

BMJ Open EdAI-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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To cite: Llauradó E, Tarro L, Moríña D, *et al.* EdAI-2 (*Educació en Alimentació*) programme: reproducibility of a cluster randomised, interventional, primary-school-based study to induce healthier lifestyle activities in children. *BMJ Open* 2014;**4**: e005496. doi:10.1136/bmjopen-2014-005496

► Prepublication history and additional material is available. To view please visit the journal (<http://dx.doi.org/10.1136/bmjopen-2014-005496>).

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Received 16 April 2014
Revised 23 October 2014
Accepted 31 October 2014



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ABSTRACT

Objectives: To assess the reproducibility of an educational intervention EdAI-2 (*Educació en Alimentació*) 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 the intervention or control group.

Participants: Pupils (n=690) of whom 320 constituted the intervention group (1 cluster) and 370 constituted the control group (1 cluster). Ethnicity was 78% Western European. The mean age (\pm SD) was 8.04 \pm 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 7–8 year; 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 eight lifestyle topics covered in 12 activities (1 h/activity/session) implemented by health promoting agents in the primary school over three 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 OB 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 in both groups remained similar. Also, 16.6% more boys in the intervention group watched ≤ 2 television (TV) h/day ($p=0.009$), compared to controls; and no changes were observed in girls in both groups.

Conclusions: Our school-based intervention is feasible and reproducible by increasing after-school PA

Strengths and limitations of this study

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

(to ≥ 4 h/week) in boys. Despite this improvement, there was no change in BMI and prevalence of OB.

Trial registration number: Clinical Trials NCT01362023.

BACKGROUND

Obesity (OB) has become a disease of epidemic proportions.¹ However, this increasing tendency towards excess weight in childhood and adulthood² observed in some countries (the UK, France, South Korea, the USA 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 multi-factorial 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 as 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 start 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 habits¹² and, as some studies have shown, such interventions have inspired changes in nutritional habits and body mass index (BMI) status^{13 14}; the message is received by all schoolchildren, irrespective of ethnic and socio-economic differences.⁹ The effectiveness of an intervention is when educational strategies and environmental factors such as healthy nutrition and physical activity (PA) 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 of energy expenditure and, as such, are risk factors for OB.¹⁶

We had designed the EdAI (*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 an intervention group) with the neighbouring towns of Salou, Cambrils and Vilaseca as a control group. The interventions focused on eight lifestyle topics covered in 12 activities (1 h/activity/session) in 7–8-year-old children, and implemented by HPAs over three school academic years. We found that the EdAI programme successfully reduced childhood OB prevalence in boys by 4.39% and increased the percentage of boys who practise ≥ 5 after-school PA h/week.¹⁸ The EdAI programme needed to be reproduced in other localities, and with other children, to demonstrate the effectiveness of this intervention.¹⁹

The outcomes of the EdAI programme supported the feasibility of improving PA in childhood. However, an educational intervention, such as our EdAI programme implemented by HPAs, also tests complex components such as healthy lifestyles including diet and PA recommendations. Owing 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 EdAI programme in a geographical area (Terres de l'Ebre) about 80 km away from

where the original EdAI 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 the primary-school-based study to reduce the prevalence of childhood OB (The EdAI-2 study); the objective remains an intervention to induce healthy lifestyles, including diet and PA recommendations. The study was conducted in 7–8-year-old schoolchildren over three academic years (22 months active school time).

METHODS

The original protocol, rationale, randomisation, techniques and results of the initial EdAI programme have been published in *Trials*.^{17 18} The current study (EdAI-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 online supplementary file 1, and in this manuscript link. The EdAI-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 online supplementary additional file 2).

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

Study population

To approximately ensure 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 the school identities matched the towns on population size. The coordinating centre (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 Gànguill and Camarles) as cluster B (control). The eligibility criteria of clusters were to be semirural towns from the southern part of Catalonia with a minimum of 500 children of 7–8 years of age in each cluster.

