al. Using the intervention mapping protocol to develop a community-based intervention for the prevention of childhood obesity in a multi-centre European project: the IDEFICS intervention. *Int J Behav Nutr Phys Act* 2011;8:82. doi:10.1186/1479-5868-8-82.
13. Vio F, Zacarías I, Lera L, et al. Prevención de la obesidad en escuelas básicas de Peñalolén: Componente alimentación y nutrición. Rev Chil Nutr 2011; 38:268-276.
14. Bacardí-Gascon M, Pérez-Morales ME, Jiménez-Cruz A. A six month randomized school intervention and an 18-month follow-up intervention to prevent childhood obesity in Mexican elementary schools. Nutr Hosp 2012; 27:755-62.
15. De Bourdeaudhuij I, Van Cauwenberghe E, Spittaels H, et al. School-based interventions promoting both physical activity and healthy eating in Europe: a systematic review within the HOPE project. *Obes Rev* 2011;12(3):205-216. doi:10.1111/j.1467-789X.2009.00711.x.
16. Papandreou D, Malindretos P, Rousso I. Risk factors for childhood obesity in a Greek paediatric population. *Public Health Nutr* 2010;13(10):1535-1539. doi:10.1017/S1368980009993156. [Published Online First: 15 January 2010]
17. Giralt M, Albaladejo R, Tarro L, et al. A primary-school-based study to reduce prevalence of childhood obesity in Catalunya (Spain)--EDAL-Educacio en

alimentacio: study protocol for a randomised controlled trial. *Trials* 2011;12:54-62. doi:10.1186/1745-6215-12-54.

18. Tarro L, Llauradó E, Albaladejo R, et al. A primary-school-based study to reduce the prevalence of childhood obesity – The EdAl (Educació en Alimentació) study: a randomized controlled trial. *Trials* 2014;15:58. doi:10.1186/1745-6215-15-58.
19. Boutron I, Moher D, Altman DG, et al. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med* 2008, 148(4):295-309.
20. Danielzik S, Pust S, Muller MJ. School-based interventions to prevent overweight and obesity in prepubertal children: process and 4-years outcome evaluation of the Kiel Obesity Prevention Study (KOPS). *Acta Paediatr Suppl* 2007;96(454):19-25.
21. Serra Majem L, Ribas Barba L, Aranceta Bartrina J, et al. Childhood and adolescent obesity in Spain. Results of EnKid study (1998-2000). *Med Clin (Barc)* 2003;12:725-732.
22. Llargues E, Franco R, Recasens A, et al. Assessment of a school-based intervention in eating habits and physical activity in school children: the AVall study. *J Epidemiol Community Health* 2011;65(10):896-901. doi:10.1136/jech.2009.102319. [Published Online First: 12 March 2011]
23. Gidding SS, Dennison BA, Birch LL, et al. Dietary recommendations for children and adolescents: a guide for practitioners: consensus statement from the American Heart Association. *Circulation* 2006;113(Suppl 23):e857.

24. Cole TJ, Bellizzi MC, Flegal KM, et al. Establishing a standard definition for child overweight and obesity worldwide: international survey. *BMJ* 2000;320(7244):1240-1243.

25. World Health Organization. Growth Reference data for 5-19 years. 2007. [http://www.who.int/growthref/en/.] Date accessed: 05/03/2014

26. Cole TJ, Flegal KM, Nicholls D, et al. Body mass index cut offs to define thinness in children and adolescents: international survey. *BMJ* 2007, 335(7612):194. [Published Online First: 25 June 2007]

27. Kain J, Uauy R, Concha F, et al. School-based obesity prevention interventions for Chilean children during the past decades: Lessons learned. Adv Nutr 2012; 3(4):616s-621s.

28. Tarro L, Llauradó E, Moriña D, et al. Five-year follow-up of a healthy lifestyle education program (the EdAl study): Two years post-cessation of intervention. (Manuscript under review)

29. Brown T, Summerbell C. Systematic review of school-based interventions that focus on changing dietary intake and physical activity levels to prevent childhood obesity: an update to the obesity guidance produced by the National Institute for Health and Clinical Excellence. *Obes Rev* 2009;10(1):110-41. doi:10.1111/j.1467-789X.2008.00515.x. [Published Online First: 30 July 2008]

30. Te Velde SJ, Brug J, Wind M, et al. Effects of a comprehensive fruit- and vegetable-promoting school-based intervention in three European countries: the Pro Children Study. *Br J Nutr* 2008;99(4):893-903. [Published Online First: 22 October 2007]

31. Pérez-Farinós N, López-Sobaler AM, Dal Re MA, et al. The ALADINO Study: A National Study of Prevalence of Overweight and Obesity in Spanish Children

in 2011. *Biomed Res Int* 2013;2013:163687. doi: 10.1155/2013/163687. [Published Online First: 8 September 2013]

32. Ochoa MC, Moreno-Aliaga MJ, Martinez-Gonzalez MA, et al. Predictor factors for childhood obesity in a Spanish case-control study. *Nutrition* 2007;23(5):379-384. [Published Online First: 3 April 2007]

FIGURE LEGEND

Figure 1: Flow of subjects through the study

Incomplete height and/or weight (measures of first and/or third academic year)

No parental consent signed (first, second or third academic year).

"Research Checklist"

CONSORT 2010 checklist of information to include when reporting a randomised trial*

EdAl-2 (*Educació en Alimentació*) program: reproducibility of a randomized, interventional, primary-school-based study to induce healthier lifestyle activities in children

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title (abstract)	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio **(described in Giralt M, Albaladejo R, Tarro L, Moriña D, Arija V, Solà R. A primary-school-based study to reduce prevalence of childhood obesity in Catalunya (Spain) – EDAL- Educació en Alimentació: Study protocol for a randomized controlled trial. Trials 2011;12:54.)**	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	-
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:		**described in Trials 2011**	
Sequence	8a	Method used to generate the random allocation sequence	7-8
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7-8
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	7-8

"Research Checklist"

concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7-8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	-
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	11-12
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1 and page 15
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1 and tables
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results (page 11-25) Tables1-5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Figure 1
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	28
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	25-29
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	25-29

"Research Checklist"

Other information			
Registration	23	Registration number and name of trial registry	Clinical Trials registration NCT01362023
Protocol	24	Where the full trial protocol can be accessed, if available	Trials 2011
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	29

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

EdAl-2 (*Educació en Alimentació*) programme: reproducibility of a randomised, interventional, primary-school-based study to induce healthier lifestyle activities in children

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Keywords: feasibility, reproducibility, childhood obesity, physical activity, school-based intervention

Word count: 3169/3000

ABSTRACT

Objectives: To assess the reproducibility of the EdAl programme in "Terres de l'Ebre" (Spain), EdAL-2, an educational intervention over a period of 22 months, to improve lifestyles, including diet and physical activity recommendations

Design*:* Reproduction of a randomised controlled trial

Setting: Primary schools, two school clusters were randomly assigned to intervention or control group

Participants: Pupils (n=690; intervention group n=320; control group n= 370) 78% of Western European ethnicity. Mean age (±SD) was 8.04±0.6 years (47.7% females) at baseline. Inclusion criteria were name, gender, date and place of birth, and written informed consent from the parent or guardian.

Intervention: The interventions focused on 8 lifestyle topics covered in 12 activities (1h/activity/session) implemented by health promoting agents (HPAs) in the primary-school over 3 school academic years.

Primary and secondary outcomes: the primary outcome was obesity prevalence and the secondary outcomes were body mass index (BMI) collected every year, and dietary habits and lifestyles collected by questionnaires filled-in by the parents at baseline and end-of-study.

Results: At 22 months, the percentage of boys in the intervention group who performed ≥4h after-school PA h/week was 15% higher (p=0.027), while there was 16.6% more boys in the intervention group watching ≤2hTV/day (p=0.009), compared to controls. The obesity prevalence was similar in intervention and control groups over the period of the program. Multivariate statistical analysis indicated that the performance of ≥4 after-school PA h/week was a protective factor against childhood OB (OR:0.600; p=0.032).

Conclusions: Our school-based intervention is feasible, adaptable to quite different

school environments, and reproducible. The main improvement was after-school PA (≥4h/week) in boys. Further, TV watching decreased to <2 TV h/day. This suggests that our intervention programme induces healthy lifestyle effects (such as more exercise and less sedentary behaviour) which can produce anti-obesity benefits in children.

Words: 294/300

Clinical Trials registration NCT01362023

ARTICLE SUMMARY

Strengths and limitations of the study

- Strengths: Reproducibility of studies is rare because of the complexity of replicating a programme. Studies in OB prevention, such as EdAl, need to be reproducible, especially those improving healthy lifestyle, including after-school PA, to reinforce beneficial practices in childhood
- Strengths: Statistical methods controlling for confounders and taking into account clustering of data
- Limitations: Failure to assess treatment adherence to evaluate reproducibility and feasibility
- Limitations: Dietary habits were noted via a questionnaire that did not take into account the quantities of the different types of food items consumed

BACKGROUND

Obesity (OB) has become a disease of epidemic proportions,[1]. However, this increasing tendency towards excess weight in childhood and adulthood,[2] observed in some countries (United Kingdom, France, South Korea, United States and Spain) has stabilised despite the absolute rates being a cause for concern,[1]. OB prevalence in children and adolescents is higher in southern regions of Europe,[3-4].

Accumulation of fat tissue in childhood constitutes an increased disease risk in childhood, as well as in adulthood,[5]. This disease risk has a multifactorial aetiology, such as an unhealthy diet and sedentary lifestyle,[6-7].

The Organization for Economic Co-operation and Development (OECD), has predicted an increase of 7% in excess weight prevalence in adulthood over the period spanning 2010 to 2020,[8]. The WHO proposes the prevention and control of OB prevalence as key in the updated "Action Plan 2008-2013" in which effective health promotion is considered the principal strategy,[9].

Since excess weight status in adulthood is almost invariably predicated on childhood and adolescent weight, OB prevention should start early in life,[10]. The optimum age to commence an intervention is between the ages of 7 and 8 years because children are more receptive to guidance,[11]. The school is an ideal place for the promotion of healthy nutrition and lifestyle habits,[12] and, as some studies have shown, such interventions have inspired changes in nutritional habits and BMI status,[13-14]; the message being received by all schoolchildren, irrespective of ethnic and socioeconomic differences,[9]. The effectiveness of an intervention is when educational strategies and environmental factors such as healthy nutrition and physical activity habits coincide since both aspects are essential in preventing childhood OB,[15]. Currently, European children spend more of their leisure time in sedentary activities such as watching

television (TV), video games or on the Internet. These activities represent a decrease in physical movement and lowering energy expenditure and, as such, are risk factors for OB,[16].

We had designed the EdAl (*Educació en Alimentació*) programme as a randomised, controlled, parallel study applied in primary schools, and implemented by university students acting as Health Promoter Agents (HPAs),[17]. This intervention was deployed in Reus (as intervention group) with the neighbouring towns of Salou, Cambrils and Vilaseca as control group. The interventions focused on 8 lifestyle topics covered in 12 activities (1h/activity/session) in 7-8 year old children, and implemented by HPAs over 3 school academic years. We found that the EdAl programme successfully reduced childhood OB prevalence in boys by 4.39% and increased the percentage of boys who practice ≥5 after-school physical activity (PA) h/week,[18]. The EdAl programme needed to be reproduced in other localities, and with other children, to demonstrate the effectiveness of this intervention[19].

The outcomes of the EdAl programme supported the feasibility of improving PA in childhood. However, an educational intervention, such as our EdAl program implemented by HPAs, also tests complex components such as healthy lifestyles including diet and physical activity recommendations. Due to the complexity, such interventions are difficult to rationalise, standardise, reproduce, and administer consistently to all participants,[19].

There has been one study in the literature that has reproduced its programmes in other locations. Described as the Kiel Obesity Prevention Study (KOPS), the results demonstrated the efficacy and feasibility of implementing new nutritional concepts,[20].

We tested the reproducibility of the EdAl programme in a geographical area (Terres de l'Ebre) about 80km away from where the original EdAl programme was designed and

implemented. We describe, here, the primary-school-based study to reduce the prevalence of childhood OB (The EdAl-2 study); the objective remains an intervention to induce healthy lifestyles, including diet and physical activity recommendations. The study was conducted in 7-8 year old school-children over 3 academic years (22 months active school time).

METHODS

The original protocol, rationale, randomisation, techniques and results of the initial EdAl programme have been published in Trials,[17-18]. The current study (EdAl-2) was conducted in exactly the same way so as to assess whether comparable results could be achieved in a different location. The EdAl-2 study was approved by the Clinical Research Ethical Committee of the *Hospital Sant Joan of Reus, Universitat Rovira i Virgili* (Catalan ethical committee registry ref 11-04-28/4proj8). This study was registered in Clinical Trials *NCT01362023*. The protocol conformed to the Helsinki Declaration and Good Clinical Practice guides of the International Conference of Harmonization (ICHGCP). The study followed the CONSORT criteria [see Additional file 1].

For logistics reasons, the EdAl-2 program was reduced by 6 months, from 28 months to 22 months.

Study population

The coordinating Center (in Reus) developed a cluster randomisation scheme to have a study sample in which the schools in Amposta were designated as Group A (intervention) and 9 towns around Amposta (Sant Jaume d'Enveja, Els Muntells,

l'Ametlla de Mar, El Perelló, l'Ampolla, Deltebre, l'Aldea, Lligalló del Gànguil and Camarles) as Group B (control).

The socio-demographic indicators in all towns were similar to that of the original EdAl Program in Reus. Children attending the schools in both groups (intervention and control) lived in close proximity within each school's catchment area. Intervention institutions were 5 schools involving 18 classrooms and 457 pupils in Amposta. Control institutions consisted of 11 schools involving 23 classrooms and 531 pupils in the 9 towns of around Amposta. Children of this study are in the 2nd and 3rd grade of primary education (7-8 year olds). Schoolchildren were enrolled in May 2011 (children born in 2002–2003) and followed-up for 3 school academic years (2012–2013). The study was completed in March 2013.

To be representative of the child population, the schools selected needed to have at least 50% of the children in the classrooms volunteer to participate. We offered the programme to all schools, whether public (funded by the government and termed "charter" schools) or private which included fee-paying and/or faith schools. Inclusion criteria were: name, gender, date and place of birth, and written informed consent from the parent or guardian. A questionnaire on eating habits (Krece Plus) developed by Serra Majem et al,[21], and physical activity, level of parental education and lifestyles developed by Llargues et al,[22] were filled-in by the parents at baseline and at the end of the study.

Intervention program

The original EdAl Reus protocol was followed,[17-18]. The educational intervention activities focused on eight lifestyle topics based on scientific evidence,[23] to improve nutritional food item choices (and avoidance of some foods), healthy habits such as

teeth-brushing and hand-washing and, overall, adoption of activities that encourage physical activity (walking to school, playground games), and to avoid sedentary behaviour,[23].

Each of the eight topics was integrated within educational intervention activities of 1h/activity, prepared and standardized by the HPAs, and implemented in the children's classrooms. In the first school academic year, we focused on four topics: 1) to improve healthy lifestyle; 2) to encourage healthy drinks intake (and avoidance of unhealthy carbonated/sweetened beverages); 3) to increase the consumption of vegetables and legumes; and 4) to decrease the consumption of candies and pastries while increasing the intake of fresh fruits and nuts. These corresponded to four standardised activities (1h/activity). In the second year, the remaining four of the eight selected lifestyle topics were addressed: 5) to improve healthy habits within a set timetable (home meals, teeth-brushing, hand-washing) and physical activity participation; 6) to increase fruit intake; 7) to improve dairy product consumption; and 8) to increase fish consumption. These corresponded to four standardised activities. Finally, in the third school academic year, four standardised activities were introduced that reinforced the eight lifestyle topics implemented in the previous 2 academic years. Thus, the intervention program was based on eight lifestyle topics incorporated within 12 activities which were disseminated over 12 sessions (1h/activity/session), and prepared, standardised and implemented as four activities per school academic year by the HPAs in the school classrooms.

Process evaluation

The measurements were performed in each school academic year, as was the original EdAl program,[17-18].

Outcomes

Assessment of the reproducibility of the EdAl program was based on primary outcomes such as prevalence of OB (overall as well as stratified by gender), according to the International Obesity Task Force (IOTF),[24] recommendations for better international comparisons of data. Secondary outcomes included: changes in measures of adiposity (overall as well as stratified by gender) such as BMI z-score (based on WHO growth charts,[25] and waist circumference, incidence and remission of excess weight (OW and OB), as well as changes in lifestyles (eating habits and physical activity h/week). Weight, height, and waist circumference values were obtained as described previously,[17]. Prevalence of underweight was analysed according to Cole et al,[26] using 17Kg/m^2 as cut-off point. BMI z-score was calculated using the population values of the WHO Global InfoBase,[25]. To identify the risk factors of OB, the OB category was determined according to WHO criteria since this is based on data from countries that have a low OB prevalence,[25] and, as such, provide an understanding of the protective (or risk factors) for OB in our own population. To obtain a measurement of overall improvement in lifestyle we generated variables such as the maintenance of status in each category as well as the status in relation to changes in each category over the 22 month period.

Sample size

We calculated that, with a sample of more than 300 pupils per group, the study would have 85% power to detect a difference of 5 percentage points between the intervention and control schools in relation to the primary outcome (prevalence of OB).

Statistical analyses

Descriptive variables were presented as means and confidence intervals (95%CI). General linear mixed models (GLM) were used to analyse differences between the intervention and control pupils with respect to prevalence of OB. Repeated measures of GLM were used to analyse the trend of BMI z-score between baseline and end-of-study values. The McNemar test was used to analyse change-over-time of food habits, after-school PA h/week and hours TV/day categories, in intervention and control group. The continuous variables studied in each group were compared using ANOVA.

To evaluate risk and protective factors involved in childhood OB, logistic regression analyses were performed at baseline, with no distinction between intervention and control group. The odds ratios (OR) and 95%CI were calculated for dietary patterns and lifestyles, based on the Krece Plus Questionnaire,[21] and the AVall Questionnaire,[22], respectively.

The main analyses were performed with the modified intention-to-treat (mITT) population i.e. subjects with baseline and end-of-study data on weight, height, and date of birth, and written inform consent. The analyses did not use any imputation missing method; the assumption being that missing data were random. Statistical significance was defined by a $P<0.05$. The statistical analyses were performed with the SPSS 20.0 for Windows (SPSS Inc., Chicago, IL, USA).

RESULTS

Enrolment

Figure 1 shows the recruitment and flow diagram of pupils in the intervention and control groups over the course of the study. The mITT population in the intervention group and control group were 320 and 370 pupils, respectively. At 22 months, the mean

age was 9.67 (95%CI: 9.60, 9.73) in the intervention group (9.68 years in boys and 9.65 years in girls) and 9.86 (95%CI: 9.79, 9.91) in the control group (9.85 years in boys and 9.84 years in girls). The differences in age were not significant in relation to gender.

The characteristics of the study group are summarised in Table 1. At baseline, the intervention and control group were homogeneous in BMI status. The ethnicity of the population was predominantly Western European in intervention and control group (77.5% *vs.* 78.9%, respectively) while 7.5% *vs.* 10.8% was Eastern European; 10.3% *vs.* 3.5% was Latin American; 3.4% *vs.* 6.2% was North African Arab. At baseline, there was a significant difference in the distribution with respect to Latin American children (10.3% in intervention and 3.5% in control group; $p<0.001$). The distribution was random. Of note is that there were no significant differences in distributions of OB and/or OW. Also, no differences were observed in terms of response to the intervention in relation to ethnicity.

