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## EdAI-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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Complete List of Authors:	Llauradó, Elisabet; Facultat de Medicina i Ciències de la Salut, Universitat Rovira i Virgili, Tarro, Lucia; Facultat de Medicina i Ciències de la Salut, Universitat Rovira i Virgili, Moriña, David; Technological Centre of Nutrition and Health (CTNS) - TECNIO - URV - CEICS, ; Facultat de Medicina, Universitat Autònoma de Barcelona, Unit of Biostatistics Queral, Rosa; Universitat Rovira i Virgili, Giralt, Montse; Facultat de Medicina i Ciències de la Salut, Universitat Rovira i Virgili, Unit of Farmacobiology Solà, Rosa; Hospital Universitari Sant Joan de Reus, Unit of Lipids and Arteriosclerosis Research, CIBERDEM
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3 **EdAI-2 (*Educació en Alimentació*) program: reproducibility of a randomized,**  
4 **interventional, primary-school-based study to induce healthier lifestyle activities in**  
5 **children**  
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10  
11 Elisabet Llauradó (elisabet.laurado@urv.cat)

12  
13 Lucia Tarro (lucia.tarro@urv.cat)

14  
15 David Morina (david.morina@ctns.cat)

16  
17 Rosa Queral (rosa.queral@urv.cat)

18  
19 Montse Giralt (montse.giralt@urv.cat)

20  
21 Rosa Solà (rosa.sola@urv.cat)

22  
23  
24  
25 E.LL. and L.T. contributed equally to the study.  
26  
27

28  
29 From the:

30  
31 Health Education and Promotion, Facultat de Medicina i Ciències de la Salut, Universitat

32  
33 Rovira i Virgili, Reus, Spain (ELL, LT)

34  
35 Technological Center of Nutrition and Health (CTNS) - TECNIO - URV – CEICS Unitat de

36  
37 Bioestadística, Facultat de Medicina, Universitat Autònoma de Barcelona (DM)

38  
39 Unit of Farmacobiology, Facultat de Medicina i Ciències de la Salut, Universitat Rovira i

40  
41 Virgili, Reus, Spain (MG)

42  
43 Unit of Lipids and Arteriosclerosis Research, CIBERDEM, Hospital Universitari Sant Joan,

44  
45 IISPV, Facultat de Medicina i Ciències de la Salut, Universitat Rovira i Virgili, Reus, Spain

46  
47 (RS)  
48  
49  
50

51  
52 **For correspondence:**

53  
54 Rosa Solà, MD, PhD

55  
56 Unitat de Recerca en Lípids i Arteriosclerosi,

57  
58 Facultat de Medicina i Ciències de la Salut,  
59  
60

1  
2  
3 C/ Sant Llorenç 21,

4  
5 43201-Reus,

6  
7 Spain

8  
9 Tel: (34) 977 759 369 / 609 906 991 (mobile)

10  
11 Fax: (34) 977 759 322

12  
13 E-mail: [rosa.sola@urv.cat](mailto:rosa.sola@urv.cat)

14  
15 or

16  
17 Montse Giralt, MD, PhD

18  
19 Unit of Farmacobiology,

20  
21 Facultat de Medicina i Ciències de la Salut,

22  
23 Universitat Rovira i Virgili,

24  
25 43201-Reus,

26  
27 Spain

28  
29 E-mail: [montse.giralt@urv.cat](mailto:montse.giralt@urv.cat)

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3 1 **ABSTRACT**

4 2 **Objectives:** To assess the reproducibility of the EdAl program in “Terres de l’Ebre” (Spain),  
5 3 EdAL-2, an educational intervention to improve lifestyles, including diet and physical activity  
6 4 recommendations; over a period of 22 months.

7 5 **Design:** reproduction of a randomized controlled trial

8 6 **Setting:** primary-secondary care, two school clusters were randomly assigned to intervention (5  
9 7 schools in Amposta) or control group (11 schools in surrounding towns of Amposta)

10 8 **Participants:** 690 pupils (320 in the intervention group and 370 in the control group); 78%  
11 9 were of Western European ethnicity. Mean age ( $\pm$ SD) was  $8.04 \pm 0.6$  years (47.7% females) at  
12 10 baseline. Inclusion criteria were name, gender, date and place of birth, and written informed  
13 11 consent from the parent or guardian.

14 12 **Intervention:** The interventions focused on 8 lifestyle topics covered in 12 activities  
15 13 (1h/activity/session) implemented by health promoting agents (HPAs) in the primary-school  
16 14 over 3 school academic years.

17 15 **Primary and secondary outcomes:** the primary outcome was obesity prevalence and the  
18 16 secondary outcomes were body mass index (BMI) collected every year, and dietary habits and  
19 17 lifestyles collected by questionnaires were filled-in by the parents at baseline and end-of-study.

20 18 **Results:** At 22-months of the EdAL-2 program reproducing the original EdAl protocol, showed  
21 19 that there was an increase of 15% ( $p=0.027$ ) in boys performing  $\geq 4$  after-school physical  
22 20 activity (PA) h/week, while watching TV was reduced to  $\leq 2$ h/day. TV watching decreased by  
23 21 23.1% ( $p=0.009$ ) in intervention compared to control group. The obesity prevalence was similar  
24 22 in intervention and control groups over the period of the program. Multivariate statistical  
25 23 analysis indicated that the performance of  $\geq 4$  after-school PA h/week was a protective factor  
26 24 against childhood OB (OR: -0.511;  $p=0.032$ ).

27 25 **Conclusions:** Our school-based intervention program is feasible, reproducible and adaptable to  
28 26 any school environment. It can lead to an increased percentage of children (mainly boys)  
29 27 performing  $\geq 4$  after-school PA h/week.

30 28 Words: 299/300

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3 29 Clinical Trials registration NCT01362023  
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7 31 **ARTICLE SUMMARY**  
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9 32 **Strengths and limitations of the study**

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11 33 - Strengths: Reproducibility of studies is rare because of the huge complexity of trying to  
12 replicate a program. However, studies in OB prevention as EdAI need to be  
13 34 reproducible, especially those improving healthy lifestyle such as after-school PA, to  
14 35 confirm best childhood practices.  
15 36  
16 37 - Strengths: Statistical methods controlling for confounders and taking clustering of data  
17 38  
18 39 - Limitations: Assessment of treatment adherence in order to evaluate reproducibility and  
19 40 feasibility  
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21 42 - Limitations: Dietary habits were observed via a questionnaire that did not take into  
22 43 account the quantities of the different types of food items consumed  
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**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

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3 85 group) with the neighboring towns of Salou, Cambrils and Vilaseca as control group. The  
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5 86 interventions focused on 8 lifestyle topics covered in 12 activities (1h/activity/session) in 7-8  
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7 87 year old children, and implemented by HPAs over 3 school academic years. We found that the  
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9 88 EdAI program successfully reduced childhood OB prevalence in boys by 4.39% and increased  
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11 89 the percentage of boys who practice  $\geq 5$  after-school physical activity (PA) h/week [16]. The  
12  
13 90 EdAI program needed to be reproduced in other localities and with other children to  
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15 91 demonstrate the effectiveness of this intervention program [17].

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17 92 The outcomes of the EdAI program support the feasibility of improving PA in childhood.  
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19 93 However, an educational intervention such as our EdAI program implemented by HPAs also  
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21 94 tests complex components such as healthy lifestyles including diet and physical activity  
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23 95 recommendations. Due to the complexity, such interventions are difficult to rationalize,  
24  
25 96 standardize, reproduce, and administer consistently to all participants [17].

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27 97 There has been one study in the literature that has reproduced its programs in other locations.  
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29 98 Described as the Kiel Obesity Prevention Study (KOPS), it demonstrated the efficacy and  
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31 99 feasibility of implementing new nutritional concepts [18]. We tested the reproducibility of the  
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33 100 EdAI program in a geographical area (Terres de l'Ebre) about 80 km away from where the  
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35 101 original EdAI program was designed and implemented. We describe, here, the primary-school-  
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37 102 based study to reduce the prevalence of childhood OB (The EdAI-2 study) which remains an  
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39 103 intervention to induce healthy lifestyles, including diet and physical activity recommendations,  
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41 104 in 7-8 year old school children over 3 academic years (22 months active school time).

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## 45 106 **METHODS**

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47 107 The original protocol, rationale, randomization, techniques and results of the initial EdAI  
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49 108 program have been published in *Trials* [15-16]. The current study (EdAI-2) was conducted in  
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51 109 exactly the same way so as to examine whether comparable results could be achieved. The  
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53 110 EdAI-2 study was approved by the Clinical Research Ethical Committee of the Hospital Sant  
54  
55 111 Joan of Reus, Universitat Rovira i Virgili (Catalan ethical committee registry ref 11-04-  
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57 112 28/4proj8). This study was registered in Clinical Trials *NCT01362023*. The protocol conformed

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3 113 to the Helsinki Declaration and Good Clinical Practice guides of the International Conference of  
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5 114 Harmonization (ICHGCP). This study followed the CONSORT criteria [see Additional file 1].  
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7 115 For logistics reasons, the EdAI-2 program was reduced by 6 months, from 28 months to 22  
8  
9 116 months.

### 117 118 **Study population**

119 The coordinating Center (in Reus) developed a randomization scheme to have a study sample in  
120 which the schools in Amposta were designated as Group A (intervention) and 9 towns around  
121 Amposta (Sant Jaume d'Enveja, Els Muntells, l'Ametlla de Mar, El Perelló, l'Ampolla,  
122 Deltebre, l'Aldea, Lligalló del Gànguill and Camarles) as Group B (control).  
123 The socio-demographic indicators in all towns were similar to that of the original EdAI Program  
124 in Reus. Children attending the schools in both groups (intervention and control) lived in close  
125 proximity within each school's catchment area. Intervention institutions were 5 schools  
126 involving 18 classrooms and 457 pupils in Amposta. Control institutions consisted of 11 schools  
127 involving 23 classrooms and 531 pupils in the 9 towns of around Amposta. Children of this  
128 study are in the 2<sup>nd</sup> and 3<sup>rd</sup> grade of primary education (7-8 year olds). Schoolchildren were  
129 enrolled since 25<sup>th</sup> May 2011 (children born in 2002–2003) and followed-up for 3 school  
130 academic years (2012–2013) and it was completed 30<sup>th</sup> March 2013.

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

136

### 137 **Intervention program**

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



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3 141 washing and, overall, adoption of activities that encourage physical activity (walking to school,  
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5 142 playground games), and to avoid sedentary behavior [19].  
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7 143 Each of the eight topics was integrated within educational intervention activities of 1  
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9 144 hour/activity, prepared and standardized by the HPAs, and implemented in the children's  
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11 145 classrooms. In the first school academic year, we focused on four topics: 1) to improve healthy  
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13 146 lifestyle; 2) to encourage healthy drinks intake (and avoidance of unhealthy carbonated/sugared  
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15 147 beverages); 3) to increase the consumption of vegetables and legumes; and 4) to decrease the  
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17 148 consumption of candies and pastries while increasing the intake of fresh fruits and nuts. These  
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19 149 corresponded to four standardized activities (1 hour/ activity). In the second year, the remaining  
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21 150 four of the eight selected lifestyle topics were addressed: 5) to improve healthy habits within a  
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23 151 set timetable (home meals, teeth-brushing, hand-washing) and physical activity participation; 6)  
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25 152 to increase fruit intake; 7) to improve dairy product consumption; and 8) to increase fish  
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27 153 consumption. These corresponded to four standardized activities. Finally, in the third school  
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29 154 academic year, four standardized activities were introduced that reinforced the eight lifestyle  
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31 155 topics implemented in the previous 2 academic years. Thus, the intervention program was based  
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33 156 on eight lifestyle topics incorporated in 12 activities which were disseminated over 12 sessions  
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35 157 (1 hour/activity/session), and prepared, standardized and implemented as four activities per  
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37 158 school academic year by the HPAs in the school classrooms.  
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#### 160 **Process evaluation**

161 The measurements were performed in each school academic year, as was the original EdAI  
162 program [15-16].  
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#### 164 **Outcomes**

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

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3 169 by gender) such as BMI z-score and waist circumference, incidence and remission of excess  
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5 170 weight (OW and OB), as well as changes in lifestyles (eating habits and physical activity  
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7 171 h/week). Weight, height, and waist circumference values were obtained as described previously  
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9 172 [15]. Prevalence of underweight was analyzed according to Cole et al [21] using 17 Kg/m<sup>2</sup> as  
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11 173 cut-off point. BMI z-score was analyzed according to the WHO Global InfoBase [22]. To  
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13 174 identify the risk factors of OB, the OB category was determined according to WHO criteria  
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15 175 since this is based on data from countries which have a low OB prevalence [22] and, as such,  
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17 176 provide an understanding of the protective (or risk factors) for OB in our own population.  
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#### 20 21 178 Sample size

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23 179 We calculated that, with a sample of more than 300 pupils per group, the study would have 85%  
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25 180 power to detect a difference of 5 percentage points between the intervention and control schools  
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27 181 in relation to the primary outcome (prevalence of OB).  
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#### 30 31 183 **Statistical analyses**

32  
33 184 Descriptive variables were presented as means and confidence intervals (95%CI). General linear  
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35 185 mixed models (GLM) were used to analyze differences between the intervention and control  
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37 186 pupils with respect to prevalence of OB. Repeated measures of GLM were used to analyze the  
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39 187 trend of BMI z-score between baseline and end-of-study. The McNemar test was used to  
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41 188 analyze change-over-time of food habits, after-school PA h/week and hours TV/day categories,  
42  
43 189 in intervention and control group. The continuous outcomes studied in each group were  
44  
45 190 compared using ANOVA.

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47 191 To evaluate risk and protective factors involved in childhood OB, logistic regression analyses  
48  
49 192 were performed at baseline, with no distinction between intervention and control group. The  
50  
51 193 odds ratios (OR) and 95%CI were calculated for dietary patterns and lifestyles, based on the  
52  
53 194 Krece Plus Questionnaire [23] and the AVall Questionnaire [24], respectively. The main  
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55 195 analyses were performed with the modified intention-to-treat (mITT) population i.e. subjects  
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57 196 with baseline and end-of-study data on weight, height, and date of birth, and written inform  
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3 197 consent. The analyses did not use any imputation missing method; the implication being that  
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5 198 missing data were random. Statistical significance was defined by a  $P < 0.05$ . The statistical  
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7 199 analyses were performed with the SPSS 20.0 for Windows (SPSS Inc., Chicago, IL, USA).  
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## 10 11 201 **RESULTS**

### 12 13 202 **Enrollment**

14  
15 203 Figure 1 shows the recruitment and flow diagram of pupils in the intervention and control  
16  
17 204 groups over the course of the study. The mITT population in the intervention group and control  
18  
19 205 group were 320 and 370 pupils, respectively.

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21 206 The characteristics of the study group are shown in Table 1. At baseline, the intervention and  
22  
23 207 control group were homogeneous in BMI status. The ethnicity of the population was  
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25 208 predominantly Western European in intervention and control group (77.5% vs. 78.9%,  
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27 209 respectively) while 7.5% vs. 10.8% was Eastern European; 10.3% vs. 3.5% was Latin  
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29 210 American; 3.4% vs. 6.2% was North African Arab.  
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211 **Table 1.** Anthropometric characteristics of pupils at baseline: Intervention *versus* Control group

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	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			
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 <sup>2</sup>	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

213 Notes to Table 1:

214 The results are expressed as Mean (95%CI)

215 <sup>1</sup>p value: general linear model (GLM) statistics

216 **Attrition rate**

217 Figure 1 shows the recruitment and retention of pupils in intervention and control schools.

218 Among the 916 pupils assessed at the beginning of the study, 690 (75.3%) pupils (73.6% of

219 those allocated to the control group and 77.5% of those allocated to the intervention group)

220 were reassessed three academic courses later, and valid measurements were obtained. The rate

221 of parental consent was 95.7%. Drop-outs in both groups are understood to be missing at

222 random.

223 **Primary outcome: Prevalence of OB**

224 At 22 months of the study, OB prevalence assessed by IOTF criteria, was similar in intervention

225 and control group (p=0.628) (Table 2).

227 **Table 2.** Baseline and end-of-intervention measurements of categorized BMI in Intervention

228 and Control group

				Baseline	End of study	Change	Baseline to	Intervention
				% (n)	% (n)	%	study end	vs. Control
Criteria/Category	Group						p- value <sup>1</sup>	p-value <sup>2</sup>
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	
			Total	17.2 (55)	23.8 (76)	6.6	0.005	
		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	
			Total	11.6 (37)	11.9 (38)	0.3	1.000	
		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	

229

230 Notes to Table 2

231 IOTF: International Obesity Task Force

232 The results are expressed as % (n)

233 <sup>1</sup>p value: McNemar's Test

234 <sup>2</sup>p value: Fisher's Exact Test

235

236 **Secondary outcomes**

237 At 22 months of the study, the progress of OW prevalence (according to IOTF criteria) was

238 similar between groups (p=0.086).

239 There were no significant differences in BMI z-score differences between intervention and

240 control group (p=0.512) (Table 3). The remission, and incidence, of OB was similar in the

241 overall intervention and control group, as well as segregated with respect to gender.

242

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

244 group

			Baseline Mean (95%CI)	End of study Mean (95%CI)	Change Mean (95%CI)	Baseline to Study end P-value <sup>1</sup>	Intervention vs. Control P-value <sup>2</sup>
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	

245

246 Notes to Table 3:

247 <sup>1</sup>p-value: Mixed Models Repeated Measures

248 <sup>2</sup>p-value: Fisher's Exact Test

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250 Differences between intervention and control pre-post intervention

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252 **Lifestyles evaluation**

253 At 22 months, food habits changes showed that control group had significantly decreased

254 (p<0.001) breakfast consumption by 7.1% (from 98.1% to 92.9%) compared to the change in

255 intervention group (98.4% to 98.8%).

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3 256 The control boys had a reduction of 14% compared to intervention boys with respect to  
4  
5 257 consumption of pastry (p=0.005). The intervention girls had an increase of 8.1% in the  
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7 258 consumption of fast-food, compared to the change in control girls (p=0.014).  
8  
9 259 The once/day consumption of vegetables was higher in intervention group compared to control,  
10  
11 260 while vegetables once/day increased by 16.2% in girls of intervention group compared to girls  
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13 261 of control group (p=0.008). The intake of a second vegetable/day increased by 13.8% in boys of  
14  
15 262 intervention group compared to boys of control group (0.024).  
16  
17 263 Table 4 summarizes the time spent doing after-school PA, watching TV, playing video games,  
18  
19 264 and other leisure-time activities. At 22 months, the percentage of boys who performed  $\geq 4$ h  
20  
21 265 after-school PA/week was increased by 15% (p=0.027) while watching TV daily was reduced to  
22  
23 266  $\leq 2$ h/day. This was equivalent to a change in TV watching of 23.1% (p=0.009) in intervention  
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25 267 compared to control group.  
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**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 <sup>1</sup>	Baseline %(n)	End of study %(n)	p-value <sup>1</sup>	p-value <sup>2</sup>	
TV and/or video games									271
0-2h/day	Boys	49.2 (62)	45.2 (57)	0.268	32.5 (51)	27.0 (43)	0.627	0.009	272
	Girls	48.4 (60)	51.2 (63)	1.000	44.0 (66)	49.7 (71)	0.430	1.000	273
	Total	48.8 (122)	48.2 (120)	0.464	38.1 (117)	37.7 (114)	0.910	0.062	274
3-4h/day	Boys	46.0 (58)	50.0 (63)	0.542	62.4 (98)	63.5 (101)	1.000	0.049	275
	Girls	43.5 (54)	44.7 (55)	0.860	54.0 (81)	47.6 (68)	0.349	0.693	276
	Total	44.8 (112)	47.4 (118)	0.489	58.3 (179)	56.0 (169)	0.606	0.080	277
>4h/day	Boys	4.8 (6)	4.8 (6)	0.375	5.1 (8)	9.4 (15)	0.607	0.301	278
	Girls	8.1 (10)	4.1 (5)	0.453	2.0 (3)	2.8 (4)	1.000	0.253	279
	Total	6.4 (16)	4.4 (11)	1.000	3.6 (11)	6.3 (19)	0.481	1.000	280
After-school PA									281
0-2h/week	Boys	26.2 (34)	14.5 (18)	0.013	21.5 (34)	19.0 (31)	0.286	0.483	282
	Girls	35.2 (43)	33.6 (41)	0.701	34.5 (50)	36.6 (52)	1.000	1.000	283
	Total	30.6 (77)	24.0 (59)	0.049	27.7 (84)	27.2 (83)	0.435	0.744	284
2-4h/week	Boys	29.2 (38)	24.2 (30)	0.418	38.0 (60)	3.1 (54)	0.780	0.067	285
	Girls	36.9 (45)	32.0 (39)	0.377	32.4 (47)	31.0 (44)	1.000	1.000	286
	Total	32.9 (83)	28.0 (69)	0.188	35.3 (107)	32.1 (98)	0.764	0.193	287
>4h/week	Boys	44.6 (58)	61.3 (76)	0.006	40.5 (64)	47.9 (78)	0.243	0.027	288
	Girls	27.9 (34)	34.4 (42)	0.136	33.1 (48)	32.4 (46)	0.868	1.000	289
	Total	36.5 (92)	48.0 (118)	0.002	37.0 (112)	40.7 (124)	0.272	0.068	290



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6 284 Notes to Table 4

7  
8 285 <sup>1</sup>p-value: McNemar's Test

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10 286 <sup>2</sup>p-value: Fisher's Exact Test.

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12 287 Differences between intervention and control pre-post intervention program  
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3 288 At 22 months, subjects who were normal weight at baseline increased after-school PA to  
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5 289  $\geq 4$ h/week. This reflects a rise to 32.7% in boys ( $p=0.002$ ) but, in girls, the changes were not  
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7 290 statistically different ( $p=0.134$ ). No statistically significant differences were observed in the  
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9 291 control group.

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### 11 293 **Impact of certain additional factors on obesity**

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13 294 The ORs of OB, using BMI z-score criteria, were related to some of the more relevant dietary  
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15 295 habits and lifestyles. Thus, breakfast dairy product consumption (OR: -1.092;  $p=0.004$ ) and  $\geq 4$   
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17 296 after-school PA h/week (OR: -0.511;  $p=0.032$ ) were protective factors against OB. Conversely,  
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19 297 doing  $< 4$  h/week PA (OR: 0.594;  $p=0.018$ ) increased the risk of childhood OB.  
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### 23 299 **DISCUSSION**

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25 300 The EdAl-2 program, a reproducibility study, in Terres de l'Ebre, shows that intervention is  
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27 301 useful for improving weekly after-school PA. However, the OB prevalence remained unchanged  
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29 302 at 22 months, as has been shown in the data on stability of OB prevalence observed in some  
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31 303 European countries [8].