The sociodemographic indicators in all towns were similar to that of the original EdAI programme in Reus. Children attending the schools in both groups (intervention and control) lived in proximity within each school's catchment area. Intervention institutions included five schools involving 18 classrooms and 457 pupils in Amposta. Control institutions consisted of 11 schools involving 23 classrooms and 531 pupils in the nine

towns around Amposta. The children in this study are in the second and third grades of primary education (7–8-year-olds). Schoolchildren were enrolled in May 2011 (children born in 2002–2003) and followed up for three 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 PA, 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 EdAI Reus protocol was followed.^{17 18} The educational intervention activities focused on eight lifestyle topics based on scientific evidence²³ to improve

nutritional food item choices (and avoidance of some foods) and healthy habits such as teeth-brushing and hand-washing and overall adoption of activities that encourage PA (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 1 h/activity, prepared and standardised by the HPAs, and implemented in the children’s classrooms. In the first school academic year, we focused on four topics: (1) to improve a 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 (1 h/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 PA 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

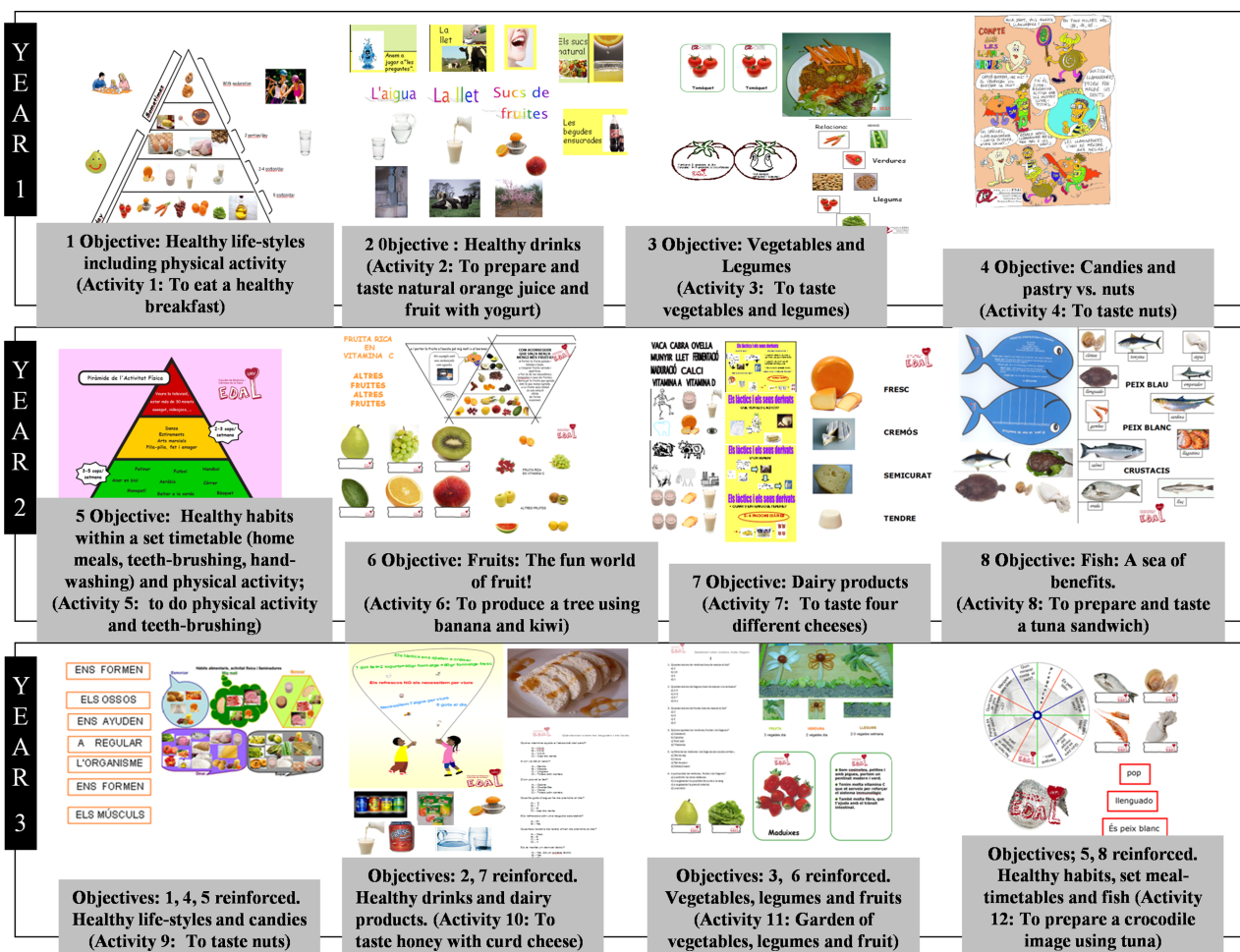


Figure 1 Eight topics of educational intervention activities. This figure shows the eight topics of 12 educational intervention activities of the EdAI programme.

standardised activities were introduced that reinforced the eight lifestyle topics implemented in the previous two academic years. Thus, the intervention programme was based on eight lifestyle topics incorporated within 12 activities which were disseminated over 12 sessions (1 h/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 programme.^{17 18}

Outcomes