Table 1. Anthropometric characteristics of pupils at baseline: Intervention *versus* Control group

	Intervention group			Control group					
	Mean (95%CI)			Mean (95%CI)			Intervention *vs.* control; P-value	Intervention *vs.* control; P-value	Intervention *vs.* control; P-value
	Boys (n=165)	Girls (n=155)	Total (n=320)	Boys (n=196)	Girls (n=174)	Total (n=370)	Boys	Girls	Total
Age; years	8.01 (7.91;8.12)	7.97 (7.88;8.07)	7.99 (7.92;8.06)	8.11 (8.03;8.19)	8.06 (7.97;8.15)	8.09 (8.03;8.15)	0.105	0.153	0.967
Weight; Kg	30.35 (29.22; 31.48)	29.86 (28.81; 30.91)	30.11 (29.34; 30.88)	31.29 (30.26; 32.33)	31.35 (30.36; 32.34)	31.32 (30.60; 32.04)	0.226	0.043	0.024
BMI; Kg/m^2	17.40 (16.93; 17.86)	17.42 (16.97; 17.88)	17.41 (17.09; 17.73)	17.70 (17.28; 18.13)	17.94 (17.51; 18.37)	17.82 (17.51; 18.12)	0.340	0.104	0.073
Height; m	1.32 (1.30; 1.33)	1.30 (1.29; 1.31)	1.31 (1.30; 1.32)	1.32 (1.31; 1.33)	1.32 (1.31; 1.33)	1.32 (1.31; 1.33)	0.242	0.045	0.027
Fat mass; Kg	6.71 (5.99; 7.42)	7.11 (6.50; 7.72)	6.90 (6.42; 7.38)	6.44 (5.78; 7.09)	7.70 (7.12; 8.27)	7.03 (6.59; 7.47)	0.584	0.167	0.698
Lean mass; Kg	23.99 (23.34; 24.64)	22.86 (22.32; 23.39)	23.44 (23.02; 23.87)	24.88 (24.28; 25.47)	23.71 (23.21; 24.22)	24.33 (23.93; 24.73)	0.049	0.022	0.003
Waist circumference; cm	60.97 (59.68; 62.27)	59.91 (58.67; 61.15)	60.46 (59.56; 61.36)	64.37 (63.18; 65.56)	65.17 (64.00; 66.34)	64.75 (63.91; 65.58)	<0.001	<0.001	<0.001

Notes to Table 1:

The results are expressed as Mean (95%CI)

[1]p value: general linear model (GLM) statistic

Attrition rate

Figure 1 shows the recruitment and retention of pupils in intervention and control schools. Among the 916 pupils assessed at the beginning of the study, 690 (75.3%) pupils (73.6% of those allocated to the control group and 77.5% of those allocated to the intervention group) were reassessed three academic courses later, and valid measurements were obtained. The rate of parental consent was 95.7%. Drop-outs in both groups are assumed to be missing at random.

Primary outcome: Prevalence of OB

At 22 months of the study, OB prevalence assessed by IOTF criteria, was similar in intervention and control group (p=0.628) (Table 2).

Criteria/Category		Group		Baseline % (n)	End of study % (n)	Change %	Baseline to study end P-value[1]	Intervention vs. Control P-value[2]
IOTF criteria	OW	Intervention	Boys	18.2 (30)	24.2 (40)	6	0.087	0.629
			Girls	16.2 (25)	23.2 (36)	7	0.043	0.066
			Total	17.2 (55)	23.8 (76)	6.6	0.005	0.086
		Control	Boys	25.5 (50)	27.0 (53)	1.5	0.690	
			Girls	28.2 (49)	32.8 (57)	4.6	0.185	
			Total	26.8 (99)	29.7 (110)	2.9	0.169	
	OB	Intervention	Boys	9.7 (16)	11.5 (19)	-1.8	0.453	0.735
			Girls	13.6 (21)	12.3 (19)	-1.3	0.754	0.732
			Total	11.6 (37)	11.9 (38)	0.3	1.000	0.628
		Control	Boys	10.7 (21)	10.2 (20)	-0.5	1.000	
			Girls	12.1 (21)	10.9 (19)	-1.2	0.687	
			Total	11.4 (42)	10.5 (39)	-0.93	0.607	

Table 2. Baseline and end-of-intervention measurements of categorised BMI in Intervention and Control group

Notes to Table 2

IOTF: International Obesity Task Force

The results are expressed as % (n)

[1]p value: McNemar's Test

[2]p value: Fisher's Exact Test

Secondary outcomes

At 22 months of the study, the status of OW prevalence (according to IOTF criteria) was similar between groups (p=0.086).

There were no significant differences in BMI z-score between intervention and control group (p=0.400) (Table 3). Despite no differences in BMI z-score, the boys of intervention group did not have an increase in percentage fat mass (19.96% to 20.02%: p=0.896), whereas intervention girls (22.06% to 23.55%; p<0.001), together with boys (19.18% to 20.64%, p<0.001) and girls (23.26% to 24.98%) of control group had a significant increase.

The remission, and incidence, of OB was similar in the overall intervention and control group, as well as when stratified with respect to gender.

Table 3. BMI z-score at baseline and at the end of intervention in Intervention and Control group

			Baseline Mean (95%CI)	End of study Mean (95%CI)	Change Mean (95%CI)	Baseline to Study end P-value[1]	Intervention *vs.* Control P-value[2]
BMI z-score	Intervention	Boys	0.73 (0.53; 0.94)	0.74 (0.54; 0.93)	0.00 (-0.07; 0.08)	0.973	0.381
		Girls	0.71 (0.50; 0.91)	0.89 (0.68; 1.10)	0.18 (0.10; 0.26)	<0.001	0.030
		Total	0.72 (0.58; 0.86)	0.81 (0.67; 0.95)	0.09 (0.03; 0.14)	0.002	0.400
	Control	Boys	0.83 (0.64; 1.01)	0.81 (0.63; 1.00)	-0.12 (-0.08; 0.06)	0.726	
		Girls	0.52 (0.33; 0.71)	0.63 (0.44; 0.83)	0.11 (0.02; 0.20)	0.013	
		Total	0.68 (0.55; 0.82)	0.73 (0.60; 0.86)	0.05 (-0.01; 0.10)	0.100	

Notes to Table 3:

[1]p-value: Mixed Models Repeated Measures

[2]p-value: ANOVA model

Differences between intervention and control pre- *vs.* post-intervention

Lifestyles evaluation

After 22 months of the study, there were 19.7%, 11.2% and 8.2% more girls in the intervention group who consumed a second fruit per day, one vegetable per day and fast-food weekly than the girls of control group ($p<0.001$, $p=0.017$ and $p=0.013$; respectively). However, there were 17.9% and 17.8% more boys in the intervention group who consumed pastry at breakfast and more than one vegetable a day, compared to boys of control group ($p=0.002$, $p= 0.001$; respectively). Conversely, there were 12.9% and 12.2% more girls in the control group who consumed legumes and cereal breakfast than girls of intervention group ($p=0.013$, $p=0.032$; respectively) (Table 4).

297 **Table 4.** Foods habits assessed at baseline and at the end of the study in the Intervention and

298 Control groups

		Intervention group			Control group			Intervention *vs.* Control
		Baseline %(n)	End of study %(n)	P Value	Baseline %(n)	End of study %(n)	P Value	P-value
Krece plus questionnaire								
Breakfast	Boys	98.4 (125)	98.3 (119)	1	97.5 (154)	92.2 (153)	0.092	0.635
	Girls	98.4 (123)	99.2 (120)	1	98.7 (148)	93.8 (135)	**0.016**	0.453
	Total	98.4 (248)	98.8 (239)	1	98.1 (302)	92.9 (288)	**0.003**	1
Dairy product	Boys	94.5 (121)	93.5 (116)	1	93.6 (147)	92.3 (155)	1	1
at breakfast	Girls	94.3 (116)	93.4 (113)	0.508	94.0 (141)	89.7 (131)	**0.039**	0.325
	Total	94.4 (237)	93.5 (229)	0.481	93.8 (288)	91.1 (286)	0.167	0.574
Cereals at	Boys	65.6 (82)	66.4 (81)	0.864	59.1 (88)	54.6 (89)	0.743	0.706
breakfast	Girls	61.5 (75)	49.6 (58)	**0.036**	59.7 (86)	60.0 (87)	0.880	**0.031**
	Total	63.6 (157)	58.2 (139)	0.098	59.4 (174)	57.1 (176)	1	0.225
Pastry at	Boys	15.8 (19)	23.5 (28)	**0.027**	22.5 (33)	12.3 (20)	**0.001**	**0.002**
breakfast	Girls	20.5 (24)	15.5 (18)	0.383	15.9 (22)	12.4 (18)	0.210	0.260
	Total	18.1 (43)	19.6 (46)	0.441	19.1 (55)	12.3 (38)	**<0.001**	**0.002**
Daily fruit or	Boys	73.4 (94)	76.2 (93)	0.523	74.8 (116)	76.0 (127)	1	0.535
natural juice	Girls	66.7 (82)	70.0 (84)	0.690	79.9 (119)	73.5 (108)	0.243	0.549
	Total	70.1 (176)	13.1 (177)	0.382	77.3 (235)	74.8 (235)	0.443	0.472
Fruit, 2nd per	Boys	39.7 (50)	41.2 (49)	0.581	44.5 (69)	34.1 (56)	**0.006**	0.141
day	Girls	26.4 (32)	47.5 (56)	**0.000**	44.8 (64)	39.0 (57)	0.281	**<0.001**
	Total	33.2 (82)	44.3 (105)	**0.001**	44.6 (133)	36.5 (113)	**0.004**	**<0.001**
Dairy product,	Boys	87.2 (109)	78.5 (95)	**0.029**	80.0 (124)	69.5 (116)	0.174	0.194
2nd per day	Girls	80.5 (99)	79.8 (95)	1	71.6 (106)	75.5 (111)	0.749	0.460
	Total	83.9 (208)	79.2 (190)	0.161	75.9 (230)	72.3 (227)	0.51	0.384
Vegetables,	Boys	65.6 (84)	74.4 (90)	**0.043**	71.1 (113)	70.8 (119)	1	0.473
daily	Girls	71.7 (86)	77.5 (93)	0.169	68.7 (101)	63.3 (93)	0.152	**0.017**
	Total	68.5 (170)	75.9 (183)	**0.011**	69.9 (214)	67.3 (212)	0.374	**0.028**
Vegetables, >1	Boys	19.3 (23)	29.1 (34)	**0.017**	28.7 (43)	20.7 (34)	**0.009**	**0.001**
per day	Girls	25.4 (31)	34.5 (40)	0.052	30.3 (43)	23.1 (33)	0.110	0.149
	Total	22.4 (54)	31.8 (74)	**0.001**	29.5 (86)	21.8 (67)	**0.002**	**0.001**
Fish, regularly	Boys	73.2 (93)	76.6 (95)	0.608	70.0 (112)	70.1 (115)	0.851	0.058

	Girls	71.8 (92)	71.4 (85)	0.307	74.5 (111)	71.0 (103)	1	0.662
	Total	74 (185)	74.1 (180)	0.896	72.2 (223)	70.6 (218)	0.791	0.312
Fast food, >1	Boys	6.3 (8)	7.4 (9)	1	7.1 (11)	4.9 (8)	0.227	0.106
per week	Girls	3.3 (4)	10.1 (12)	0.109	4.2 (6)	2.8 (4)	0.219	**0.013**
	Total	4.8 (12)	8.8 (21)	0.21	5.7 (17)	3.9 (12)	**0.049**	**0.003**
Legumes >1	Boys	70.3 (90)	71.1 (86)	0.648	67.5 (106)	65.9 (110)	1	0.555
per week	Girls	72.8 (91)	73.3 (88)	0.815	62.8 (145)	76.2 (112)	**0.001**	**0.013**
	Total	71.5 (181)	72.2 (174)	1	65.2 (251)	70.7 (222)	**0.025**	**0.027**
Candy > per	Boys	14.3 (18)	12.6 (15)	1	17.2 (27)	18.2 (30)	1	0.367
day	Girls	12.9 (16)	12.0 (14)	1	18.7 (26)	11.1 (16)	0.078	1
	Total	13.6 (34)	12.3 (29)	1	17.9 (53)	14.9 (46)	0.262	0.479
Pasta or rice	Boys	63.8 (81)	67.5 (83)	0.839	69.0 (109)	67.9 (114)	0.871	0.708
daily	Girls	59.2 (74)	64.7 (77)	0.377	68.0 (100)	69.4 (102)	0.618	0.724
	Total	61.5 (155)	66.1 ()	0.35	68.5 (209)	68.6 (216)	0.561	1
Cooking with	Boys	97.7 (126)	98.4 (122)	1	98.1 (157)	98.8 (167)	1	0.636
olive oil at	Girls	98.4 (125)	99.2 (120)	0.623	97.3 (145)	98.0 (145)	1	0.628
home	Total	98 (251)	98.8 (242)	0.5	97.7 (302)	98.4 (312)	0.754	0.476
Avall questionnaire								
Before leaving home								
Dairy	Boys	90 (117)	87.3 (110)	0.065	83.6 (133)	95.3 (139)	1	0.074
products	Girls	87.3 (110)	87.8 (108)	0.503	83 (122)	76.4 (110)	**0.004**	0.235
	Total	90.9 (227)	87.6 (218)	0.071	86.2 (255)	81.1 (249)	**0.044**	0.836
Pastry	Boys	4 (5)	2.4 (3)	1	0.7 (1)	1.4 (2)	1	0.610
	Girls	0.8 (1)	1. 7 (2)	1	0.7 (1)	0 (0)	1	1
	Total	2.5 (6)	2 (5)	1	0.7 (2)	0.7 (2)	1	0.606
Cereals	Boys	33.9 (43)	36.8 (46)	0.711	30.7 (46)	35.0 (55)	0.608	1
	Girls	32.2 (38)	26.2 (32)	0.405	25.2 (37)	26.2 (37)	0.458	0.297
	Total	33.1 (81)	31.6 (78)	0.89	27.9 (83)	30.9 (92)	0.314	0.409
Fresh fruit	Boys	18.4 (23)	24.6 (31)	0.189	17.0 (26)	21.2 (32)	1	0.537
or natural	Girls	14.2 (17)	24.6 (30)	0.064	18.5 (27)	23.6 (33)	0.541	0.332
juice	Total	16.3 (40)	24.6 (61)	**0.016**	17.7 (53)	22.3 (65)	0.560	0.256
	Boys	6.6 (8)	17.7 (22)	0.115	17.3 (26)	21.1 (32)	0.458	1
	Girls	0.3 (12)	19.7 (24)	**0.049**	14.9 (21)	18.4 (26)	0.572	1
Sandwich	Total	8.4 (20)	18.7 (46)	**0.008**	16.2 (47)	19.8 (58)	0.289	0.889
Juice	Boys	6.7 (8)	7.4 (9)	0.754	8.7 (13)	7.1 (11)	1	0.756
package/sof	Girls	7.7 (9)	5.0 (6)	0.508	8.6 (12)	10.8 (15)	1	0.507

t drinks								
	Total	7.2 (17)	6.2 (15)	0.359	8.6 (25)	8.9 (26)	0.845	0.483
Break (Midmorning)								
Dairy	Boys	16.0 (20)	20.0 (24)	0.824	15.3 (22)	14.4 (21)	1	0.819
products	Girls	8.7 (10)	9.6 (11)	0.388	10.7 (15)	8.4 (11)	1	0.595
	Total	12.5 (30)	15 (35)	0.367	13.0 (37)	11.6 (32)	1	0.488
Pastry	Boys	4.1 (5)	0.8 (1)	0.625	4.1 (6)	2.1 (3)	1	1
	Girls	0.9 (1)	0.9 (1)	1	1.5 (2)	2.3 (3)	1	0.480
	Total	2.5 (6)	0.9 (2)	0.687	2.8 (8)	2.2 (6)	0.687	1
Cereals	Boys	3.3 (4)	5.9 (7)	0.727	5.7 (8)	4.9 (7)	1	1
	Girls	3.5 (4)	3.4 (4)	1	4.3 (6)	6.9 (9)	0.180	0.544
	Total	3.4 (8)	4.7 (11)	0.804	5 (14)	5.9 (16)	0.238	0.659
Fresh fruit or	Boys	16.3 (20)	10.1 (12)	0.804	19.5 (30)	14.5 (22)	0.189	0.787
natural juice	Girls	15.5 (18)	16.8 (20)	0.424	20.1 (29)	20.3 (28)	0.815	1
	Total	15.9 (38)	13.4 (32)	0.856	19.8 (59)	17.2 (50)	0.522	0.721
Sandwich	Boys	28.3 (36)	37.7 (46)	0.087	43.2 (67)	41.6 (67)	0.701	0.080
	Girls	24.8 (30)	33.6 (41)	0.064	29.7 (44)	41.1 (58)	**0.016**	0.860
	Total	26.6 (66)	35.7 (87)	**0.008**	36.6 (111)	41.4 (125)	0.185	0.299
Juice	Boys	7.4 (9)	9.1 (11)	0.344	12.2 (18)	12.6 (19)	1	1
package/soft	Girls	7.8 (9)	6.1 (7)	0.727	12.1 (17)	13.2 (18)	1	0.233
drinks	Total	7.6 (18)	7.7 (18)	0.815	12.2 (35)	12.9 (37)	1	0.543

Notes to Table 4:

[1]p-value: McNemar's Test (changes in intervention group)

[2]p-value: McNemar's Test (changes in control group)

[3]p-value: Fisher's Exact Test.

Table 5 summarises the time spent in after-school PA, watching TV, playing video games, and other leisure-time activities. At 22 months, the percentage of boys of the intervention group who performed ≥4h after-school PA/week was increased by 15% (p=0.027) while there was 16.6% more boys in the intervention group watching ≤2hTV/day (p<0.009). The results indicate less sedentary behaviour in intervention than control individuals.

311 **Table 5.** Lifestyles assessed at baseline and at the end of study in Intervention and Control

		Intervention			Control			Intervention vs. Control
		Baseline %(n)	End of study %(n)	p-value[1]	Baseline %(n)	End of study %(n)	P-value[2]	P-value[3]
TV and/or video games								
0-2h/day	Boys	49.2 (62)	45.2 (57)	0.268	32.5 (51)	27.0 (43)	0.627	0.71
	Girls	48.4 (60)	51.2 (63)	1	44.0 (66)	49.7 (71)	0.43	0.287
	Total	48.8 (122)	48.2 (120)	0.464	38.1 (117)	37.7 (114)	0.91	0.697
3-4h/day	Boys	46.0 (58)	50.0 (63)	0.542	62.4 (98)	63.5 (101)	1	0.874
	Girls	43.5 (54)	44.7 (55)	0.86	54.0 (81)	47.6 (68)	0.349	0.71
	Total	44.8 (112)	47.4 (118)	0.489	58.3 (179)	56.0 (169)	0.606	0.632
>4h/day	Boys	4.8 (6)	4.8 (6)	0.375	5.1 (8)	9.4 (15)	0.607	0.393
	Girls	8.1 (10)	4.1 (5)	0.453	2.0 (3)	2.8 (4)	1	1
	Total	6.4 (16)	4.4 (11)	1	3.6 (11)	6.3 (19)	0.481	0.462
After-school PA								
0-2h/week	Boys	26.2 (34)	14.5 (18)	0.013	21.5 (34)	19.0 (31)	0.286	0.354
	Girls	35.2 (43)	33.6 (41)	0.701	34.5 (50)	36.6 (52)	1	0.557
	Total	30.6 (77)	24.0 (59)	**0.049**	27.7 (84)	27.2 (83)	0.435	0.254
2-4h/week	Boys	29.2 (38)	24.2 (30)	0.418	38.0 (60)	3.1 (54)	0.78	0.602
	Girls	36.9 (45)	32.0 (39)	0.377	32.4 (47)	31.0 (44)	1	0.155
	Total	32.9 (83)	28.0 (69)	0.188	35.3 (107)	32.1 (98)	0.764	0.135

>4h/week	Boys	44.6 (58)	61.3 (76)	**0.006**	40.5 (64)	47.9 (78)	0.243	0.643
	Girls	27.9 (34)	34.4 (42)	0.136	33.1 (48)	32.4 (46)	0.868	0.598
	Total	36.5 (92)	48.0 (118)	**0.002**	37.0 (112)	40.7 (124)	0.272	0.485

Notes to Table 5

[1]P-value: McNemar's Test (changes in intervention group)

[2]P-value: McNemar's Test (changes in control group)

[3]P-value: Fisher's Exact Test.

Differences between intervention and control pre-post intervention program

At 22 months, subjects who were normal weight at baseline increased after-school PA to ≥4h/week. This reflects a rise to 32.7% in boys (p=0.002). However, in girls, the changes were not statistically different (p=0.134). No statistically significant differences were observed in the control group.

Impact of certain additional factors on obesity

The ORs of OB, using BMI z-score criteria, were related to some of the more relevant dietary habits and lifestyles. Thus, breakfast dairy product consumption (OR: 0.336; p=0.004) and ≥4 after-school PA h/week (OR: 0.600; p=0.032) were protective factors against OB. Conversely, doing <4 h/week PA (OR: 1.811; p=0.018) increased the risk of childhood OB.

DISCUSSION

The EdAl-2 program, a reproducibility study in Terres de l'Ebre, shows that intervention is useful for improving weekly after-school PA. However, the OB prevalence remained unchanged at 22 months, as has been shown in the data on stability of OB prevalence observed in some European countries,[8]. Despite that OW and OB remained similar between groups, we observed percentage fat mass maintenance in the boys of the intervention group, whereas girls of the intervention and control group had increases.