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33 304 The EdAl-2 program confirmed that after-school PA (in terms of h/week) can be stimulated in  
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35 305 primary school as part of a healthy lifestyle. As we had observed in the original EdAL program  
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37 306 [16] at 28 months of intervention, there was an increase of up to 19.7% of children dedicating  
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39 307  $> 5$  hours/week to extra-curricular physical activities [16]. Further, the after-school PA was  
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41 308 maintained despite cessation of the intervention program [25]. The effect of EdAl program  
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43 309 during its implementation and after the official cessation indicated an impact on PA, whereas  
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45 310 modification towards healthy food-choices occurred according to the site of the program's  
46  
47 311 implementation, and was not consistent.

48 312 Interventions to prevent OB in the school setting have shown dramatic improvements [26].

49 313 However, successful studies in OB prevention need to be reproducible, especially those

50 314 improving healthy lifestyle such as after-school PA, to confirm best childhood practices.

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2  
3 315 Reproducibility of studies is rare because of the huge complexity of trying to replicate a  
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5 316 program. For the standardization of any method it is essential to be able to reproduce  
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7 317 appropriate levels of an intervention study, especially one that involves behavioral changes.  
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9 318 Feasibility of our intervention was confirmed in two different towns and over two different  
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11 319 time-courses (the first in Reus over 28 months, and the second in Amposta over 22 months).  
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13 320 It is also important to assess treatment adherence in order to evaluate reproducibility and  
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15 321 feasibility [17]. For example, the KOPS study [18] demonstrated that nutritional knowledge was  
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17 322 increased as a result of their intervention in the two cohort studies (KOPS 1 and KOPS 2) [18].  
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19 323 However, the study was unable to show whether there were differences in overweight outcomes,  
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21 324 weight categories or lifestyles between the two cohorts. Some multi-centered studies have  
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23 325 attempted to reproduce methodological aspects in interventions conducted in different countries  
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25 326 or different populations. However, while multi-centered studies are usually implemented  
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27 327 concurrently, reproducibility involves the applicability of the intervention in different sites  
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29 328 and/or different times in order to validate the initial findings. One example of this is the Pro  
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31 329 Children Study [27] which, as a multi-centered study, had been applied in different countries  
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33 330 simultaneously and had demonstrated its efficacy and feasibility.  
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35 331 The ALADINO study presented the obesity status prevalence in Spain which, according to the  
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37 332 IOTF is about 11.4% in children of around 9 years of age [28]. In the EdAI-2 study, the OB  
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39 333 prevalence was similar, but lower in the intervention group than the equivalent in the  
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41 334 ALADINO study, as well as in the EDAL-2 control group.  
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43 335 The EdAI-2 study showed a significant improvement of 16.7% in the young boys in the  
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45 336 intervention group who participated in  $\geq 4$  h/week after-school PA. Further, the increased  
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47 337 numbers of children in the intervention group who performed  $\geq 4$  h/week after-school PA who  
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49 338 were normal-weight at baseline, suggested that the intervention was effective not only in the  
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51 339 primary-school healthy population but also effective in preventing OB over the longer-term due  
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53 340 to the PA being maintained.  
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56 341 In the dietary habits aspect of the EdAI-2 study, we observed that there was an increase in  
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58 342 breakfast consumption. A recent study [29] showed that frequent breakfast eaters had  
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3 343 significantly lower levels of body-weight, BMI, z-score BMI, and waist circumference  
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5 344 compared to those who partook of breakfast infrequently. In the EdAl-2 study we observed that  
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7 345 consumption of dairy products at breakfast was a protective factor against obesity.  
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9 346 Several studies have shown that participating in PA was a protective factor against OB and that  
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11 347 spending >2h watching TV was a risk factor for childhood OB. A recent Spanish study showed  
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13 348 that leisure-time PA was a protective factor against OB (as with our present study) and that  
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15 349 performing >4 h/week is a protective factor while watching TV for this amount of time was,  
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17 350 according to Ochoa et al [30], associated with OB.  
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19 351 A limitation of our study is that it only observed dietary habits via a questionnaire that did not  
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21 352 take into account the quantities of the different types of food items consumed. These data would  
22  
23 353 be important in contributing to the quantity *versus* quality debate in OB or OW prevalence.  
24  
25 354 Furthermore, EdAl-2 demonstrated that performing >4h/week after-school PA, plus having  
26  
27 355 dairy product at breakfast are protective factors. Hence, we believe that a participating in  
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29 356 >4h/week after-school PA, and continuing with a healthy breakfast, are key points in preventing  
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31 357 childhood OB.

358

### 359 CONCLUSION

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

364

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3 371 schools of Amposta, Sant Jaume d'Enveja, Els Muntells, l'Ametlla de Mar, El Perelló,  
4  
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6  
7 373 this study.  
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9 374

#### 10 11 375 **COMPETING INTERESTS**

12  
13 376 The authors declare that they have no competing interests.  
14

15 377

#### 16 17 378 **LIST OF ABBREVIATIONS**

18  
19 379 OB: Obesity

20  
21 380 OW: Overweight

22  
23 381 PA: Physical Activity

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25 382 mITT: modified Intention to Treat

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27 383 HPAs: Health Promoter Agents

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29 384 WHO: World Health Organization

30  
31 385 BMI: Body Mass Index

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33 386 OR: Odds Ratio

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35 387

#### 36 37 388 **Authors' contributions**

38  
39 389 MG, EL, LT, RS designed the study (project, conception, development of overall research plan,  
40  
41 390 and study oversight)

42  
43 391 MG, EL, LT, RQ, RS conducted research (hands-on conduct of the experiments and data  
44  
45 392 collection)

46  
47 393 EL, LT, MG, RS provided essential materials (applies to authors who contributed by providing  
48  
49 394 constructs, database, etc. necessary for the research)

50  
51 395 DM, EL, LT analyzed data or performed statistical analysis

52  
53 396 RS, MG, LT, DM, EL drafted and revised the manuscript (authors who made a major  
54  
55 397 contribution). The final manuscript was read and approved by all co-authors

56  
57 398 RS, MG take primary responsibility for the study, and manuscript content  
58  
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3 483 **FIGURE LEGENDS**

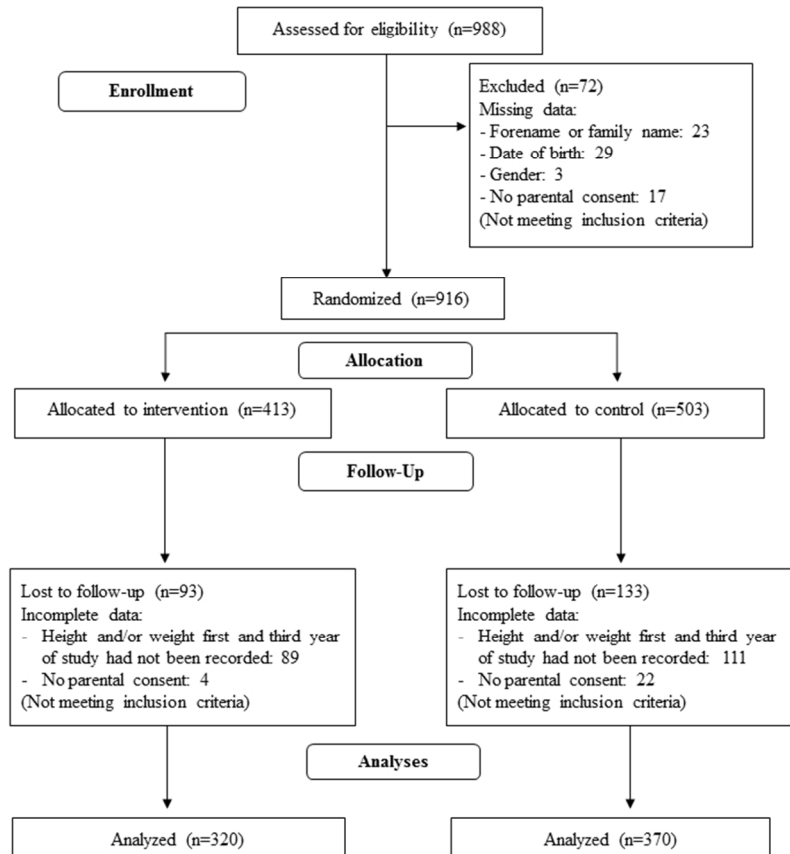
4  
5 484 **Figure 1:** Flow of subjects through the study.

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7 485 Incomplete height and/or weight (measures of first and/or third academic year)

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9 486 No parental consent signed (first, second or third academic year).

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For peer review only



190x275mm (96 x 96 DPI)

“Research Checklist”



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

EdAI-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
<b>Title and abstract</b>			
	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
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio ( <b>described in Giralt M, Albaladejo R, Tarro L, Moríña 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. <i>Trials</i> 2011;12:54.</b> )	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	-
<b>Randomisation: described in <i>Trials</i> 2011</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	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

1				
2			“Research Checklist”	
3				
4	concealment		describing any steps taken to conceal the sequence until interventions were assigned	
5	mechanism			
6	Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
7				
8	Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	-
9				
10		11b	If relevant, description of the similarity of interventions	-
11				
12	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9-10
13		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9-10
14				
15	<b>Results</b>			
16	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
17		13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
18	Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
19		14b	Why the trial ended or was stopped	-
20	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1 and page 9
21				
22	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
23				
24	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
25		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
26	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
27				
28	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Figure 1
29				
30	<b>Discussion</b>			
31	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	19
32	Generalisability	21	Generalisability (external validity, applicability) of the trial findings	17-19
33	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	17-19
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44	CONSORT 2010 checklist			
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## “Research Checklist”

**Other information**

Registration	23	Registration number and name of trial registry	Clinical Trials registration NCT0136202 3
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](http://www.consort-statement.org).

# BMJ Open

## EdAI-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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Manuscripts

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3 **EdAl-2 (*Educació en Alimentació*) programme: reproducibility of a randomised,**  
4 **interventional, primary-school-based study to induce healthier lifestyle activities in**  
5 **children**  
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8  
9

10  
11 Elisabeth Llauradó ([elisabet.laurado@urv.cat](mailto:elisabet.laurado@urv.cat))

12  
13 Lucia Tarro ([lucia.tarro@urv.cat](mailto:lucia.tarro@urv.cat))

14  
15 David Morina ([david.morina@uab.cat](mailto:david.morina@uab.cat))

16  
17 Rosa Queral ([rosa.querall@urv.cat](mailto:rosa.querall@urv.cat))

18  
19 Montse Giralt ([montse.giralt@urv.cat](mailto:montse.giralt@urv.cat))

20  
21 Rosa Solà ([rosa.sola@urv.cat](mailto:rosa.sola@urv.cat))  
22  
23  
24  
25  
26

27 E.LL. and L.T. contributed equally to the study.  
28  
29  
30  
31

32 **From the:**

33  
34 Health Education and Promotion, Facultat de Medicina i Ciències de la Salut,

35  
36 Universitat Rovira i Virgili, Reus, Spain (ELL, LT)

37  
38 Technological Centre of Nutrition and Health (CTNS) - TECNIO - URV – CEICS;

39  
40 Centre for Research in Environmental Epidemiology (CREAL) - Unitat de

41  
42 Bioestadística, Facultat de Medicina, Universitat Autònoma de Barcelona (DM)

43  
44 Unit of Farmacobiology, Facultat de Medicina i Ciències de la Salut, Universitat Rovira  
45  
46 i Virgili, Reus, Spain (MG)  
47  
48

49  
50 Unit of Lipids and Arteriosclerosis Research, CIBERDEM, Hospital Universitari Sant

51  
52 Joan, IISPV, Facultat de Medicina i Ciències de la Salut, Universitat Rovira i Virgili,

53  
54 Reus, Spain (RS)  
55  
56  
57  
58  
59  
60

**For correspondence:**

Rosa Solà, MD, PhD

Unitat de Recerca en Lípids i Arteriosclerosi,

Facultat de Medicina i Ciències de la Salut,

C/ Sant Llorenç 21,

43201-Reus,

Spain

Tel: (34) 977 759 369 / 609 906 991 (mobile)

Fax: (34) 977 759 322

E-mail: [rosa.sola@urv.cat](mailto:rosa.sola@urv.cat)

or

Montse Giralt, MD, PhD

Unit of Farmacobiology,

Facultat de Medicina i Ciències de la Salut,

Universitat Rovira i Virgili,

43201-Reus,

Spain

E-mail: [montse.giralt@urv.cat](mailto:montse.giralt@urv.cat)

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

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1  
2  
3 **1 ABSTRACT**

4  
5 **2 Objectives:** To assess the reproducibility of the EdAl programme in “Terres de l’Ebre”  
6  
7 (Spain), EdAL-2, an educational intervention over a period of 22 months, to improve  
8  
9 lifestyles, including diet and physical activity recommendations  
10

11 **5 Design:** Reproduction of a randomised controlled trial

12  
13  
14 **6 Setting:** Primary schools, two school clusters were randomly assigned to intervention  
15  
16 or control group  
17

18  
19 **8 Participants:** Pupils (n=690; intervention group n=320; control group n= 370) 78% of  
20  
21 Western European ethnicity. Mean age ( $\pm$ SD) was 8.04 $\pm$ 0.6 years (47.7% females) at  
22  
23 baseline. Inclusion criteria were name, gender, date and place of birth, and written  
24  
25 informed consent from the parent or guardian.  
26

27  
28 **12 Intervention:** The interventions focused on 8 lifestyle topics covered in 12 activities  
29  
30 (1h/activity/session) implemented by health promoting agents (HPAs) in the primary-  
31  
32 school over 3 school academic years.  
33

34  
35 **15 Primary and secondary outcomes:** the primary outcome was obesity prevalence and  
36  
37 the secondary outcomes were body mass index (BMI) collected every year, and dietary  
38  
39 habits and lifestyles collected by questionnaires filled-in by the parents at baseline and  
40  
41 end-of-study.  
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43  
44 **19 Results:** At 22 months, the percentage of boys in the intervention group who performed  
45  
46  $\geq$ 4h after-school PA h/week was 15% higher (p=0.027), while there was 16.6% more  
47  
48 boys in the intervention group watching  $\leq$ 2hTV/day (p=0.009), compared to controls.

49  
50 The obesity prevalence was similar in intervention and control groups over the period of  
51  
52 the program. Multivariate statistical analysis indicated that the performance of  $\geq$ 4 after-  
53  
54 school PA h/week was a protective factor against childhood OB (OR:0.600; p=0.032).  
55

56  
57 **25 Conclusions:** Our school-based intervention is feasible, adaptable to quite different  
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3 26 school environments, and reproducible. The main improvement was after-school PA  
4  
5 27 ( $\geq 4$ h/week) in boys. Further, TV watching decreased to  $< 2$  TV h/day. This suggests that  
6  
7 28 our intervention programme induces healthy lifestyle effects (such as more exercise and  
8  
9 29 less sedentary behaviour) which can produce anti-obesity benefits in children.

10  
11 30 Words: 294/300

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13 31 Clinical Trials registration NCT01362023

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### 17 18 33 **ARTICLE SUMMARY**

#### 19 20 34 **Strengths and limitations of the study**

- 21  
22 35 - Strengths: Reproducibility of studies is rare because of the complexity of  
23  
24 36 replicating a programme. Studies in OB prevention, such as EdAI, need to be  
25  
26 37 reproducible, especially those improving healthy lifestyle, including after-school  
27  
28 38 PA, to reinforce beneficial practices in childhood
  - 29  
30 39 - Strengths: Statistical methods controlling for confounders and taking into  
31  
32 40 account clustering of data
  - 33  
34 41 - Limitations: Failure to assess treatment adherence to evaluate reproducibility  
35  
36 42 and feasibility
  - 37  
38 43 - Limitations: Dietary habits were noted via a questionnaire that did not take into  
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40 44 account the quantities of the different types of food items consumed
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**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

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3 70 television (TV), video games or on the Internet. These activities represent a decrease in  
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5 71 physical movement and lowering energy expenditure and, as such, are risk factors for  
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7 72 OB,[16].

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9 73 We had designed the EdAI (*Educació en Alimentació*) programme as a randomised,  
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11 74 controlled, parallel study applied in primary schools, and implemented by university  
12  
13 75 students acting as Health Promoter Agents (HPAs),[17]. This intervention was deployed  
14  
15 76 in Reus (as intervention group) with the neighbouring towns of Salou, Cambrils and  
16  
17 77 Vilaseca as control group. The interventions focused on 8 lifestyle topics covered in 12  
18  
19 78 activities (1h/activity/session) in 7-8 year old children, and implemented by HPAs over  
20  
21 79 3 school academic years. We found that the EdAI programme successfully reduced  
22  
23 80 childhood OB prevalence in boys by 4.39% and increased the percentage of boys who  
24  
25 81 practice  $\geq 5$  after-school physical activity (PA) h/week,[18]. The EdAI programme  
26  
27 82 needed to be reproduced in other localities, and with other children, to demonstrate the  
28  
29 83 effectiveness of this intervention[19].

30  
31 84 The outcomes of the EdAI programme supported the feasibility of improving PA in  
32  
33 85 childhood. However, an educational intervention, such as our EdAI program  
34  
35 86 implemented by HPAs, also tests complex components such as healthy lifestyles  
36  
37 87 including diet and physical activity recommendations. Due to the complexity, such  
38  
39 88 interventions are difficult to rationalise, standardise, reproduce, and administer  
40  
41 89 consistently to all participants,[19].

42  
43 90 There has been one study in the literature that has reproduced its programmes in other  
44  
45 91 locations. Described as the Kiel Obesity Prevention Study (KOPS), the results  
46  
47 92 demonstrated the efficacy and feasibility of implementing new nutritional concepts,[20].  
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49 93 We tested the reproducibility of the EdAI programme in a geographical area (Terres de  
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51 94 l'Ebre) about 80km away from where the original EdAI programme was designed and  
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3 95 implemented. We describe, here, the primary-school-based study to reduce the  
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5 96 prevalence of childhood OB (The EdAI-2 study); the objective remains an intervention  
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7 97 to induce healthy lifestyles, including diet and physical activity recommendations. The  
8  
9 98 study was conducted in 7-8 year old school-children over 3 academic years (22 months  
10  
11 99 active school time).

100

## 101 **METHODS**

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

112 For logistics reasons, the EdAI-2 program was reduced by 6 months, from 28 months to  
113 22 months.

114

### 115 **Study population**

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

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3 119 l'Ametlla de Mar, El Perelló, l'Ampolla, Deltebre, l'Aldea, Lligalló del Gànguïl and  
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5 120 Camarles) as Group B (control).  
6  
7 121 The socio-demographic indicators in all towns were similar to that of the original EdAl  
8  
9 122 Program in Reus. Children attending the schools in both groups (intervention and  
10  
11 123 control) lived in close proximity within each school's catchment area. Intervention  
12  
13 124 institutions were 5 schools involving 18 classrooms and 457 pupils in Amposta. Control  
14  
15 125 institutions consisted of 11 schools involving 23 classrooms and 531 pupils in the 9  
16  
17 126 towns of around Amposta. Children of this study are in the 2<sup>nd</sup> and 3<sup>rd</sup> grade of primary  
18  
19 127 education (7-8 year olds). Schoolchildren were enrolled in May 2011 (children born in  
20  
21 128 2002–2003) and followed-up for 3 school academic years (2012–2013). The study was  
22  
23 129 completed in March 2013.

24  
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26  
27 130 To be representative of the child population, the schools selected needed to have at least  
28  
29 131 50% of the children in the classrooms volunteer to participate. We offered the  
30  
31 132 programme to all schools, whether public (funded by the government and termed  
32  
33 133 “charter” schools) or private which included fee-paying and/or faith schools. Inclusion  
34  
35 134 criteria were: name, gender, date and place of birth, and written informed consent from  
36  
37 135 the parent or guardian. A questionnaire on eating habits (Krece Plus) developed by  
38  
39 136 Serra Majem et al,[21], and physical activity, level of parental education and lifestyles  
40  
41 137 developed by Llargues et al,[22] were filled-in by the parents at baseline and at the end  
42  
43 138 of the study.