Assessment of the reproducibility of the EdAl programme was based on primary outcomes such as the 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 the BMI z-score (based on the WHO growth charts²⁵ and waist circumference, incidence and remission of excess weight (overweight (OW) and OB), as well as changes in lifestyles (eating habits and PA 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 17 kg/m² as a cut-off point. The 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 the WHO criteria since this is based on data from countries that have a low OB prevalence²⁵ 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 an 85% chance (at a two-tailed 5% significance level) of detecting a difference of five percentage points between the intervention and control groups (3–8%) with respect to OB prevalence at baseline of the 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 participants in each group.

Statistical analyses

Analyses were conducted on student-level data. Descriptive variables were presented as means and CIs (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 the 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 the intervention and control groups. The continuous variables studied in each group were compared using analysis of variance (ANOVA).

To evaluate the risk and protective factors involved in childhood OB, logistic regression analyses were performed at baseline, with no distinction between the intervention and control groups. The OR and 95% CI were calculated for dietary patterns and lifestyles, based on the Krece Plus Questionnaire²¹ and the AVall Questionnaire,²² respectively.

The main analyses were performed with the modified intention-to-treat (mITT) population, that is, participants with baseline and end-of-study data on weight, height and date of birth, and written informed 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 SPSS V.20.0 for Windows (SPSS Inc, Chicago, Illinois, 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 and control groups was 320 and 370 pupils, respectively. At 22 months, the mean age was 9.67 (95% CI 9.60 to 9.73) in the intervention group (9.68 years in boys and 9.65 years in girls) and 9.86 (95% CI 9.79 to 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 groups were homogeneous in BMI status. The ethnicity of the population was predominantly Western European in the intervention and control groups (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 the intervention group and 3.5% in the control group; $p < 0.001$). The distribution was random. Of note, 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.

Attrition rate

Figure 2 shows the recruitment and retention of pupils in intervention and control schools. Among the 916