As proposed by Kain J et al, designing a new school-based intervention study needs to have some critical aspects considered. These include: the random allocation of schools, although methodologically desirable, is not always possible; participation of parents is very limited; obesity is not recognised as a problem; and increasing physical activity

and implementing training programmes for teachers is difficult due to an inflexible curriculum and lack of teachers' time. Unless these barriers are overcome, obesity prevention programmes will not produce positive and lasting outcomes,[27]. As such, our programme of HPA-implemented intervention activities in classrooms is an attractive alternative that circumvents lack-of-teacher-time.

The EdAl-2 program confirmed that after-school PA (in terms of h/week) can be stimulated in primary school as part of a healthy lifestyle. As we had observed in the original EdAL program,[18] at 28 months of intervention, there was an increase of up to 19.7% of children dedicating >5 hours/week to extra-curricular physical activities,[18]. Further, the after-school PA was maintained despite cessation of the intervention program,[28]. The effect of EdAl program during its implementation and after the official cessation indicated an impact on PA, whereas modification towards healthy food choices occurred according to the site of the program's implementation, and was not consistent.

Interventions to prevent OB in the school setting have shown dramatic improvements,[29]. However, successful studies in OB prevention need to be reproducible, especially those improving healthy lifestyle such as after-school PA, to confirm best childhood practices.

Reproducibility of studies is rare because of the complexity of trying to replicate a programme. To standardise a method it is essential to be able to reproduce appropriate levels of an intervention, especially one that involves behavioural changes. Feasibility of our intervention was confirmed in two different towns and over two different time-courses (the first in Reus over 28 months, and the second in Amposta over 22 months). Also, it is important to assess treatment adherence in order to evaluate reproducibility and feasibility,[19]. For example, the KOPS study,[20] demonstrated that nutritional

knowledge was increased as a result of the intervention in the two cohort studies (KOPS 1 and KOPS 2),[20]. However, the study was unable to show whether there were differences in overweight outcomes, weight categories or lifestyles between the two cohorts. Some multi-centred studies have attempted to reproduce methodological aspects in interventions conducted in different countries or different populations. However, while multi-centred studies are usually implemented concurrently, reproducibility involves the applicability of the intervention at different sites and/or different times in order to validate the initial findings. One example of this is the Pro Children Study,[30] which, as a multi-centred study, had been applied in different countries simultaneously and had demonstrated its efficacy and feasibility.

The ALADINO study presented the obesity status prevalence in Spain which, according to the IOTF, is about 11.4% in children of around 9 years of age,[31]. In the EdAl-2 study, the OB prevalence was similar, but lower in the intervention group than the equivalent in the ALADINO study and, as well, in the EDAL-2 control group.

The EdAl-2 study showed a significant improvement of 16.7% in the young boys in the intervention group who participated in ≥4 h/week after-school PA. Further, the increased numbers of children in the intervention group who performed ≥4 h/week after-school PA who were normal-weight at baseline, suggested that the intervention was effective not only in the primary-school healthy population but also effective in preventing OB over the longer-term due to the PA being maintained.

In the dietary habits aspect of EdAl-2 study, we observed that the increase in healthy lifestyle habits such as the increase in fruit and vegetables consumption and increasing PA h/week while maintaining low TV h/d, are promising lifestyle changes that could induce a reduction of OW and OB over the long-term.

In the EdAl-2 study we observed that consumption of dairy products at breakfast was a protective factor against obesity.

Several studies have shown that participating in PA was a protective factor against OB and that spending >2h watching TV was a risk factor for childhood OB. A recent Spanish study showed that leisure-time PA was a protective factor against OB (as with our present study) and that performing >4 h/week is a protective factor while watching TV for this amount of time was, according to Ochoa et al,[32], associated with OB.

There are several limitations to our study. Firstly, we evaluated dietary habits via a questionnaire that did not take into account the quantities of the different types of food items consumed. These data would be important in addressing the quantity *versus* quality debate in OB or OW prevalence. Secondly, assigning control groups according to towns surrounding the intervention town could be a limitation. However, schools of the same town have good relationships and communications with each other and this could entail a possible contamination between schools if assigned to intervention or control status within the same town. This cross-contamination would be minimised if the schools themselves were assigned to intervention or control. Thirdly, the significant difference in Latin American ethnicity between the two groups of the study at baseline could be a limitation. However, there were no significant differences in distributions of OB and/or OW. Also, no differences were observed in terms of response to the intervention study in relation to ethnicity. Fourthly, when asked about fast-food consumption, the participants interpreted this as pertaining only to fast-food outlets such a burger shops, and did consider other concepts such as frozen pizza consumed at home. Finally, another limitation could be the proportion of females who may have started puberty in the course of the study. This implies changes in body composition. However,

both study groups (intervention and control) had a similar proportion of females with a similar age, and this could cancel-out the effect.

Further, EdAl-2 demonstrated that performing >4h/week after-school PA, plus having dairy product at breakfast are protective factors. Hence, we believe that a participating in >4h/week after-school PA, and continuing with a healthy breakfast, are key points in preventing childhood OB.

CONCLUSION

Our school-based intervention is feasible, adaptable to quite different school environments, and reproducible. The main improvement was after-school PA (≥4h/week) in boys. Further, TV watching decreased to <2 TV h/day. This suggests that our intervention programme induces healthy lifestyle effects (such as more exercise and less sedentary behaviour) which can produce anti-obesity benefits in children.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

LIST OF ABBREVIATIONS

OB: Obesity

OW: Overweight

PA: Physical Activity

mITT: modified Intention to Treat

HPAs: Health Promoter Agents

WHO: World Health Organization

BMI: Body Mass Index

OR: Odds Ratio

Authors' contributions

MG, EL, LT, RS designed the study (project conception, development of overall research plan, and study oversight)

MG, EL, LT, RQ, RS conducted research (hands-on conduct of the experiments and data collection)

EL, LT, MG, RS provided essential materials (applies to authors who contributed by providing constructs, database, etc. necessary for the research)

DM, EL, LT analysed data or performed statistical analysis

RS, MG, LT, DM, EL drafted and revised the manuscript (authors who made a major contribution). The final manuscript was read and approved by all co-authors

RS, MG take primary responsibility for the study, and manuscript content

REFERENCES

1. Organización para la Cooperación y el Desarrollo Económicos (OCDE): *Obesity update.* 2012.
2. World Health Organization. The Challenge of Obesity in the WHO European Region and the strategies for response. Denmark; 2007.
3. Ahrens W, Bammann K, Siani A, et al. The IDEFICS cohort: design, characteristics and participation in the baseline survey. *Int J Obes* 2011;35(Suppl 1:)S3-15. doi:10.1038/ijo.2011.30
4. Brug J, van Stralen MM, Te Velde SJ, et al. Differences in weight status and energy-balance related behaviors among schoolchildren across Europe: the ENERGY-project. *PLoS One* 2012;7(4):e34742. doi: 10.1371/journal.pone.0034742. [Published Online First: 25 April 2012]
5. Martos-Moreno GA, Argente J. Paediatric obesities: from childhood to adolescence. *An Pediatr (Barc)* 2011;75(1):63e1-23. doi:10.1016/j.anpedi.2011.03.018. [Published Online First: 23 May 2011]
6. Manco M, Dallapiccola B. Genetics of pediatric obesity. *Pediatrics* 2012;130(1):123-133. doi:10.1542/peds.2011-2717. [Published Online First: 4 June 2012]
7. Vos MB, Welsh J. Childhood obesity: update on predisposing factors and prevention strategies. *Curr Gastroenterol Rep* 2010;12(4):280-287. doi:10.1007/s11894-010-0116-1.
8. The Organisation for Economic Co-operation and Development (OECD): Obesity Update 2012. [http://www.oecd.org/health/49716427.pdf]
9. Van Cauwenberghe E, Maes L, Spittaels H. Effectiveness of school-based interventions in Europe to promote healthy nutrition in children and adolescents:

systematic review of published and 'grey' literature. *Br J Nutr* 2010;103(6):781-797. doi:10.1017/S0007114509993370. [Published Online First: 14 January 2010]

10. Reinehr T, Wabitsch M. Childhood obesity. *Curr Opin Lipidol* 2011;22:21-5.
11. Guia de práctica clínica (GPC). *AATRM* 2007.
12. Verbestel V, De Henauw S, Maes L, et al. Using the intervention mapping protocol to develop a community-based intervention for the prevention of childhood obesity in a multi-centre European project: the IDEFICS intervention. *Int J Behav Nutr Phys Act* 2011;8:82. doi:10.1186/1479-5868-8-82.
13. Vio F, Zacarías I, Lera L, et al. Prevención de la obesidad en escuelas básicas de Peñalolén: Componente alimentación y nutrición. Rev Chil Nutr 2011; 38:268-276.
14. Bacardí-Gascon M, Pérez-Morales ME, Jiménez-Cruz A. A six month randomized school intervention and an 18-month follow-up intervention to prevent childhood obesity in Mexican elementary schools. Nutr Hosp 2012; 27:755-62.
15. De Bourdeaudhuij I, Van Cauwenberghe E, Spittaels H, et al. School-based interventions promoting both physical activity and healthy eating in Europe: a systematic review within the HOPE project. *Obes Rev* 2011;12(3):205-216. doi:10.1111/j.1467-789X.2009.00711.x.
16. Papandreou D, Malindretos P, Rousso I. Risk factors for childhood obesity in a Greek paediatric population. *Public Health Nutr* 2010;13(10):1535-1539. doi:10.1017/S1368980009993156. [Published Online First: 15 January 2010]
17. Giralt M, Albaladejo R, Tarro L, et al. A primary-school-based study to reduce prevalence of childhood obesity in Catalunya (Spain)--EDAL-Educacio en

alimentacio: study protocol for a randomised controlled trial. *Trials* 2011;12:54-62. doi:10.1186/1745-6215-12-54.

18. Tarro L, Llauradó E, Albaladejo R, et al. A primary-school-based study to reduce the prevalence of childhood obesity – The EdAl (Educació en Alimentació) study: a randomized controlled trial. *Trials* 2014;15:58. doi:10.1186/1745-6215-15-58.
19. Boutron I, Moher D, Altman DG, et al. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med* 2008, 148(4):295-309.
20. Danielzik S, Pust S, Muller MJ. School-based interventions to prevent overweight and obesity in prepubertal children: process and 4-years outcome evaluation of the Kiel Obesity Prevention Study (KOPS). *Acta Paediatr Suppl* 2007;96(454):19-25.
21. Serra Majem L, Ribas Barba L, Aranceta Bartrina J, et al. Childhood and adolescent obesity in Spain. Results of EnKid study (1998-2000). *Med Clin (Barc)* 2003;12:725-732.
22. Llargues E, Franco R, Recasens A, et al. Assessment of a school-based intervention in eating habits and physical activity in school children: the AVall study. *J Epidemiol Community Health* 2011;65(10):896-901. doi:10.1136/jech.2009.102319. [Published Online First: 12 March 2011]
23. Gidding SS, Dennison BA, Birch LL, et al. Dietary recommendations for children and adolescents: a guide for practitioners: consensus statement from the American Heart Association. *Circulation* 2006;113(Suppl 23):e857.

24. Cole TJ, Bellizzi MC, Flegal KM, et al. Establishing a standard definition for child overweight and obesity worldwide: international survey. *BMJ* 2000;320(7244):1240-1243.

25. World Health Organization. Growth Reference data for 5-19 years. 2007. [http://www.who.int/growthref/en/.] Date accessed: 05/03/2014

26. Cole TJ, Flegal KM, Nicholls D, et al. Body mass index cut offs to define thinness in children and adolescents: international survey. *BMJ* 2007, 335(7612):194. [Published Online First: 25 June 2007]

27. Kain J, Uauy R, Concha F, et al. School-based obesity prevention interventions for Chilean children during the past decades: Lessons learned. Adv Nutr 2012; 3(4):616s-621s.

28. Tarro L, Llauradó E, Moriña D, et al. Five-year follow-up of a healthy lifestyle education program (the EdAl study): Two years post-cessation of intervention. (Manuscript under review)

29. Brown T, Summerbell C. Systematic review of school-based interventions that focus on changing dietary intake and physical activity levels to prevent childhood obesity: an update to the obesity guidance produced by the National Institute for Health and Clinical Excellence. *Obes Rev* 2009;10(1):110-41. doi:10.1111/j.1467-789X.2008.00515.x. [Published Online First: 30 July 2008]

30. Te Velde SJ, Brug J, Wind M, et al. Effects of a comprehensive fruit- and vegetable-promoting school-based intervention in three European countries: the Pro Children Study. *Br J Nutr* 2008;99(4):893-903. [Published Online First: 22 October 2007]

31. Pérez-Farinós N, López-Sobaler AM, Dal Re MA, et al. The ALADINO Study: A National Study of Prevalence of Overweight and Obesity in Spanish Children

in 2011. *Biomed Res Int* 2013;2013:163687. doi: 10.1155/2013/163687. [Published Online First: 8 September 2013]

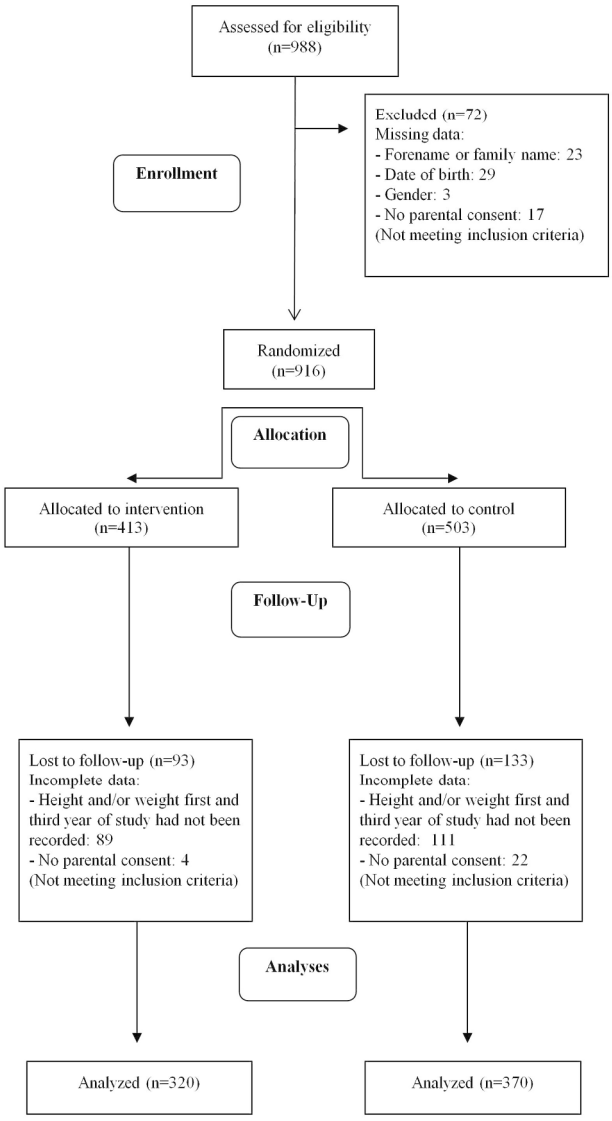
32. Ochoa MC, Moreno-Aliaga MJ, Martinez-Gonzalez MA, et al. Predictor factors for childhood obesity in a Spanish case-control study. *Nutrition* 2007;23(5):379-384. [Published Online First: 3 April 2007]

FIGURE LEGEND

Figure 1: Flow of subjects through the study

Incomplete height and/or weight (measures of first and/or third academic year)

No parental consent signed (first, second or third academic year).



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EdAl-2 (Educació en Alimentació) programme: reproducibility of a cluster randomised, interventional, primary-school-based study to induce healthier lifestyle activities in children

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EdAl-2 (*Educació en Alimentació*) programme: reproducibility of a cluster randomised, interventional, primary-school-based study to induce healthier lifestyle activities in children

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Keywords: feasibility, reproducibility, childhood obesity, physical activity, school-based intervention

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ABSTRACT

Objectives: To assess the reproducibility of an educational intervention EdAl-2 programme in "Terres de l'Ebre" (Spain), over 22 months, to improve lifestyles, including diet and physical activity (PA)

Design: Reproduction of a cluster randomised controlled trial

Setting: Two semi-rural town-group primary-school clusters were randomly assigned to intervention or control group

Participants: Pupils (n=690) of which 320 constituted intervention group (1 cluster) and 370 constituted control group (1 cluster). Ethnicity was 78% Western European. Mean age (±SD) was 8.04±0.6 years (47.7% females) at baseline. Inclusion criteria for clusters were towns from the southern part of Catalonia having a minimum of 500 children aged 7 to 8 year; and complete data for participants, including name, gender, date and place of birth, and written informed consent from parents or guardians.

Intervention: The intervention focused on 8 lifestyle topics covered in 12 activities (1h/activity/session) implemented by health promoting agents in the primary-school over 3 academic years.

Primary and secondary outcomes: the primary outcome was obesity (OB) prevalence and the secondary outcomes were body mass index (BMI) collected every year, and dietary habits and lifestyles collected by questionnaires filled-in by parents at baseline and end-of-study.

Results: At 22 months, the obesity prevalence and BMI values were similar in intervention and control groups. Relative to children in control schools, the percentage of boys in the intervention group who performed ≥4 after-school PA h/week was 15% higher (p=0.027), whereas the percentage of girls of both groups remained similar.

Also, 16.6% more boys in the intervention group watched ≤2 TV h/day (p=0.009), compared to controls; and no changes were observed in girls of both groups.

Conclusions: Our school-based intervention is feasible and reproducible by increasing after-school PA (to ≥4h/week) in boys induced healthy lifestyle effects while, the prevalence of OB was not significantly changed.

Words: 295

Clinical Trials registration NCT01362023

ARTICLE SUMMARY

Strengths and limitations of the study

- Strengths: Reproducibility of studies is rare because of the complexity of replicating an intervention programme. Studies in OB prevention, such as EdAl, need to be reproducible, especially those improving healthy lifestyle, including after-school PA, to reinforce beneficial practices in childhood
- Strengths: Statistical methods controlling for confounders and taking into account clustering of data
- Limitations: Failure to assess treatment adherence to evaluate reproducibility and feasibility
- Limitations: Dietary habits were noted via a questionnaire that did not take into account the quantities of the different types of food items consumed

BACKGROUND

Obesity (OB) has become a disease of epidemic proportions,[1]. However, this increasing tendency towards excess weight in childhood and adulthood,[2] observed in some countries (United Kingdom, France, South Korea, United States and Spain) has stabilised despite the absolute rates being a cause for concern,[1]. OB prevalence in children and adolescents is higher in southern regions of Europe,[3-4].

Accumulation of fat tissue constitutes an increased disease risk in childhood, as well as in adulthood,[5]. This disease risk has a multifactorial aetiology, such as an unhealthy diet and sedentary lifestyle,[6-7].

The Organization for Economic Co-operation and Development (OECD), has predicted an increase of 7% in excess weight prevalence in adulthood over the period spanning 2010 to 2020,[8]. The WHO proposes the prevention and control of OB prevalence as key in the updated "Action Plan 2008-2013" in which effective health promotion is considered the principal strategy,[9].

Since excess weight status in adulthood is almost invariably predicated on childhood and adolescent weight, OB prevention should start early in life,[10]. The optimum age to commence an intervention is between the ages of 7 and 8 years because children are more receptive to guidance,[11]. The school is an ideal place for the promotion of healthy nutrition and lifestyle habits,[12] and, as some studies have shown, such interventions have inspired changes in nutritional habits and BMI status,[13-14]; the message being received by all schoolchildren, irrespective of ethnic and socioeconomic differences,[9]. The effectiveness of an intervention is when educational strategies and environmental factors such as healthy nutrition and physical activity habits coincide since both aspects are essential in preventing childhood OB,[15]. Currently, European children spend more of their leisure time in sedentary activities such as watching

television (TV), video games or on the Internet. These activities represent a decrease in physical movement and lowering energy expenditure and, as such, are risk factors for OB,[16].

We had designed the EdAl (*Educació en Alimentació*) programme as a randomised, controlled, parallel study applied in primary schools, and implemented by university students acting as Health Promoter Agents (HPAs),[17]. This intervention was deployed in Reus (as intervention group) with the neighbouring towns of Salou, Cambrils and Vilaseca as control group. The interventions focused on 8 lifestyle topics covered in 12 activities (1h/activity/session) in 7-8 year old children, and implemented by HPAs over 3 school academic years. We found that the EdAl programme successfully reduced childhood OB prevalence in boys by 4.39% and increased the percentage of boys who practice ≥5 after-school physical activity (PA) h/week,[18]. The EdAl programme needed to be reproduced in other localities, and with other children, to demonstrate the effectiveness of this intervention[19].