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#### 48 49 140 **Intervention program**

50  
51 141 The original EdAl Reus protocol was followed,[17-18]. The educational intervention  
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53 142 activities focused on eight lifestyle topics based on scientific evidence,[23] to improve  
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55 143 nutritional food item choices (and avoidance of some foods), healthy habits such as  
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3 144 teeth-brushing and hand-washing and, overall, adoption of activities that encourage  
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5 145 physical activity (walking to school, playground games), and to avoid sedentary  
6  
7 146 behaviour,[23].  
8  
9  
10 147 Each of the eight topics was integrated within educational intervention activities of  
11  
12 148 1h/activity, prepared and standardized by the HPAs, and implemented in the children's  
13  
14 149 classrooms. In the first school academic year, we focused on four topics: 1) to improve  
15  
16 150 healthy lifestyle; 2) to encourage healthy drinks intake (and avoidance of unhealthy  
17  
18 151 carbonated/sweetened beverages); 3) to increase the consumption of vegetables and  
19  
20 152 legumes; and 4) to decrease the consumption of candies and pastries while increasing  
21  
22 153 the intake of fresh fruits and nuts. These corresponded to four standardised activities  
23  
24 154 (1h/activity). In the second year, the remaining four of the eight selected lifestyle topics  
25  
26 155 were addressed: 5) to improve healthy habits within a set timetable (home meals, teeth-  
27  
28 156 brushing, hand-washing) and physical activity participation; 6) to increase fruit intake;  
29  
30 157 7) to improve dairy product consumption; and 8) to increase fish consumption. These  
31  
32 158 corresponded to four standardised activities. Finally, in the third school academic year,  
33  
34 159 four standardised activities were introduced that reinforced the eight lifestyle topics  
35  
36 160 implemented in the previous 2 academic years. Thus, the intervention program was  
37  
38 161 based on eight lifestyle topics incorporated within 12 activities which were  
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40 162 disseminated over 12 sessions (1h/activity/session), and prepared, standardised and  
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42 163 implemented as four activities per school academic year by the HPAs in the school  
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44 164 classrooms.  
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### 166 **Process evaluation**

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

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3 1694  
5 170 **Outcomes**

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7 171 Assessment of the reproducibility of the EdAI program was based on primary outcomes  
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9 172 such as prevalence of OB (overall as well as stratified by gender), according to the  
10  
11 173 International Obesity Task Force (IOTF),[24] recommendations for better international  
12  
13 174 comparisons of data. Secondary outcomes included: changes in measures of adiposity  
14  
15 175 (overall as well as stratified by gender) such as BMI z-score (based on WHO growth  
16  
17 176 charts,[25] and waist circumference, incidence and remission of excess weight (OW and  
18  
19 177 OB), as well as changes in lifestyles (eating habits and physical activity h/week).  
20  
21 178 Weight, height, and waist circumference values were obtained as described  
22  
23 179 previously,[17]. Prevalence of underweight was analysed according to Cole et al,[26]  
24  
25 180 using 17Kg/m<sup>2</sup> as cut-off point. BMI z-score was calculated using the population values  
26  
27 181 of the WHO Global InfoBase,[25]. To identify the risk factors of OB, the OB category  
28  
29 182 was determined according to WHO criteria since this is based on data from countries  
30  
31 183 that have a low OB prevalence,[25] and, as such, provide an understanding of the  
32  
33 184 protective (or risk factors) for OB in our own population. To obtain a measurement of  
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35 185 overall improvement in lifestyle we generated variables such as the maintenance of  
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37 186 status in each category as well as the status in relation to changes in each category over  
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39 187 the 22 month period.  
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47 189 **Sample size**

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49 190 We calculated that, with a sample of more than 300 pupils per group, the study would  
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51 191 have 85% power to detect a difference of 5 percentage points between the intervention  
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53 192 and control schools in relation to the primary outcome (prevalence of OB).  
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## 194 **Statistical analyses**

195 Descriptive variables were presented as means and confidence intervals (95%CI).  
196 General linear mixed models (GLM) were used to analyse differences between the  
197 intervention and control pupils with respect to prevalence of OB. Repeated measures of  
198 GLM were used to analyse the trend of BMI z-score between baseline and end-of-study  
199 values. The McNemar test was used to analyse change-over-time of food habits, after-  
200 school PA h/week and hours TV/day categories, in intervention and control group. The  
201 continuous variables studied in each group were compared using ANOVA.  
202 To evaluate risk and protective factors involved in childhood OB, logistic regression  
203 analyses were performed at baseline, with no distinction between intervention and  
204 control group. The odds ratios (OR) and 95%CI were calculated for dietary patterns and  
205 lifestyles, based on the Krece Plus Questionnaire,[21] and the AVall Questionnaire,[22],  
206 respectively.  
207 The main analyses were performed with the modified intention-to-treat (mITT)  
208 population i.e. subjects with baseline and end-of-study data on weight, height, and date  
209 of birth, and written inform consent. The analyses did not use any imputation missing  
210 method; the assumption being that missing data were random. Statistical significance  
211 was defined by a  $P < 0.05$ . The statistical analyses were performed with the SPSS 20.0  
212 for Windows (SPSS Inc., Chicago, IL, USA).

213

## 214 **RESULTS**

### 215 **Enrolment**

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

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3 219 age was 9.67 (95%CI: 9.60, 9.73) in the intervention group (9.68 years in boys and 9.65  
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5 220 years in girls) and 9.86 (95%CI: 9.79, 9.91) in the control group (9.85 years in boys and  
6  
7 221 9.84 years in girls). The differences in age were not significant in relation to gender.  
8  
9 222 The characteristics of the study group are summarised in Table 1. At baseline, the  
10  
11 223 intervention and control group were homogeneous in BMI status. The ethnicity of the  
12  
13 224 population was predominantly Western European in intervention and control group  
14  
15 225 (77.5% vs. 78.9%, respectively) while 7.5% vs. 10.8% was Eastern European; 10.3% vs.  
16  
17 226 3.5% was Latin American; 3.4% vs. 6.2% was North African Arab. At baseline, there  
18  
19 227 was a significant difference in the distribution with respect to Latin American children  
20  
21 228 (10.3% in intervention and 3.5% in control group;  $p < 0.001$ ). The distribution was  
22  
23 229 random. Of note is that there were no significant differences in distributions of OB  
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25 230 and/or OW. Also, no differences were observed in terms of response to the intervention  
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29 231 in relation to ethnicity.  
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232 **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
	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;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 <sup>2</sup>	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

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6 233 Notes to Table 1:  
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8 234 The results are expressed as Mean (95%CI)  
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10 235 <sup>1</sup>p value: general linear model (GLM) statistic  
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For peer review only

236 **Attrition rate**

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

243 **Primary outcome: Prevalence of OB**

244 At 22 months of the study, OB prevalence assessed by IOTF criteria, was similar in  
 245 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 <sup>1</sup>	Intervention vs. Control P-value <sup>2</sup>
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	
			Total	17.2 (55)	23.8 (76)	6.6	0.005	
	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		
		Total	11.6 (37)	11.9 (38)	0.3	1.000		
	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		

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3 247 **Table 2.** Baseline and end-of-intervention measurements of categorised BMI in  
4 Intervention and Control group

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9 250 Notes to Table 2

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11 251 IOTF: International Obesity Task Force

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13 252 The results are expressed as % (n)

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15 253 <sup>1</sup>p value: McNemar's Test

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17 254 <sup>2</sup>p value: Fisher's Exact Test

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## 22 256 **Secondary outcomes**

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25 257 At 22 months of the study, the status of OW prevalence (according to IOTF criteria)  
26 was similar between groups (p=0.086).

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29 259 There were no significant differences in BMI z-score between intervention and control  
30 group (p=0.400) (Table 3). Despite no differences in BMI z-score, the boys of  
31 intervention group did not have an increase in percentage fat mass (19.96% to 20.02%:  
32 p=0.896), whereas intervention girls (22.06% to 23.55%; p<0.001), together with boys  
33 (19.18% to 20.64%, p<0.001) and girls (23.26% to 24.98%) of control group had a  
34 significant increase.  
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42 265 The remission, and incidence, of OB was similar in the overall intervention and control  
43 group, as well as when stratified with respect to gender.  
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271 **Table 3.** BMI z-score at baseline and at the end of intervention in Intervention and Control group

				Baseline	Change	Baseline	
				to Study	end	Interven	
				end	vs. Control		
				P-value <sup>1</sup>	P-value <sup>2</sup>		
				Mean (95%CI)	Mean (95%CI)	Mean (95%CI)	
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	

282 Notes to Table 3:

283 <sup>1</sup>p-value: Mixed Models Repeated Measures

284 <sup>2</sup>p-value: ANOVA model

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

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5 287 **Lifestyles evaluation**  
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7 288 After 22 months of the study, there were 19.7%, 11.2% and 8.2% more girls in the  
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9 289 intervention group who consumed a second fruit per day, one vegetable per day and  
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11 290 fast-food weekly than the girls of control group ( $p<0.001$ ,  $p=0.017$  and  $p=0.013$ ;  
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13 291 respectively). However, there were 17.9% and 17.8% more boys in the intervention  
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15 292 group who consumed pastry at breakfast and more than one vegetable a day, compared  
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17 293 to boys of control group ( $p=0.002$ ,  $p=0.001$ ; respectively). Conversely, there were  
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19 294 12.9% and 12.2% more girls in the control group who consumed legumes and cereal  
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21 295 breakfast than girls of intervention group ( $p=0.013$ ,  $p=0.032$ ; respectively) (Table 4).  
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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			Interven
		Baseline	End of	P	Baseline	End of	P	tion vs.
		%(n)	study	Value	%(n)	study	Value	Control
			%(n)			%(n)		P-value
<b>Krece plus questionnaire</b>								
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)	<b>0.016</b>	0.453
	Total	98.4 (248)	98.8 (239)	1	98.1 (302)	92.9 (288)	<b>0.003</b>	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)	<b>0.039</b>	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)	<b>0.036</b>	59.7 (86)	60.0 (87)	0.880	<b>0.031</b>
	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)	<b>0.027</b>	22.5 (33)	12.3 (20)	<b>0.001</b>	<b>0.002</b>
	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)	<b>&lt;0.001</b>	<b>0.002</b>
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, 2 <sup>nd</sup> per day	Boys	39.7 (50)	41.2 (49)	0.581	44.5 (69)	34.1 (56)	<b>0.006</b>	0.141
	Girls	26.4 (32)	47.5 (56)	<b>0.000</b>	44.8 (64)	39.0 (57)	0.281	<b>&lt;0.001</b>
	Total	33.2 (82)	44.3 (105)	<b>0.001</b>	44.6 (133)	36.5 (113)	<b>0.004</b>	<b>&lt;0.001</b>
Dairy product, 2 <sup>nd</sup> per day	Boys	87.2 (109)	78.5 (95)	<b>0.029</b>	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)	<b>0.043</b>	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	<b>0.017</b>
	Total	68.5 (170)	75.9 (183)	<b>0.011</b>	69.9 (214)	67.3 (212)	0.374	<b>0.028</b>
Vegetables, >1 per day	Boys	19.3 (23)	29.1 (34)	<b>0.017</b>	28.7 (43)	20.7 (34)	<b>0.009</b>	<b>0.001</b>
	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)	<b>0.001</b>	29.5 (86)	21.8 (67)	<b>0.002</b>	<b>0.001</b>
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	<b>0.013</b>
	Total	4.8 (12)	8.8 (21)	0.21	5.7 (17)	3.9 (12)	<b>0.049</b>	<b>0.003</b>
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)	<b>0.001</b>	<b>0.013</b>
	Total	71.5 (181)	72.2 (174)	1	65.2 (251)	70.7 (222)	<b>0.025</b>	<b>0.027</b>
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
<hr/>								
<b>Avall questionnaire</b>								
<i>Before leaving home</i>								
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)	<b>0.004</b>	0.235
	Total	90.9 (227)	87.6 (218)	0.071	86.2 (255)	81.1 (249)	<b>0.044</b>	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)	<b>0.016</b>	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)	<b>0.049</b>	14.9 (21)	18.4 (26)	0.572	1
Sandwich	Total	8.4 (20)	18.7 (46)	<b>0.008</b>	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
<i>Break (Midmorning)</i>								
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)	<b>0.016</b>	0.860
	Total	26.6 (66)	35.7 (87)	<b>0.008</b>	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

299 Notes to Table 4:

300 <sup>1</sup>p-value: McNemar's Test (changes in intervention group)

301 <sup>2</sup>p-value: McNemar's Test (changes in control group)

302 <sup>3</sup>p-value: Fisher's Exact Test.

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3 305 Table 5 summarises the time spent in after-school PA, watching TV, playing video  
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5 306 games, and other leisure-time activities. At 22 months, the percentage of boys of the  
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7 307 intervention group who performed  $\geq 4$ h after-school PA/week was increased by 15%  
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9 308 ( $p=0.027$ ) while there was 16.6% more boys in the intervention group watching  
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11 309  $\leq 2$ hTV/day ( $p<0.009$ ). The results indicate less sedentary behaviour in intervention than  
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14 310 control individuals.  
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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 <sup>1</sup>	Baseline %(n)	End of study %(n)	P-value <sup>2</sup>	P-value <sup>3</sup>	
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)	<b>0.049</b>	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	

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>4h/week	Boys	44.6 (58)	61.3 (76)	<b>0.006</b>	40.5 (64)	47.9 (78)	0.243	0.643	312
	Girls	27.9 (34)	34.4 (42)	0.136	33.1 (48)	32.4 (46)	0.868	0.598	313
	Total	36.5 (92)	48.0 (118)	<b>0.002</b>	37.0 (112)	40.7 (124)	0.272	0.485	314

315 Notes to Table 5

316 <sup>1</sup>P-value: McNemar's Test (changes in intervention group)

317 <sup>2</sup>P-value: McNemar's Test (changes in control group)

318 <sup>3</sup>P-value: Fisher's Exact Test.

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3 319 Differences between intervention and control pre-post intervention program  
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5 320 At 22 months, subjects who were normal weight at baseline increased after-school PA  
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7 321 to  $\geq 4$ h/week. This reflects a rise to 32.7% in boys ( $p=0.002$ ). However, in girls, the  
8  
9 322 changes were not statistically different ( $p=0.134$ ). No statistically significant differences  
10  
11 323 were observed in the control group.  
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### 325 **Impact of certain additional factors on obesity**

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17  
18 326 The ORs of OB, using BMI z-score criteria, were related to some of the more relevant  
19  
20 327 dietary habits and lifestyles. Thus, breakfast dairy product consumption (OR: 0.336;  
21  
22 328  $p=0.004$ ) and  $\geq 4$  after-school PA h/week (OR: 0.600;  $p=0.032$ ) were protective factors  
23  
24 329 against OB. Conversely, doing  $< 4$  h/week PA (OR: 1.811;  $p=0.018$ ) increased the risk  
25  
26 330 of childhood OB.  
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### 332 **DISCUSSION**

33  
34 333 The EdAl-2 program, a reproducibility study in Terres de l'Ebre, shows that  
35  
36 334 intervention is useful for improving weekly after-school PA. However, the OB  
37  
38 335 prevalence remained unchanged at 22 months, as has been shown in the data on stability  
39  
40 336 of OB prevalence observed in some European countries,[8]. Despite that OW and OB  
41  
42 337 remained similar between groups, we observed percentage fat mass maintenance in the  
43  
44 338 boys of the intervention group, whereas girls of the intervention and control group had  
45  
46 339 increases.  
47

48  
49 340 As proposed by Kain J et al, designing a new school-based intervention study needs to  
50  
51 341 have some critical aspects considered. These include: the random allocation of schools,  
52  
53 342 although methodologically desirable, is not always possible; participation of parents is  
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55 343 very limited; obesity is not recognised as a problem; and increasing physical activity  
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3 344 and implementing training programmes for teachers is difficult due to an inflexible  
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5 345 curriculum and lack of teachers' time. Unless these barriers are overcome, obesity  
6  
7 346 prevention programmes will not produce positive and lasting outcomes,[27]. As such,  
8  
9 347 our programme of HPA-implemented intervention activities in classrooms is an  
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11 348 attractive alternative that circumvents lack-of-teacher-time.

12  
13 349 The EdAl-2 program confirmed that after-school PA (in terms of h/week) can be  
14  
15 350 stimulated in primary school as part of a healthy lifestyle. As we had observed in the  
16  
17 351 original EdAL program,[18] at 28 months of intervention, there was an increase of up to  
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19 352 19.7% of children dedicating >5 hours/week to extra-curricular physical activities,[18].  
20  
21 353 Further, the after-school PA was maintained despite cessation of the intervention  
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23 354 program,[28]. The effect of EdAl program during its implementation and after the  
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25 355 official cessation indicated an impact on PA, whereas modification towards healthy  
26  
27 356 food choices occurred according to the site of the program's implementation, and was  
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29 357 not consistent.

30  
31 358 Interventions to prevent OB in the school setting have shown dramatic  
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33 359 improvements,[29]. However, successful studies in OB prevention need to be  
34  
35 360 reproducible, especially those improving healthy lifestyle such as after-school PA, to  
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37 361 confirm best childhood practices.

38  
39 362 Reproducibility of studies is rare because of the complexity of trying to replicate a  
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41 363 programme. To standardise a method it is essential to be able to reproduce appropriate  
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43 364 levels of an intervention, especially one that involves behavioural changes. Feasibility  
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45 365 of our intervention was confirmed in two different towns and over two different time-  
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47 366 courses (the first in Reus over 28 months, and the second in Amposta over 22 months).

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49 367 Also, it is important to assess treatment adherence in order to evaluate reproducibility  
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51 368 and feasibility,[19]. For example, the KOPS study,[20] demonstrated that nutritional  
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3 369 knowledge was increased as a result of the intervention in the two cohort studies (KOPS  
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5 370 1 and KOPS 2),[20]. However, the study was unable to show whether there were  
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7 371 differences in overweight outcomes, weight categories or lifestyles between the two  
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9 372 cohorts. Some multi-centred studies have attempted to reproduce methodological  
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11 373 aspects in interventions conducted in different countries or different populations.  
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13 374 However, while multi-centred studies are usually implemented concurrently,  
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15 375 reproducibility involves the applicability of the intervention at different sites and/or  
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17 376 different times in order to validate the initial findings. One example of this is the Pro  
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19 377 Children Study,[30] which, as a multi-centred study, had been applied in different  
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21 378 countries simultaneously and had demonstrated its efficacy and feasibility.  
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23 379 The ALADINO study presented the obesity status prevalence in Spain which, according  
24  
25 380 to the IOTF, is about 11.4% in children of around 9 years of age,[31]. In the EdAl-2  
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27 381 study, the OB prevalence was similar, but lower in the intervention group than the  
28  
29 382 equivalent in the ALADINO study and, as well, in the EDAL-2 control group.  
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31 383 The EdAl-2 study showed a significant improvement of 16.7% in the young boys in the  
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33 384 intervention group who participated in  $\geq 4$  h/week after-school PA. Further, the  
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35 385 increased numbers of children in the intervention group who performed  $\geq 4$  h/week  
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37 386 after-school PA who were normal-weight at baseline, suggested that the intervention  
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39 387 was effective not only in the primary-school healthy population but also effective in  
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41 388 preventing OB over the longer-term due to the PA being maintained.  
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43 389 In the dietary habits aspect of EdAl-2 study, we observed that the increase in healthy  
44  
45 390 lifestyle habits such as the increase in fruit and vegetables consumption and increasing  
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47 391 PA h/week while maintaining low TV h/d, are promising lifestyle changes that could  
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49 392 induce a reduction of OW and OB over the long-term.  
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3 393 In the EdA1-2 study we observed that consumption of dairy products at breakfast was a  
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5 394 protective factor against obesity.  
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7 395 Several studies have shown that participating in PA was a protective factor against OB  
8  
9 396 and that spending >2h watching TV was a risk factor for childhood OB. A recent  
10  
11 397 Spanish study showed that leisure-time PA was a protective factor against OB (as with  
12  
13 398 our present study) and that performing >4 h/week is a protective factor while watching  
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15 399 TV for this amount of time was, according to Ochoa et al,[32], associated with OB.  
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17 400 There are several limitations to our study. Firstly, we evaluated dietary habits via a  
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19 401 questionnaire that did not take into account the quantities of the different types of food  
20  
21 402 items consumed. These data would be important in addressing the quantity *versus*  
22  
23 403 quality debate in OB or OW prevalence. Secondly, assigning control groups according  
24  
25 404 to towns surrounding the intervention town could be a limitation. However, schools of  
26  
27 405 the same town have good relationships and communications with each other and this  
28  
29 406 could entail a possible contamination between schools if assigned to intervention or  
30  
31 407 control status within the same town. This cross-contamination would be minimised if  
32  
33 408 the schools themselves were assigned to intervention or control. Thirdly, the significant  
34  
35 409 difference in Latin American ethnicity between the two groups of the study at baseline  
36  
37 410 could be a limitation. However, there were no significant differences in distributions of  
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39 411 OB and/or OW. Also, no differences were observed in terms of response to the  
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41 412 intervention study in relation to ethnicity. Fourthly, when asked about fast-food  
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43 413 consumption, the participants interpreted this as pertaining only to fast-food outlets such  
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45 414 a burger shops, and did consider other concepts such as frozen pizza consumed at home.  
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47 415 Finally, another limitation could be the proportion of females who may have started  
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49 416 puberty in the course of the study. This implies changes in body composition. However,  
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3 417 both study groups (intervention and control) had a similar proportion of females with a  
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5 418 similar age, and this could cancel-out the effect.

6  
7 419 Further, EdA1-2 demonstrated that performing >4h/week after-school PA, plus having  
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9 420 dairy product at breakfast are protective factors. Hence, we believe that a participating  
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11 421 in >4h/week after-school PA, and continuing with a healthy breakfast, are key points in  
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13 422 preventing childhood OB.

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## 17 18 424 **CONCLUSION**

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20 425 Our school-based intervention is feasible, adaptable to quite different school  
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22 426 environments, and reproducible. The main improvement was after-school PA  
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24 427 ( $\geq 4$ h/week) in boys. Further, TV watching decreased to <2 TV h/day. This suggests that  
25  
26 428 our intervention programme induces healthy lifestyle effects (such as more exercise and  
27  
28 429 less sedentary behaviour) which can produce anti-obesity benefits in children.

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## 32 33 431 **ACKNOWLEDGEMENTS**

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42  
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44  
45 437 parents of the pupils of the primary schools of Amposta, Sant Jaume d'Enveja, Els  
46  
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48  
49 439 Gànguill and Camarles for their enthusiastic support in this study.

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## 53 54 441 **COMPETING INTERESTS**

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3 442 The authors declare that they have no competing interests.  
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#### 444 **LIST OF ABBREVIATIONS**

445 OB: Obesity

446 OW: Overweight

447 PA: Physical Activity

448 mITT: modified Intention to Treat

449 HPAs: Health Promoter Agents

450 WHO: World Health Organization

451 BMI: Body Mass Index

452 OR: Odds Ratio

453

#### 454 **Authors' contributions**

455 MG, EL, LT, RS designed the study (project conception, development of overall

456 research plan, and study oversight)

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

458 data collection)

459 EL, LT, MG, RS provided essential materials (applies to authors who contributed by

460 providing constructs, database, etc. necessary for the research)

461 DM, EL, LT analysed data or performed statistical analysis

462 RS, MG, LT, DM, EL drafted and revised the manuscript (authors who made a major

463 contribution). The final manuscript was read and approved by all co-authors

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

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For peer review only

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3 568 **FIGURE LEGEND**  
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5 569 **Figure 1:** Flow of subjects through the study  
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7 570 Incomplete height and/or weight (measures of first and/or third academic year)  
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9 571 No parental consent signed (first, second or third academic year).  
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“Research Checklist”



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

## EdAI-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
<b>Title and abstract</b>			
	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
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	7
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio ( <b>described in Giralt M, Albaladejo R, Tarro L, Moríña 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. <i>Trials</i> 2011;12:54.</b> )	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	-
<b>Randomisation: described in <i>Trials</i> 2011</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	7-8
	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

CONSORT 2010 checklist

		“Research Checklist”		
	concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	
6	Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7-8
8	Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	-
11		11b	If relevant, description of the similarity of interventions	-
12	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11
13		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
15	<b>Results</b>			
16	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
18		13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
20	Recruitment	14a	Dates defining the periods of recruitment and follow-up	11-12
21		14b	Why the trial ended or was stopped	-
22	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1 and page 15
25	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
28	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) Tables 1-5
32		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
33	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
36	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Figure 1
37	<b>Discussion</b>			
38	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	28
40	Generalisability	21	Generalisability (external validity, applicability) of the trial findings	25-29
41	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 NCT0136202 3
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](http://www.consort-statement.org).