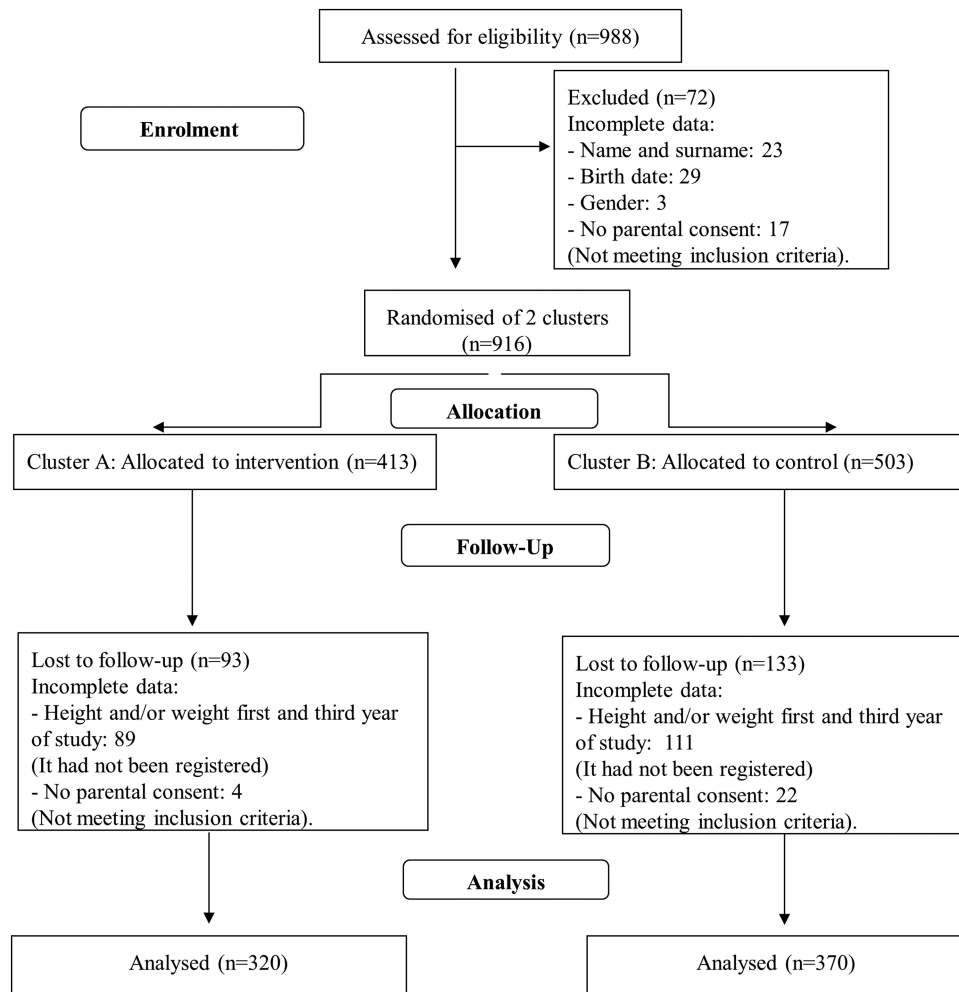


Figure 2 Flow of participants through the study. Incomplete height and/or weight (measures of the first and/or third academic year); No parental consent signed (first, second or third academic year).

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%. Dropouts 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 the intervention and control groups ($p=0.628$; [table 2](#)).

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 the BMI z-score between the intervention and control groups ($p=0.400$; [table 3](#)). Despite no differences in the BMI z-score, the boys in the intervention group did not have an increase in percentage fat mass (19.96–20.02%:

$p=0.896$), whereas girls in the intervention group (22.06–23.55%; $p<0.001$), together with boys (19.18–20.64%, $p<0.001$) and girls (23.26–24.98%) in the control group, had a significant increase.

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

Lifestyle 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 girls in the 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 in the control group ($p=0.002$ and $p=0.001$, respectively). Conversely, there were 12.9% and 12.2% more girls in the control group who consumed legumes and cereal breakfast than girls in the intervention group ($p=0.013$ and $p=0.032$, respectively; [table 4](#)).

Table 1 Anthropometric characteristics of pupils at baseline: intervention versus control group

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

The results are expressed as mean (95% CI).

*p Value: GLM statistic.

BMI, body mass index; GLM, general linear model.

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 in the intervention group who performed ≥ 4 h after-school PA/week was increased by 15% ($p=0.027$) while there were 16.6% more boys in the intervention group watching ≤ 2 h TV/day ($p<0.009$). The results indicate less sedentary behaviour in intervention than control individuals.

Differences between intervention and control pre-post intervention programme.

At 22 months, participants who were normal weight at baseline increased after-school PA to ≥ 4 h/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 OB

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 PAh/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 EdAI-2 programme, 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 the maintenance of OW and OB prevalence in both groups, fat mass percentage had increased in girls of the intervention and control group, whereas it remained similar in boys of intervention group.