The outcomes of the EdAl programme supported the feasibility of improving PA in childhood. However, an educational intervention, such as our EdAl program implemented by HPAs, also tests complex components such as healthy lifestyles including diet and physical activity recommendations. Due to the complexity, such interventions are difficult to rationalise, standardise, reproduce, and administer consistently to all participants,[19].

There has been one study in the literature that has reproduced its programmes in other locations. Described as the Kiel Obesity Prevention Study (KOPS), the results demonstrated the efficacy and feasibility of implementing new nutritional concepts,[20].

We tested the reproducibility of the EdAl programme in a geographical area (Terres de l'Ebre) about 80km away from where the original EdAl programme was designed and

implemented. We designed a cluster (town group) randomised controlled trial; the rationale being that since good communications exist between the schools of the same town, this could contribute to schools of the intervention group "contaminating" those of the putative control group.

We describe, here, the primary-school-based study to reduce the prevalence of childhood OB (The EdAl-2 study); the objective remains an intervention to induce healthy lifestyles, including diet and physical activity recommendations. The study was conducted in 7-8 year old school-children over 3 academic years (22 months active school time).

METHODS

The original protocol, rationale, randomisation, techniques and results of the initial EdAl programme have been published in Trials,[17-18]. The current study (EdAl-2) was conducted in exactly the same way so as to assess whether comparable results could be achieved in a different location. The exact intervention is described in more detail in Supplemental File 1, and in this manuscript link. The EdAl-2 study was approved by the Clinical Research Ethical Committee of the *Hospital Sant Joan of Reus, Universitat Rovira i Virgili* (Catalan ethical committee registry ref 11-04-28/4proj8). This study was registered in Clinical Trials *NCT01362023*. The protocol conformed to the Helsinki Declaration and Good Clinical Practice guides of the International Conference of Harmonization (ICHGCP). The study followed the CONSORT criteria [see Additional File 2].

For logistics reasons, the EdAl-2 program was reduced by 6 months, from 28 months to 22 months.

Study population

To ensure approximately a minimum 500 inhabitants of 7-8 years of age per cluster, before randomising the towns (clusters), a statistician who was not familiar with the study objectives and of the school identities, matched the towns on population size. The coordinating Center (in Reus) developed a cluster randomisation scheme to have a study sample in which the schools in Amposta were designated as Cluster A (intervention) and 9 towns around Amposta (Sant Jaume d'Enveja, Els Muntells, l'Ametlla de Mar, El Perelló, l'Ampolla, Deltebre, l'Aldea, Lligalló del Gànguil and Camarles) as Cluster B (control). The eligibility criteria of clusters were to be semi-rural towns from the southern part of Catalonia with a minimum of 500 children of 7 to 8 years of age in each cluster.

The socio-demographic indicators in all towns were similar to that of the original EdAl Program in Reus. Children attending the schools in both groups (intervention and control) lived in close proximity within each school's catchment area. Intervention institutions were 5 schools involving 18 classrooms and 457 pupils in Amposta. Control institutions consisted of 11 schools involving 23 classrooms and 531 pupils in the 9 towns of around Amposta. Children of this study are in the 2nd and 3rd grade of primary education (7-8 year olds). Schoolchildren were enrolled in May 2011 (children born in 2002–2003) and followed-up for 3 school academic years (2012–2013). The study was completed in March 2013.

To be representative of the child population, the schools selected needed to have at least 50% of the children in the classrooms volunteer to participate. We offered the programme to all schools, whether public (funded by the government and termed "charter" schools) or private which included fee-paying and/or faith schools. Inclusion criteria were: name, gender, date and place of birth, and written informed consent from

the parent or guardian of each participant. A questionnaire on eating habits (Krece Plus) developed by Serra Majem et al,[21], and physical activity, level of parental education and lifestyles developed by Llargues et al,[22] were filled-in by the parents at baseline and at the end of the study.

Intervention program

The original EdAl Reus protocol was followed,[17-18]. The educational intervention activities focused on eight lifestyle topics based on scientific evidence,[23] to improve nutritional food item choices (and avoidance of some foods), healthy habits such as teeth-brushing and hand-washing and, overall, adoption of activities that encourage physical activity (walking to school, playground games), and to avoid sedentary behaviour,[23].

Each of the eight topics described in Figure 1, was integrated within educational intervention activities of 1h/activity, prepared and standardized by the HPAs, and implemented in the children's classrooms. In the first school academic year, we focused on four topics: 1) to improve healthy lifestyle; 2) to encourage healthy drinks intake (and avoidance of unhealthy carbonated/sweetened beverages); 3) to increase the consumption of vegetables and legumes; and 4) to decrease the consumption of candies and pastries while increasing the intake of fresh fruits and nuts. These corresponded to four standardised activities (1h/activity). In the second year, the remaining four of the eight selected lifestyle topics were addressed: 5) to improve healthy habits within a set timetable (home meals, teeth-brushing, hand-washing) and physical activity participation; 6) to increase fruit intake; 7) to improve dairy product consumption; and 8) to increase fish consumption. These corresponded to four standardised activities. Finally, in the third school academic year, four standardised activities were introduced

that reinforced the eight lifestyle topics implemented in the previous 2 academic years. Thus, the intervention program was based on eight lifestyle topics incorporated within 12 activities which were disseminated over 12 sessions (1h/activity/session), and prepared, standardised and implemented as four activities per school academic year by the HPAs in the school classrooms.

Process evaluation

The measurements were performed in each school academic year, as was the original EdAl program,[17-18].

Outcomes

Assessment of the reproducibility of the EdAl program was based on primary outcomes such as prevalence of OB (overall as well as stratified by gender), according to the International Obesity Task Force (IOTF),[24] recommendations for better international comparisons of data. Secondary outcomes included: changes in measures of adiposity (overall as well as stratified by gender) such as BMI z-score (based on WHO growth charts,[25] and waist circumference, incidence and remission of excess weight (OW and OB), as well as changes in lifestyles (eating habits and physical activity h/week). All outcomes were analysed in the intervention and control groups. Weight, height, and waist circumference values were obtained as described previously,[17]. Prevalence of underweight was analysed according to Cole et al,[26] using 17Kg/m^2 as cut-off point. BMI z-score was calculated using the population values of the WHO Global InfoBase,[25]. To identify the risk factors of OB, the OB category was determined according to WHO criteria since this is based on data from countries that have a low OB prevalence,[25] and, as such, provide an understanding of the protective (or risk factors)

for OB in our own population. To obtain a measurement of overall improvement in lifestyle we generated variables such as the maintenance of status in each category as well as the status in relation to changes in each category over the 22 month period.

Sample size

We calculated that, to have 85% chance (at a two-tailed 5% significance level) of detecting a difference of 5 percentage points between the intervention and control group (3% - 8%) with respect to OB prevalence at baseline of EdAl study [18], 354 participants would be required in each of the participation groups. Allowing for an attrition rate of up to 10%, we aimed for 393 in each group.

Statistical analyses

Analyses were conducted on student-level data. Descriptive variables were presented as means and confidence intervals (95%CI). General linear mixed models (GLM) were used to analyse differences between the intervention and control pupils with respect to prevalence of OB. Repeated measures of GLM were used to analyse the trend of BMI z-score between baseline and end-of-study values. The McNemar test was used to analyse change-over-time of food habits, after-school PA h/week and hours TV/day categories, in intervention and control group. The continuous variables studied in each group were compared using ANOVA.

To evaluate risk and protective factors involved in childhood OB, logistic regression analyses were performed at baseline, with no distinction between intervention and control group. The odds ratios (OR) and 95%CI were calculated for dietary patterns and lifestyles, based on the Krece Plus Questionnaire,[21] and the AVall Questionnaire,[22], respectively.

The main analyses were performed with the modified intention-to-treat (mITT) population i.e. subjects with baseline and end-of-study data on weight, height, and date of birth, and written inform consent. The analyses did not use any imputation missing method; the assumption being that missing data were random. Statistical significance was defined by a $P<0.05$. The statistical analyses were performed with the SPSS 20.0 for Windows (SPSS Inc., Chicago, IL, USA).

RESULTS

Enrolment

Figure 2 shows the recruitment and flow diagram of pupils in the intervention and control groups over the course of the study. The mITT population in the intervention group and control group were 320 and 370 pupils, respectively. At 22 months, the mean age was 9.67 (95%CI: 9.60, 9.73) in the intervention group (9.68 years in boys and 9.65 years in girls) and 9.86 (95%CI: 9.79, 9.91) in the control group (9.85 years in boys and 9.84 years in girls). The differences in age were not significant in relation to gender. The characteristics of the study group are summarised in Table 1. At baseline, the intervention and control group were homogeneous in BMI status. The ethnicity of the population was predominantly Western European in intervention and control group (77.5% *vs.* 78.9%, respectively) while 7.5% *vs.* 10.8% was Eastern European; 10.3% *vs.* 3.5% was Latin American; 3.4% *vs.* 6.2% was North African Arab. At baseline, there was a significant difference in the distribution with respect to Latin American children (10.3% in intervention and 3.5% in control group; $p<0.001$). The distribution was random. Of note is that there were no significant differences in distributions of OB and/or OW. Also, no differences were observed in terms of response to the intervention in relation to ethnicity.

Table 1. Anthropometric characteristics of pupils at baseline: Intervention *versus* Control group

	Intervention group			Control group					
	Mean (95%CI)			Mean (95%CI)			Intervention *vs.* control; P-value	Intervention *vs.* control; P-value	Intervention *vs.* control; P-value
	Boys (n=165)	Girls (n=155)	Total (n=320)	Boys (n=196)	Girls (n=174)	Total (n=370)	Boys	Girls	Total
Age; years	8.01 (7.91;8.12)	7.97 (7.88;8.07)	7.99 (7.92;8.06)	8.11 (8.03;8.19)	8.06 (7.97;8.15)	8.09 (8.03;8.15)	0.105	0.153	0.967
Weight; Kg	30.35 (29.22; 31.48)	29.86 (28.81; 30.91)	30.11 (29.34; 30.88)	31.29 (30.26; 32.33)	31.35 (30.36; 32.34)	31.32 (30.60; 32.04)	0.226	0.043	0.024
BMI; Kg/m^2	17.40 (16.93; 17.86)	17.42 (16.97; 17.88)	17.41 (17.09; 17.73)	17.70 (17.28; 18.13)	17.94 (17.51; 18.37)	17.82 (17.51; 18.12)	0.340	0.104	0.073
Height; m	1.32 (1.30; 1.33)	1.30 (1.29; 1.31)	1.31 (1.30; 1.32)	1.32 (1.31; 1.33)	1.32 (1.31; 1.33)	1.32 (1.31; 1.33)	0.242	0.045	0.027
Fat mass; Kg	6.71 (5.99; 7.42)	7.11 (6.50; 7.72)	6.90 (6.42; 7.38)	6.44 (5.78; 7.09)	7.70 (7.12; 8.27)	7.03 (6.59; 7.47)	0.584	0.167	0.698
Lean mass; Kg	23.99 (23.34; 24.64)	22.86 (22.32; 23.39)	23.44 (23.02; 23.87)	24.88 (24.28; 25.47)	23.71 (23.21; 24.22)	24.33 (23.93; 24.73)	0.049	0.022	0.003
Waist circumference; cm	60.97 (59.68; 62.27)	59.91 (58.67; 61.15)	60.46 (59.56; 61.36)	64.37 (63.18; 65.56)	65.17 (64.00; 66.34)	64.75 (63.91; 65.58)	<0.001	<0.001	<0.001

Notes to Table 1:

The results are expressed as Mean (95%CI)

[1]p value: general linear model (GLM) statistic

Attrition rate

Figure 2 shows the recruitment and retention of pupils in intervention and control schools. Among the 916 pupils assessed at the beginning of the study, 690 (75.3%) pupils (73.6% of those allocated to the control group and 77.5% of those allocated to the intervention group) were reassessed three academic courses later, and valid measurements were obtained. The rate of parental consent was 95.7%. Drop-outs in both groups are assumed to be missing at random.

Primary outcome: Prevalence of OB

At 22 months of the study, OB prevalence assessed by IOTF criteria, was similar in intervention and control group (p=0.628) (Table 2).

Criteria/Category		Group		Baseline % (n)	End of study % (n)	Change %	Baseline to study end P-value[1]	Intervention vs. Control P-value[2]
IOTF criteria	OW	Intervention	Boys	18.2 (30)	24.2 (40)	6	0.087	0.629
			Girls	16.2 (25)	23.2 (36)	7	0.043	0.066
			Total	17.2 (55)	23.8 (76)	6.6	0.005	0.086
		Control	Boys	25.5 (50)	27.0 (53)	1.5	0.690	
			Girls	28.2 (49)	32.8 (57)	4.6	0.185	
			Total	26.8 (99)	29.7 (110)	2.9	0.169	
	OB	Intervention	Boys	9.7 (16)	11.5 (19)	-1.8	0.453	0.735
			Girls	13.6 (21)	12.3 (19)	-1.3	0.754	0.732
			Total	11.6 (37)	11.9 (38)	0.3	1.000	0.628
		Control	Boys	10.7 (21)	10.2 (20)	-0.5	1.000	
			Girls	12.1 (21)	10.9 (19)	-1.2	0.687	
			Total	11.4 (42)	10.5 (39)	-0.93	0.607	

Table 2. Baseline and end-of-intervention measurements of categorised BMI in Intervention and Control group

Notes to Table 2

IOTF: International Obesity Task Force

The results are expressed as % (n)

[1]p value: McNemar's Test

[2]p value: Fisher's Exact Test

Secondary outcomes

At 22 months of the study, the status of OW prevalence (according to IOTF criteria) was similar between groups (p=0.086).

There were no significant differences in BMI z-score between intervention and control group (p=0.400) (Table 3). Despite no differences in BMI z-score, the boys of intervention group did not have an increase in percentage fat mass (19.96% to 20.02%: p=0.896), whereas intervention girls (22.06% to 23.55%; p<0.001), together with boys (19.18% to 20.64%, p<0.001) and girls (23.26% to 24.98%) of control group had a significant increase.

The remission, and incidence, of OB was similar in the overall intervention and control group, as well as when stratified with respect to gender.

Table 3. BMI z-score at baseline and at the end of intervention in Intervention and Control group

			Baseline Mean (95%CI)	End of study Mean (95%CI)	Change Mean (95%CI)	Baseline to Study end P-value[1]	Intervention *vs.* Control P-value[2]
BMI z-score	Intervention	Boys	0.73 (0.53; 0.94)	0.74 (0.54; 0.93)	0.00 (-0.07; 0.08)	0.973	0.381
		Girls	0.71 (0.50; 0.91)	0.89 (0.68; 1.10)	0.18 (0.10; 0.26)	<0.001	0.030
		Total	0.72 (0.58; 0.86)	0.81 (0.67; 0.95)	0.09 (0.03; 0.14)	0.002	0.400
	Control	Boys	0.83 (0.64; 1.01)	0.81 (0.63; 1.00)	-0.12 (-0.08; 0.06)	0.726	
		Girls	0.52 (0.33; 0.71)	0.63 (0.44; 0.83)	0.11 (0.02; 0.20)	0.013	
		Total	0.68 (0.55; 0.82)	0.73 (0.60; 0.86)	0.05 (-0.01; 0.10)	0.100	

Notes to Table 3:

[1]p-value: Mixed Models Repeated Measures

[2]p-value: ANOVA model

Differences between intervention and control pre- *vs.* post-intervention

Lifestyles evaluation

After 22 months of the study, there were 19.7%, 11.2% and 8.2% more girls in the intervention group who consumed a second fruit per day, one vegetable per day and fast-food weekly than the girls of control group ($p<0.001$, $p=0.017$ and $p=0.013$; respectively). However, there were 17.9% and 17.8% more boys in the intervention group who consumed pastry at breakfast and more than one vegetable a day, compared to boys of control group ($p=0.002$, $p= 0.001$; respectively). Conversely, there were 12.9% and 12.2% more girls in the control group who consumed legumes and cereal breakfast than girls of intervention group ($p=0.013$, $p=0.032$; respectively) (Table 4).

Table 4. Foods habits assessed at baseline and at the end of the study in the Intervention and Control groups

		Intervention group			Control group			Intervention *vs.* Control
		Baseline %(n)	End of study %(n)	P Value	Baseline %(n)	End of study %(n)	P Value	P-value
Krece plus questionnaire								
Breakfast	Boys	98.4 (125)	98.3 (119)	1	97.5 (154)	92.2 (153)	0.092	0.635
	Girls	98.4 (123)	99.2 (120)	1	98.7 (148)	93.8 (135)	**0.016**	0.453
	Total	98.4 (248)	98.8 (239)	1	98.1 (302)	92.9 (288)	**0.003**	1
Dairy product	Boys	94.5 (121)	93.5 (116)	1	93.6 (147)	92.3 (155)	1	1
at breakfast	Girls	94.3 (116)	93.4 (113)	0.508	94.0 (141)	89.7 (131)	**0.039**	0.325
	Total	94.4 (237)	93.5 (229)	0.481	93.8 (288)	91.1 (286)	0.167	0.574
Cereals at	Boys	65.6 (82)	66.4 (81)	0.864	59.1 (88)	54.6 (89)	0.743	0.706
breakfast	Girls	61.5 (75)	49.6 (58)	**0.036**	59.7 (86)	60.0 (87)	0.880	**0.031**
	Total	63.6 (157)	58.2 (139)	0.098	59.4 (174)	57.1 (176)	1	0.225
Pastry at	Boys	15.8 (19)	23.5 (28)	**0.027**	22.5 (33)	12.3 (20)	**0.001**	**0.002**
breakfast	Girls	20.5 (24)	15.5 (18)	0.383	15.9 (22)	12.4 (18)	0.210	0.260
	Total	18.1 (43)	19.6 (46)	0.441	19.1 (55)	12.3 (38)	**<0.001**	**0.002**
Daily fruit or	Boys	73.4 (94)	76.2 (93)	0.523	74.8 (116)	76.0 (127)	1	0.535
natural juice	Girls	66.7 (82)	70.0 (84)	0.690	79.9 (119)	73.5 (108)	0.243	0.549
	Total	70.1 (176)	13.1 (177)	0.382	77.3 (235)	74.8 (235)	0.443	0.472
Fruit, 2nd per	Boys	39.7 (50)	41.2 (49)	0.581	44.5 (69)	34.1 (56)	**0.006**	0.141
day	Girls	26.4 (32)	47.5 (56)	**0.000**	44.8 (64)	39.0 (57)	0.281	**<0.001**
	Total	33.2 (82)	44.3 (105)	**0.001**	44.6 (133)	36.5 (113)	**0.004**	**<0.001**
Dairy product,	Boys	87.2 (109)	78.5 (95)	**0.029**	80.0 (124)	69.5 (116)	0.174	0.194
2nd per day	Girls	80.5 (99)	79.8 (95)	1	71.6 (106)	75.5 (111)	0.749	0.460
	Total	83.9 (208)	79.2 (190)	0.161	75.9 (230)	72.3 (227)	0.51	0.384
Vegetables,	Boys	65.6 (84)	74.4 (90)	**0.043**	71.1 (113)	70.8 (119)	1	0.473
daily	Girls	71.7 (86)	77.5 (93)	0.169	68.7 (101)	63.3 (93)	0.152	**0.017**
	Total	68.5 (170)	75.9 (183)	**0.011**	69.9 (214)	67.3 (212)	0.374	**0.028**
Vegetables, >1	Boys	19.3 (23)	29.1 (34)	**0.017**	28.7 (43)	20.7 (34)	**0.009**	**0.001**
per day	Girls	25.4 (31)	34.5 (40)	0.052	30.3 (43)	23.1 (33)	0.110	0.149
	Total	22.4 (54)	31.8 (74)	**0.001**	29.5 (86)	21.8 (67)	**0.002**	**0.001**
Fish, regularly	Boys	73.2 (93)	76.6 (95)	0.608	70.0 (112)	70.1 (115)	0.851	0.058