Peer review only

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2  
3 **EdAl-2 (*Educació en Alimentació*) programme: reproducibility of a randomised,**  
4 **interventional, primary-school-based study to induce healthier lifestyle activities in**  
5 **children**  
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10  
11 Elisabet Llauradó ([elisabet.laurado@urv.cat](mailto:elisabet.laurado@urv.cat))

12  
13 Lucia Tarro ([lucia.tarro@urv.cat](mailto:lucia.tarro@urv.cat))

14  
15 David Morina ([david.morina@uab.cat](mailto:david.morina@uab.cat))

16  
17 Rosa Queral ([rosa.querall@urv.cat](mailto:rosa.querall@urv.cat))

18  
19 Montse Giralt ([montse.giralt@urv.cat](mailto:montse.giralt@urv.cat))

20  
21 Rosa Solà ([rosa.sola@urv.cat](mailto:rosa.sola@urv.cat))  
22  
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27 E.LL. and L.T. contributed equally to the study.  
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30  
31

32 **From the:**

33 Health Education and Promotion, Facultat de Medicina i Ciències de la Salut,  
34 Universitat Rovira i Virgili, Reus, Spain (ELL, LT)

35  
36 Technological Centre of Nutrition and Health (CTNS) - TECNIO - URV – CEICS;  
37  
38 Centre for Research in Environmental Epidemiology (CREAL) - Unitat de  
39  
40 Bioestadística, Facultat de Medicina, Universitat Autònoma de Barcelona (DM)

41  
42 Unit of Farmacobiology, Facultat de Medicina i Ciències de la Salut, Universitat Rovira  
43  
44 i Virgili, Reus, Spain (MG)

45  
46 Unit of Lipids and Arteriosclerosis Research, CIBERDEM, Hospital Universitari Sant  
47  
48 Joan, IISPV, Facultat de Medicina i Ciències de la Salut, Universitat Rovira i Virgili,  
49  
50 Reus, Spain (RS)  
51  
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59  
60

**For correspondence:**

Rosa Solà, MD, PhD

Unitat de Recerca en Lípids i Arteriosclerosi,

Facultat de Medicina i Ciències de la Salut,

C/ Sant Llorenç 21,

43201-Reus,

Spain

Tel: (34) 977 759 369 / 609 906 991 (mobile)

Fax: (34) 977 759 322

E-mail: [rosa.sola@urv.cat](mailto:rosa.sola@urv.cat)

or

Montse Giralt, MD, PhD

Unit of Farmacobiology,

Facultat de Medicina i Ciències de la Salut,

Universitat Rovira i Virgili,

43201-Reus,

Spain

E-mail: [montse.giralt@urv.cat](mailto:montse.giralt@urv.cat)

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

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## 1 ABSTRACT

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

5 **Design:** Reproduction of a randomised controlled trial

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

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

12 **Intervention:** The interventions focused on 8 lifestyle topics covered in 12 activities  
13 (1h/activity/session) implemented by health promoting agents (HPAs) in the primary-  
14 school over 3 school academic years.

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

19 **Results:** At 22 months, the percentage of boys in the intervention group who performed  
20  $\geq$ 4h after-school PA h/week was 15% higher (p=0.027), while there was 16.6% more  
21 boys in the intervention group watching  $\leq$ 2hTV/day (p=0.009), compared to controls.

22 The obesity prevalence was similar in intervention and control groups over the period of  
23 the program. Multivariate statistical analysis indicated that the performance of  $\geq$ 4 after-  
24 school PA h/week was a protective factor against childhood OB (OR: 0.600; p=0.032).

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



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3 26 school environments, and reproducible. The main improvement was after-school PA  
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5 27 ( $\geq 4$ h/week) in boys. Further, TV watching decreased to  $< 2$  TV h/day. This suggests that  
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7 28 our intervention programme induces healthy lifestyle effects (such as more exercise and  
8  
9 29 less sedentary behaviour) which can produce anti-obesity benefits in children.

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12 30 Words: 294/300

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14 31 Clinical Trials registration NCT01362023

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19 33 **ARTICLE SUMMARY**

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21 34 **Strengths and limitations of the study**

- 22  
23 35 - Strengths: Reproducibility of studies is rare because of the complexity of  
24  
25 36 replicating a programme. Studies in OB prevention, such as EdAI, need to be  
26  
27 37 reproducible, especially those improving healthy lifestyle, including after-school  
28  
29 38 PA, to reinforce beneficial practices in childhood  
30  
31 39 - Strengths: Statistical methods controlling for confounders and taking into  
32  
33 40 account clustering of data  
34  
35  
36 41 - Limitations: Failure to assess treatment adherence to evaluate reproducibility  
37  
38 42 and feasibility  
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40 43 - Limitations: Dietary habits were noted via a questionnaire that did not take into  
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42 44 account the quantities of the different types of food items consumed  
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## 45 BACKGROUND

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

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

54 The Organization for Economic Co-operation and Development (OECD), has predicted  
55 an increase of 7% in excess weight prevalence in adulthood over the period spanning  
56 2010 to 2020,[8]. The WHO proposes the prevention and control of OB prevalence as  
57 key in the updated “Action Plan 2008-2013” in which effective health promotion is  
58 considered the principal strategy,[9].

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

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3 70 television (TV), video games or on the Internet. These activities represent a decrease in  
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5 71 physical movement and lowering energy expenditure and, as such, are risk factors for  
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7 72 OB,[16].

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10 73 We had designed the EdAI (*Educació en Alimentació*) programme as a randomised,  
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12 74 controlled, parallel study applied in primary schools, and implemented by university  
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14 75 students acting as Health Promoter Agents (HPAs),[17]. This intervention was deployed  
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16 76 in Reus (as intervention group) with the neighbouring towns of Salou, Cambrils and  
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18 77 Vilaseca as control group. The interventions focused on 8 lifestyle topics covered in 12  
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20 78 activities (1h/activity/session) in 7-8 year old children, and implemented by HPAs over  
21  
22 79 3 school academic years. We found that the EdAI programme successfully reduced  
23  
24 80 childhood OB prevalence in boys by 4.39% and increased the percentage of boys who  
25  
26 81 practice  $\geq 5$  after-school physical activity (PA) h/week,[18]. The EdAI programme  
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28 82 needed to be reproduced in other localities, and with other children, to demonstrate the  
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30 83 effectiveness of this intervention[19].

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34 84 The outcomes of the EdAI programme supported the feasibility of improving PA in  
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36 85 childhood. However, an educational intervention, such as our EdAI program  
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38 86 implemented by HPAs, also tests complex components such as healthy lifestyles  
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40 87 including diet and physical activity recommendations. Due to the complexity, such  
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42 88 interventions are difficult to rationalise, standardise, reproduce, and administer  
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44 89 consistently to all participants,[19].

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47 90 There has been one study in the literature that has reproduced its programmes in other  
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49 91 locations. Described as the Kiel Obesity Prevention Study (KOPS), the results  
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51 92 demonstrated the efficacy and feasibility of implementing new nutritional concepts,[20].  
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53 93 We tested the reproducibility of the EdAI programme in a geographical area (Terres de  
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55 94 l'Ebre) about 80km away from where the original EdAI programme was designed and  
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3 95 implemented. We describe, here, the primary-school-based study to reduce the  
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5 96 prevalence of childhood OB (The EdAI-2 study); the objective remains an intervention  
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7 97 to induce healthy lifestyles, including diet and physical activity recommendations. The  
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9 98 study was conducted in 7-8 year old school-children over 3 academic years (22 months  
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11 99 active school time).  
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## 14 15 16 101 **METHODS**

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18 102 The original protocol, rationale, randomisation, techniques and results of the initial  
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20 103 EdAI programme have been published in *Trials*, [17-18]. The current study (EdAI-2)  
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22 104 was conducted in exactly the same way so as to assess whether comparable results  
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24 105 could be achieved in a different location. The EdAI-2 study was approved by the  
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26 106 Clinical Research Ethical Committee of the *Hospital Sant Joan of Reus, Universitat*  
27  
28 107 *Rovira i Virgili* (Catalan ethical committee registry ref 11-04-28/4proj8). This study  
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30 108 was registered in Clinical Trials *NCT01362023*. The protocol conformed to the Helsinki  
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32 109 Declaration and Good Clinical Practice guides of the International Conference of  
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34 110 Harmonization (ICHGCP). The study followed the CONSORT criteria [see Additional  
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36 111 file 1].  
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40 112 For logistics reasons, the EdAI-2 program was reduced by 6 months, from 28 months to  
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42 113 22 months.  
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### 45 46 47 115 **Study population**

48  
49 116 The coordinating Center (in Reus) developed a cluster randomisation scheme to have a  
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51 117 study sample in which the schools in Amposta were designated as Group A  
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53 118 (intervention) and 9 towns around Amposta (Sant Jaume d'Enveja, Els Muntells,  
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3 119 l'Ametlla de Mar, El Perelló, l'Ampolla, Deltebre, l'Aldea, Lligalló del Gànguïl and  
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5 120 Camarles) as Group B (control).  
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7 121 The socio-demographic indicators in all towns were similar to that of the original EdAl  
8  
9 122 Program in Reus. Children attending the schools in both groups (intervention and  
10  
11 123 control) lived in close proximity within each school's catchment area. Intervention  
12  
13 124 institutions were 5 schools involving 18 classrooms and 457 pupils in Amposta. Control  
14  
15 125 institutions consisted of 11 schools involving 23 classrooms and 531 pupils in the 9  
16  
17 126 towns of around Amposta. Children of this study are in the 2<sup>nd</sup> and 3<sup>rd</sup> grade of primary  
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19 127 education (7-8 year olds). Schoolchildren were enrolled in May 2011 (children born in  
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21 128 2002–2003) and followed-up for 3 school academic years (2012–2013). The study was  
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23 129 completed in March 2013.

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27 130 To be representative of the child population, the schools selected needed to have at least  
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29 131 50% of the children in the classrooms volunteer to participate. We offered the  
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31 132 programme to all schools, whether public (funded by the government and termed  
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33 133 “charter” schools) or private which included fee-paying and/or faith schools. Inclusion  
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35 134 criteria were: name, gender, date and place of birth, and written informed consent from  
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37 135 the parent or guardian. A questionnaire on eating habits (Krece Plus) developed by  
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39 136 Serra Majem et al,[21], and physical activity, level of parental education and lifestyles  
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41 137 developed by Llargues et al,[22] were filled-in by the parents at baseline and at the end  
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43 138 of the study.

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#### 48 49 140 **Intervention program**

50  
51 141 The original EdAl Reus protocol was followed,[17-18]. The educational intervention  
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53 142 activities focused on eight lifestyle topics based on scientific evidence,[23] to improve  
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55 143 nutritional food item choices (and avoidance of some foods), healthy habits such as  
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3 144 teeth-brushing and hand-washing and, overall, adoption of activities that encourage  
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5 145 physical activity (walking to school, playground games), and to avoid sedentary  
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7 146 behaviour,[23].  
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10 147 Each of the eight topics was integrated within educational intervention activities of  
11  
12 148 1h/activity, prepared and standardized by the HPAs, and implemented in the children's  
13  
14 149 classrooms. In the first school academic year, we focused on four topics: 1) to improve  
15  
16 150 healthy lifestyle; 2) to encourage healthy drinks intake (and avoidance of unhealthy  
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18 151 carbonated/sweetened beverages); 3) to increase the consumption of vegetables and  
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20 152 legumes; and 4) to decrease the consumption of candies and pastries while increasing  
21  
22 153 the intake of fresh fruits and nuts. These corresponded to four standardised activities  
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24 154 (1h/activity). In the second year, the remaining four of the eight selected lifestyle topics  
25  
26 155 were addressed: 5) to improve healthy habits within a set timetable (home meals, teeth-  
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28 156 brushing, hand-washing) and physical activity participation; 6) to increase fruit intake;  
29  
30 157 7) to improve dairy product consumption; and 8) to increase fish consumption. These  
31  
32 158 corresponded to four standardised activities. Finally, in the third school academic year,  
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34 159 four standardised activities were introduced that reinforced the eight lifestyle topics  
35  
36 160 implemented in the previous 2 academic years. Thus, the intervention program was  
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38 161 based on eight lifestyle **topics incorporated** within 12 activities which were  
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40 162 disseminated over 12 sessions (1h/activity/session), and prepared, standardised and  
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42 163 implemented as four activities per school academic year by the HPAs in the school  
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44 164 classrooms.  
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## 51 166 **Process evaluation**

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53 167 The measurements were performed in each school academic year, as was the original  
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55 168 EdAI program,[17-18].  
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**Outcomes**

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

188

**Sample size**

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

193

## 194 **Statistical analyses**

195 Descriptive variables were presented as means and confidence intervals (95%CI).

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

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

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

213

## 214 **RESULTS**

### 215 **Enrolment**

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



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3 219 age was 9.67 (95%CI: 9.60, 9.73) in the intervention group (9.68 years in boys and 9.65  
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5 220 years in girls) and 9.86 (95%CI: 9.79, 9.91) in the control group (9.85 years in boys and  
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7 221 9.84 years in girls). The differences in age were not significant in relation to gender.  
8  
9 222 The characteristics of the study group are summarised in Table 1. At baseline, the  
10  
11 223 intervention and control group were homogeneous in BMI status. The ethnicity of the  
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13 224 population was predominantly Western European in intervention and control group  
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15 225 (77.5% vs. 78.9%, respectively) while 7.5% vs. 10.8% was Eastern European; 10.3% vs.  
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17 226 3.5% was Latin American; 3.4% vs. 6.2% was North African Arab. At baseline, there  
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19 227 was a significant difference in the distribution with respect to Latin American children  
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21 228 (10.3% in intervention and 3.5% in control group;  $p < 0.001$ ). The distribution was  
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23 229 random. Of note is that there were no significant differences in distributions of OB  
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25 230 and/or OW. Also, no differences were observed in terms of response to the intervention  
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29 231 in relation to ethnicity.  
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232 **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
	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;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 <sup>2</sup>	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

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233 Notes to Table 1:

234 The results are expressed as Mean (95%CI)

235 <sup>1</sup>p value: general linear model (GLM) statistic

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236 **Attrition rate**

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

243 **Primary outcome: Prevalence of OB**

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

Criteria/Category	Group		Baseline % (n)	End of study % (n)	Change %	Baseline to	Intervention		
						P-value <sup>1</sup>	vs. Control P-value <sup>2</sup>		
<b>IOTF</b>									
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		
	Control	Boys	25.5 (50)	27.0 (53)	1.5	0.690	0.169		
		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	0.607		
		Girls	12.1 (21)	10.9 (19)	-1.2	0.687			
		Total	11.4 (42)	10.5 (39)	-0.93	0.607			

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3 247 **Table 2.** Baseline and end-of-intervention measurements of categorised BMI in  
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5 248 Intervention and Control group

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9 250 Notes to Table 2

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11 251 IOTF: International Obesity Task Force

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13 252 The results are expressed as % (n)

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15 253 <sup>1</sup>p value: McNemar's Test

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17 254 <sup>2</sup>p value: Fisher's Exact Test

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23 256 **Secondary outcomes**

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25 257 At 22 months of the study, the status of OW prevalence (according to IOTF criteria)

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27 258 was similar between groups (p=0.086).

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29 259 There were no significant differences in BMI z-score between intervention and control

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31 260 group (p=0.400) (Table 3). Despite no differences in BMI z-score, the boys of

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33 261 intervention group did not have an increase in percentage fat mass (19.96% to 20.02%;

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35 262 p=0.896), whereas intervention girls (22.06% to 23.55%; p<0.001), together with boys

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37 263 (19.18% to 20.64%, p<0.001) and girls (23.26% to 24.98%) of control group had a

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39 264 significant increase.

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41 265 The remission, and incidence, of OB was similar in the overall intervention and control

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43 266 group, as well as when stratified with respect to gender.

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

						Baseline		272	
						to Study	Interven	273	
						end	vs. Control	274	
						P-value <sup>1</sup>	P-value <sup>2</sup>	275	
BMI z-score		Baseline	End of study	Change					
		Mean (95%CI)	Mean (95%CI)	Mean (95%CI)					
Intervention	Boys	0.73 (0.53; 0.94)	0.74 (0.54; 0.93)	0.00 (-0.07; 0.08)	0.973	0.381		276	
	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		277	
	Control	Boys	0.83 (0.64; 1.01)	0.81 (0.63; 1.00)	-0.12 (-0.08; 0.06)	0.726			278
		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			279

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282 Notes to Table 3:

283 <sup>1</sup>p-value: Mixed Models Repeated Measures

284 <sup>2</sup>p-value: ANOVA model

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

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**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).

296

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			Interven
		Baseline	End of	P	Baseline	End of	tion vs.	
		%(n)	study	Value	%(n)	study	Control	
		%(n)	%(n)	Value	%(n)	%(n)	P-value	
<b>Krece plus questionnaire</b>								
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)	<b>0.016</b>	0.453
	Total	98.4 (248)	98.8 (239)	1	98.1 (302)	92.9 (288)	<b>0.003</b>	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)	<b>0.039</b>	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)	<b>0.036</b>	59.7 (86)	60.0 (87)	0.880	<b>0.031</b>
	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)	<b>0.027</b>	22.5 (33)	12.3 (20)	<b>0.001</b>	<b>0.002</b>
	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)	<b>&lt;0.001</b>	<b>0.002</b>
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, 2 <sup>nd</sup> per day	Boys	39.7 (50)	41.2 (49)	0.581	44.5 (69)	34.1 (56)	<b>0.006</b>	0.141
	Girls	26.4 (32)	47.5 (56)	<b>0.000</b>	44.8 (64)	39.0 (57)	0.281	<b>&lt;0.001</b>
	Total	33.2 (82)	44.3 (105)	<b>0.001</b>	44.6 (133)	36.5 (113)	<b>0.004</b>	<b>&lt;0.001</b>
Dairy product, 2 <sup>nd</sup> per day	Boys	87.2 (109)	78.5 (95)	<b>0.029</b>	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)	<b>0.043</b>	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	<b>0.017</b>
	Total	68.5 (170)	75.9 (183)	<b>0.011</b>	69.9 (214)	67.3 (212)	0.374	<b>0.028</b>
Vegetables, >1 per day	Boys	19.3 (23)	29.1 (34)	<b>0.017</b>	28.7 (43)	20.7 (34)	<b>0.009</b>	<b>0.001</b>
	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)	<b>0.001</b>	29.5 (86)	21.8 (67)	<b>0.002</b>	<b>0.001</b>
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	<b>0.013</b>
	Total	4.8 (12)	8.8 (21)	0.21	5.7 (17)	3.9 (12)	<b>0.049</b>	<b>0.003</b>
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)	<b>0.001</b>	<b>0.013</b>
	Total	71.5 (181)	72.2 (174)	1	65.2 (251)	70.7 (222)	<b>0.025</b>	<b>0.027</b>
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
<hr/>								
<b>Avall questionnaire</b>								
<i>Before leaving home</i>								
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)	<b>0.004</b>	0.235
	Total	90.9 (227)	87.6 (218)	0.071	86.2 (255)	81.1 (249)	<b>0.044</b>	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)	<b>0.016</b>	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)	<b>0.049</b>	14.9 (21)	18.4 (26)	0.572	1
Sandwich	Total	8.4 (20)	18.7 (46)	<b>0.008</b>	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
<i>Break (Midmorning)</i>								
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)	<b>0.016</b>	0.860
	Total	26.6 (66)	35.7 (87)	<b>0.008</b>	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

299 Notes to Table 4:

300 <sup>1</sup>p-value: McNemar's Test (changes in intervention group)

301 <sup>2</sup>p-value: McNemar's Test (changes in control group)

302 <sup>3</sup>p-value: Fisher's Exact Test.

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3 305 Table 5 summarises the time spent in after-school PA, watching TV, playing video  
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5 306 games, and other leisure-time activities. At 22 months, the percentage of boys of the  
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7 307 intervention group who performed  $\geq 4$ h after-school PA/week was increased by 15%  
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9 308 ( $p=0.027$ ) while there was 16.6% more boys in the intervention group watching  
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11 309  $\leq 2$ hTV/day ( $p<0.009$ ). The results indicate less sedentary behaviour in intervention than  
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14 310 control individuals.  
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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 <sup>1</sup>	Baseline %(n)	End of study %(n)	P-value <sup>2</sup>	P-value <sup>3</sup>
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)	<b>0.049</b>	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

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>4h/week	Boys	44.6 (58)	61.3 (76)	<b>0.006</b>	40.5 (64)	47.9 (78)	0.243	0.643	312
	Girls	27.9 (34)	34.4 (42)	0.136	33.1 (48)	32.4 (46)	0.868	0.598	313
	Total	36.5 (92)	48.0 (118)	<b>0.002</b>	37.0 (112)	40.7 (124)	0.272	0.485	

314

315 Notes to Table 5

316 <sup>1</sup>P-value: McNemar's Test (changes in intervention group)

317 <sup>2</sup>P-value: McNemar's Test (changes in control group)

318 <sup>3</sup>P-value: Fisher's Exact Test.

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3 319 Differences between intervention and control pre-post intervention program  
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5 320 At 22 months, subjects who were normal weight at baseline increased after-school PA  
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7 321 to  $\geq 4$ h/week. This reflects a rise to 32.7% in boys ( $p=0.002$ ). However, in girls, the  
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9 322 changes were not statistically different ( $p=0.134$ ). No statistically significant differences  
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11 323 were observed in the control group.  
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### 325 **Impact of certain additional factors on obesity**

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18 326 The ORs of OB, using BMI z-score criteria, were related to some of the more relevant  
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20 327 dietary habits and lifestyles. Thus, breakfast dairy product consumption (OR: 0.336;  
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22 328  $p=0.004$ ) and  $\geq 4$  after-school PA h/week (OR: 0.600;  $p=0.032$ ) were protective factors  
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24 329 against OB. Conversely, doing  $< 4$  h/week PA (OR: 1.811;  $p=0.018$ ) increased the risk  
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26 330 of childhood OB.  
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### 332 **DISCUSSION**

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34 333 The EdAl-2 program, a reproducibility study in Terres de l'Ebre, shows that  
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36 334 intervention is useful for improving weekly after-school PA. However, the OB  
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38 335 prevalence remained unchanged at 22 months, as has been shown in the data on stability  
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40 336 of OB prevalence observed in some European countries,[8]. Despite that OW and OB  
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42 337 remained similar between groups, we observed percentage fat mass maintenance in the  
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44 338 boys of the intervention group, whereas girls of the intervention and control group had  
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46 339 increases.  
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49 340 As proposed by Kain J et al, designing a new school-based intervention study needs to  
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51 341 have some critical aspects considered. These include: the random allocation of schools,  
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53 342 although methodologically desirable, is not always possible; participation of parents is  
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55 343 very limited; obesity is not recognised as a problem; and increasing physical activity  
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3 344 and implementing training programmes for teachers is difficult due to an inflexible  
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5 345 curriculum and lack of teachers' time. Unless these barriers are overcome, obesity  
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7 346 prevention programmes will not produce positive and lasting outcomes,[27]. As such,  
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9 347 our programme of HPA-implemented intervention activities in classrooms is an  
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11 348 attractive alternative that circumvents lack-of-teacher-time.