As proposed by Kain *et al*, designing a new school-based intervention study needs to have some critical aspects considered. These include the following: the random allocation of schools, although methodologically desirable, is not always possible; participation of parents is very limited; OB is not recognised as a problem; and increasing PA and implementing training programmes for teachers is difficult due to an inflexible curriculum and lack of teachers' time. Unless these barriers are overcome, OB 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 EdAI-2 programme 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 EdAI programme¹⁸ at 28 months of intervention, there was an increase of up to 19.7% of children dedicating > 5 h/week to extra-curricular physical activities.¹⁸

Table 2 Baseline and end-of-intervention measurements of categorised BMI in the intervention and control groups

Criteria/ category	Group	Baseline, % (n)	End of study, % (n)	Change, %	Baseline to study end p Value*	Intervention vs control p Value†
<i>IOTF criteria</i>						
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	
OB	Girls	28.2 (49)	32.8 (57)	4.6	0.185	
	Total	26.8 (99)	29.7 (110)	2.9	0.169	
	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	

The results are expressed as % (n).

*p Value: McNemar's test.

†p Value: Fisher's exact test.

BMI, body mass index; OB, obesity; OW, overweight; IOTF, International Obesity Task Force.

Further, the after-school PA was maintained despite cessation of the intervention programme.²⁸ The effect of the EdAI programme 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 programme'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. The feasibility of our intervention was confirmed in two different towns and over two different timecourses (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 study²⁰ 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 OW outcomes, weight categories or lifestyles between the two cohorts. Some multicentred studies have

Table 3 BMI z-score at baseline and at the end of intervention in the intervention and control groups

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

Differences between intervention and control preintervention versus postintervention.

*p Value: mixed models repeated measures.

†p Value: analysis of variance (ANOVA) model.

BMI, body mass index.

Table 4 Food habits assessed at baseline and at the end of study in the intervention and control groups

	Intervention group			Control group			Intervention vs control p Value‡
	Baseline, % (n)	End of study, % (n)	p Value*	Baseline, % (n)	End of study, % (n)	p Value†	
<i>Krece Plus Questionnaire</i>							
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)	73.1 (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 per week							
Boys	6.3 (8)	7.4 (9)	1	7.1 (11)	4.9 (8)	0.227	0.106
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 per week							
Boys	70.3 (90)	71.1 (86)	0.648	67.5 (106)	65.9 (110)	1	0.555
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, >1 per day							
Boys	14.3 (18)	12.6 (15)	1	17.2 (27)	18.2 (30)	1	0.367
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 daily							
Boys	63.8 (81)	67.5 (83)	0.839	69.0 (109)	67.9 (114)	0.871	0.708
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 (160)	0.35	68.5 (209)	68.6 (216)	0.561	1

Continued

Table 4 Continued

	Intervention group			Control group			Intervention vs control p Value‡
	Baseline, % (n)	End of study, % (n)	p Value*	Baseline, % (n)	End of study, % (n)	p Value†	
Cooking with olive oil at home							
Boys	97.7 (126)	98.4 (122)	1	98.1 (157)	98.8 (167)	1	0.636
Girls	98.4 (125)	99.2 (120)	0.623	97.3 (145)	98.0 (145)	1	0.628
Total	98 (251)	98.8 (242)	0.5	97.7 (302)	98.4 (312)	0.754	0.476
<i>All questionnaire</i>							
Before leaving home							
Dairy products							
Boys	90 (117)	87.3 (110)	0.065	83.6 (133)	95.3 (139)	1	0.074
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 or natural juice							
Boys	18.4 (23)	24.6 (31)	0.189	17.0 (26)	21.2 (32)	1	0.537
Girls	14.2 (17)	24.6 (30)	0.064	18.5 (27)	23.6 (33)	0.541	0.332
Total	16.3 (40)	24.6 (61)	0.016	17.7 (53)	22.3 (65)	0.560	0.256
Sandwich							
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
Total	8.4 (20)	18.7 (46)	0.008	16.2 (47)	19.8 (58)	0.289	0.889
Juice package/soft drinks							
Boys	6.7 (8)	7.4 (9)	0.754	8.7 (13)	7.1 (11)	1	0.756
Girls	7.7 (9)	5.0 (6)	0.508	8.6 (12)	10.8 (15)	1	0.507
Total	7.2 (17)	6.2 (15)	0.359	8.6 (25)	8.9 (26)	0.845	0.483
Break (midmorning)							
Dairy products							
Boys	16.0 (20)	20.0 (24)	0.824	15.3 (22)	14.4 (21)	1	0.819
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 natural juice							
Boys	16.3 (20)	10.1 (12)	0.804	19.5 (30)	14.5 (22)	0.189	0.787
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 package/soft drinks							
Boys	7.4 (9)	9.1 (11)	0.344	12.2 (18)	12.6 (19)	1	1
Girls	7.8 (9)	6.1 (7)	0.727	12.1 (17)	13.2 (18)	1	0.233
Total	7.6 (18)	7.7 (18)	0.815	12.2 (35)	12.9 (37)	1	0.543

Bold typeface indicates $p < 0.05$.