	Girls	71.8 (92)	71.4 (85)	0.307	74.5 (111)	71.0 (103)	1	0.662
	Total	74 (185)	74.1 (180)	0.896	72.2 (223)	70.6 (218)	0.791	0.312
Fast food, >1	Boys	6.3 (8)	7.4 (9)	1	7.1 (11)	4.9 (8)	0.227	0.106
per week	Girls	3.3 (4)	10.1 (12)	0.109	4.2 (6)	2.8 (4)	0.219	**0.013**
	Total	4.8 (12)	8.8 (21)	0.21	5.7 (17)	3.9 (12)	**0.049**	**0.003**
Legumes >1	Boys	70.3 (90)	71.1 (86)	0.648	67.5 (106)	65.9 (110)	1	0.555
per week	Girls	72.8 (91)	73.3 (88)	0.815	62.8 (145)	76.2 (112)	**0.001**	**0.013**
	Total	71.5 (181)	72.2 (174)	1	65.2 (251)	70.7 (222)	**0.025**	**0.027**
Candy > per	Boys	14.3 (18)	12.6 (15)	1	17.2 (27)	18.2 (30)	1	0.367
day	Girls	12.9 (16)	12.0 (14)	1	18.7 (26)	11.1 (16)	0.078	1
	Total	13.6 (34)	12.3 (29)	1	17.9 (53)	14.9 (46)	0.262	0.479
Pasta or rice	Boys	63.8 (81)	67.5 (83)	0.839	69.0 (109)	67.9 (114)	0.871	0.708
daily	Girls	59.2 (74)	64.7 (77)	0.377	68.0 (100)	69.4 (102)	0.618	0.724
	Total	61.5 (155)	66.1 ()	0.35	68.5 (209)	68.6 (216)	0.561	1
Cooking with	Boys	97.7 (126)	98.4 (122)	1	98.1 (157)	98.8 (167)	1	0.636
olive oil at	Girls	98.4 (125)	99.2 (120)	0.623	97.3 (145)	98.0 (145)	1	0.628
home	Total	98 (251)	98.8 (242)	0.5	97.7 (302)	98.4 (312)	0.754	0.476
Avall questionnaire								
Before leaving home								
Dairy	Boys	90 (117)	87.3 (110)	0.065	83.6 (133)	95.3 (139)	1	0.074
products	Girls	87.3 (110)	87.8 (108)	0.503	83 (122)	76.4 (110)	**0.004**	0.235
	Total	90.9 (227)	87.6 (218)	0.071	86.2 (255)	81.1 (249)	**0.044**	0.836
Pastry	Boys	4 (5)	2.4 (3)	1	0.7 (1)	1.4 (2)	1	0.610
	Girls	0.8 (1)	1. 7 (2)	1	0.7 (1)	0 (0)	1	1
	Total	2.5 (6)	2 (5)	1	0.7 (2)	0.7 (2)	1	0.606
Cereals	Boys	33.9 (43)	36.8 (46)	0.711	30.7 (46)	35.0 (55)	0.608	1
	Girls	32.2 (38)	26.2 (32)	0.405	25.2 (37)	26.2 (37)	0.458	0.297
	Total	33.1 (81)	31.6 (78)	0.89	27.9 (83)	30.9 (92)	0.314	0.409
Fresh fruit	Boys	18.4 (23)	24.6 (31)	0.189	17.0 (26)	21.2 (32)	1	0.537
or natural	Girls	14.2 (17)	24.6 (30)	0.064	18.5 (27)	23.6 (33)	0.541	0.332
juice	Total	16.3 (40)	24.6 (61)	**0.016**	17.7 (53)	22.3 (65)	0.560	0.256
	Boys	6.6 (8)	17.7 (22)	0.115	17.3 (26)	21.1 (32)	0.458	1
	Girls	0.3 (12)	19.7 (24)	**0.049**	14.9 (21)	18.4 (26)	0.572	1
Sandwich	Total	8.4 (20)	18.7 (46)	**0.008**	16.2 (47)	19.8 (58)	0.289	0.889
Juice	Boys	6.7 (8)	7.4 (9)	0.754	8.7 (13)	7.1 (11)	1	0.756
package/sof	Girls	7.7 (9)	5.0 (6)	0.508	8.6 (12)	10.8 (15)	1	0.507

t drinks								
	Total	7.2 (17)	6.2 (15)	0.359	8.6 (25)	8.9 (26)	0.845	0.483
Break (Midmorning)								
Dairy	Boys	16.0 (20)	20.0 (24)	0.824	15.3 (22)	14.4 (21)	1	0.819
products	Girls	8.7 (10)	9.6 (11)	0.388	10.7 (15)	8.4 (11)	1	0.595
	Total	12.5 (30)	15 (35)	0.367	13.0 (37)	11.6 (32)	1	0.488
Pastry	Boys	4.1 (5)	0.8 (1)	0.625	4.1 (6)	2.1 (3)	1	1
	Girls	0.9 (1)	0.9 (1)	1	1.5 (2)	2.3 (3)	1	0.480
	Total	2.5 (6)	0.9 (2)	0.687	2.8 (8)	2.2 (6)	0.687	1
Cereals	Boys	3.3 (4)	5.9 (7)	0.727	5.7 (8)	4.9 (7)	1	1
	Girls	3.5 (4)	3.4 (4)	1	4.3 (6)	6.9 (9)	0.180	0.544
	Total	3.4 (8)	4.7 (11)	0.804	5 (14)	5.9 (16)	0.238	0.659
Fresh fruit or	Boys	16.3 (20)	10.1 (12)	0.804	19.5 (30)	14.5 (22)	0.189	0.787
natural juice	Girls	15.5 (18)	16.8 (20)	0.424	20.1 (29)	20.3 (28)	0.815	1
	Total	15.9 (38)	13.4 (32)	0.856	19.8 (59)	17.2 (50)	0.522	0.721
Sandwich	Boys	28.3 (36)	37.7 (46)	0.087	43.2 (67)	41.6 (67)	0.701	0.080
	Girls	24.8 (30)	33.6 (41)	0.064	29.7 (44)	41.1 (58)	**0.016**	0.860
	Total	26.6 (66)	35.7 (87)	**0.008**	36.6 (111)	41.4 (125)	0.185	0.299
Juice	Boys	7.4 (9)	9.1 (11)	0.344	12.2 (18)	12.6 (19)	1	1
package/soft	Girls	7.8 (9)	6.1 (7)	0.727	12.1 (17)	13.2 (18)	1	0.233
drinks	Total	7.6 (18)	7.7 (18)	0.815	12.2 (35)	12.9 (37)	1	0.543

Notes to Table 4:

[1]p-value: McNemar's Test (changes in intervention group)

[2]p-value: McNemar's Test (changes in control group)

[3]p-value: Fisher's Exact Test.

Table 5 summarises the time spent in after-school PA, watching TV, playing video games, and other leisure-time activities. At 22 months, the percentage of boys of the intervention group who performed ≥4h after-school PA/week was increased by 15% (p=0.027) while there was 16.6% more boys in the intervention group watching ≤2hTV/day (p<0.009). The results indicate less sedentary behaviour in intervention than control individuals.

Table 5. Lifestyles assessed at baseline and at the end of study in Intervention and Control

		Intervention			Control			Intervention vs. Control
		Baseline %(n)	End of study %(n)	p-value[1]	Baseline %(n)	End of study %(n)	P-value[2]	P-value[3]
TV and/or video games								
0-2h/day	Boys	49.2 (62)	45.2 (57)	0.268	32.5 (51)	27.0 (43)	0.627	0.71
	Girls	48.4 (60)	51.2 (63)	1	44.0 (66)	49.7 (71)	0.43	0.287
	Total	48.8 (122)	48.2 (120)	0.464	38.1 (117)	37.7 (114)	0.91	0.697
3-4h/day	Boys	46.0 (58)	50.0 (63)	0.542	62.4 (98)	63.5 (101)	1	0.874
	Girls	43.5 (54)	44.7 (55)	0.86	54.0 (81)	47.6 (68)	0.349	0.71
	Total	44.8 (112)	47.4 (118)	0.489	58.3 (179)	56.0 (169)	0.606	0.632
>4h/day	Boys	4.8 (6)	4.8 (6)	0.375	5.1 (8)	9.4 (15)	0.607	0.393
	Girls	8.1 (10)	4.1 (5)	0.453	2.0 (3)	2.8 (4)	1	1
	Total	6.4 (16)	4.4 (11)	1	3.6 (11)	6.3 (19)	0.481	0.462
After-school PA								
0-2h/week	Boys	26.2 (34)	14.5 (18)	0.013	21.5 (34)	19.0 (31)	0.286	0.354
	Girls	35.2 (43)	33.6 (41)	0.701	34.5 (50)	36.6 (52)	1	0.557
	Total	30.6 (77)	24.0 (59)	**0.049**	27.7 (84)	27.2 (83)	0.435	0.254
2-4h/week	Boys	29.2 (38)	24.2 (30)	0.418	38.0 (60)	3.1 (54)	0.78	0.602
	Girls	36.9 (45)	32.0 (39)	0.377	32.4 (47)	31.0 (44)	1	0.155
	Total	32.9 (83)	28.0 (69)	0.188	35.3 (107)	32.1 (98)	0.764	0.135

>4h/week	Boys	44.6 (58)	61.3 (76)	**0.006**	40.5 (64)	47.9 (78)	0.243	0.643
	Girls	27.9 (34)	34.4 (42)	0.136	33.1 (48)	32.4 (46)	0.868	0.598
	Total	36.5 (92)	48.0 (118)	**0.002**	37.0 (112)	40.7 (124)	0.272	0.485

Notes to Table 5

[1]P-value: McNemar's Test (changes in intervention group)

[2]P-value: McNemar's Test (changes in control group)

[3]P-value: Fisher's Exact Test.

Differences between intervention and control pre-post intervention program

At 22 months, subjects who were normal weight at baseline increased after-school PA to ≥4h/week. This reflects a rise to 32.7% in boys (p=0.002). However, in girls, the changes were not statistically different (p=0.134). No statistically significant differences were observed in the control group.

Impact of certain additional factors on obesity

The ORs of OB, using BMI z-score criteria, were related to some of the more relevant dietary habits and lifestyles. Thus, breakfast dairy product consumption (OR: 0.336; p=0.004) and ≥4 after-school PA h/week (OR: 0.600; p=0.032) were protective factors against OB. Conversely, doing <4 h/week PA (OR: 1.811; p=0.018) increased the risk of childhood OB.

DISCUSSION

The EdAl-2 program, a reproducibility study in Terres de l'Ebre, shows that intervention is useful for improving weekly after-school PA. However, the OB prevalence remained unchanged at 22 months, as has been shown in the data on stability of OB prevalence observed in some European countries,[8]. Despite that OW and OB remained similar between groups, we observed percentage fat mass maintenance in the boys of the intervention group, whereas girls of the intervention and control group had increases.

As proposed by Kain J et al, designing a new school-based intervention study needs to have some critical aspects considered. These include: the random allocation of schools, although methodologically desirable, is not always possible; participation of parents is very limited; obesity is not recognised as a problem; and increasing physical activity

and implementing training programmes for teachers is difficult due to an inflexible curriculum and lack of teachers' time. Unless these barriers are overcome, obesity prevention programmes will not produce positive and lasting outcomes,[27]. As such, our programme of HPA-implemented intervention activities in classrooms is an attractive alternative that circumvents lack-of-teacher-time.

The EdAl-2 program confirmed that after-school PA (in terms of h/week) can be stimulated in primary school as part of a healthy lifestyle. As we had observed in the original EdAL program,[18] at 28 months of intervention, there was an increase of up to 19.7% of children dedicating >5 hours/week to extra-curricular physical activities,[18]. Further, the after-school PA was maintained despite cessation of the intervention program,[28]. The effect of EdAl program during its implementation and after the official cessation indicated an impact on PA, whereas modification towards healthy food choices occurred according to the site of the program's implementation, and was not consistent.

Interventions to prevent OB in the school setting have shown dramatic improvements,[29]. However, successful studies in OB prevention need to be reproducible, especially those improving healthy lifestyle such as after-school PA, to confirm best childhood practices.

Reproducibility of studies is rare because of the complexity of trying to replicate a programme. To standardise a method it is essential to be able to reproduce appropriate levels of an intervention, especially one that involves behavioural changes. Feasibility of our intervention was confirmed in two different towns and over two different time-courses (the first in Reus over 28 months, and the second in Amposta over 22 months). Also, it is important to assess treatment adherence in order to evaluate reproducibility and feasibility,[19]. For example, the KOPS study,[20] demonstrated that nutritional

knowledge was increased as a result of the intervention in the two cohort studies (KOPS 1 and KOPS 2),[20]. However, the study was unable to show whether there were differences in overweight outcomes, weight categories or lifestyles between the two cohorts. Some multi-centred studies have attempted to reproduce methodological aspects in interventions conducted in different countries or different populations. However, while multi-centred studies are usually implemented concurrently, reproducibility involves the applicability of the intervention at different sites and/or different times in order to validate the initial findings. One example of this is the Pro Children Study,[30] which, as a multi-centred study, had been applied in different countries simultaneously and had demonstrated its efficacy and feasibility.

The ALADINO study presented the obesity status prevalence in Spain which, according to the IOTF, is about 11.4% in children of around 9 years of age,[31]. In the EdAl-2 study, the OB prevalence was similar, but lower in the intervention group than the equivalent in the ALADINO study and, as well, in the EDAL-2 control group.

The EdAl-2 study showed a significant improvement of 16.7% in the young boys in the intervention group who participated in ≥4 h/week after-school PA. Further, the increased numbers of children in the intervention group who performed ≥4 h/week after-school PA who were normal-weight at baseline, suggested that the intervention was effective not only in the primary-school healthy population but also effective in preventing OB over the longer-term due to the PA being maintained.

In the dietary habits aspect of EdAl-2 study, we observed that the increase in healthy lifestyle habits such as the increase in fruit and vegetables consumption and increasing PA h/week while maintaining low TV h/d, are promising lifestyle changes that could induce a reduction of OW and OB over the long-term.

In the EdAl-2 study we observed that consumption of dairy products at breakfast was a protective factor against obesity.

Several studies have shown that participating in PA was a protective factor against OB and that spending >2h watching TV was a risk factor for childhood OB. A recent Spanish study showed that leisure-time PA was a protective factor against OB (as with our present study) and that performing >4 h/week is a protective factor while watching TV for this amount of time was, according to Ochoa et al,[32], associated with OB.

There are several limitations to our study. Firstly, we evaluated dietary habits via a questionnaire that did not take into account the quantities of the different types of food items consumed. These data would be important in addressing the quantity *versus* quality debate in OB or OW prevalence. Secondly, assigning control groups according to towns surrounding the intervention town could be a limitation. However, schools of the same town have good relationships and communications with each other and this could entail a possible contamination between schools if assigned to intervention or control status within the same town. This cross-contamination would be minimised if the schools themselves were assigned to intervention or control. Thirdly, the significant difference in Latin American ethnicity between the two groups of the study at baseline could be a limitation. However, there were no significant differences in distributions of OB and/or OW. Also, no differences were observed in terms of response to the intervention study in relation to ethnicity. Fourthly, when asked about fast-food consumption, the participants interpreted this as pertaining only to fast-food outlets such a burger shops, and did consider other concepts such as frozen pizza consumed at home. Finally, another limitation could be the proportion of females who may have started puberty in the course of the study. This implies changes in body composition. However,

both study groups (intervention and control) had a similar proportion of females with a similar age, and this could cancel-out the effect.

Further, EdAl-2 demonstrated that performing >4h/week after-school PA, plus having dairy product at breakfast are protective factors. Hence, we believe that a participating in >4h/week after-school PA, and continuing with a healthy breakfast, are key points in preventing childhood OB.

CONCLUSION

Our school-based intervention is feasible and reproducible by increasing after-school PA (to ≥4h/week) in boys. Despite this improvement, there was no statistically significant change in the prevalence of OB. This suggests that our intervention programme induces healthy lifestyle effects (such as more exercise and less sedentary behaviour) which can produce anti-obesity benefits in children in the near future beyond the limited length of our current study. However, the effects on girls' behaviour need to be more closely studied, together with a future repeat of our study in a different population.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

ETHICS

The EdAl-2 study was approved by the Clinical Research Ethical Committee of the *Hospital Sant Joan of Reus, Universitat Rovira i Virgili* (Catalan ethical committee registry ref 11-04-28/4proj8).

DATA SHARING

Technical appendix, statistical code, and dataset available at Dryad repository in: "Data from: EdAl-2 (Educació en Alimentació) programme: reproducibility of a cluster randomised, interventional, primary-school-based study to induce healthier lifestyle activities in children" (*expecting the definitive DOI*).

LIST OF ABBREVIATIONS

OB: Obesity

OW: Overweight

PA: Physical Activity

mITT: modified Intention to Treat

HPAs: Health Promoter Agents

WHO: World Health Organization

BMI: Body Mass Index

OR: Odds Ratio

Authors' contributions

MG, EL, LT, RS designed the study (project conception, development of overall research plan, and study oversight)

MG, EL, LT, RQ, RS conducted research (hands-on conduct of the experiments and data collection)

EL, LT, MG, RS provided essential materials (applies to authors who contributed by providing constructs, database, etc. necessary for the research)

DM, EL, LT analysed data or performed statistical analysis

RS, MG, LT, DM, EL drafted and revised the manuscript (authors who made a major contribution). The final manuscript was read and approved by all co-authors

RS, MG take primary responsibility for the study, and manuscript content

REFERENCES

1. Organización para la Cooperación y el Desarrollo Económicos (OCDE): *Obesity update.* 2012.
2. World Health Organization. The Challenge of Obesity in the WHO European Region and the strategies for response. Denmark; 2007.
3. Ahrens W, Bammann K, Siani A, et al. The IDEFICS cohort: design, characteristics and participation in the baseline survey. *Int J Obes* 2011;35(Suppl 1:)S3-15. doi:10.1038/ijo.2011.30
4. Brug J, van Stralen MM, Te Velde SJ, et al. Differences in weight status and energy-balance related behaviors among schoolchildren across Europe: the ENERGY-project. *PLoS One* 2012;7(4):e34742. doi: 10.1371/journal.pone.0034742. [Published Online First: 25 April 2012]
5. Martos-Moreno GA, Argente J. Paediatric obesities: from childhood to adolescence. *An Pediatr (Barc)* 2011;75(1):63e1-23. doi:10.1016/j.anpedi.2011.03.018. [Published Online First: 23 May 2011]
6. Manco M, Dallapiccola B. Genetics of pediatric obesity. *Pediatrics* 2012;130(1):123-133. doi:10.1542/peds.2011-2717. [Published Online First: 4 June 2012]
7. Vos MB, Welsh J. Childhood obesity: update on predisposing factors and prevention strategies. *Curr Gastroenterol Rep* 2010;12(4):280-287. doi:10.1007/s11894-010-0116-1.
8. The Organisation for Economic Co-operation and Development (OECD): Obesity Update 2012. [http://www.oecd.org/health/49716427.pdf]
9. Van Cauwenberghe E, Maes L, Spittaels H. Effectiveness of school-based interventions in Europe to promote healthy nutrition in children and adolescents:

systematic review of published and 'grey' literature. *Br J Nutr* 2010;103(6):781-797. doi:10.1017/S0007114509993370. [Published Online First: 14 January 2010]

10. Reinehr T, Wabitsch M. Childhood obesity. *Curr Opin Lipidol* 2011;22:21-5.
11. Guia de práctica clínica (GPC). *AATRM* 2007.
12. Verbestel V, De Henauw S, Maes L, et al. Using the intervention mapping protocol to develop a community-based intervention for the prevention of childhood obesity in a multi-centre European project: the IDEFICS intervention. *Int J Behav Nutr Phys Act* 2011;8:82. doi:10.1186/1479-5868-8-82.
13. Vio F, Zacarías I, Lera L, et al. Prevención de la obesidad en escuelas básicas de Peñalolén: Componente alimentación y nutrición. Rev Chil Nutr 2011; 38:268-276.
14. Bacardí-Gascon M, Pérez-Morales ME, Jiménez-Cruz A. A six month randomized school intervention and an 18-month follow-up intervention to prevent childhood obesity in Mexican elementary schools. Nutr Hosp 2012; 27:755-62.
15. De Bourdeaudhuij I, Van Cauwenberghe E, Spittaels H, et al. School-based interventions promoting both physical activity and healthy eating in Europe: a systematic review within the HOPE project. *Obes Rev* 2011;12(3):205-216. doi:10.1111/j.1467-789X.2009.00711.x.
16. Papandreou D, Malindretos P, Rousso I. Risk factors for childhood obesity in a Greek paediatric population. *Public Health Nutr* 2010;13(10):1535-1539. doi:10.1017/S1368980009993156. [Published Online First: 15 January 2010]
17. Giralt M, Albaladejo R, Tarro L, et al. A primary-school-based study to reduce prevalence of childhood obesity in Catalunya (Spain)--EDAL-Educacio en

alimentacio: study protocol for a randomised controlled trial. *Trials* 2011;12:54-62. doi:10.1186/1745-6215-12-54.