14 349 The EdAl-2 program confirmed that after-school PA (in terms of h/week) can be  
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16 350 stimulated in primary school as part of a healthy lifestyle. As we had observed in the  
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18 351 original EdAL program,[18] at 28 months of intervention, there was an increase of up to  
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20 352 19.7% of children dedicating >5 hours/week to extra-curricular physical activities,[18].  
21  
22 353 Further, the after-school PA was maintained despite cessation of the intervention  
23  
24 354 program,[28]. The effect of EdAl program during its implementation and after the  
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26 355 official cessation indicated an impact on PA, whereas modification towards healthy  
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28 356 food choices occurred according to the site of the program's implementation, and was  
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30 357 not consistent.

34 358 Interventions to prevent OB in the school setting have shown dramatic  
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36 359 improvements,[29]. However, successful studies in OB prevention need to be  
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38 360 reproducible, especially those improving healthy lifestyle such as after-school PA, to  
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40 361 confirm best childhood practices.

42 362 Reproducibility of studies is rare because of the complexity of trying to replicate a  
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44 363 programme. To standardise a method it is essential to be able to reproduce appropriate  
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46 364 levels of an intervention, especially one that involves behavioural changes. Feasibility  
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48 365 of our intervention was confirmed in two different towns and over two different time-  
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50 366 courses (the first in Reus over 28 months, and the second in Amposta over 22 months).

54 367 Also, it is important to assess treatment adherence in order to evaluate reproducibility  
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56 368 and feasibility,[19]. For example, the KOPS study,[20] demonstrated that nutritional

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3 369 knowledge was increased as a result of the intervention in the two cohort studies (KOPS  
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5 370 1 and KOPS 2),[20]. However, the study was unable to show whether there were  
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7 371 differences in overweight outcomes, weight categories or lifestyles between the two  
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9 372 cohorts. Some multi-centred studies have attempted to reproduce methodological  
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11 373 aspects in interventions conducted in different countries or different populations.  
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13 374 However, while multi-centred studies are usually implemented concurrently,  
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15 375 reproducibility involves the applicability of the intervention at different sites and/or  
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17 376 different times in order to validate the initial findings. One example of this is the Pro  
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19 377 Children Study,[30] which, as a multi-centred study, had been applied in different  
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21 378 countries simultaneously and had demonstrated its efficacy and feasibility.  
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23 379 The ALADINO study presented the obesity status prevalence in Spain which, according  
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25 380 to the IOTF, is about 11.4% in children of around 9 years of age,[31]. In the EdA1-2  
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27 381 study, the OB prevalence was similar, but lower in the intervention group than the  
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29 382 equivalent in the ALADINO study and, as well, in the EDAL-2 control group.  
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31 383 The EdA1-2 study showed a significant improvement of 16.7% in the young boys in the  
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33 384 intervention group who participated in  $\geq 4$  h/week after-school PA. Further, the  
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35 385 increased numbers of children in the intervention group who performed  $\geq 4$  h/week  
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37 386 after-school PA who were normal-weight at baseline, suggested that the intervention  
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39 387 was effective not only in the primary-school healthy population but also effective in  
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41 388 preventing OB over the longer-term due to the PA being maintained.  
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43 389 In the dietary habits aspect of EdA1-2 study, we observed that the increase in healthy  
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45 390 lifestyle habits such as the increase in fruit and vegetables consumption and increasing  
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47 391 PA h/week while maintaining low TV h/d, are promising lifestyle changes that could  
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49 392 induce a reduction of OW and OB over the long-term.  
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3 393 In the EdA1-2 study we observed that consumption of dairy products at breakfast was a  
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5 394 protective factor against obesity.  
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7 395 Several studies have shown that participating in PA was a protective factor against OB  
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9 396 and that spending >2h watching TV was a risk factor for childhood OB. A recent  
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11 397 Spanish study showed that leisure-time PA was a protective factor against OB (as with  
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13 398 our present study) and that performing >4 h/week is a protective factor while watching  
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15 399 TV for this amount of time was, according to Ochoa et al,[32], associated with OB.  
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17 400 **There are several limitations to our study. Firstly,** we evaluated dietary habits via a  
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19 401 questionnaire that did not take into account the quantities of the different types of food  
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21 402 items consumed. These data would be important in addressing the quantity *versus*  
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23 403 quality debate in OB or OW prevalence. **Secondly, assigning control groups according**  
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25 404 **to towns surrounding the intervention town could be a limitation. However, schools of**  
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27 405 **the same town have good relationships and communications with each other and this**  
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29 406 **could entail a possible contamination between schools if assigned to intervention or**  
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31 407 **control status within the same town. This cross-contamination would be minimised if**  
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33 408 **the schools themselves were assigned to intervention or control. Thirdly, the significant**  
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35 409 **difference in Latin American ethnicity between the two groups of the study at baseline**  
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37 410 **could be a limitation. However, there were no significant differences in distributions of**  
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39 411 **OB and/or OW. Also, no differences were observed in terms of response to the**  
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41 412 **intervention study in relation to ethnicity. Fourthly, when asked about fast-food**  
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43 413 **consumption, the participants interpreted this as pertaining only to fast-food outlets such**  
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45 414 **a burger shops, and did consider other concepts such as frozen pizza consumed at home.**  
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47 415 **Finally, another limitation could be the proportion of females who may have started**  
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49 416 **puberty in the course of the study. This implies changes in body composition. However,**  
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3 417 both study groups (intervention and control) had a similar proportion of females with a  
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5 418 similar age, and this could cancel-out the effect.  
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7 419 Further, EdA1-2 demonstrated that performing >4h/week after-school PA, plus having  
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9 420 dairy product at breakfast are protective factors. Hence, we believe that a participating  
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11 421 in >4h/week after-school PA, and continuing with a healthy breakfast, are key points in  
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13 422 preventing childhood OB.  
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## 18 424 CONCLUSION

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20 425 Our school-based intervention is feasible, adaptable to quite different school  
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22 426 environments, and reproducible. The main improvement was after-school PA  
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24 427 ( $\geq 4$ h/week) in boys. Further, TV watching decreased to <2 TV h/day. This suggests that  
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26 428 our intervention programme induces healthy lifestyle effects (such as more exercise and  
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28 429 less sedentary behaviour) which can produce anti-obesity benefits in children.  
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## 55 441 COMPETING INTERESTS

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3 442 The authors declare that they have no competing interests.  
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7 444 **LIST OF ABBREVIATIONS**  
8

9 445 OB: Obesity

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11 446 OW: Overweight

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13 447 PA: Physical Activity

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15 448 mITT: modified Intention to Treat

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17 449 HPAs: Health Promoter Agents

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19 450 WHO: World Health Organization

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21 451 BMI: Body Mass Index

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23 452 OR: Odds Ratio

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27 454 **Authors' contributions**  
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29  
30 455 MG, EL, LT, RS designed the study (project conception, development of overall

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32 456 research plan, and study oversight)

33  
34 457 MG, EL, LT, RQ, RS conducted research (hands-on conduct of the experiments and

35  
36 458 data collection)

37  
38 459 EL, LT, MG, RS provided essential materials (applies to authors who contributed by

39  
40 460 providing constructs, database, etc. necessary for the research)

41  
42 461 DM, EL, LT analysed data or performed statistical analysis

43  
44 462 RS, MG, LT, DM, EL drafted and revised the manuscript (authors who made a major

45  
46 463 contribution). The final manuscript was read and approved by all co-authors

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48 464 RS, MG take primary responsibility for the study, and manuscript content  
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For peer review only



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568 **FIGURE LEGEND**

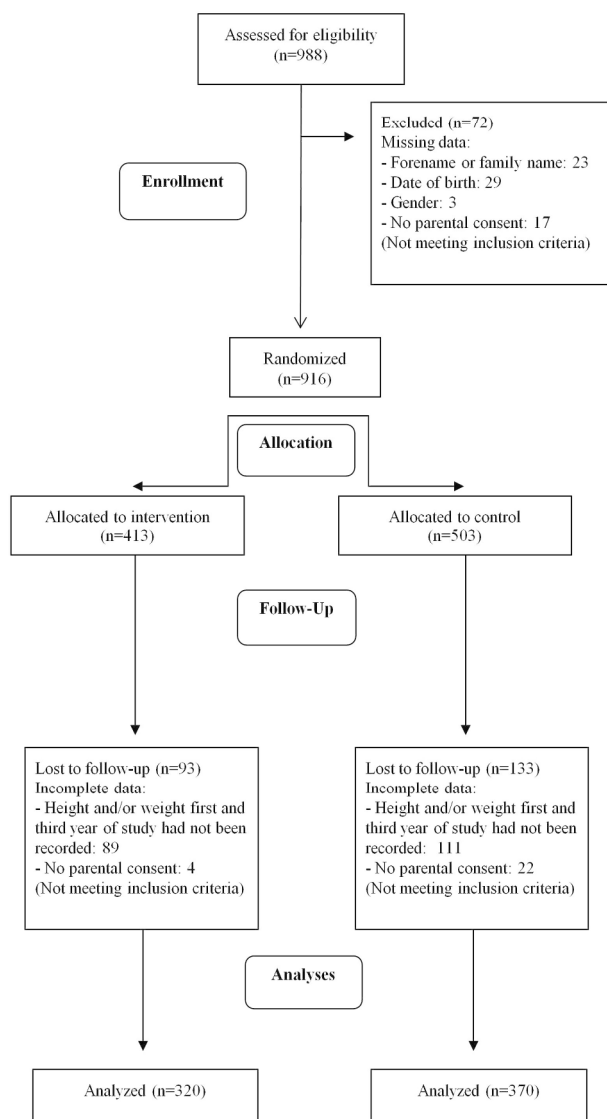
569 **Figure 1:** Flow of subjects through the study

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

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

For peer review only

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# 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**

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2014-005496.R2
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<b>Primary Subject Heading</b>:	Public health
Secondary Subject Heading:	Public health
Keywords:	PUBLIC HEALTH, PRIMARY CARE, PREVENTIVE MEDICINE, PAEDIATRICS

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Manuscripts

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3 **EdAl-2 (*Educació en Alimentació*) programme: reproducibility of a cluster**  
4 **randomised, interventional, primary-school-based study to induce healthier**  
5 **lifestyle activities in children**  
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10  
11 Elisabet Llauradó ([elisabet.laurado@urv.cat](mailto:elisabet.laurado@urv.cat))

12  
13 Lucia Tarro ([lucia.tarro@urv.cat](mailto:lucia.tarro@urv.cat))

14  
15 David Morina ([david.morina@uab.cat](mailto:david.morina@uab.cat))

16  
17 Rosa Queral ([rosa.querall@urv.cat](mailto:rosa.querall@urv.cat))

18  
19 Montse Giralt ([montse.giralt@urv.cat](mailto:montse.giralt@urv.cat))

20  
21 Rosa Solà ([rosa.sola@urv.cat](mailto:rosa.sola@urv.cat))  
22  
23  
24  
25  
26

27 E.LL. and L.T. contributed equally to the study.  
28  
29  
30  
31

32 **From the:**

33  
34 Health Education and Promotion, Facultat de Medicina i Ciències de la Salut,

35  
36 Universitat Rovira i Virgili, Reus, Spain (ELL, LT)

37  
38 Technological Centre of Nutrition and Health (CTNS) - TECNIO - URV – CEICS;

39  
40 Centre for Research in Environmental Epidemiology (CREAL) - Unitat de

41  
42 Bioestadística, Facultat de Medicina, Universitat Autònoma de Barcelona (DM)

43  
44 Unit of Farmacobiology, Facultat de Medicina i Ciències de la Salut, Universitat Rovira  
45  
46 i Virgili, Reus, Spain (MG)  
47  
48

49  
50 Unit of Lipids and Arteriosclerosis Research, CIBERDEM, Hospital Universitari Sant

51  
52 Joan, IISPV, Facultat de Medicina i Ciències de la Salut, Universitat Rovira i Virgili,

53  
54 Reus, Spain (RS)  
55  
56  
57  
58  
59  
60

**For correspondence:**

Rosa Solà, MD, PhD

Unitat de Recerca en Lípids i Arteriosclerosi,

Facultat de Medicina i Ciències de la Salut,

C/ Sant Llorenç 21,

43201-Reus,

Spain

Tel: (34) 977 759 369 / 609 906 991 (mobile)

Fax: (34) 977 759 322

E-mail: [rosa.sola@urv.cat](mailto:rosa.sola@urv.cat)

or

Montse Giralt, MD, PhD

Unit of Farmacobiology,

Facultat de Medicina i Ciències de la Salut,

Universitat Rovira i Virgili,

43201-Reus,

Spain

E-mail: [montse.giralt@urv.cat](mailto:montse.giralt@urv.cat)

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3 1 **ABSTRACT**

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5 2 **Objectives:** To assess the reproducibility of an educational intervention EdAI-2  
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7 3 programme in “Terres de l’Ebre” (Spain), over 22 months, to improve lifestyles,  
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9 4 including diet and physical activity (PA)

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11 5 **Design:** Reproduction of a cluster randomised controlled trial

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13 6 **Setting:** Two semi-rural town-group primary-school clusters were randomly assigned to  
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15 7 intervention or control group

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17 8 **Participants:** Pupils (n=690) of which 320 constituted intervention group (1 cluster)  
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19 9 and 370 constituted control group (1 cluster). Ethnicity was 78% Western European.

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21 10 Mean age ( $\pm$ SD) was 8.04 $\pm$ 0.6 years (47.7% females) at baseline. Inclusion criteria for  
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23 11 clusters were towns from the southern part of Catalonia having a minimum of 500  
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25 12 children aged 7 to 8 year; and complete data for participants, including name, gender,  
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27 13 date and place of birth, and written informed consent from parents or guardians.

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29 14 **Intervention:** The intervention focused on 8 lifestyle topics covered in 12 activities  
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31 15 (1h/activity/session) implemented by health promoting agents in the primary-school  
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33 16 over 3 academic years.

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35 17 **Primary and secondary outcomes:** the primary outcome was obesity (OB) prevalence  
36  
37 18 and the secondary outcomes were body mass index (BMI) collected every year, and  
38  
39 19 dietary habits and lifestyles collected by questionnaires filled-in by parents at baseline  
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41 20 and end-of-study.

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43 21 **Results:** At 22 months, the obesity prevalence and BMI values were similar in  
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45 22 intervention and control groups. Relative to children in control schools, the percentage  
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47 23 of boys in the intervention group who performed  $\geq$ 4 after-school PA h/week was 15%  
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49 24 higher ( $p=0.027$ ), whereas the percentage of girls of both groups remained similar.  
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3 25 Also, 16.6% more boys in the intervention group watched  $\leq 2$  TV h/day ( $p=0.009$ ),  
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5 26 compared to controls; and no changes were observed in girls of both groups.  
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7 **Conclusions:** Our school-based intervention is feasible and reproducible by increasing  
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9 28 after-school PA (to  $\geq 4$ h/week) in boys induced healthy lifestyle effects while, the  
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11 29 prevalence of OB was not significantly changed.  
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16 31 Words: 295  
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18 32 Clinical Trials registration NCT01362023  
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## 22 23 34 **ARTICLE SUMMARY**

### 24 25 35 **Strengths and limitations of the study**

- 26  
27 36 - Strengths: Reproducibility of studies is rare because of the complexity of  
28  
29 37 replicating an intervention programme. Studies in OB prevention, such as EdAI,  
30  
31 38 need to be reproducible, especially those improving healthy lifestyle, including  
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33 39 after-school PA, to reinforce beneficial practices in childhood  
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35 40 - Strengths: Statistical methods controlling for confounders and taking into  
36  
37 41 account clustering of data  
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39 42 - Limitations: Failure to assess treatment adherence to evaluate reproducibility  
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41 43 and feasibility  
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43 44 - Limitations: Dietary habits were noted via a questionnaire that did not take into  
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45 45 account the quantities of the different types of food items consumed  
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3 46 **BACKGROUND**

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5 47 Obesity (OB) has become a disease of epidemic proportions,[1]. However, this  
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7 48 increasing tendency towards excess weight in childhood and adulthood,[2] observed in  
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9 49 some countries (United Kingdom, France, South Korea, United States and Spain) has  
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11 50 stabilised despite the absolute rates being a cause for concern,[1]. OB prevalence in  
12  
13 51 children and adolescents is higher in southern regions of Europe,[3-4].

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16 52 Accumulation of fat tissue constitutes an increased disease risk in childhood, as well as  
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18 53 in adulthood,[5]. This disease risk has a multifactorial aetiology, such as an unhealthy  
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20 54 diet and sedentary lifestyle,[6-7].

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23 55 The Organization for Economic Co-operation and Development (OECD), has predicted  
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25 56 an increase of 7% in excess weight prevalence in adulthood over the period spanning  
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27 57 2010 to 2020,[8]. The WHO proposes the prevention and control of OB prevalence as  
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29 58 key in the updated “Action Plan 2008-2013” in which effective health promotion is  
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31 59 considered the principal strategy,[9].

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34 60 Since excess weight status in adulthood is almost invariably predicated on childhood  
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36 61 and adolescent weight, OB prevention should start early in life,[10]. The optimum age  
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38 62 to commence an intervention is between the ages of 7 and 8 years because children are  
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40 63 more receptive to guidance,[11]. The school is an ideal place for the promotion of  
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42 64 healthy nutrition and lifestyle habits,[12] and, as some studies have shown, such  
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44 65 interventions have inspired changes in nutritional habits and BMI status,[13-14]; the  
45  
46 66 message being received by all schoolchildren, irrespective of ethnic and socioeconomic  
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48 67 differences,[9]. The effectiveness of an intervention is when educational strategies and  
49  
50 68 environmental factors such as healthy nutrition and physical activity habits coincide  
51  
52 69 since both aspects are essential in preventing childhood OB,[15]. Currently, European  
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54 70 children spend more of their leisure time in sedentary activities such as watching  
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3 71 television (TV), video games or on the Internet. These activities represent a decrease in  
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5 72 physical movement and lowering energy expenditure and, as such, are risk factors for  
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7 73 OB,[16].

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9 74 We had designed the EdAI (*Educació en Alimentació*) programme as a randomised,  
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11 75 controlled, parallel study applied in primary schools, and implemented by university  
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13 76 students acting as Health Promoter Agents (HPAs),[17]. This intervention was deployed  
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15 77 in Reus (as intervention group) with the neighbouring towns of Salou, Cambrils and  
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17 78 Vilaseca as control group. The interventions focused on 8 lifestyle topics covered in 12  
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19 79 activities (1h/activity/session) in 7-8 year old children, and implemented by HPAs over  
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21 80 3 school academic years. We found that the EdAI programme successfully reduced  
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23 81 childhood OB prevalence in boys by 4.39% and increased the percentage of boys who  
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25 82 practice  $\geq 5$  after-school physical activity (PA) h/week,[18]. The EdAI programme  
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27 83 needed to be reproduced in other localities, and with other children, to demonstrate the  
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29 84 effectiveness of this intervention[19].

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34 85 The outcomes of the EdAI programme supported the feasibility of improving PA in  
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36 86 childhood. However, an educational intervention, such as our EdAI program  
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38 87 implemented by HPAs, also tests complex components such as healthy lifestyles  
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40 88 including diet and physical activity recommendations. Due to the complexity, such  
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42 89 interventions are difficult to rationalise, standardise, reproduce, and administer  
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44 90 consistently to all participants,[19].

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47 91 There has been one study in the literature that has reproduced its programmes in other  
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49 92 locations. Described as the Kiel Obesity Prevention Study (KOPS), the results  
50  
51 93 demonstrated the efficacy and feasibility of implementing new nutritional concepts,[20].  
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53 94 We tested the reproducibility of the EdAI programme in a geographical area (Terres de  
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55 95 l'Ebre) about 80km away from where the original EdAI programme was designed and  
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3 96 implemented. We designed a cluster (town group) randomised controlled trial; the  
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5 97 rationale being that since good communications exist between the schools of the same  
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7 98 town, this could contribute to schools of the intervention group “contaminating” those  
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9 99 of the putative control group.

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11 We describe, here, the primary-school-based study to reduce the prevalence of  
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13 101 childhood OB (The EdAI-2 study); the objective remains an intervention to induce  
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15 102 healthy lifestyles, including diet and physical activity recommendations. The study was  
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17 103 conducted in 7-8 year old school-children over 3 academic years (22 months active  
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19 104 school time).

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## 24 25 106 **METHODS**

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27 107 The original protocol, rationale, randomisation, techniques and results of the initial  
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29 108 EdAI programme have been published in *Trials*, [17-18]. The current study (EdAI-2)  
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31 109 was conducted in exactly the same way so as to assess whether comparable results  
32  
33 110 could be achieved in a different location. The exact intervention is described in more  
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35 111 detail in Supplemental File 1, and in this manuscript link. The EdAI-2 study was  
36  
37 112 approved by the Clinical Research Ethical Committee of the *Hospital Sant Joan of*  
38  
39 113 *Reus, Universitat Rovira i Virgili* (Catalan ethical committee registry ref 11-04-  
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41 114 28/4proj8). This study was registered in Clinical Trials *NCT01362023*. The protocol  
42  
43 115 conformed to the Helsinki Declaration and Good Clinical Practice guides of the  
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45 116 International Conference of Harmonization (ICHGCP). The study followed the  
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47 117 CONSORT criteria [see Additional File 2].

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51 118 For logistics reasons, the EdAI-2 program was reduced by 6 months, from 28 months to  
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53 119 22 months.

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3 121 **Study population**  
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5 122 To ensure approximately a minimum 500 inhabitants of 7-8 years of age per cluster,  
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7 123 before randomising the towns (clusters), a statistician who was not familiar with the  
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9 124 study objectives and of the school identities, matched the towns on population size. The  
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11 125 coordinating Center (in Reus) developed a cluster randomisation scheme to have a study  
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13 126 sample in which the schools in Amposta were designated as Cluster A (intervention)  
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15 127 and 9 towns around Amposta (Sant Jaume d'Enveja, Els Muntells, l'Ametlla de Mar, El  
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17 128 Perelló, l'Ampolla, Deltebre, l'Aldea, Lligalló del Gànguill and Camarles) as Cluster B  
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19 129 (control). The eligibility criteria of clusters were to be semi-rural towns from the  
20  
21 130 southern part of Catalonia with a minimum of 500 children of 7 to 8 years of age in  
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23 131 each cluster.  
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27 132 The socio-demographic indicators in all towns were similar to that of the original EdAl  
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29 133 Program in Reus. Children attending the schools in both groups (intervention and  
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31 134 control) lived in close proximity within each school's catchment area. Intervention  
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33 135 institutions were 5 schools involving 18 classrooms and 457 pupils in Amposta. Control  
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35 136 institutions consisted of 11 schools involving 23 classrooms and 531 pupils in the 9  
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37 137 towns of around Amposta. Children of this study are in the 2<sup>nd</sup> and 3<sup>rd</sup> grade of primary  
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39 138 education (7-8 year olds). Schoolchildren were enrolled in May 2011 (children born in  
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41 139 2002–2003) and followed-up for 3 school academic years (2012–2013). The study was  
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43 140 completed in March 2013.  
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47 141 To be representative of the child population, the schools selected needed to have at least  
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49 142 50% of the children in the classrooms volunteer to participate. We offered the  
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51 143 programme to all schools, whether public (funded by the government and termed  
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53 144 “charter” schools) or private which included fee-paying and/or faith schools. Inclusion  
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55 145 criteria were: name, gender, date and place of birth, and written informed consent from  
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3 146 the parent or guardian of each participant. A questionnaire on eating habits (Krece Plus)  
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5 147 developed by Serra Majem et al,[21], and physical activity, level of parental education  
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7 148 and lifestyles developed by Llargues et al,[22] were filled-in by the parents at baseline  
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10 149 and at the end of the study.