*p Value: McNemar's test (changes in the intervention group).

†p Value: McNemar's test (changes in the control group).

‡p Value: Fisher's exact test.

Table 5 Lifestyles assessed at baseline and at the end of study in intervention and control

	Intervention			Control			Intervention vs control p Value‡
	Baseline, % (n)	End of study, % (n)	p Value*	Baseline, % (n)	End of study, % (n)	p Value†	
<i>TV and/or video games</i>							
0–2 h/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
3–4 h/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
>4 h/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
<i>After-school PA</i>							
0–2 h/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
2–4 h/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
>4 h/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

Bold typeface indicates $p < 0.05$.

*p Value: McNemar's test (changes in the intervention group).

†p Value: McNemar's test (changes in the control group).

‡p Value: Fisher's exact test.

PA, physical activity; TV, television.

attempted to reproduce methodological aspects in interventions conducted in different countries or different populations. However, while multicentred 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 multicentred study, had been applied in different countries simultaneously and had demonstrated its efficacy and feasibility.

The ALADINO study presented the OB status prevalence in Spain, which, according to the IOTF, is about 11.4% in children around 9 years of age.³¹ In the EdAI-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 EdAI-2 control group.

The EdAI-2 study showed a significant improvement of 16.7% in the young boys in the intervention group who participated in the ≥ 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 in preventing OB over the longer term due to the PA being maintained.

In the dietary habits aspect of the EdAI-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/day, is promising lifestyle changes that could induce a reduction of OW and OB over the long term.

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

Several studies have shown that participating in PA was a protective factor against OB and that spending > 2 h 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. First, 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. Second, assigning control groups according to towns surrounding the intervention town could be a limitation. However, schools in 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. Third, 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. Fourth, when asked about fast-food consumption, the participants interpreted this as pertaining only to fast-food outlets such as burger shops, and did not 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, EdAI-2 demonstrated that performing >4 h/week after-school PA, plus having dairy products at breakfast are protective factors. Hence, we believe that participating in >4 h/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 ≥ 4 h/week) in boys. Despite this improvement, there was no change in BMI and 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-OB 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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Acknowledgements The authors express their appreciation to the university medical and health science students of the *Facultat de Medicina i Ciències de la Salut, Universitat Rovira i Virgili* (Reus, Spain) as well as the staff and parents of the pupils of the primary schools of Amposta, Sant Jaume d'Enveja, Els Muntells, l'Ametlla de Mar, El Perelló, l'Ampolla, Deltebre, l'Aldea, Lligalló del Gànguill and Camarles for their enthusiastic support of this study.

Contributors MG, EL, LT and RS designed the study (project conception, development of the overall research plan and study oversight). MG, EL, LT, RQ and RS conducted research (hands-on conduct of the experiments and data collection). EL, LT, MG and RS provided essential materials (applies to authors who contributed by providing constructs, database, etc. necessary for the research). DM, EL and LT analysed data or performed statistical analysis. RS, MG, LT, DM and 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.

Funding This work has been supported by Diputació de Tarragona 2011 which give a grant to Universitat Rovira i Virgili, and Ajuntament d'Amposta which provided the foods to develop the activities in the schools.

Competing interests None.

Patient consent Obtained.

Ethics approval The EdAI-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).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Technical appendix, statistical code and data set available at the Dryad repository in: "Data from: EdAI-2 (Educació en Alimentació) programme: reproducibility of a cluster randomised, interventional, primary-school-based study to induce healthier lifestyle activities in children" (10.5061/dryad.t5825;005496).

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