18. Tarro L, Llauradó E, Albaladejo R, et al. A primary-school-based study to reduce the prevalence of childhood obesity – The EdAl (Educació en Alimentació) study: a randomized controlled trial. *Trials* 2014;15:58. doi:10.1186/1745-6215-15-58.
19. Boutron I, Moher D, Altman DG, et al. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med* 2008, 148(4):295-309.
20. Danielzik S, Pust S, Muller MJ. School-based interventions to prevent overweight and obesity in prepubertal children: process and 4-years outcome evaluation of the Kiel Obesity Prevention Study (KOPS). *Acta Paediatr Suppl* 2007;96(454):19-25.
21. Serra Majem L, Ribas Barba L, Aranceta Bartrina J, et al. Childhood and adolescent obesity in Spain. Results of EnKid study (1998-2000). *Med Clin (Barc)* 2003;12:725-732.
22. Llargues E, Franco R, Recasens A, et al. Assessment of a school-based intervention in eating habits and physical activity in school children: the AVall study. *J Epidemiol Community Health* 2011;65(10):896-901. doi:10.1136/jech.2009.102319. [Published Online First: 12 March 2011]
23. Gidding SS, Dennison BA, Birch LL, et al. Dietary recommendations for children and adolescents: a guide for practitioners: consensus statement from the American Heart Association. *Circulation* 2006;113(Suppl 23):e857.

24. Cole TJ, Bellizzi MC, Flegal KM, et al. Establishing a standard definition for child overweight and obesity worldwide: international survey. *BMJ* 2000;320(7244):1240-1243.

25. World Health Organization. Growth Reference data for 5-19 years. 2007. [http://www.who.int/growthref/en/.] Date accessed: 05/03/2014

26. Cole TJ, Flegal KM, Nicholls D, et al. Body mass index cut offs to define thinness in children and adolescents: international survey. *BMJ* 2007, 335(7612):194. [Published Online First: 25 June 2007]

27. Kain J, Uauy R, Concha F, et al. School-based obesity prevention interventions for Chilean children during the past decades: Lessons learned. Adv Nutr 2012; 3(4):616s-621s.

28. Tarro L, Llauradó E, Moriña D, et al. Five-year follow-up of a healthy lifestyle education program (the EdAl study): Two years post-cessation of intervention. (Manuscript under review)

29. Brown T, Summerbell C. Systematic review of school-based interventions that focus on changing dietary intake and physical activity levels to prevent childhood obesity: an update to the obesity guidance produced by the National Institute for Health and Clinical Excellence. *Obes Rev* 2009;10(1):110-41. doi:10.1111/j.1467-789X.2008.00515.x. [Published Online First: 30 July 2008]

30. Te Velde SJ, Brug J, Wind M, et al. Effects of a comprehensive fruit- and vegetable-promoting school-based intervention in three European countries: the Pro Children Study. *Br J Nutr* 2008;99(4):893-903. [Published Online First: 22 October 2007]

31. Pérez-Farinós N, López-Sobaler AM, Dal Re MA, et al. The ALADINO Study: A National Study of Prevalence of Overweight and Obesity in Spanish Children

in 2011. *Biomed Res Int* 2013;2013:163687. doi: 10.1155/2013/163687. [Published Online First: 8 September 2013]

32. Ochoa MC, Moreno-Aliaga MJ, Martinez-Gonzalez MA, et al. Predictor factors for childhood obesity in a Spanish case-control study. *Nutrition* 2007;23(5):379-384. [Published Online First: 3 April 2007]

FIGURE LEGEND

Figure 1: Eight topics of educational intervention activities

This figure shows the 8 topics of 12 educational intervention activities of EdAl program

Figure 2: Flow of subjects through the study

Incomplete height and/or weight (measures of first and/or third academic year); No parental consent signed (first, second or third academic year).

EdAl-2 (*Educació en Alimentació*) programme: reproducibility of a cluster randomised, interventional, primary-school-based study to induce healthier lifestyle activities in children

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ABSTRACT

Objectives: To assess the reproducibility of an educational intervention EdAl-2 programme in "Terres de l'Ebre" (Spain), over 22 months, to improve lifestyles, including diet and physical activity (PA)

Design: Reproduction of a cluster randomised controlled trial

Setting: Two semi-rural town-group primary-school clusters were randomly assigned to intervention or control group

Participants: Pupils (n=690) of which 320 constituted intervention group (1 cluster) and 370 constituted control group (1 cluster). Ethnicity was 78% Western European. Mean age (±SD) was 8.04±0.6 years (47.7% females) at baseline. Inclusion criteria for clusters were towns from the southern part of Catalonia having a minimum of 500 children aged 7 to 8 year; and complete data for participants, including name, gender, date and place of birth, and written informed consent from parents or guardians.

Intervention: The intervention focused on 8 lifestyle topics covered in 12 activities (1h/activity/session) implemented by health promoting agents in the primary-school over 3 academic years.

Primary and secondary outcomes: the primary outcome was obesity (OB) prevalence and the secondary outcomes were body mass index (BMI) collected every year, and dietary habits and lifestyles collected by questionnaires filled-in by parents at baseline and end-of-study.

Results: At 22 months, the obesity prevalence and BMI values were similar in intervention and control groups. Relative to children in control schools, the percentage of boys in the intervention group who performed ≥4 after-school PA h/week was 15% higher (p=0.027), whereas the percentage of girls of both groups remained similar.

Also, 16.6% more boys in the intervention group watched ≤2 TV h/day (p=0.009), compared to controls; and no changes were observed in girls of both groups.

Conclusions: Our school-based intervention is feasible and reproducible by increasing after-school PA (to ≥4h/week) in boys induced healthy lifestyle effects while, the prevalence of OB was not significantly changed.

Words: 295

Clinical Trials registration NCT01362023

ARTICLE SUMMARY

Strengths and limitations of the study

- Strengths: Reproducibility of studies is rare because of the complexity of replicating an intervention programme. Studies in OB prevention, such as EdAl, need to be reproducible, especially those improving healthy lifestyle, including after-school PA, to reinforce beneficial practices in childhood
- Strengths: Statistical methods controlling for confounders and taking into account clustering of data
- Limitations: Failure to assess treatment adherence to evaluate reproducibility and feasibility
- Limitations: Dietary habits were noted via a questionnaire that did not take into account the quantities of the different types of food items consumed

BACKGROUND

Obesity (OB) has become a disease of epidemic proportions,[1]. However, this increasing tendency towards excess weight in childhood and adulthood,[2] observed in some countries (United Kingdom, France, South Korea, United States and Spain) has stabilised despite the absolute rates being a cause for concern,[1]. OB prevalence in children and adolescents is higher in southern regions of Europe,[3-4].

Accumulation of fat tissue constitutes an increased disease risk in childhood, as well as in adulthood,[5]. This disease risk has a multifactorial aetiology, such as an unhealthy diet and sedentary lifestyle,[6-7].

The Organization for Economic Co-operation and Development (OECD), has predicted an increase of 7% in excess weight prevalence in adulthood over the period spanning 2010 to 2020,[8]. The WHO proposes the prevention and control of OB prevalence as key in the updated "Action Plan 2008-2013" in which effective health promotion is considered the principal strategy,[9].

Since excess weight status in adulthood is almost invariably predicated on childhood and adolescent weight, OB prevention should start early in life,[10]. The optimum age to commence an intervention is between the ages of 7 and 8 years because children are more receptive to guidance,[11]. The school is an ideal place for the promotion of healthy nutrition and lifestyle habits,[12] and, as some studies have shown, such interventions have inspired changes in nutritional habits and BMI status,[13-14]; the message being received by all schoolchildren, irrespective of ethnic and socioeconomic differences,[9]. The effectiveness of an intervention is when educational strategies and environmental factors such as healthy nutrition and physical activity habits coincide since both aspects are essential in preventing childhood OB,[15]. Currently, European children spend more of their leisure time in sedentary activities such as watching

television (TV), video games or on the Internet. These activities represent a decrease in physical movement and lowering energy expenditure and, as such, are risk factors for OB,[16].

We had designed the EdAl (*Educació en Alimentació*) programme as a randomised, controlled, parallel study applied in primary schools, and implemented by university students acting as Health Promoter Agents (HPAs),[17]. This intervention was deployed in Reus (as intervention group) with the neighbouring towns of Salou, Cambrils and Vilaseca as control group. The interventions focused on 8 lifestyle topics covered in 12 activities (1h/activity/session) in 7-8 year old children, and implemented by HPAs over 3 school academic years. We found that the EdAl programme successfully reduced childhood OB prevalence in boys by 4.39% and increased the percentage of boys who practice ≥5 after-school physical activity (PA) h/week,[18]. The EdAl programme needed to be reproduced in other localities, and with other children, to demonstrate the effectiveness of this intervention[19].

The outcomes of the EdAl programme supported the feasibility of improving PA in childhood. However, an educational intervention, such as our EdAl program implemented by HPAs, also tests complex components such as healthy lifestyles including diet and physical activity recommendations. Due to the complexity, such interventions are difficult to rationalise, standardise, reproduce, and administer consistently to all participants,[19].

There has been one study in the literature that has reproduced its programmes in other locations. Described as the Kiel Obesity Prevention Study (KOPS), the results demonstrated the efficacy and feasibility of implementing new nutritional concepts,[20].

We tested the reproducibility of the EdAl programme in a geographical area (Terres de l'Ebre) about 80km away from where the original EdAl programme was designed and

implemented. We designed a cluster (town group) randomised controlled trial; the rationale being that since good communications exist between the schools of the same town, this could contribute to schools of the intervention group "contaminating" those of the putative control group.

We describe, here, the primary-school-based study to reduce the prevalence of childhood OB (The EdAl-2 study); the objective remains an intervention to induce healthy lifestyles, including diet and physical activity recommendations. The study was conducted in 7-8 year old school-children over 3 academic years (22 months active school time).

METHODS

The original protocol, rationale, randomisation, techniques and results of the initial EdAl programme have been published in Trials,[17-18]. The current study (EdAl-2) was conducted in exactly the same way so as to assess whether comparable results could be achieved in a different location. The exact intervention is described in more detail in Supplemental File 1, and in this manuscript link. The EdAl-2 study was approved by the Clinical Research Ethical Committee of the *Hospital Sant Joan of Reus, Universitat Rovira i Virgili* (Catalan ethical committee registry ref 11-04-28/4proj8). This study was registered in Clinical Trials *NCT01362023*. The protocol conformed to the Helsinki Declaration and Good Clinical Practice guides of the International Conference of Harmonization (ICHGCP). The study followed the CONSORT criteria [see Additional File 2].

For logistics reasons, the EdAl-2 program was reduced by 6 months, from 28 months to 22 months.

Study population

To ensure approximately a minimum 500 inhabitants of 7-8 years of age per cluster, before randomising the towns (clusters), a statistician who was not familiar with the study objectives and of the school identities, matched the towns on population size. The coordinating Center (in Reus) developed a cluster randomisation scheme to have a study sample in which the schools in Amposta were designated as Cluster A (intervention) and 9 towns around Amposta (Sant Jaume d'Enveja, Els Muntells, l'Ametlla de Mar, El Perelló, l'Ampolla, Deltebre, l'Aldea, Lligalló del Gànguil and Camarles) as Cluster B (control). The eligibility criteria of clusters were to be semi-rural towns from the southern part of Catalonia with a minimum of 500 children of 7 to 8 years of age in each cluster.

The socio-demographic indicators in all towns were similar to that of the original EdAl Program in Reus. Children attending the schools in both groups (intervention and control) lived in close proximity within each school's catchment area. Intervention institutions were 5 schools involving 18 classrooms and 457 pupils in Amposta. Control institutions consisted of 11 schools involving 23 classrooms and 531 pupils in the 9 towns of around Amposta. Children of this study are in the 2nd and 3rd grade of primary education (7-8 year olds). Schoolchildren were enrolled in May 2011 (children born in 2002–2003) and followed-up for 3 school academic years (2012–2013). The study was completed in March 2013.

To be representative of the child population, the schools selected needed to have at least 50% of the children in the classrooms volunteer to participate. We offered the programme to all schools, whether public (funded by the government and termed "charter" schools) or private which included fee-paying and/or faith schools. Inclusion criteria were: name, gender, date and place of birth, and written informed consent from

the parent or guardian of each participant. A questionnaire on eating habits (Krece Plus) developed by Serra Majem et al,[21], and physical activity, level of parental education and lifestyles developed by Llargues et al,[22] were filled-in by the parents at baseline and at the end of the study.

Intervention program

The original EdAl Reus protocol was followed,[17-18]. The educational intervention activities focused on eight lifestyle topics based on scientific evidence,[23] to improve nutritional food item choices (and avoidance of some foods), healthy habits such as teeth-brushing and hand-washing and, overall, adoption of activities that encourage physical activity (walking to school, playground games), and to avoid sedentary behaviour,[23].

Each of the eight topics described in Figure 1, was integrated within educational intervention activities of 1h/activity, prepared and standardized by the HPAs, and implemented in the children's classrooms. In the first school academic year, we focused on four topics: 1) to improve healthy lifestyle; 2) to encourage healthy drinks intake (and avoidance of unhealthy carbonated/sweetened beverages); 3) to increase the consumption of vegetables and legumes; and 4) to decrease the consumption of candies and pastries while increasing the intake of fresh fruits and nuts. These corresponded to four standardised activities (1h/activity). In the second year, the remaining four of the eight selected lifestyle topics were addressed: 5) to improve healthy habits within a set timetable (home meals, teeth-brushing, hand-washing) and physical activity participation; 6) to increase fruit intake; 7) to improve dairy product consumption; and 8) to increase fish consumption. These corresponded to four standardised activities. Finally, in the third school academic year, four standardised activities were introduced

that reinforced the eight lifestyle topics implemented in the previous 2 academic years. Thus, the intervention program was based on eight lifestyle topics incorporated within 12 activities which were disseminated over 12 sessions (1h/activity/session), and prepared, standardised and implemented as four activities per school academic year by the HPAs in the school classrooms.

Process evaluation

The measurements were performed in each school academic year, as was the original EdAl program,[17-18].

Outcomes

Assessment of the reproducibility of the EdAl program was based on primary outcomes such as prevalence of OB (overall as well as stratified by gender), according to the International Obesity Task Force (IOTF),[24] recommendations for better international comparisons of data. Secondary outcomes included: changes in measures of adiposity (overall as well as stratified by gender) such as BMI z-score (based on WHO growth charts,[25] and waist circumference, incidence and remission of excess weight (OW and OB), as well as changes in lifestyles (eating habits and physical activity h/week). All outcomes were analysed in the intervention and control groups. Weight, height, and waist circumference values were obtained as described previously,[17]. Prevalence of underweight was analysed according to Cole et al,[26] using 17Kg/m^2 as cut-off point. BMI z-score was calculated using the population values of the WHO Global InfoBase,[25]. To identify the risk factors of OB, the OB category was determined according to WHO criteria since this is based on data from countries that have a low OB prevalence,[25] and, as such, provide an understanding of the protective (or risk factors)

for OB in our own population. To obtain a measurement of overall improvement in lifestyle we generated variables such as the maintenance of status in each category as well as the status in relation to changes in each category over the 22 month period.

Sample size

We calculated that, to have 85% chance (at a two-tailed 5% significance level) of detecting a difference of 5 percentage points between the intervention and control group (3% - 8%) with respect to OB prevalence at baseline of EdAl study [18], 354 participants would be required in each of the participation groups. Allowing for an attrition rate of up to 10%, we aimed for 393 in each group.

Statistical analyses

Analyses were conducted on student-level data. Descriptive variables were presented as means and confidence intervals (95%CI). General linear mixed models (GLM) were used to analyse differences between the intervention and control pupils with respect to prevalence of OB. Repeated measures of GLM were used to analyse the trend of BMI z-score between baseline and end-of-study values. The McNemar test was used to analyse change-over-time of food habits, after-school PA h/week and hours TV/day categories, in intervention and control group. The continuous variables studied in each group were compared using ANOVA.

To evaluate risk and protective factors involved in childhood OB, logistic regression analyses were performed at baseline, with no distinction between intervention and control group. The odds ratios (OR) and 95%CI were calculated for dietary patterns and lifestyles, based on the Krece Plus Questionnaire,[21] and the AVall Questionnaire,[22], respectively.

The main analyses were performed with the modified intention-to-treat (mITT) population i.e. subjects with baseline and end-of-study data on weight, height, and date of birth, and written inform consent. The analyses did not use any imputation missing method; the assumption being that missing data were random. Statistical significance was defined by a $P<0.05$. The statistical analyses were performed with the SPSS 20.0 for Windows (SPSS Inc., Chicago, IL, USA).

RESULTS

Enrolment

Figure 2 shows the recruitment and flow diagram of pupils in the intervention and control groups over the course of the study. The mITT population in the intervention group and control group were 320 and 370 pupils, respectively. At 22 months, the mean age was 9.67 (95%CI: 9.60, 9.73) in the intervention group (9.68 years in boys and 9.65 years in girls) and 9.86 (95%CI: 9.79, 9.91) in the control group (9.85 years in boys and 9.84 years in girls). The differences in age were not significant in relation to gender. The characteristics of the study group are summarised in Table 1. At baseline, the intervention and control group were homogeneous in BMI status. The ethnicity of the population was predominantly Western European in intervention and control group (77.5% *vs.* 78.9%, respectively) while 7.5% *vs.* 10.8% was Eastern European; 10.3% *vs.* 3.5% was Latin American; 3.4% *vs.* 6.2% was North African Arab. At baseline, there was a significant difference in the distribution with respect to Latin American children (10.3% in intervention and 3.5% in control group; $p<0.001$). The distribution was random. Of note is that there were no significant differences in distributions of OB and/or OW. Also, no differences were observed in terms of response to the intervention in relation to ethnicity.

Table 1. Anthropometric characteristics of pupils at baseline: Intervention *versus* Control group

	Intervention group			Control group					
	Mean (95%CI)			Mean (95%CI)			Intervention *vs.* control; P-value	Intervention *vs.* control; P-value	Intervention *vs.* control; P-value
	Boys (n=165)	Girls (n=155)	Total (n=320)	Boys (n=196)	Girls (n=174)	Total (n=370)	Boys	Girls	Total
Age; years	8.01 (7.91;8.12)	7.97 (7.88;8.07)	7.99 (7.92;8.06)	8.11 (8.03;8.19)	8.06 (7.97;8.15)	8.09 (8.03;8.15)	0.105	0.153	0.967
Weight; Kg	30.35 (29.22; 31.48)	29.86 (28.81; 30.91)	30.11 (29.34; 30.88)	31.29 (30.26; 32.33)	31.35 (30.36; 32.34)	31.32 (30.60; 32.04)	0.226	0.043	0.024
BMI; Kg/m^2	17.40 (16.93; 17.86)	17.42 (16.97; 17.88)	17.41 (17.09; 17.73)	17.70 (17.28; 18.13)	17.94 (17.51; 18.37)	17.82 (17.51; 18.12)	0.340	0.104	0.073
Height; m	1.32 (1.30; 1.33)	1.30 (1.29; 1.31)	1.31 (1.30; 1.32)	1.32 (1.31; 1.33)	1.32 (1.31; 1.33)	1.32 (1.31; 1.33)	0.242	0.045	0.027
Fat mass; Kg	6.71 (5.99; 7.42)	7.11 (6.50; 7.72)	6.90 (6.42; 7.38)	6.44 (5.78; 7.09)	7.70 (7.12; 8.27)	7.03 (6.59; 7.47)	0.584	0.167	0.698
Lean mass; Kg	23.99 (23.34; 24.64)	22.86 (22.32; 23.39)	23.44 (23.02; 23.87)	24.88 (24.28; 25.47)	23.71 (23.21; 24.22)	24.33 (23.93; 24.73)	0.049	0.022	0.003
Waist circumference; cm	60.97 (59.68; 62.27)	59.91 (58.67; 61.15)	60.46 (59.56; 61.36)	64.37 (63.18; 65.56)	65.17 (64.00; 66.34)	64.75 (63.91; 65.58)	<0.001	<0.001	<0.001

Notes to Table 1:

The results are expressed as Mean (95%CI)

[1]p value: general linear model (GLM) statistic

Attrition rate

Figure 2 shows the recruitment and retention of pupils in intervention and control schools. Among the 916 pupils assessed at the beginning of the study, 690 (75.3%) pupils (73.6% of those allocated to the control group and 77.5% of those allocated to the intervention group) were reassessed three academic courses later, and valid measurements were obtained. The rate of parental consent was 95.7%. Drop-outs in both groups are assumed to be missing at random.