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### 14 151 **Intervention program**

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16 152 The original EdAl Reus protocol was followed,[17-18]. The educational intervention  
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18 153 activities focused on eight lifestyle topics based on scientific evidence,[23] to improve  
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20 154 nutritional food item choices (and avoidance of some foods), healthy habits such as  
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22 155 teeth-brushing and hand-washing and, overall, adoption of activities that encourage  
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24 156 physical activity (walking to school, playground games), and to avoid sedentary  
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26 157 behaviour,[23].

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29 158 Each of the eight topics described in Figure 1, was integrated within educational  
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31 159 intervention activities of 1h/activity, prepared and standardized by the HPAs, and  
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33 160 implemented in the children's classrooms. In the first school academic year, we focused  
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35 161 on four topics: 1) to improve healthy lifestyle; 2) to encourage healthy drinks intake  
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37 162 (and avoidance of unhealthy carbonated/sweetened beverages); 3) to increase the  
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39 163 consumption of vegetables and legumes; and 4) to decrease the consumption of candies  
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41 164 and pastries while increasing the intake of fresh fruits and nuts. These corresponded to  
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43 165 four standardised activities (1h/activity). In the second year, the remaining four of the  
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45 166 eight selected lifestyle topics were addressed: 5) to improve healthy habits within a set  
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47 167 timetable (home meals, teeth-brushing, hand-washing) and physical activity  
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49 168 participation; 6) to increase fruit intake; 7) to improve dairy product consumption; and  
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51 169 8) to increase fish consumption. These corresponded to four standardised activities.  
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54 170 Finally, in the third school academic year, four standardised activities were introduced  
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3 171 that reinforced the eight lifestyle topics implemented in the previous 2 academic years.  
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5 172 Thus, the intervention program was based on eight lifestyle topics incorporated within  
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7 173 12 activities which were disseminated over 12 sessions (1h/activity/session), and  
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10 174 prepared, standardised and implemented as four activities per school academic year by  
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12 175 the HPAs in the school classrooms.  
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### 177 **Process evaluation**

178 The measurements were performed in each school academic year, as was the original  
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21 179 EdAI program,[17-18].  
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### 181 **Outcomes**

182 Assessment of the reproducibility of the EdAI program was based on primary outcomes  
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29 183 such as prevalence of OB (overall as well as stratified by gender), according to the  
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32 184 International Obesity Task Force (IOTF),[24] recommendations for better international  
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34 185 comparisons of data. Secondary outcomes included: changes in measures of adiposity  
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36 186 (overall as well as stratified by gender) such as BMI z-score (based on WHO growth  
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38 187 charts,[25] and waist circumference, incidence and remission of excess weight (OW and  
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40 188 OB), as well as changes in lifestyles (eating habits and physical activity h/week). All  
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43 189 outcomes were analysed in the intervention and control groups. Weight, height, and  
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45 190 waist circumference values were obtained as described previously,[17]. Prevalence of  
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47 191 underweight was analysed according to Cole et al,[26] using  $17\text{Kg/m}^2$  as cut-off point.  
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49 192 BMI z-score was calculated using the population values of the WHO Global  
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51 193 InfoBase,[25]. To identify the risk factors of OB, the OB category was determined  
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54 194 according to WHO criteria since this is based on data from countries that have a low OB  
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56 195 prevalence,[25] and, as such, provide an understanding of the protective (or risk factors)  
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3 196 for OB in our own population. To obtain a measurement of overall improvement in  
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5 197 lifestyle we generated variables such as the maintenance of status in each category as  
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7 198 well as the status in relation to changes in each category over the 22 month period.  
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## 200 **Sample size**

201 We calculated that, to have 85% chance (at a two-tailed 5% significance level) of  
202 detecting a difference of 5 percentage points between the intervention and control group  
203 (3% - 8%) with respect to OB prevalence at baseline of EdAI study [18], 354  
204 participants would be required in each of the participation groups. Allowing for an  
205 attrition rate of up to 10%, we aimed for 393 in each group.

## 206 **Statistical analyses**

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

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

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3 220 The main analyses were performed with the modified intention-to-treat (mITT)  
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5 221 population i.e. subjects with baseline and end-of-study data on weight, height, and date  
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7 222 of birth, and written inform consent. The analyses did not use any imputation missing  
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9 223 method; the assumption being that missing data were random. Statistical significance  
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11 224 was defined by a  $P < 0.05$ . The statistical analyses were performed with the SPSS 20.0  
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13 225 for Windows (SPSS Inc., Chicago, IL, USA).  
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## 19 227 **RESULTS**

### 20 228 **Enrolment**

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22 229 Figure 2 shows the recruitment and flow diagram of pupils in the intervention and  
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24 230 control groups over the course of the study. The mITT population in the intervention  
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26 231 group and control group were 320 and 370 pupils, respectively. At 22 months, the mean  
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28 232 age was 9.67 (95%CI: 9.60, 9.73) in the intervention group (9.68 years in boys and 9.65  
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30 233 years in girls) and 9.86 (95%CI: 9.79, 9.91) in the control group (9.85 years in boys and  
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32 234 9.84 years in girls). The differences in age were not significant in relation to gender.  
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34 235 The characteristics of the study group are summarised in Table 1. At baseline, the  
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36 236 intervention and control group were homogeneous in BMI status. The ethnicity of the  
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38 237 population was predominantly Western European in intervention and control group  
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40 238 (77.5% vs. 78.9%, respectively) while 7.5% vs. 10.8% was Eastern European; 10.3% vs.  
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42 239 3.5% was Latin American; 3.4% vs. 6.2% was North African Arab. At baseline, there  
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44 240 was a significant difference in the distribution with respect to Latin American children  
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46 241 (10.3% in intervention and 3.5% in control group;  $p < 0.001$ ). The distribution was  
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48 242 random. Of note is that there were no significant differences in distributions of OB  
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50 243 and/or OW. Also, no differences were observed in terms of response to the intervention  
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52 244 in relation to ethnicity.  
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245 **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
	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;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 <sup>2</sup>	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



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6 246 Notes to Table 1:  
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8 247 The results are expressed as Mean (95%CI)  
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10 248 <sup>1</sup>p value: general linear model (GLM) statistic  
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For peer review only

249 **Attrition rate**

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

256 **Primary outcome: Prevalence of OB**

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

						Baseline to	Intervention	
						study end	vs. Control	
				Baseline	End of	Change		
Criteria/Category	Group			% (n)	study % (n)	%	P-value <sup>1</sup>	P-value <sup>2</sup>
<b>IOTF</b>								
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		

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3 260 **Table 2.** Baseline and end-of-intervention measurements of categorised BMI in  
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5 261 Intervention and Control group  
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9 263 Notes to Table 2

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11 264 IOTF: International Obesity Task Force

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13 265 The results are expressed as % (n)

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15 266 <sup>1</sup>p value: McNemar's Test

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17 267 <sup>2</sup>p value: Fisher's Exact Test

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23 269 **Secondary outcomes**

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25 270 At 22 months of the study, the status of OW prevalence (according to IOTF criteria)

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27 271 was similar between groups (p=0.086).

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29 272 There were no significant differences in BMI z-score between intervention and control

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31 273 group (p=0.400) (Table 3). Despite no differences in BMI z-score, the boys of

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33 274 intervention group did not have an increase in percentage fat mass (19.96% to 20.02%:

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35 275 p=0.896), whereas intervention girls (22.06% to 23.55%; p<0.001), together with boys

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37 276 (19.18% to 20.64%, p<0.001) and girls (23.26% to 24.98%) of control group had a

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39 277 significant increase.

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41 278 The remission, and incidence, of OB was similar in the overall intervention and control

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43 279 group, as well as when stratified with respect to gender.

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

		Baseline		End of study		Change		Baseline	Interven
		Mean (95%CI)		Mean (95%CI)		Mean (95%CI)		to Study	vs. Control
								end	P-value <sup>2</sup>
								P-value <sup>1</sup>	
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	285	286
		Girls	0.71 (0.50; 0.91)	0.89 (0.68; 1.10)	0.18 (0.10; 0.26)	<0.001	0.030	287	288
		Total	0.72 (0.58; 0.86)	0.81 (0.67; 0.95)	0.09 (0.03; 0.14)	0.002	0.400	289	290
	Control	Boys	0.83 (0.64; 1.01)	0.81 (0.63; 1.00)	-0.12 (-0.08; 0.06)	0.726		291	
		Girls	0.52 (0.33; 0.71)	0.63 (0.44; 0.83)	0.11 (0.02; 0.20)	0.013		292	
		Total	0.68 (0.55; 0.82)	0.73 (0.60; 0.86)	0.05 (-0.01; 0.10)	0.100		293	

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295 Notes to Table 3:

296 <sup>1</sup>p-value: Mixed Models Repeated Measures297 <sup>2</sup>p-value: ANOVA model

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

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5 300 **Lifestyles evaluation**  
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7 301 After 22 months of the study, there were 19.7%, 11.2% and 8.2% more girls in the  
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9 302 intervention group who consumed a second fruit per day, one vegetable per day and  
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11 303 fast-food weekly than the girls of control group ( $p < 0.001$ ,  $p = 0.017$  and  $p = 0.013$ ;  
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13 304 respectively). However, there were 17.9% and 17.8% more boys in the intervention  
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15 305 group who consumed pastry at breakfast and more than one vegetable a day, compared  
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17 306 to boys of control group ( $p = 0.002$ ,  $p = 0.001$ ; respectively). Conversely, there were  
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19 307 12.9% and 12.2% more girls in the control group who consumed legumes and cereal  
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21 308 breakfast than girls of intervention group ( $p = 0.013$ ,  $p = 0.032$ ; respectively) (Table 4).  
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310 **Table 4.** Foods habits assessed at baseline and at the end of the study in the Intervention and  
 311 Control groups

		Intervention group			Control group			Interven
		Baseline	End of	P	Baseline	End of	P	tion vs.
		%(n)	%(n)	Value	%(n)	%(n)	Value	Control
		P-value						
<b>Krece plus questionnaire</b>								
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)	<b>0.016</b>	0.453
	Total	98.4 (248)	98.8 (239)	1	98.1 (302)	92.9 (288)	<b>0.003</b>	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)	<b>0.039</b>	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)	<b>0.036</b>	59.7 (86)	60.0 (87)	0.880	<b>0.031</b>
	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)	<b>0.027</b>	22.5 (33)	12.3 (20)	<b>0.001</b>	<b>0.002</b>
	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)	<b>&lt;0.001</b>	<b>0.002</b>
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, 2 <sup>nd</sup> per day	Boys	39.7 (50)	41.2 (49)	0.581	44.5 (69)	34.1 (56)	<b>0.006</b>	0.141
	Girls	26.4 (32)	47.5 (56)	<b>0.000</b>	44.8 (64)	39.0 (57)	0.281	<b>&lt;0.001</b>
	Total	33.2 (82)	44.3 (105)	<b>0.001</b>	44.6 (133)	36.5 (113)	<b>0.004</b>	<b>&lt;0.001</b>
Dairy product, 2 <sup>nd</sup> per day	Boys	87.2 (109)	78.5 (95)	<b>0.029</b>	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)	<b>0.043</b>	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	<b>0.017</b>
	Total	68.5 (170)	75.9 (183)	<b>0.011</b>	69.9 (214)	67.3 (212)	0.374	<b>0.028</b>
Vegetables, >1 per day	Boys	19.3 (23)	29.1 (34)	<b>0.017</b>	28.7 (43)	20.7 (34)	<b>0.009</b>	<b>0.001</b>
	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)	<b>0.001</b>	29.5 (86)	21.8 (67)	<b>0.002</b>	<b>0.001</b>
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	<b>0.013</b>
	Total	4.8 (12)	8.8 (21)	0.21	5.7 (17)	3.9 (12)	<b>0.049</b>	<b>0.003</b>
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)	<b>0.001</b>	<b>0.013</b>
	Total	71.5 (181)	72.2 (174)	1	65.2 (251)	70.7 (222)	<b>0.025</b>	<b>0.027</b>
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
<hr/>								
<b>Avall questionnaire</b>								
<i>Before leaving home</i>								
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)	<b>0.004</b>	0.235
	Total	90.9 (227)	87.6 (218)	0.071	86.2 (255)	81.1 (249)	<b>0.044</b>	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)	<b>0.016</b>	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)	<b>0.049</b>	14.9 (21)	18.4 (26)	0.572	1
Sandwich	Total	8.4 (20)	18.7 (46)	<b>0.008</b>	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
<i>Break (Midmorning)</i>								
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)	<b>0.016</b>	0.860
	Total	26.6 (66)	35.7 (87)	<b>0.008</b>	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

312 Notes to Table 4:

313 <sup>1</sup>p-value: McNemar's Test (changes in intervention group)

314 <sup>2</sup>p-value: McNemar's Test (changes in control group)

315 <sup>3</sup>p-value: Fisher's Exact Test.

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3 318 Table 5 summarises the time spent in after-school PA, watching TV, playing video  
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5 319 games, and other leisure-time activities. At 22 months, the percentage of boys of the  
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7 320 intervention group who performed  $\geq 4$ h after-school PA/week was increased by 15%  
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9 321 ( $p=0.027$ ) while there was 16.6% more boys in the intervention group watching  
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11 322  $\leq 2$ hTV/day ( $p<0.009$ ). The results indicate less sedentary behaviour in intervention than  
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14 323 control individuals.  
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324 **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 <sup>1</sup>	Baseline %(n)	End of study %(n)	P-value <sup>2</sup>	P-value <sup>3</sup>	
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)	<b>0.049</b>	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)	<b>0.006</b>	40.5 (64)	47.9 (78)	0.243	0.643	325
	Girls	27.9 (34)	34.4 (42)	0.136	33.1 (48)	32.4 (46)	0.868	0.598	326
	Total	36.5 (92)	48.0 (118)	<b>0.002</b>	37.0 (112)	40.7 (124)	0.272	0.485	327

328 Notes to Table 5

329 <sup>1</sup>P-value: McNemar's Test (changes in intervention group)

330 <sup>2</sup>P-value: McNemar's Test (changes in control group)

331 <sup>3</sup>P-value: Fisher's Exact Test.

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3 332 Differences between intervention and control pre-post intervention program  
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5 333 At 22 months, subjects who were normal weight at baseline increased after-school PA  
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7 334 to  $\geq 4$ h/week. This reflects a rise to 32.7% in boys ( $p=0.002$ ). However, in girls, the  
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9 335 changes were not statistically different ( $p=0.134$ ). No statistically significant differences  
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11 336 were observed in the control group.  
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### 338 **Impact of certain additional factors on obesity**

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18 339 The ORs of OB, using BMI z-score criteria, were related to some of the more relevant  
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20 340 dietary habits and lifestyles. Thus, breakfast dairy product consumption (OR: 0.336;  
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22 341  $p=0.004$ ) and  $\geq 4$  after-school PA h/week (OR: 0.600;  $p=0.032$ ) were protective factors  
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24 342 against OB. Conversely, doing  $<4$  h/week PA (OR: 1.811;  $p=0.018$ ) increased the risk  
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26 343 of childhood OB.  
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### 345 **DISCUSSION**

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32 346 The EdAl-2 program, a reproducibility study in Terres de l'Ebre, shows that  
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34 347 intervention is useful for improving weekly after-school PA. However, the OB  
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36 348 prevalence remained unchanged at 22 months, as has been shown in the data on stability  
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38 349 of OB prevalence observed in some European countries,[8]. Despite that OW and OB  
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40 350 remained similar between groups, we observed percentage fat mass maintenance in the  
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42 351 boys of the intervention group, whereas girls of the intervention and control group had  
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44 352 increases.  
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49 353 As proposed by Kain J et al, designing a new school-based intervention study needs to  
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51 354 have some critical aspects considered. These include: the random allocation of schools,  
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53 355 although methodologically desirable, is not always possible; participation of parents is  
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55 356 very limited; obesity is not recognised as a problem; and increasing physical activity  
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3 357 and implementing training programmes for teachers is difficult due to an inflexible  
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5 358 curriculum and lack of teachers' time. Unless these barriers are overcome, obesity  
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7 359 prevention programmes will not produce positive and lasting outcomes,[27]. As such,  
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10 360 our programme of HPA-implemented intervention activities in classrooms is an  
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12 361 attractive alternative that circumvents lack-of-teacher-time.

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14 362 The EdAl-2 program confirmed that after-school PA (in terms of h/week) can be  
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16 363 stimulated in primary school as part of a healthy lifestyle. As we had observed in the  
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18 364 original EdAL program,[18] at 28 months of intervention, there was an increase of up to  
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20 365 19.7% of children dedicating >5 hours/week to extra-curricular physical activities,[18].  
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22 366 Further, the after-school PA was maintained despite cessation of the intervention  
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24 367 program,[28]. The effect of EdAl program during its implementation and after the  
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26 368 official cessation indicated an impact on PA, whereas modification towards healthy  
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28 369 food choices occurred according to the site of the program's implementation, and was  
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30 370 not consistent.

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34 371 Interventions to prevent OB in the school setting have shown dramatic  
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36 372 improvements,[29]. However, successful studies in OB prevention need to be  
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38 373 reproducible, especially those improving healthy lifestyle such as after-school PA, to  
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40 374 confirm best childhood practices.

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43 375 Reproducibility of studies is rare because of the complexity of trying to replicate a  
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45 376 programme. To standardise a method it is essential to be able to reproduce appropriate  
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47 377 levels of an intervention, especially one that involves behavioural changes. Feasibility  
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49 378 of our intervention was confirmed in two different towns and over two different time-  
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51 379 courses (the first in Reus over 28 months, and the second in Amposta over 22 months).

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54 380 Also, it is important to assess treatment adherence in order to evaluate reproducibility  
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56 381 and feasibility,[19]. For example, the KOPS study,[20] demonstrated that nutritional  
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3 382 knowledge was increased as a result of the intervention in the two cohort studies (KOPS  
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5 383 1 and KOPS 2),[20]. However, the study was unable to show whether there were  
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7 384 differences in overweight outcomes, weight categories or lifestyles between the two  
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9 385 cohorts. Some multi-centred studies have attempted to reproduce methodological  
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11 386 aspects in interventions conducted in different countries or different populations.  
12  
13 387 However, while multi-centred studies are usually implemented concurrently,  
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15 388 reproducibility involves the applicability of the intervention at different sites and/or  
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17 389 different times in order to validate the initial findings. One example of this is the Pro  
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19 390 Children Study,[30] which, as a multi-centred study, had been applied in different  
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21 391 countries simultaneously and had demonstrated its efficacy and feasibility.  
22  
23 392 The ALADINO study presented the obesity status prevalence in Spain which, according  
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25 393 to the IOTF, is about 11.4% in children of around 9 years of age,[31]. In the EdA1-2  
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27 394 study, the OB prevalence was similar, but lower in the intervention group than the  
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29 395 equivalent in the ALADINO study and, as well, in the EDAL-2 control group.  
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31 396 The EdA1-2 study showed a significant improvement of 16.7% in the young boys in the  
32  
33 397 intervention group who participated in  $\geq 4$  h/week after-school PA. Further, the  
34  
35 398 increased numbers of children in the intervention group who performed  $\geq 4$  h/week  
36  
37 399 after-school PA who were normal-weight at baseline, suggested that the intervention  
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39 400 was effective not only in the primary-school healthy population but also effective in  
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41 401 preventing OB over the longer-term due to the PA being maintained.  
42  
43 402 In the dietary habits aspect of EdA1-2 study, we observed that the increase in healthy  
44  
45 403 lifestyle habits such as the increase in fruit and vegetables consumption and increasing  
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47 404 PA h/week while maintaining low TV h/d, are promising lifestyle changes that could  
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49 405 induce a reduction of OW and OB over the long-term.  
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3 406 In the EdA1-2 study we observed that consumption of dairy products at breakfast was a  
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5 407 protective factor against obesity.  
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7 408 Several studies have shown that participating in PA was a protective factor against OB  
8  
9 409 and that spending >2h watching TV was a risk factor for childhood OB. A recent  
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11 410 Spanish study showed that leisure-time PA was a protective factor against OB (as with  
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13 411 our present study) and that performing >4 h/week is a protective factor while watching  
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15 412 TV for this amount of time was, according to Ochoa et al,[32], associated with OB.  
16  
17 413 There are several limitations to our study. Firstly, we evaluated dietary habits via a  
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19 414 questionnaire that did not take into account the quantities of the different types of food  
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21 415 items consumed. These data would be important in addressing the quantity *versus*  
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23 416 quality debate in OB or OW prevalence. Secondly, assigning control groups according  
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25 417 to towns surrounding the intervention town could be a limitation. However, schools of  
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27 418 the same town have good relationships and communications with each other and this  
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29 419 could entail a possible contamination between schools if assigned to intervention or  
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31 420 control status within the same town. This cross-contamination would be minimised if  
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33 421 the schools themselves were assigned to intervention or control. Thirdly, the significant  
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35 422 difference in Latin American ethnicity between the two groups of the study at baseline  
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37 423 could be a limitation. However, there were no significant differences in distributions of  
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39 424 OB and/or OW. Also, no differences were observed in terms of response to the  
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41 425 intervention study in relation to ethnicity. Fourthly, when asked about fast-food  
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43 426 consumption, the participants interpreted this as pertaining only to fast-food outlets such  
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45 427 a burger shops, and did consider other concepts such as frozen pizza consumed at home.  
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47 428 Finally, another limitation could be the proportion of females who may have started  
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49 429 puberty in the course of the study. This implies changes in body composition. However,  
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3 430 both study groups (intervention and control) had a similar proportion of females with a  
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5 431 similar age, and this could cancel-out the effect.

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7 432 Further, EdA1-2 demonstrated that performing >4h/week after-school PA, plus having  
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9 433 dairy product at breakfast are protective factors. Hence, we believe that a participating  
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11 434 in >4h/week after-school PA, and continuing with a healthy breakfast, are key points in  
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13 435 preventing childhood OB.

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### 17 18 437 **CONCLUSION**

19  
20 438 Our school-based intervention is feasible and reproducible by increasing after-school PA  
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22 439 (to  $\geq$ 4h/week) in boys. Despite this improvement, there was no statistically significant  
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24 440 change in the prevalence of OB. This suggests that our intervention programme induces  
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26 441 healthy lifestyle effects (such as more exercise and less sedentary behaviour) which can  
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28 442 produce anti-obesity benefits in children in the near future beyond the limited length of  
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30 443 our current study. However, the effects on girls' behaviour need to be more closely  
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32 444 studied, together with a future repeat of our study in a different population.

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10 458 **COMPETING INTERESTS**

11 459 The authors declare that they have no competing interests.  
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16 461 **ETHICS**

17 462 The EdAl-2 study was approved by the Clinical Research Ethical Committee of the  
18  
19 463 *Hospital Sant Joan of Reus, Universitat Rovira i Virgili* (Catalan ethical committee  
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21 464 registry ref 11-04-28/4proj8).  
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27 466 **DATA SHARING**

28  
29 467 Technical appendix, statistical code, and dataset available at Dryad repository in: "Data  
30  
31 468 from: EdAl-2 (Educació en Alimentació) programme: reproducibility of a cluster  
32  
33 469 randomised, interventional, primary-school-based study to induce healthier lifestyle  
34  
35 470 activities in children" (*expecting the definitive DOI*).  
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40 472 **LIST OF ABBREVIATIONS**

41  
42 473 OB: Obesity

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44 474 OW: Overweight

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46 475 PA: Physical Activity

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48 476 mITT: modified Intention to Treat

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50 477 HPAs: Health Promoter Agents

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52 478 WHO: World Health Organization

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54 479 BMI: Body Mass Index  
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3 480 OR: Odds Ratio  
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7 482 **Authors' contributions**  
8  
9  
10 483 MG, EL, LT, RS designed the study (project conception, development of overall  
11  
12 484 research plan, and study oversight)  
13  
14 485 MG, EL, LT, RQ, RS conducted research (hands-on conduct of the experiments and  
15  
16 486 data collection)  
17  
18 487 EL, LT, MG, RS provided essential materials (applies to authors who contributed by  
19  
20 488 providing constructs, database, etc. necessary for the research)  
21  
22 489 DM, EL, LT analysed data or performed statistical analysis  
23  
24 490 RS, MG, LT, DM, EL drafted and revised the manuscript (authors who made a major  
25  
26 491 contribution). The final manuscript was read and approved by all co-authors  
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29 492 RS, MG take primary responsibility for the study, and manuscript content  
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For peer review only

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3 596 **FIGURE LEGEND**

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5 597 **Figure 1:** Eight topics of educational intervention activities

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7 598 This figure shows the 8 topics of 12 educational intervention activities of EdAI program

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9 599 **Figure 2:** Flow of subjects through the study

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11 600 Incomplete height and/or weight (measures of first and/or third academic year); No

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13 601 parental consent signed (first, second or third academic year).  
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3 **EdAl-2 (*Educació en Alimentació*) programme: reproducibility of a cluster**  
4 **randomised, interventional, primary-school-based study to induce healthier**  
5 **lifestyle activities in children**  
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10  
11 Elisabet Llauradó ([elisabet.laurado@urv.cat](mailto:elisabet.laurado@urv.cat))

12  
13 Lucia Tarro ([lucia.tarro@urv.cat](mailto:lucia.tarro@urv.cat))

14  
15 David Morina ([david.morina@uab.cat](mailto:david.morina@uab.cat))

16  
17 Rosa Queral ([rosa.queral@urv.cat](mailto:rosa.queral@urv.cat))

18  
19 Montse Giralt ([montse.giralt@urv.cat](mailto:montse.giralt@urv.cat))

20  
21 Rosa Solà ([rosa.sola@urv.cat](mailto:rosa.sola@urv.cat))  
22  
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27 E.LL. and L.T. contributed equally to the study.  
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30  
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32 **From the:**

33 Health Education and Promotion, Facultat de Medicina i Ciències de la Salut,  
34

35 Universitat Rovira i Virgili, Reus, Spain (ELL, LT)  
36  
37

38 Technological Centre of Nutrition and Health (CTNS) - TECNIO - URV – CEICS;  
39

40 Centre for Research in Environmental Epidemiology (CREAL) - Unitat de  
41

42 Bioestadística, Facultat de Medicina, Universitat Autònoma de Barcelona (DM)  
43  
44

45 Unit of Farmacobiology, Facultat de Medicina i Ciències de la Salut, Universitat Rovira  
46  
47 i Virgili, Reus, Spain (MG)  
48

49 Unit of Lipids and Arteriosclerosis Research, CIBERDEM, Hospital Universitari Sant  
50

51 Joan, IISPV, Facultat de Medicina i Ciències de la Salut, Universitat Rovira i Virgili,  
52

53 Reus, Spain (RS)  
54  
55  
56  
57  
58  
59  
60

**For correspondence:**

Rosa Solà, MD, PhD

Unitat de Recerca en Lípids i Arteriosclerosi,

Facultat de Medicina i Ciències de la Salut,

C/ Sant Llorenç 21,

43201-Reus,

Spain

Tel: (34) 977 759 369 / 609 906 991 (mobile)

Fax: (34) 977 759 322

E-mail: [rosa.sola@urv.cat](mailto:rosa.sola@urv.cat)

or

Montse Giralt, MD, PhD

Unit of Farmacobiology,

Facultat de Medicina i Ciències de la Salut,

Universitat Rovira i Virgili,

43201-Reus,

Spain

E-mail: [montse.giralt@urv.cat](mailto:montse.giralt@urv.cat)

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

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## 1 ABSTRACT

2 **Objectives:** To assess the reproducibility of an educational intervention EdA1-2  
3 programme in “Terres de l’Ebre” (Spain), over 22 months, to improve lifestyles,  
4 including diet and physical activity (PA)

5 **Design:** Reproduction of a cluster randomised controlled trial

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

8 **Participants:** Pupils (n=690) of which 320 constituted intervention group (1 cluster)  
9 and 370 constituted control group (1 cluster). Ethnicity was 78% Western European.

10 Mean age ( $\pm$ SD) was 8.04 $\pm$ 0.6 years (47.7% females) at baseline. Inclusion criteria for  
11 clusters were towns from the southern part of Catalonia having a minimum of 500  
12 children aged 7 to 8 year; and complete data for participants, including name, gender,  
13 date and place of birth, and written informed consent from parents or guardians.

14 **Intervention:** The intervention focused on 8 lifestyle topics covered in 12 activities  
15 (1h/activity/session) implemented by health promoting agents in the primary-school  
16 over 3 academic years.

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

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

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3 25 Also, 16.6% more boys in the intervention group watched  $\leq 2$  TV h/day ( $p=0.009$ ),  
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5 26 compared to controls; and no changes were observed in girls of both groups.  
6

7 **Conclusions:** Our school-based intervention is feasible and reproducible by increasing  
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9 after-school PA (to  $\geq 4$ h/week) in boys induced healthy lifestyle effects while, the  
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11 prevalence of OB was not significantly changed.  
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16 31 Words: 295

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18 32 Clinical Trials registration NCT01362023  
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## 21 33

### 22 34 **ARTICLE SUMMARY**

#### 23 35 **Strengths and limitations of the study**

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27 36 - Strengths: Reproducibility of studies is rare because of the complexity of  
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29 37 replicating an intervention programme. Studies in OB prevention, such as EdAI,  
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31 38 need to be reproducible, especially those improving healthy lifestyle, including  
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33 39 after-school PA, to reinforce beneficial practices in childhood  
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35  
36 40 - Strengths: Statistical methods controlling for confounders and taking into  
37  
38 41 account clustering of data  
39  
40 42 - Limitations: Failure to assess treatment adherence to evaluate reproducibility  
41  
42 43 and feasibility  
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44 44 - Limitations: Dietary habits were noted via a questionnaire that did not take into  
45  
46 45 account the quantities of the different types of food items consumed  
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3 46 **BACKGROUND**

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5 47 Obesity (OB) has become a disease of epidemic proportions,[1]. However, this  
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7 48 increasing tendency towards excess weight in childhood and adulthood,[2] observed in  
8  
9 49 some countries (United Kingdom, France, South Korea, United States and Spain) has  
10  
11 50 stabilised despite the absolute rates being a cause for concern,[1]. OB prevalence in  
12  
13 51 children and adolescents is higher in southern regions of Europe,[3-4].

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15  
16 52 Accumulation of fat tissue constitutes an increased disease risk in childhood, as well as  
17  
18 53 in adulthood,[5]. This disease risk has a multifactorial aetiology, such as an unhealthy  
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20 54 diet and sedentary lifestyle,[6-7].

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22  
23 55 The Organization for Economic Co-operation and Development (OECD), has predicted  
24  
25 56 an increase of 7% in excess weight prevalence in adulthood over the period spanning  
26  
27 57 2010 to 2020,[8]. The WHO proposes the prevention and control of OB prevalence as  
28  
29 58 key in the updated “Action Plan 2008-2013” in which effective health promotion is  
30  
31 59 considered the principal strategy,[9].

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33  
34 60 Since excess weight status in adulthood is almost invariably predicated on childhood  
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36 61 and adolescent weight, OB prevention should start early in life,[10]. The optimum age  
37  
38 62 to commence an intervention is between the ages of 7 and 8 years because children are  
39  
40 63 more receptive to guidance,[11]. The school is an ideal place for the promotion of  
41  
42 64 healthy nutrition and lifestyle habits,[12] and, as some studies have shown, such  
43  
44 65 interventions have inspired changes in nutritional habits and BMI status,[13-14]; the  
45  
46 66 message being received by all schoolchildren, irrespective of ethnic and socioeconomic  
47  
48 67 differences,[9]. The effectiveness of an intervention is when educational strategies and  
49  
50 68 environmental factors such as healthy nutrition and physical activity habits coincide  
51  
52 69 since both aspects are essential in preventing childhood OB,[15]. Currently, European  
53  
54 70 children spend more of their leisure time in sedentary activities such as watching

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3 71 television (TV), video games or on the Internet. These activities represent a decrease in  
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5 72 physical movement and lowering energy expenditure and, as such, are risk factors for  
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7 73 OB,[16].

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9  
10 74 We had designed the EdAI (*Educació en Alimentació*) programme as a randomised,  
11  
12 75 controlled, parallel study applied in primary schools, and implemented by university  
13  
14 76 students acting as Health Promoter Agents (HPAs),[17]. This intervention was deployed  
15  
16 77 in Reus (as intervention group) with the neighbouring towns of Salou, Cambrils and  
17  
18 78 Vilaseca as control group. The interventions focused on 8 lifestyle topics covered in 12  
19  
20 79 activities (1h/activity/session) in 7-8 year old children, and implemented by HPAs over  
21  
22 80 3 school academic years. We found that the EdAI programme successfully reduced  
23  
24 81 childhood OB prevalence in boys by 4.39% and increased the percentage of boys who  
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26 82 practice  $\geq 5$  after-school physical activity (PA) h/week,[18]. The EdAI programme  
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28 83 needed to be reproduced in other localities, and with other children, to demonstrate the  
29  
30 84 effectiveness of this intervention[19].

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34 85 The outcomes of the EdAI programme supported the feasibility of improving PA in  
35  
36 86 childhood. However, an educational intervention, such as our EdAI program  
37  
38 87 implemented by HPAs, also tests complex components such as healthy lifestyles  
39  
40 88 including diet and physical activity recommendations. Due to the complexity, such  
41  
42 89 interventions are difficult to rationalise, standardise, reproduce, and administer  
43  
44 90 consistently to all participants,[19].

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46  
47 91 There has been one study in the literature that has reproduced its programmes in other  
48  
49 92 locations. Described as the Kiel Obesity Prevention Study (KOPS), the results  
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51 93 demonstrated the efficacy and feasibility of implementing new nutritional concepts,[20].  
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53 94 We tested the reproducibility of the EdAI programme in a geographical area (Terres de  
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55 95 l'Ebre) about 80km away from where the original EdAI programme was designed and  
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3 96 implemented. We designed a cluster (town group) randomised controlled trial; the  
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5 97 rationale being that since good communications exist between the schools of the same  
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7 98 town, this could contribute to schools of the intervention group “contaminating” those  
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9 99 of the putative control group.

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11 We describe, here, the primary-school-based study to reduce the prevalence of  
12  
13 101 childhood OB (The EdAI-2 study); the objective remains an intervention to induce  
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15 102 healthy lifestyles, including diet and physical activity recommendations. The study was  
16  
17 103 conducted in 7-8 year old school-children over 3 academic years (22 months active  
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19 104 school time).

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## 24 25 106 **METHODS**

26  
27 107 The original protocol, rationale, randomisation, techniques and results of the initial  
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29 108 EdAI programme have been published in *Trials*, [17-18]. The current study (EdAI-2)  
30  
31 109 was conducted in exactly the same way so as to assess whether comparable results  
32  
33 110 could be achieved in a different location. The exact intervention is described in more  
34  
35 111 detail in Supplemental File 1, and in this manuscript link. The EdAI-2 study was  
36  
37 112 approved by the Clinical Research Ethical Committee of the *Hospital Sant Joan of*  
38  
39 113 *Reus, Universitat Rovira i Virgili* (Catalan ethical committee registry ref 11-04-  
40  
41 114 28/4proj8). This study was registered in Clinical Trials *NCT01362023*. The protocol  
42  
43 115 conformed to the Helsinki Declaration and Good Clinical Practice guides of the  
44  
45 116 International Conference of Harmonization (ICHGCP). The study followed the  
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47 117 CONSORT criteria [see Additional File 2].

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51 118 For logistics reasons, the EdAI-2 program was reduced by 6 months, from 28 months to  
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53 119 22 months.

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3 121 **Study population**  
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5 122 To ensure approximately a minimum 500 inhabitants of 7-8 years of age per cluster,  
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7 123 before randomising the towns (clusters), a statistician who was not familiar with the  
8  
9 124 study objectives and of the school identities, matched the towns on population size. The  
10  
11 125 coordinating Center (in Reus) developed a cluster randomisation scheme to have a study  
12  
13 126 sample in which the schools in Amposta were designated as Cluster A (intervention)  
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15 127 and 9 towns around Amposta (Sant Jaume d'Enveja, Els Muntells, l'Ametlla de Mar, El  
16  
17 128 Perelló, l'Ampolla, Deltebre, l'Aldea, Lligalló del Gànguil and Camarles) as Cluster B  
18  
19 129 (control). The eligibility criteria of clusters were to be semi-rural towns from the  
20  
21 130 southern part of Catalonia with a minimum of 500 children of 7 to 8 years of age in  
22  
23 131 each cluster.  
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27 132 The socio-demographic indicators in all towns were similar to that of the original EdAl  
28  
29 133 Program in Reus. Children attending the schools in both groups (intervention and  
30  
31 134 control) lived in close proximity within each school's catchment area. Intervention  
32  
33 135 institutions were 5 schools involving 18 classrooms and 457 pupils in Amposta. Control  
34  
35 136 institutions consisted of 11 schools involving 23 classrooms and 531 pupils in the 9  
36  
37 137 towns of around Amposta. Children of this study are in the 2<sup>nd</sup> and 3<sup>rd</sup> grade of primary  
38  
39 138 education (7-8 year olds). Schoolchildren were enrolled in May 2011 (children born in  
40  
41 139 2002–2003) and followed-up for 3 school academic years (2012–2013). The study was  
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43 140 completed in March 2013.  
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47 141 To be representative of the child population, the schools selected needed to have at least  
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49 142 50% of the children in the classrooms volunteer to participate. We offered the  
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51 143 programme to all schools, whether public (funded by the government and termed  
52  
53 144 “charter” schools) or private which included fee-paying and/or faith schools. Inclusion  
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55 145 criteria were: name, gender, date and place of birth, and written informed consent from  
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3 146 the parent or guardian of each participant. A questionnaire on eating habits (Krece Plus)  
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5 147 developed by Serra Majem et al,[21], and physical activity, level of parental education  
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7 148 and lifestyles developed by Llargues et al,[22] were filled-in by the parents at baseline  
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9 149 and at the end of the study.  
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### 13 14 151 **Intervention program**

15 152 The original EdAl Reus protocol was followed,[17-18]. The educational intervention  
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17 153 activities focused on eight lifestyle topics based on scientific evidence,[23] to improve  
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19 154 nutritional food item choices (and avoidance of some foods), healthy habits such as  
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21 155 teeth-brushing and hand-washing and, overall, adoption of activities that encourage  
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23 156 physical activity (walking to school, playground games), and to avoid sedentary  
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25 157 behaviour,[23].  
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29 158 Each of the eight topics described in Figure 1, was integrated within educational  
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31 159 intervention activities of 1h/activity, prepared and standardized by the HPAs, and  
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33 160 implemented in the children's classrooms. In the first school academic year, we focused  
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35 161 on four topics: 1) to improve healthy lifestyle; 2) to encourage healthy drinks intake  
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37 162 (and avoidance of unhealthy carbonated/sweetened beverages); 3) to increase the  
38  
39 163 consumption of vegetables and legumes; and 4) to decrease the consumption of candies  
40  
41 164 and pastries while increasing the intake of fresh fruits and nuts. These corresponded to  
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43 165 four standardised activities (1h/activity). In the second year, the remaining four of the  
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45 166 eight selected lifestyle topics were addressed: 5) to improve healthy habits within a set  
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47 167 timetable (home meals, teeth-brushing, hand-washing) and physical activity  
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49 168 participation; 6) to increase fruit intake; 7) to improve dairy product consumption; and  
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51 169 8) to increase fish consumption. These corresponded to four standardised activities.  
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54 170 Finally, in the third school academic year, four standardised activities were introduced  
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3 171 that reinforced the eight lifestyle topics implemented in the previous 2 academic years.  
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5 172 Thus, the intervention program was based on eight lifestyle topics incorporated within  
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7 173 12 activities which were disseminated over 12 sessions (1h/activity/session), and  
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10 174 prepared, standardised and implemented as four activities per school academic year by  
11  
12 175 the HPAs in the school classrooms.  
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### 177 **Process evaluation**

178 The measurements were performed in each school academic year, as was the original  
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21 179 EdAI program,[17-18].  
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### 181 **Outcomes**

182 Assessment of the reproducibility of the EdAI program was based on primary outcomes  
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30 183 such as prevalence of OB (overall as well as stratified by gender), according to the  
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32 184 International Obesity Task Force (IOTF),[24] recommendations for better international  
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34 185 comparisons of data. Secondary outcomes included: changes in measures of adiposity  
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36 186 (overall as well as stratified by gender) such as BMI z-score (based on WHO growth  
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38 187 charts,[25] and waist circumference, incidence and remission of excess weight (OW and  
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40 188 OB), as well as changes in lifestyles (eating habits and physical activity h/week). **All**  
41  
42 189 **outcomes were analysed in the intervention and control groups.** Weight, height, and  
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45 190 waist circumference values were obtained as described previously,[17]. Prevalence of  
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47 191 underweight was analysed according to Cole et al,[26] using  $17\text{Kg/m}^2$  as cut-off point.  
48  
49 192 BMI z-score was calculated using the population values of the WHO Global  
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51 193 InfoBase,[25]. To identify the risk factors of OB, the OB category was determined  
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53 194 according to WHO criteria since this is based on data from countries that have a low OB  
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55 195 prevalence,[25] and, as such, provide an understanding of the protective (or risk factors)  
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3 196 for OB in our own population. To obtain a measurement of overall improvement in  
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5 197 lifestyle we generated variables such as the maintenance of status in each category as  
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7 198 well as the status in relation to changes in each category over the 22 month period.  
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## 200 **Sample size**

201 We calculated that, to have 85% chance (at a two-tailed 5% significance level) of  
202 detecting a difference of 5 percentage points between the intervention and control group  
203 (3% - 8%) with respect to OB prevalence at baseline of EdAI study [18], 354  
204 participants would be required in each of the participation groups. Allowing for an  
205 attrition rate of up to 10%, we aimed for 393 in each group.

## 206 **Statistical analyses**

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

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

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3 220 The main analyses were performed with the modified intention-to-treat (mITT)  
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5 221 population i.e. subjects with baseline and end-of-study data on weight, height, and date  
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7 222 of birth, and written informed consent. The analyses did not use any imputation missing  
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9 223 method; the assumption being that missing data were random. Statistical significance  
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11 224 was defined by a  $P < 0.05$ . The statistical analyses were performed with the SPSS 20.0  
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13 225 for Windows (SPSS Inc., Chicago, IL, USA).  
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## 19 227 **RESULTS**

### 20 228 **Enrolment**

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23 229 Figure 2 shows the recruitment and flow diagram of pupils in the intervention and  
24  
25 230 control groups over the course of the study. The mITT population in the intervention  
26  
27 231 group and control group were 320 and 370 pupils, respectively. At 22 months, the mean  
28  
29 232 age was 9.67 (95%CI: 9.60, 9.73) in the intervention group (9.68 years in boys and 9.65  
30  
31 233 years in girls) and 9.86 (95%CI: 9.79, 9.91) in the control group (9.85 years in boys and  
32  
33 234 9.84 years in girls). The differences in age were not significant in relation to gender.  
34  
35 235 The characteristics of the study group are summarised in Table 1. At baseline, the  
36  
37 236 intervention and control group were homogeneous in BMI status. The ethnicity of the  
38  
39 237 population was predominantly Western European in intervention and control group  
40  
41 238 (77.5% vs. 78.9%, respectively) while 7.5% vs. 10.8% was Eastern European; 10.3% vs.  
42  
43 239 3.5% was Latin American; 3.4% vs. 6.2% was North African Arab. At baseline, there  
44  
45 240 was a significant difference in the distribution with respect to Latin American children  
46  
47 241 (10.3% in intervention and 3.5% in control group;  $p < 0.001$ ). The distribution was  
48  
49 242 random. Of note is that there were no significant differences in distributions of OB  
50  
51 243 and/or OW. Also, no differences were observed in terms of response to the intervention  
52  
53 244 in relation to ethnicity.  
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245 **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
	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;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 <sup>2</sup>	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

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246 Notes to Table 1:

247 The results are expressed as Mean (95%CI)

248 <sup>1</sup>p value: general linear model (GLM) statistic

For peer review only

249 **Attrition rate**

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

256 **Primary outcome: Prevalence of OB**

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

Criteria/Category	Group			Baseline to		Change	Intervention	
				Baseline	End of		study end	vs. Control
			% (n)	study % (n)	%	P-value <sup>1</sup>	P-value <sup>2</sup>	
<b>IOTF</b>								
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	
			Total	17.2 (55)	23.8 (76)	6.6	0.005	
	Control	Boys	25.5 (50)	27.0 (53)	1.5	0.690	0.086	
		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		
		Total	11.6 (37)	11.9 (38)	0.3	1.000		
	Control	Boys	10.7 (21)	10.2 (20)	-0.5	1.000	0.628	
		Girls	12.1 (21)	10.9 (19)	-1.2	0.687		
		Total	11.4 (42)	10.5 (39)	-0.93	0.607		

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3 260 **Table 2.** Baseline and end-of-intervention measurements of categorised BMI in  
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5 261 Intervention and Control group

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9 263 Notes to Table 2

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11 264 IOTF: International Obesity Task Force

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13 265 The results are expressed as % (n)

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15 266 <sup>1</sup>p value: McNemar's Test

16  
17 267 <sup>2</sup>p value: Fisher's Exact Test

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23 269 **Secondary outcomes**

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25 270 At 22 months of the study, the status of OW prevalence (according to IOTF criteria)

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27 271 was similar between groups (p=0.086).