Primary outcome: Prevalence of OB

At 22 months of the study, OB prevalence assessed by IOTF criteria, was similar in intervention and control group (p=0.628) (Table 2).

Criteria/Category		Group		Baseline % (n)	End of study % (n)	Change %	Baseline to study end P-value[1]	Intervention vs. Control P-value[2]
IOTF criteria	OW	Intervention	Boys	18.2 (30)	24.2 (40)	6	0.087	0.629
			Girls	16.2 (25)	23.2 (36)	7	0.043	0.066
			Total	17.2 (55)	23.8 (76)	6.6	0.005	0.086
		Control	Boys	25.5 (50)	27.0 (53)	1.5	0.690	
			Girls	28.2 (49)	32.8 (57)	4.6	0.185	
			Total	26.8 (99)	29.7 (110)	2.9	0.169	
	OB	Intervention	Boys	9.7 (16)	11.5 (19)	-1.8	0.453	0.735
			Girls	13.6 (21)	12.3 (19)	-1.3	0.754	0.732
			Total	11.6 (37)	11.9 (38)	0.3	1.000	0.628
		Control	Boys	10.7 (21)	10.2 (20)	-0.5	1.000	
			Girls	12.1 (21)	10.9 (19)	-1.2	0.687	
			Total	11.4 (42)	10.5 (39)	-0.93	0.607	

Table 2. Baseline and end-of-intervention measurements of categorised BMI in Intervention and Control group

Notes to Table 2

IOTF: International Obesity Task Force

The results are expressed as % (n)

[1]p value: McNemar's Test

[2]p value: Fisher's Exact Test

Secondary outcomes

At 22 months of the study, the status of OW prevalence (according to IOTF criteria) was similar between groups (p=0.086).

There were no significant differences in BMI z-score between intervention and control group (p=0.400) (Table 3). Despite no differences in BMI z-score, the boys of intervention group did not have an increase in percentage fat mass (19.96% to 20.02%: p=0.896), whereas intervention girls (22.06% to 23.55%; p<0.001), together with boys (19.18% to 20.64%, p<0.001) and girls (23.26% to 24.98%) of control group had a significant increase.

The remission, and incidence, of OB was similar in the overall intervention and control group, as well as when stratified with respect to gender.

Table 3. BMI z-score at baseline and at the end of intervention in Intervention and Control group

			Baseline Mean (95%CI)	End of study Mean (95%CI)	Change Mean (95%CI)	Baseline to Study end P-value[1]	Intervention *vs.* Control P-value[2]
BMI z-score	Intervention	Boys	0.73 (0.53; 0.94)	0.74 (0.54; 0.93)	0.00 (-0.07; 0.08)	0.973	0.381
		Girls	0.71 (0.50; 0.91)	0.89 (0.68; 1.10)	0.18 (0.10; 0.26)	<0.001	0.030
		Total	0.72 (0.58; 0.86)	0.81 (0.67; 0.95)	0.09 (0.03; 0.14)	0.002	0.400
	Control	Boys	0.83 (0.64; 1.01)	0.81 (0.63; 1.00)	-0.12 (-0.08; 0.06)	0.726	
		Girls	0.52 (0.33; 0.71)	0.63 (0.44; 0.83)	0.11 (0.02; 0.20)	0.013	
		Total	0.68 (0.55; 0.82)	0.73 (0.60; 0.86)	0.05 (-0.01; 0.10)	0.100	

Notes to Table 3:

[1]p-value: Mixed Models Repeated Measures

[2]p-value: ANOVA model

Differences between intervention and control pre- *vs.* post-intervention

Lifestyles evaluation

After 22 months of the study, there were 19.7%, 11.2% and 8.2% more girls in the intervention group who consumed a second fruit per day, one vegetable per day and fast-food weekly than the girls of control group ($p<0.001$, $p=0.017$ and $p=0.013$; respectively). However, there were 17.9% and 17.8% more boys in the intervention group who consumed pastry at breakfast and more than one vegetable a day, compared to boys of control group ($p=0.002$, $p= 0.001$; respectively). Conversely, there were 12.9% and 12.2% more girls in the control group who consumed legumes and cereal breakfast than girls of intervention group ($p=0.013$, $p=0.032$; respectively) (Table 4).

Table 4. Foods habits assessed at baseline and at the end of the study in the Intervention and Control groups

		Intervention group			Control group			Intervention *vs.* Control
		Baseline %(n)	End of study %(n)	P Value	Baseline %(n)	End of study %(n)	P Value	P-value
Krece plus questionnaire								
Breakfast	Boys	98.4 (125)	98.3 (119)	1	97.5 (154)	92.2 (153)	0.092	0.635
	Girls	98.4 (123)	99.2 (120)	1	98.7 (148)	93.8 (135)	**0.016**	0.453
	Total	98.4 (248)	98.8 (239)	1	98.1 (302)	92.9 (288)	**0.003**	1
Dairy product at breakfast	Boys	94.5 (121)	93.5 (116)	1	93.6 (147)	92.3 (155)	1	1
	Girls	94.3 (116)	93.4 (113)	0.508	94.0 (141)	89.7 (131)	**0.039**	0.325
	Total	94.4 (237)	93.5 (229)	0.481	93.8 (288)	91.1 (286)	0.167	0.574
Cereals at breakfast	Boys	65.6 (82)	66.4 (81)	0.864	59.1 (88)	54.6 (89)	0.743	0.706
	Girls	61.5 (75)	49.6 (58)	**0.036**	59.7 (86)	60.0 (87)	0.880	**0.031**
	Total	63.6 (157)	58.2 (139)	0.098	59.4 (174)	57.1 (176)	1	0.225
Pastry at breakfast	Boys	15.8 (19)	23.5 (28)	**0.027**	22.5 (33)	12.3 (20)	**0.001**	**0.002**
	Girls	20.5 (24)	15.5 (18)	0.383	15.9 (22)	12.4 (18)	0.210	0.260
	Total	18.1 (43)	19.6 (46)	0.441	19.1 (55)	12.3 (38)	**<0.001**	**0.002**
Daily fruit or natural juice	Boys	73.4 (94)	76.2 (93)	0.523	74.8 (116)	76.0 (127)	1	0.535
	Girls	66.7 (82)	70.0 (84)	0.690	79.9 (119)	73.5 (108)	0.243	0.549
	Total	70.1 (176)	13.1 (177)	0.382	77.3 (235)	74.8 (235)	0.443	0.472
Fruit, 2nd per day	Boys	39.7 (50)	41.2 (49)	0.581	44.5 (69)	34.1 (56)	**0.006**	0.141
	Girls	26.4 (32)	47.5 (56)	**0.000**	44.8 (64)	39.0 (57)	0.281	**<0.001**
	Total	33.2 (82)	44.3 (105)	**0.001**	44.6 (133)	36.5 (113)	**0.004**	**<0.001**
Dairy product, 2nd per day	Boys	87.2 (109)	78.5 (95)	**0.029**	80.0 (124)	69.5 (116)	0.174	0.194
	Girls	80.5 (99)	79.8 (95)	1	71.6 (106)	75.5 (111)	0.749	0.460
	Total	83.9 (208)	79.2 (190)	0.161	75.9 (230)	72.3 (227)	0.51	0.384
Vegetables, daily	Boys	65.6 (84)	74.4 (90)	**0.043**	71.1 (113)	70.8 (119)	1	0.473
	Girls	71.7 (86)	77.5 (93)	0.169	68.7 (101)	63.3 (93)	0.152	**0.017**
	Total	68.5 (170)	75.9 (183)	**0.011**	69.9 (214)	67.3 (212)	0.374	**0.028**
Vegetables, >1 per day	Boys	19.3 (23)	29.1 (34)	**0.017**	28.7 (43)	20.7 (34)	**0.009**	**0.001**
	Girls	25.4 (31)	34.5 (40)	0.052	30.3 (43)	23.1 (33)	0.110	0.149
	Total	22.4 (54)	31.8 (74)	**0.001**	29.5 (86)	21.8 (67)	**0.002**	**0.001**
Fish, regularly	Boys	73.2 (93)	76.6 (95)	0.608	70.0 (112)	70.1 (115)	0.851	0.058

	Girls	71.8 (92)	71.4 (85)	0.307	74.5 (111)	71.0 (103)	1	0.662
	Total	74 (185)	74.1 (180)	0.896	72.2 (223)	70.6 (218)	0.791	0.312
Fast food, >1	Boys	6.3 (8)	7.4 (9)	1	7.1 (11)	4.9 (8)	0.227	0.106
per week	Girls	3.3 (4)	10.1 (12)	0.109	4.2 (6)	2.8 (4)	0.219	**0.013**
	Total	4.8 (12)	8.8 (21)	0.21	5.7 (17)	3.9 (12)	**0.049**	**0.003**
Legumes >1	Boys	70.3 (90)	71.1 (86)	0.648	67.5 (106)	65.9 (110)	1	0.555
per week	Girls	72.8 (91)	73.3 (88)	0.815	62.8 (145)	76.2 (112)	**0.001**	**0.013**
	Total	71.5 (181)	72.2 (174)	1	65.2 (251)	70.7 (222)	**0.025**	**0.027**
Candy > per	Boys	14.3 (18)	12.6 (15)	1	17.2 (27)	18.2 (30)	1	0.367
day	Girls	12.9 (16)	12.0 (14)	1	18.7 (26)	11.1 (16)	0.078	1
	Total	13.6 (34)	12.3 (29)	1	17.9 (53)	14.9 (46)	0.262	0.479
Pasta or rice	Boys	63.8 (81)	67.5 (83)	0.839	69.0 (109)	67.9 (114)	0.871	0.708
daily	Girls	59.2 (74)	64.7 (77)	0.377	68.0 (100)	69.4 (102)	0.618	0.724
	Total	61.5 (155)	66.1 ()	0.35	68.5 (209)	68.6 (216)	0.561	1
Cooking with	Boys	97.7 (126)	98.4 (122)	1	98.1 (157)	98.8 (167)	1	0.636
olive oil at	Girls	98.4 (125)	99.2 (120)	0.623	97.3 (145)	98.0 (145)	1	0.628
home	Total	98 (251)	98.8 (242)	0.5	97.7 (302)	98.4 (312)	0.754	0.476
Avall questionnaire								
Before leaving home								
Dairy	Boys	90 (117)	87.3 (110)	0.065	83.6 (133)	95.3 (139)	1	0.074
products	Girls	87.3 (110)	87.8 (108)	0.503	83 (122)	76.4 (110)	**0.004**	0.235
	Total	90.9 (227)	87.6 (218)	0.071	86.2 (255)	81.1 (249)	**0.044**	0.836
Pastry	Boys	4 (5)	2.4 (3)	1	0.7 (1)	1.4 (2)	1	0.610
	Girls	0.8 (1)	1. 7 (2)	1	0.7 (1)	0 (0)	1	1
	Total	2.5 (6)	2 (5)	1	0.7 (2)	0.7 (2)	1	0.606
Cereals	Boys	33.9 (43)	36.8 (46)	0.711	30.7 (46)	35.0 (55)	0.608	1
	Girls	32.2 (38)	26.2 (32)	0.405	25.2 (37)	26.2 (37)	0.458	0.297
	Total	33.1 (81)	31.6 (78)	0.89	27.9 (83)	30.9 (92)	0.314	0.409
Fresh fruit	Boys	18.4 (23)	24.6 (31)	0.189	17.0 (26)	21.2 (32)	1	0.537
or natural	Girls	14.2 (17)	24.6 (30)	0.064	18.5 (27)	23.6 (33)	0.541	0.332
juice	Total	16.3 (40)	24.6 (61)	**0.016**	17.7 (53)	22.3 (65)	0.560	0.256
	Boys	6.6 (8)	17.7 (22)	0.115	17.3 (26)	21.1 (32)	0.458	1
	Girls	0.3 (12)	19.7 (24)	**0.049**	14.9 (21)	18.4 (26)	0.572	1
Sandwich	Total	8.4 (20)	18.7 (46)	**0.008**	16.2 (47)	19.8 (58)	0.289	0.889
Juice	Boys	6.7 (8)	7.4 (9)	0.754	8.7 (13)	7.1 (11)	1	0.756
package/sof	Girls	7.7 (9)	5.0 (6)	0.508	8.6 (12)	10.8 (15)	1	0.507

t drinks								
	Total	7.2 (17)	6.2 (15)	0.359	8.6 (25)	8.9 (26)	0.845	0.483
Break (Midmorning)								
Dairy	Boys	16.0 (20)	20.0 (24)	0.824	15.3 (22)	14.4 (21)	1	0.819
products	Girls	8.7 (10)	9.6 (11)	0.388	10.7 (15)	8.4 (11)	1	0.595
	Total	12.5 (30)	15 (35)	0.367	13.0 (37)	11.6 (32)	1	0.488
Pastry	Boys	4.1 (5)	0.8 (1)	0.625	4.1 (6)	2.1 (3)	1	1
	Girls	0.9 (1)	0.9 (1)	1	1.5 (2)	2.3 (3)	1	0.480
	Total	2.5 (6)	0.9 (2)	0.687	2.8 (8)	2.2 (6)	0.687	1
Cereals	Boys	3.3 (4)	5.9 (7)	0.727	5.7 (8)	4.9 (7)	1	1
	Girls	3.5 (4)	3.4 (4)	1	4.3 (6)	6.9 (9)	0.180	0.544
	Total	3.4 (8)	4.7 (11)	0.804	5 (14)	5.9 (16)	0.238	0.659
Fresh fruit or	Boys	16.3 (20)	10.1 (12)	0.804	19.5 (30)	14.5 (22)	0.189	0.787
natural juice	Girls	15.5 (18)	16.8 (20)	0.424	20.1 (29)	20.3 (28)	0.815	1
	Total	15.9 (38)	13.4 (32)	0.856	19.8 (59)	17.2 (50)	0.522	0.721
Sandwich	Boys	28.3 (36)	37.7 (46)	0.087	43.2 (67)	41.6 (67)	0.701	0.080
	Girls	24.8 (30)	33.6 (41)	0.064	29.7 (44)	41.1 (58)	**0.016**	0.860
	Total	26.6 (66)	35.7 (87)	**0.008**	36.6 (111)	41.4 (125)	0.185	0.299
Juice	Boys	7.4 (9)	9.1 (11)	0.344	12.2 (18)	12.6 (19)	1	1
package/soft	Girls	7.8 (9)	6.1 (7)	0.727	12.1 (17)	13.2 (18)	1	0.233
drinks	Total	7.6 (18)	7.7 (18)	0.815	12.2 (35)	12.9 (37)	1	0.543

Notes to Table 4:

[1]p-value: McNemar's Test (changes in intervention group)

[2]p-value: McNemar's Test (changes in control group)

[3]p-value: Fisher's Exact Test.

Table 5 summarises the time spent in after-school PA, watching TV, playing video games, and other leisure-time activities. At 22 months, the percentage of boys of the intervention group who performed ≥4h after-school PA/week was increased by 15% (p=0.027) while there was 16.6% more boys in the intervention group watching ≤2hTV/day (p<0.009). The results indicate less sedentary behaviour in intervention than control individuals.

Table 5. Lifestyles assessed at baseline and at the end of study in Intervention and Control

		Intervention			Control			Intervention vs. Control
		Baseline %(n)	End of study %(n)	p-value[1]	Baseline %(n)	End of study %(n)	P-value[2]	P-value[3]
TV and/or video games								
0-2h/day	Boys	49.2 (62)	45.2 (57)	0.268	32.5 (51)	27.0 (43)	0.627	0.71
	Girls	48.4 (60)	51.2 (63)	1	44.0 (66)	49.7 (71)	0.43	0.287
	Total	48.8 (122)	48.2 (120)	0.464	38.1 (117)	37.7 (114)	0.91	0.697
3-4h/day	Boys	46.0 (58)	50.0 (63)	0.542	62.4 (98)	63.5 (101)	1	0.874
	Girls	43.5 (54)	44.7 (55)	0.86	54.0 (81)	47.6 (68)	0.349	0.71
	Total	44.8 (112)	47.4 (118)	0.489	58.3 (179)	56.0 (169)	0.606	0.632
>4h/day	Boys	4.8 (6)	4.8 (6)	0.375	5.1 (8)	9.4 (15)	0.607	0.393
	Girls	8.1 (10)	4.1 (5)	0.453	2.0 (3)	2.8 (4)	1	1
	Total	6.4 (16)	4.4 (11)	1	3.6 (11)	6.3 (19)	0.481	0.462
After-school PA								
0-2h/week	Boys	26.2 (34)	14.5 (18)	0.013	21.5 (34)	19.0 (31)	0.286	0.354
	Girls	35.2 (43)	33.6 (41)	0.701	34.5 (50)	36.6 (52)	1	0.557
	Total	30.6 (77)	24.0 (59)	**0.049**	27.7 (84)	27.2 (83)	0.435	0.254
2-4h/week	Boys	29.2 (38)	24.2 (30)	0.418	38.0 (60)	3.1 (54)	0.78	0.602
	Girls	36.9 (45)	32.0 (39)	0.377	32.4 (47)	31.0 (44)	1	0.155
	Total	32.9 (83)	28.0 (69)	0.188	35.3 (107)	32.1 (98)	0.764	0.135

>4h/week	Boys	44.6 (58)	61.3 (76)	**0.006**	40.5 (64)	47.9 (78)	0.243	0.643	
	Girls	27.9 (34)	34.4 (42)	0.136	33.1 (48)	32.4 (46)	0.868	0.598	
	Total	36.5 (92)	48.0 (118)	**0.002**	37.0 (112)	40.7 (124)	0.272	0.485	

Notes to Table 5

[1]P-value: McNemar's Test (changes in intervention group)

[2]P-value: McNemar's Test (changes in control group)

[3]P-value: Fisher's Exact Test.

Differences between intervention and control pre-post intervention program

At 22 months, subjects who were normal weight at baseline increased after-school PA to ≥4h/week. This reflects a rise to 32.7% in boys (p=0.002). However, in girls, the changes were not statistically different (p=0.134). No statistically significant differences were observed in the control group.

Impact of certain additional factors on obesity

The ORs of OB, using BMI z-score criteria, were related to some of the more relevant dietary habits and lifestyles. Thus, breakfast dairy product consumption (OR: 0.336; p=0.004) and ≥4 after-school PA h/week (OR: 0.600; p=0.032) were protective factors against OB. Conversely, doing <4 h/week PA (OR: 1.811; p=0.018) increased the risk of childhood OB.

DISCUSSION

The EdAl-2 program, a reproducibility study in Terres de l'Ebre, shows that intervention is useful for improving weekly after-school PA. However, the OB prevalence remained unchanged at 22 months, as has been shown in the data on stability of OB prevalence observed in some European countries,[8]. Despite that OW and OB remained similar between groups, we observed percentage fat mass maintenance in the boys of the intervention group, whereas girls of the intervention and control group had increases.

As proposed by Kain J et al, designing a new school-based intervention study needs to have some critical aspects considered. These include: the random allocation of schools, although methodologically desirable, is not always possible; participation of parents is very limited; obesity is not recognised as a problem; and increasing physical activity

and implementing training programmes for teachers is difficult due to an inflexible curriculum and lack of teachers' time. Unless these barriers are overcome, obesity prevention programmes will not produce positive and lasting outcomes,[27]. As such, our programme of HPA-implemented intervention activities in classrooms is an attractive alternative that circumvents lack-of-teacher-time.

The EdAl-2 program confirmed that after-school PA (in terms of h/week) can be stimulated in primary school as part of a healthy lifestyle. As we had observed in the original EdAL program,[18] at 28 months of intervention, there was an increase of up to 19.7% of children dedicating >5 hours/week to extra-curricular physical activities,[18]. Further, the after-school PA was maintained despite cessation of the intervention program,[28]. The effect of EdAl program during its implementation and after the official cessation indicated an impact on PA, whereas modification towards healthy food choices occurred according to the site of the program's implementation, and was not consistent.

Interventions to prevent OB in the school setting have shown dramatic improvements,[29]. However, successful studies in OB prevention need to be reproducible, especially those improving healthy lifestyle such as after-school PA, to confirm best childhood practices.