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29 272 There were no significant differences in BMI z-score between intervention and control

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31 273 group (p=0.400) (Table 3). Despite no differences in BMI z-score, the boys of

32  
33 274 intervention group did not have an increase in percentage fat mass (19.96% to 20.02%:

34  
35 275 p=0.896), whereas intervention girls (22.06% to 23.55%; p<0.001), together with boys

36  
37 276 (19.18% to 20.64%, p<0.001) and girls (23.26% to 24.98%) of control group had a

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39 277 significant increase.

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41 278 The remission, and incidence, of OB was similar in the overall intervention and control

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43 279 group, as well as when stratified with respect to gender.

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

		Baseline		End of study		Change		Baseline	
		Mean (95%CI)		Mean (95%CI)		Mean (95%CI)		to Study	Interven
								end	vs. Control
								P-value <sup>1</sup>	P-value <sup>2</sup>
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	285	286
		Girls	0.71 (0.50; 0.91)	0.89 (0.68; 1.10)	0.18 (0.10; 0.26)	<0.001	0.030	287	288
		Total	0.72 (0.58; 0.86)	0.81 (0.67; 0.95)	0.09 (0.03; 0.14)	0.002	0.400	289	290
	Control	Boys	0.83 (0.64; 1.01)	0.81 (0.63; 1.00)	-0.12 (-0.08; 0.06)	0.726		291	
		Girls	0.52 (0.33; 0.71)	0.63 (0.44; 0.83)	0.11 (0.02; 0.20)	0.013		292	
		Total	0.68 (0.55; 0.82)	0.73 (0.60; 0.86)	0.05 (-0.01; 0.10)	0.100		293	

294

295 Notes to Table 3:

296 <sup>1</sup>p-value: Mixed Models Repeated Measures

297 <sup>2</sup>p-value: ANOVA model

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

299

**300 Lifestyles evaluation**

301 After 22 months of the study, there were 19.7%, 11.2% and 8.2% more girls in the  
302 intervention group who consumed a second fruit per day, one vegetable per day and  
303 fast-food weekly than the girls of control group ( $p<0.001$ ,  $p=0.017$  and  $p=0.013$ ;  
304 respectively). However, there were 17.9% and 17.8% more boys in the intervention  
305 group who consumed pastry at breakfast and more than one vegetable a day, compared  
306 to boys of control group ( $p=0.002$ ,  $p=0.001$ ; respectively). Conversely, there were  
307 12.9% and 12.2% more girls in the control group who consumed legumes and cereal  
308 breakfast than girls of intervention group ( $p=0.013$ ,  $p=0.032$ ; respectively) (Table 4).  
309

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

		Intervention group			Control group			Interven
		Baseline	End of	P	Baseline	End of	P	tion vs.
		%(n)	study	Value	%(n)	study	Value	Control
			%(n)			%(n)		P-value
<b>Krece plus questionnaire</b>								
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)	<b>0.016</b>	0.453
	Total	98.4 (248)	98.8 (239)	1	98.1 (302)	92.9 (288)	<b>0.003</b>	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)	<b>0.039</b>	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)	<b>0.036</b>	59.7 (86)	60.0 (87)	0.880	<b>0.031</b>
	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)	<b>0.027</b>	22.5 (33)	12.3 (20)	<b>0.001</b>	<b>0.002</b>
	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)	<b>&lt;0.001</b>	<b>0.002</b>
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, 2 <sup>nd</sup> per day	Boys	39.7 (50)	41.2 (49)	0.581	44.5 (69)	34.1 (56)	<b>0.006</b>	0.141
	Girls	26.4 (32)	47.5 (56)	<b>0.000</b>	44.8 (64)	39.0 (57)	0.281	<b>&lt;0.001</b>
	Total	33.2 (82)	44.3 (105)	<b>0.001</b>	44.6 (133)	36.5 (113)	<b>0.004</b>	<b>&lt;0.001</b>
Dairy product, 2 <sup>nd</sup> per day	Boys	87.2 (109)	78.5 (95)	<b>0.029</b>	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)	<b>0.043</b>	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	<b>0.017</b>
	Total	68.5 (170)	75.9 (183)	<b>0.011</b>	69.9 (214)	67.3 (212)	0.374	<b>0.028</b>
Vegetables, >1 per day	Boys	19.3 (23)	29.1 (34)	<b>0.017</b>	28.7 (43)	20.7 (34)	<b>0.009</b>	<b>0.001</b>
	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)	<b>0.001</b>	29.5 (86)	21.8 (67)	<b>0.002</b>	<b>0.001</b>
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	<b>0.013</b>
	Total	4.8 (12)	8.8 (21)	0.21	5.7 (17)	3.9 (12)	<b>0.049</b>	<b>0.003</b>
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)	<b>0.001</b>	<b>0.013</b>
	Total	71.5 (181)	72.2 (174)	1	65.2 (251)	70.7 (222)	<b>0.025</b>	<b>0.027</b>
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
<hr/>								
<b>Avall questionnaire</b>								
<i>Before leaving home</i>								
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)	<b>0.004</b>	0.235
	Total	90.9 (227)	87.6 (218)	0.071	86.2 (255)	81.1 (249)	<b>0.044</b>	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)	<b>0.016</b>	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)	<b>0.049</b>	14.9 (21)	18.4 (26)	0.572	1
Sandwich	Total	8.4 (20)	18.7 (46)	<b>0.008</b>	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
<i>Break (Midmorning)</i>								
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)	<b>0.016</b>	0.860
	Total	26.6 (66)	35.7 (87)	<b>0.008</b>	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

312 Notes to Table 4:

313 <sup>1</sup>p-value: McNemar's Test (changes in intervention group)

314 <sup>2</sup>p-value: McNemar's Test (changes in control group)

315 <sup>3</sup>p-value: Fisher's Exact Test.

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3 318 Table 5 summarises the time spent in after-school PA, watching TV, playing video  
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5 319 games, and other leisure-time activities. At 22 months, the percentage of boys of the  
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7 320 intervention group who performed  $\geq 4$ h after-school PA/week was increased by 15%  
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9 321 ( $p=0.027$ ) while there was 16.6% more boys in the intervention group watching  
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11 322  $\leq 2$ hTV/day ( $p<0.009$ ). The results indicate less sedentary behaviour in intervention than  
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14 323 control individuals.  
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324 **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 <sup>1</sup>	Baseline %(n)	End of study %(n)	P-value <sup>2</sup>	P-value <sup>3</sup>	
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)	<b>0.049</b>	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	

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>4h/week	Boys	44.6 (58)	61.3 (76)	<b>0.006</b>	40.5 (64)	47.9 (78)	0.243	0.643	325
	Girls	27.9 (34)	34.4 (42)	0.136	33.1 (48)	32.4 (46)	0.868	0.598	326
	Total	36.5 (92)	48.0 (118)	<b>0.002</b>	37.0 (112)	40.7 (124)	0.272	0.485	

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328 Notes to Table 5

329 <sup>1</sup>P-value: McNemar's Test (changes in intervention group)

330 <sup>2</sup>P-value: McNemar's Test (changes in control group)

331 <sup>3</sup>P-value: Fisher's Exact Test.

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3 332 Differences between intervention and control pre-post intervention program  
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5 333 At 22 months, subjects who were normal weight at baseline increased after-school PA  
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7 334 to  $\geq 4$ h/week. This reflects a rise to 32.7% in boys ( $p=0.002$ ). However, in girls, the  
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9 335 changes were not statistically different ( $p=0.134$ ). No statistically significant differences  
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11 336 were observed in the control group.  
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### 15 338 **Impact of certain additional factors on obesity**

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17 339 The ORs of OB, using BMI z-score criteria, were related to some of the more relevant  
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19 340 dietary habits and lifestyles. Thus, breakfast dairy product consumption (OR: 0.336;  
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21 341  $p=0.004$ ) and  $\geq 4$  after-school PA h/week (OR: 0.600;  $p=0.032$ ) were protective factors  
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23 342 against OB. Conversely, doing  $<4$  h/week PA (OR: 1.811;  $p=0.018$ ) increased the risk  
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25 343 of childhood OB.  
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### 30 345 **DISCUSSION**

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32 346 The EdAl-2 program, a reproducibility study in Terres de l'Ebre, shows that  
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34 347 intervention is useful for improving weekly after-school PA. However, the OB  
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36 348 prevalence remained unchanged at 22 months, as has been shown in the data on stability  
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38 349 of OB prevalence observed in some European countries,[8]. Despite that OW and OB  
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40 350 remained similar between groups, we observed percentage fat mass maintenance in the  
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42 351 boys of the intervention group, whereas girls of the intervention and control group had  
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44 352 increases.  
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49 353 As proposed by Kain J et al, designing a new school-based intervention study needs to  
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51 354 have some critical aspects considered. These include: the random allocation of schools,  
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53 355 although methodologically desirable, is not always possible; participation of parents is  
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55 356 very limited; obesity is not recognised as a problem; and increasing physical activity  
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3 357 and implementing training programmes for teachers is difficult due to an inflexible  
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5 358 curriculum and lack of teachers' time. Unless these barriers are overcome, obesity  
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7 359 prevention programmes will not produce positive and lasting outcomes,[27]. As such,  
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10 360 our programme of HPA-implemented intervention activities in classrooms is an  
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12 361 attractive alternative that circumvents lack-of-teacher-time.  
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14 362 The EdAl-2 program confirmed that after-school PA (in terms of h/week) can be  
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16 363 stimulated in primary school as part of a healthy lifestyle. As we had observed in the  
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18 364 original EdAL program,[18] at 28 months of intervention, there was an increase of up to  
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20 365 19.7% of children dedicating >5 hours/week to extra-curricular physical activities,[18].  
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23 366 Further, the after-school PA was maintained despite cessation of the intervention  
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25 367 program,[28]. The effect of EdAl program during its implementation and after the  
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27 368 official cessation indicated an impact on PA, whereas modification towards healthy  
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29 369 food choices occurred according to the site of the program's implementation, and was  
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31 370 not consistent.  
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34 371 Interventions to prevent OB in the school setting have shown dramatic  
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36 372 improvements,[29]. However, successful studies in OB prevention need to be  
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38 373 reproducible, especially those improving healthy lifestyle such as after-school PA, to  
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40 374 confirm best childhood practices.  
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43 375 Reproducibility of studies is rare because of the complexity of trying to replicate a  
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45 376 programme. To standardise a method it is essential to be able to reproduce appropriate  
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47 377 levels of an intervention, especially one that involves behavioural changes. Feasibility  
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49 378 of our intervention was confirmed in two different towns and over two different time-  
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51 379 courses (the first in Reus over 28 months, and the second in Amposta over 22 months).  
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54 380 Also, it is important to assess treatment adherence in order to evaluate reproducibility  
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56 381 and feasibility,[19]. For example, the KOPS study,[20] demonstrated that nutritional  
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3 382 knowledge was increased as a result of the intervention in the two cohort studies (KOPS  
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5 383 1 and KOPS 2),[20]. However, the study was unable to show whether there were  
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7 384 differences in overweight outcomes, weight categories or lifestyles between the two  
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9 385 cohorts. Some multi-centred studies have attempted to reproduce methodological  
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11 386 aspects in interventions conducted in different countries or different populations.  
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13 387 However, while multi-centred studies are usually implemented concurrently,  
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15 388 reproducibility involves the applicability of the intervention at different sites and/or  
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17 389 different times in order to validate the initial findings. One example of this is the Pro  
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19 390 Children Study,[30] which, as a multi-centred study, had been applied in different  
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21 391 countries simultaneously and had demonstrated its efficacy and feasibility.  
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23 392 The ALADINO study presented the obesity status prevalence in Spain which, according  
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25 393 to the IOTF, is about 11.4% in children of around 9 years of age,[31]. In the EdA1-2  
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27 394 study, the OB prevalence was similar, but lower in the intervention group than the  
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29 395 equivalent in the ALADINO study and, as well, in the EDAL-2 control group.  
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31 396 The EdA1-2 study showed a significant improvement of 16.7% in the young boys in the  
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33 397 intervention group who participated in  $\geq 4$  h/week after-school PA. Further, the  
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35 398 increased numbers of children in the intervention group who performed  $\geq 4$  h/week  
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37 399 after-school PA who were normal-weight at baseline, suggested that the intervention  
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39 400 was effective not only in the primary-school healthy population but also effective in  
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41 401 preventing OB over the longer-term due to the PA being maintained.  
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43 402 In the dietary habits aspect of EdA1-2 study, we observed that the increase in healthy  
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45 403 lifestyle habits such as the increase in fruit and vegetables consumption and increasing  
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47 404 PA h/week while maintaining low TV h/d, are promising lifestyle changes that could  
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49 405 induce a reduction of OW and OB over the long-term.  
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3 406 In the EdAl-2 study we observed that consumption of dairy products at breakfast was a  
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5 407 protective factor against obesity.  
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7 408 Several studies have shown that participating in PA was a protective factor against OB  
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9 409 and that spending >2h watching TV was a risk factor for childhood OB. A recent  
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11 410 Spanish study showed that leisure-time PA was a protective factor against OB (as with  
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13 411 our present study) and that performing >4 h/week is a protective factor while watching  
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15 412 TV for this amount of time was, according to Ochoa et al,[32], associated with OB.  
16  
17 413 There are several limitations to our study. Firstly, we evaluated dietary habits via a  
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19 414 questionnaire that did not take into account the quantities of the different types of food  
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21 415 items consumed. These data would be important in addressing the quantity *versus*  
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23 416 quality debate in OB or OW prevalence. Secondly, assigning control groups according  
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25 417 to towns surrounding the intervention town could be a limitation. However, schools of  
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27 418 the same town have good relationships and communications with each other and this  
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29 419 could entail a possible contamination between schools if assigned to intervention or  
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31 420 control status within the same town. This cross-contamination would be minimised if  
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33 421 the schools themselves were assigned to intervention or control. Thirdly, the significant  
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35 422 difference in Latin American ethnicity between the two groups of the study at baseline  
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37 423 could be a limitation. However, there were no significant differences in distributions of  
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39 424 OB and/or OW. Also, no differences were observed in terms of response to the  
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41 425 intervention study in relation to ethnicity. Fourthly, when asked about fast-food  
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43 426 consumption, the participants interpreted this as pertaining only to fast-food outlets such  
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45 427 a burger shops, and did consider other concepts such as frozen pizza consumed at home.  
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47 428 Finally, another limitation could be the proportion of females who may have started  
48  
49 429 puberty in the course of the study. This implies changes in body composition. However,  
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3 430 both study groups (intervention and control) had a similar proportion of females with a  
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5 431 similar age, and this could cancel-out the effect.

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7 432 Further, EdA1-2 demonstrated that performing >4h/week after-school PA, plus having  
8  
9 433 dairy product at breakfast are protective factors. Hence, we believe that a participating  
10  
11 434 in >4h/week after-school PA, and continuing with a healthy breakfast, are key points in  
12  
13 435 preventing childhood OB.

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16 436

## 17 18 437 **CONCLUSION**

19  
20 438 Our school-based intervention is feasible and reproducible by increasing after-school PA  
21  
22 439 (to  $\geq 4$ h/week) in boys. Despite this improvement, there was no statistically significant  
23  
24 440 change in the prevalence of OB. This suggests that our intervention programme induces  
25  
26 441 healthy lifestyle effects (such as more exercise and less sedentary behaviour) which can  
27  
28 442 produce anti-obesity benefits in children in the near future beyond the limited length of  
29  
30 443 our current study. However, the effects on girls' behaviour need to be more closely  
31  
32 444 studied, together with a future repeat of our study in a different population.

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35 445

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38  
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53  
54 454 as well as the staff and parents of the pupils of the primary schools of Amposta, Sant  
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4  
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10 458 **COMPETING INTERESTS**

11 459 The authors declare that they have no competing interests.  
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16 461 **ETHICS**

17  
18 462 The EdAl-2 study was approved by the Clinical Research Ethical Committee of the  
19  
20 463 *Hospital Sant Joan of Reus, Universitat Rovira i Virgili* (Catalan ethical committee  
21  
22 464 registry ref 11-04-28/4proj8).  
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27 466 **DATA SHARING**

28  
29 467 Technical appendix, statistical code, and dataset available at Dryad repository in: "Data  
30  
31 468 from: EdAl-2 (Educació en Alimentació) programme: reproducibility of a cluster  
32  
33 469 randomised, interventional, primary-school-based study to induce healthier lifestyle  
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35 470 activities in children" (*expecting the definitive DOI*).  
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40 472 **LIST OF ABBREVIATIONS**

41  
42  
43 473 OB: Obesity

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45 474 OW: Overweight

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47 475 PA: Physical Activity

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49 476 mITT: modified Intention to Treat

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51 477 HPAs: Health Promoter Agents

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53 478 WHO: World Health Organization

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55 479 BMI: Body Mass Index  
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3 480 OR: Odds Ratio  
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8 **482 Authors' contributions**

9  
10 483 MG, EL, LT, RS designed the study (project conception, development of overall  
11  
12 484 research plan, and study oversight)

13  
14 485 MG, EL, LT, RQ, RS conducted research (hands-on conduct of the experiments and  
15  
16 486 data collection)

17  
18 487 EL, LT, MG, RS provided essential materials (applies to authors who contributed by  
19  
20 488 providing constructs, database, etc. necessary for the research)

21  
22 489 DM, EL, LT analysed data or performed statistical analysis

23  
24 490 RS, MG, LT, DM, EL drafted and revised the manuscript (authors who made a major  
25  
26 491 contribution). The final manuscript was read and approved by all co-authors

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29 492 RS, MG take primary responsibility for the study, and manuscript content  
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3 596 **FIGURE LEGEND**

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5 597 **Figure 1:** Eight topics of educational intervention activities

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7 598 **This figure shows the 8 topics of 12 educational intervention activities of EdAI program**

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9 599 **Figure 2:** Flow of subjects through the study

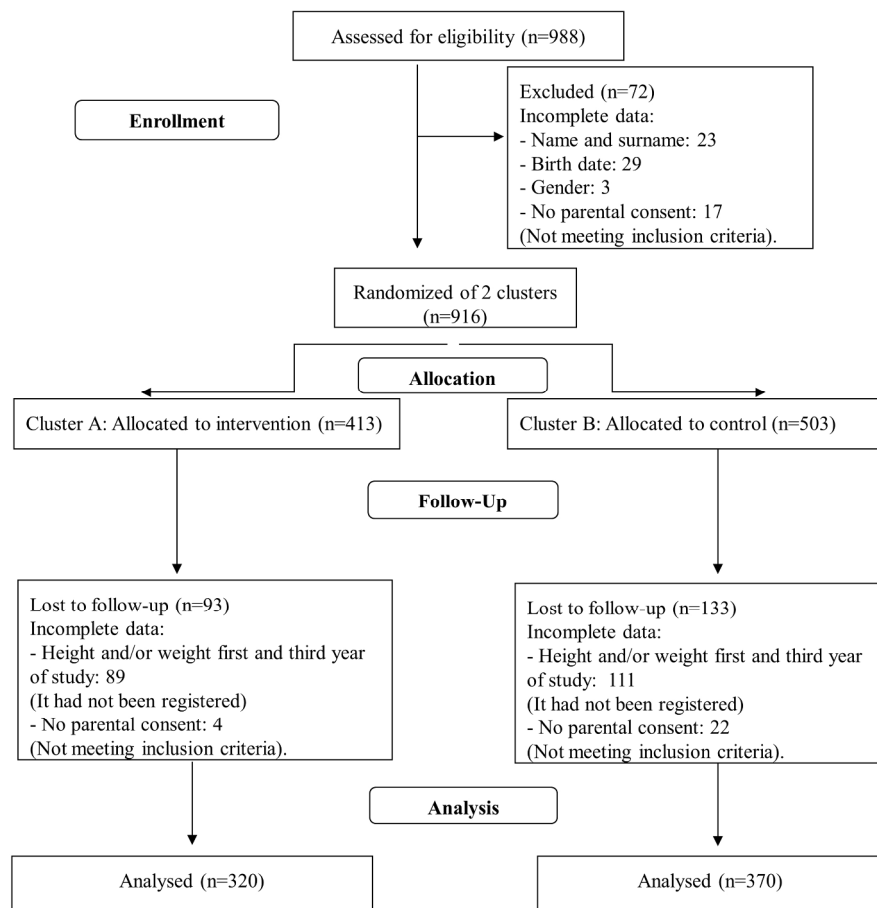
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11 600 Incomplete height and/or weight (measures of first and/or third academic year); No

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13 601 parental consent signed (first, second or third academic year).  
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This figure shows the 8 topics of 12 educational intervention activities of EdAI 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.



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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.

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3 Teaching practice used specific booklets designed to  
4 address the same lifestyle topics as the educational inter-  
5 vention activities (see Additional file 2). The booklets  
6 (teaching aids) were also employed by the regular school  
7 teacher over the 28 months of the program.  
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11 Another aspect of the intervention program was to in-  
12 volve parents in activities with their children. This inter-  
13 vention for parents was the same educational nutritional  
14 activities that were directed towards the children by the  
15 HPA. The intention was to have parents and their children  
16 interact in the healthy nutrition and lifestyle choices.  
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### 31 Section extracted to:

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34 - Tarro L, Llauradó E, Albaladejo R, et al. A primary-school-  
35 based study to reduce the prevalence of childhood obesity –  
36 The EdAl (Educació en Alimentació) study: a randomized  
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