Reproducibility of studies is rare because of the complexity of trying to replicate a programme. To standardise a method it is essential to be able to reproduce appropriate levels of an intervention, especially one that involves behavioural changes. Feasibility of our intervention was confirmed in two different towns and over two different time-courses (the first in Reus over 28 months, and the second in Amposta over 22 months). Also, it is important to assess treatment adherence in order to evaluate reproducibility and feasibility,[19]. For example, the KOPS study,[20] demonstrated that nutritional

knowledge was increased as a result of the intervention in the two cohort studies (KOPS 1 and KOPS 2),[20]. However, the study was unable to show whether there were differences in overweight outcomes, weight categories or lifestyles between the two cohorts. Some multi-centred studies have attempted to reproduce methodological aspects in interventions conducted in different countries or different populations. However, while multi-centred studies are usually implemented concurrently, reproducibility involves the applicability of the intervention at different sites and/or different times in order to validate the initial findings. One example of this is the Pro Children Study,[30] which, as a multi-centred study, had been applied in different countries simultaneously and had demonstrated its efficacy and feasibility.

The ALADINO study presented the obesity status prevalence in Spain which, according to the IOTF, is about 11.4% in children of around 9 years of age,[31]. In the EdAl-2 study, the OB prevalence was similar, but lower in the intervention group than the equivalent in the ALADINO study and, as well, in the EDAL-2 control group.

The EdAl-2 study showed a significant improvement of 16.7% in the young boys in the intervention group who participated in ≥4 h/week after-school PA. Further, the increased numbers of children in the intervention group who performed ≥4 h/week after-school PA who were normal-weight at baseline, suggested that the intervention was effective not only in the primary-school healthy population but also effective in preventing OB over the longer-term due to the PA being maintained.

In the dietary habits aspect of EdAl-2 study, we observed that the increase in healthy lifestyle habits such as the increase in fruit and vegetables consumption and increasing PA h/week while maintaining low TV h/d, are promising lifestyle changes that could induce a reduction of OW and OB over the long-term.

In the EdAl-2 study we observed that consumption of dairy products at breakfast was a protective factor against obesity.

Several studies have shown that participating in PA was a protective factor against OB and that spending >2h watching TV was a risk factor for childhood OB. A recent Spanish study showed that leisure-time PA was a protective factor against OB (as with our present study) and that performing >4 h/week is a protective factor while watching TV for this amount of time was, according to Ochoa et al,[32], associated with OB.

There are several limitations to our study. Firstly, we evaluated dietary habits via a questionnaire that did not take into account the quantities of the different types of food items consumed. These data would be important in addressing the quantity *versus* quality debate in OB or OW prevalence. Secondly, assigning control groups according to towns surrounding the intervention town could be a limitation. However, schools of the same town have good relationships and communications with each other and this could entail a possible contamination between schools if assigned to intervention or control status within the same town. This cross-contamination would be minimised if the schools themselves were assigned to intervention or control. Thirdly, the significant difference in Latin American ethnicity between the two groups of the study at baseline could be a limitation. However, there were no significant differences in distributions of OB and/or OW. Also, no differences were observed in terms of response to the intervention study in relation to ethnicity. Fourthly, when asked about fast-food consumption, the participants interpreted this as pertaining only to fast-food outlets such a burger shops, and did consider other concepts such as frozen pizza consumed at home. Finally, another limitation could be the proportion of females who may have started puberty in the course of the study. This implies changes in body composition. However,

both study groups (intervention and control) had a similar proportion of females with a similar age, and this could cancel-out the effect.

Further, EdAl-2 demonstrated that performing >4h/week after-school PA, plus having dairy product at breakfast are protective factors. Hence, we believe that a participating in >4h/week after-school PA, and continuing with a healthy breakfast, are key points in preventing childhood OB.

CONCLUSION

Our school-based intervention is feasible and reproducible by increasing after-school PA (to ≥4h/week) in boys. Despite this improvement, there was no statistically significant change in the prevalence of OB. This suggests that our intervention programme induces healthy lifestyle effects (such as more exercise and less sedentary behaviour) which can produce anti-obesity benefits in children in the near future beyond the limited length of our current study. However, the effects on girls' behaviour need to be more closely studied, together with a future repeat of our study in a different population.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

ETHICS

The EdAl-2 study was approved by the Clinical Research Ethical Committee of the *Hospital Sant Joan of Reus, Universitat Rovira i Virgili* (Catalan ethical committee registry ref 11-04-28/4proj8).

DATA SHARING

Technical appendix, statistical code, and dataset available at Dryad repository in: "Data from: EdAl-2 (Educació en Alimentació) programme: reproducibility of a cluster randomised, interventional, primary-school-based study to induce healthier lifestyle activities in children" (*expecting the definitive DOI*).

LIST OF ABBREVIATIONS

OB: Obesity

OW: Overweight

PA: Physical Activity

mITT: modified Intention to Treat

HPAs: Health Promoter Agents

WHO: World Health Organization

BMI: Body Mass Index

OR: Odds Ratio

Authors' contributions

MG, EL, LT, RS designed the study (project conception, development of overall research plan, and study oversight)

MG, EL, LT, RQ, RS conducted research (hands-on conduct of the experiments and data collection)

EL, LT, MG, RS provided essential materials (applies to authors who contributed by providing constructs, database, etc. necessary for the research)

DM, EL, LT analysed data or performed statistical analysis

RS, MG, LT, DM, EL drafted and revised the manuscript (authors who made a major contribution). The final manuscript was read and approved by all co-authors

RS, MG take primary responsibility for the study, and manuscript content

REFERENCES

1. Organización para la Cooperación y el Desarrollo Económicos (OCDE): *Obesity update.* 2012.
2. World Health Organization. The Challenge of Obesity in the WHO European Region and the strategies for response. Denmark; 2007.
3. Ahrens W, Bammann K, Siani A, et al. The IDEFICS cohort: design, characteristics and participation in the baseline survey. *Int J Obes* 2011;35(Suppl 1:)S3-15. doi:10.1038/ijo.2011.30
4. Brug J, van Stralen MM, Te Velde SJ, et al. Differences in weight status and energy-balance related behaviors among schoolchildren across Europe: the ENERGY-project. *PLoS One* 2012;7(4):e34742. doi: 10.1371/journal.pone.0034742. [Published Online First: 25 April 2012]
5. Martos-Moreno GA, Argente J. Paediatric obesities: from childhood to adolescence. *An Pediatr (Barc)* 2011;75(1):63e1-23. doi:10.1016/j.anpedi.2011.03.018. [Published Online First: 23 May 2011]
6. Manco M, Dallapiccola B. Genetics of pediatric obesity. *Pediatrics* 2012;130(1):123-133. doi:10.1542/peds.2011-2717. [Published Online First: 4 June 2012]
7. Vos MB, Welsh J. Childhood obesity: update on predisposing factors and prevention strategies. *Curr Gastroenterol Rep* 2010;12(4):280-287. doi:10.1007/s11894-010-0116-1.
8. The Organisation for Economic Co-operation and Development (OECD): Obesity Update 2012. [http://www.oecd.org/health/49716427.pdf]
9. Van Cauwenberghe E, Maes L, Spittaels H. Effectiveness of school-based interventions in Europe to promote healthy nutrition in children and adolescents:

systematic review of published and 'grey' literature. *Br J Nutr* 2010;103(6):781-797. doi:10.1017/S0007114509993370. [Published Online First: 14 January 2010]

10. Reinehr T, Wabitsch M. Childhood obesity. *Curr Opin Lipidol* 2011;22:21-5.
11. Guia de práctica clínica (GPC). *AATRM* 2007.
12. Verbestel V, De Henauw S, Maes L, et al. Using the intervention mapping protocol to develop a community-based intervention for the prevention of childhood obesity in a multi-centre European project: the IDEFICS intervention. *Int J Behav Nutr Phys Act* 2011;8:82. doi:10.1186/1479-5868-8-82.
13. Vio F, Zacarías I, Lera L, et al. Prevención de la obesidad en escuelas básicas de Peñalolén: Componente alimentación y nutrición. Rev Chil Nutr 2011; 38:268-276.
14. Bacardí-Gascon M, Pérez-Morales ME, Jiménez-Cruz A. A six month randomized school intervention and an 18-month follow-up intervention to prevent childhood obesity in Mexican elementary schools. Nutr Hosp 2012; 27:755-62.
15. De Bourdeaudhuij I, Van Cauwenberghe E, Spittaels H, et al. School-based interventions promoting both physical activity and healthy eating in Europe: a systematic review within the HOPE project. *Obes Rev* 2011;12(3):205-216. doi:10.1111/j.1467-789X.2009.00711.x.
16. Papandreou D, Malindretos P, Rousso I. Risk factors for childhood obesity in a Greek paediatric population. *Public Health Nutr* 2010;13(10):1535-1539. doi:10.1017/S1368980009993156. [Published Online First: 15 January 2010]
17. Giralt M, Albaladejo R, Tarro L, et al. A primary-school-based study to reduce prevalence of childhood obesity in Catalunya (Spain)--EDAL-Educacio en

alimentacio: study protocol for a randomised controlled trial. *Trials* 2011;12:54-62. doi:10.1186/1745-6215-12-54.

18. Tarro L, Llauradó E, Albaladejo R, et al. A primary-school-based study to reduce the prevalence of childhood obesity – The EdAl (Educació en Alimentació) study: a randomized controlled trial. *Trials* 2014;15:58. doi:10.1186/1745-6215-15-58.
19. Boutron I, Moher D, Altman DG, et al. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med* 2008, 148(4):295-309.
20. Danielzik S, Pust S, Muller MJ. School-based interventions to prevent overweight and obesity in prepubertal children: process and 4-years outcome evaluation of the Kiel Obesity Prevention Study (KOPS). *Acta Paediatr Suppl* 2007;96(454):19-25.
21. Serra Majem L, Ribas Barba L, Aranceta Bartrina J, et al. Childhood and adolescent obesity in Spain. Results of EnKid study (1998-2000). *Med Clin (Barc)* 2003;12:725-732.
22. Llargues E, Franco R, Recasens A, et al. Assessment of a school-based intervention in eating habits and physical activity in school children: the AVall study. *J Epidemiol Community Health* 2011;65(10):896-901. doi:10.1136/jech.2009.102319. [Published Online First: 12 March 2011]
23. Gidding SS, Dennison BA, Birch LL, et al. Dietary recommendations for children and adolescents: a guide for practitioners: consensus statement from the American Heart Association. *Circulation* 2006;113(Suppl 23):e857.

24. Cole TJ, Bellizzi MC, Flegal KM, et al. Establishing a standard definition for child overweight and obesity worldwide: international survey. *BMJ* 2000;320(7244):1240-1243.

25. World Health Organization. Growth Reference data for 5-19 years. 2007. [http://www.who.int/growthref/en/.] Date accessed: 05/03/2014

26. Cole TJ, Flegal KM, Nicholls D, et al. Body mass index cut offs to define thinness in children and adolescents: international survey. *BMJ* 2007, 335(7612):194. [Published Online First: 25 June 2007]

27. Kain J, Uauy R, Concha F, et al. School-based obesity prevention interventions for Chilean children during the past decades: Lessons learned. Adv Nutr 2012; 3(4):616s-621s.

28. Tarro L, Llauradó E, Moriña D, et al. Five-year follow-up of a healthy lifestyle education program (the EdAl study): Two years post-cessation of intervention. (Manuscript under review)

29. Brown T, Summerbell C. Systematic review of school-based interventions that focus on changing dietary intake and physical activity levels to prevent childhood obesity: an update to the obesity guidance produced by the National Institute for Health and Clinical Excellence. *Obes Rev* 2009;10(1):110-41. doi:10.1111/j.1467-789X.2008.00515.x. [Published Online First: 30 July 2008]

30. Te Velde SJ, Brug J, Wind M, et al. Effects of a comprehensive fruit- and vegetable-promoting school-based intervention in three European countries: the Pro Children Study. *Br J Nutr* 2008;99(4):893-903. [Published Online First: 22 October 2007]

31. Pérez-Farinós N, López-Sobaler AM, Dal Re MA, et al. The ALADINO Study: A National Study of Prevalence of Overweight and Obesity in Spanish Children

in 2011. *Biomed Res Int* 2013;2013:163687. doi: 10.1155/2013/163687. [Published Online First: 8 September 2013]

32. Ochoa MC, Moreno-Aliaga MJ, Martinez-Gonzalez MA, et al. Predictor factors for childhood obesity in a Spanish case-control study. *Nutrition* 2007;23(5):379-384. [Published Online First: 3 April 2007]

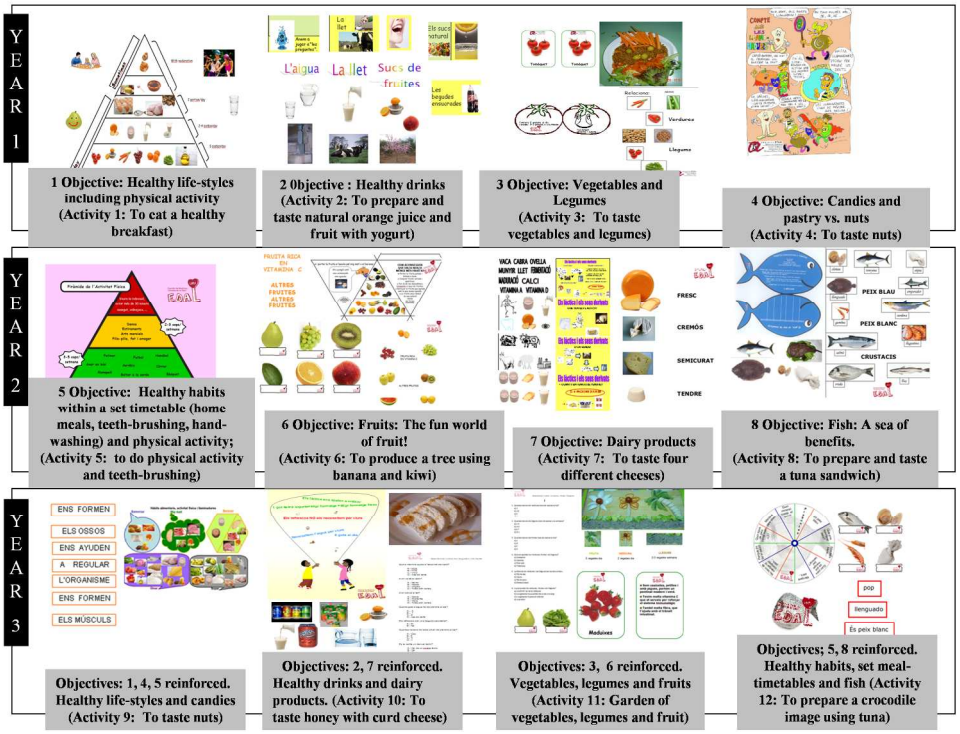
FIGURE LEGEND

Figure 1: Eight topics of educational intervention activities

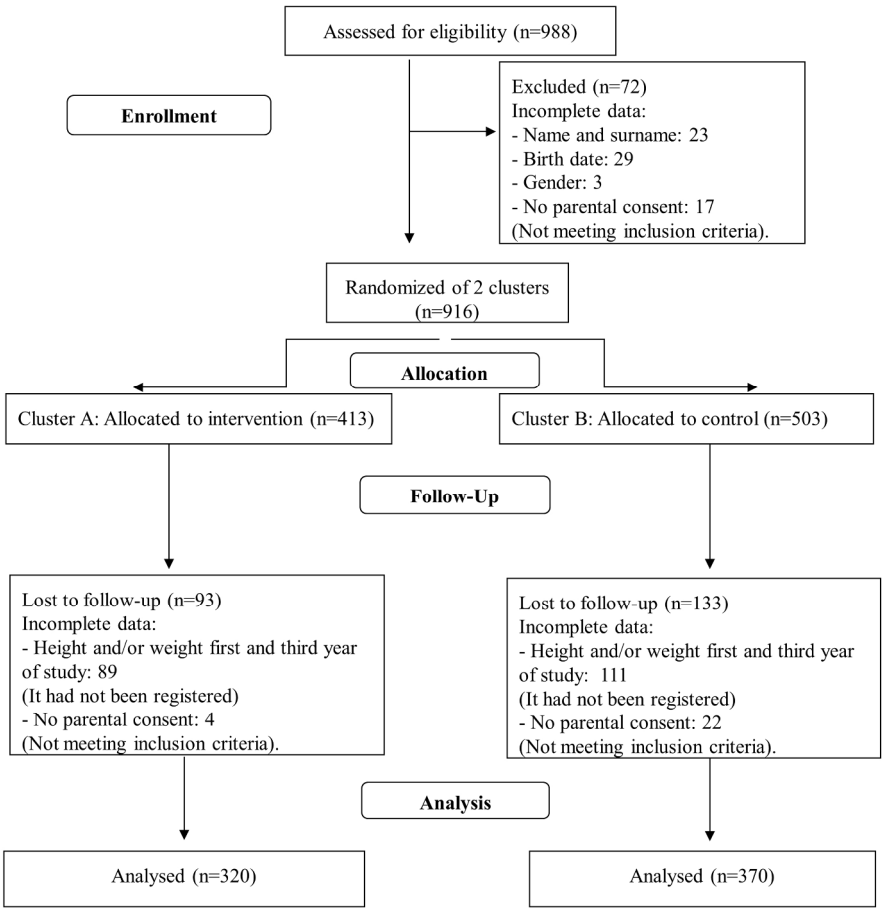
This figure shows the 8 topics of 12 educational intervention activities of EdAl program

Figure 2: Flow of subjects through the study

Incomplete height and/or weight (measures of first and/or third academic year); No parental consent signed (first, second or third academic year).



This figure shows the 8 topics of 12 educational intervention activities of EdAl program
254x190mm (300 x 300 DPI)



Incomplete height and/or weight (measures of first and/or third academic year); No parental consent signed (first, second or third academic year).
190x254mm (300 x 300 DPI)

ADDITIONAL FILE 1 - Description of the Intervention

Intervention program

The intervention program consisted of three components: 1) classroom practice by the HPA to highlight eight healthy lifestyle habits [23], termed educational intervention activities; 2) teaching practice by the HPA using specially-designed booklets (as teaching aids) which focused on the same lifestyle topics presented as educational activities; 3) parental activities to be included with that of their children.

The educational intervention activities focused on eight lifestyle topics based on scientific evidence [23] to improve nutritional food item choices (and avoidance of some foods), healthy habits such as teeth-brushing and hand-washing and, overall, adoption of activities that encourage physical activity (walking to school, playground games) and to avoid sedentary behavior [23].

Each of the eight topics was integrated within educational intervention activities of 1 hour/activity, prepared and standardized by the HPAs and then implemented in children's classrooms. In the first school academic year, we focused on four topics: 1) to improve healthy lifestyle; 2) to encourage healthy drinks intake (and avoidance of unhealthy carbonated/sugared beverages); 3) to increase vegetables and legumes consumption; and 4) to decrease candies and pastries while increasing the intake of fresh fruits and nuts.

These corresponded to four standardized activities (1 hour/activity). In the second year, the remaining four of the eight selected lifestyle topics were addressed: 5) to improve healthy habits within a set timetable (home meals, teeth-brushing, hand-washing) and physical activity participation; 6) to increase fruit intake; 7) to improve dairy product consumption; and 8) to increase fish consumption. These corresponded to four standardized activities. Finally, in the third school academic year, four standardized activities were introduced that reinforced the eight lifestyle topics implemented in the previous 2 academic years. Thus, the intervention program was based on eight lifestyle topics incorporated in 12 activities which were disseminated over 12 sessions (1 hour/activity/session), and prepared, standardized and implemented as four activities per school academic year by the HPAs in the school classrooms. The activities or sessions were implemented every 2 weeks over a 2-month period, each academic year. All 12 activities or sessions were conducted over a period of 28 months (3 school academic years).

The educational intervention activity as a classroom practice consisted of three components: 1) experimental development of activities relating to healthy lifestyle habits using food-item selection (free food items provided by local producers) for the children to experience the organoleptic quality of the items which may, or may not, be new to them; 2) assessment of activity performed in classroom; and 3) activities developed for use at home.

Teaching practice used specific booklets designed to address the same lifestyle topics as the educational intervention activities (see Additional file 2). The booklets (teaching aids) were also employed by the regular school teacher over the 28 months of the program.

Another aspect of the intervention program was to involve parents in activities with their children. This intervention for parents was the same educational nutritional activities that were directed towards the children by the HPA. The intention was to have parents and their children interact in the healthy nutrition and lifestyle choices.

Section extracted to:

- Tarro L, Llauradó E, Albaladejo R, et al. A primary-school-based study to reduce the prevalence of childhood obesity – The EdAl (Educació en Alimentació) study: a randomized controlled trial. *Trials* 2014;15:58. doi:10.1186/1745-6215-15-58.