UNIVERSITAT ROVIRA I VIRGILI

HEALTHY LIFESTYLES -EDUCATION AND HEALTH PROMOTION. EDUCACIÓ EN ALIMENTACIÓ (EDAL) COHORT.

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HEALTHY LIFESTYLES - EDUCATION AND HEALTH PROMOTION. EDUCACIÓ EN ALIMENTACIÓ (EDAL) COHORT

INTERNATIONAL THESIS

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FAIG CONSTAR:

Que aquest treball, titulat "*Healthy lifestyles – Education and Health Promotion. Educació en Alimentació (EdAl) Cohort.*", que presenta **Lucía Tarro Sánchez**, ha estat realitzat sota la meva direcció al Departament de Medicina i Cirurgia i que acompleix els requeriments per a poder optar al títol de Doctor.

Reus, 30 d'abril 2014

Les directores de la Tesi doctoral

Dra. Rosa SOLÀ ALBERICH BATISTA

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DADES IDENTIFICATIVES DE LA TESI DOCTORAL	
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	SI	NO
La tesi consisteix en un treball original de recerca	X	
El títol reflecteix acuradament el contingut de la tesi	X	
Les hipòtesis i/o els objectius de la tesi estan clarament formulats	X	
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Les conclusions de la tesi corresponen a les hipòtesis i/o objectius formulats	X	
La bibliografia està ben reflectida	X	

D'aquesta tesi es deriven les següents aportacions científiques:

- Giralt M, Albaladejo R, Tarro L, Moriña D, Arija V, Solà R. A primary-school-based study to reduce prevalence of childhood obesity in Catalunya (Spain)-EDAL-Educació en alimentació: study protocol for a randomised controlled trial. Trials. 2011;12:54. doi: 10.1186/1745-6215-12-54.
- Tarro L, Llauradó E, Albaladejo R, Moriña D, Arija V, Solà R,Giralt M. A primary-school-based study to reduce the prevalence of childhood obesity—the EdAl (Educació en Alimentació) study: a randomized controlled trial. Trials. 2014;15:58. doi: 10.1186/1745-6215-15-58.
- Tarro L, Llauradó E, Moriña D, Solà R, Giralt M. Five-year Follow-up of a Healthy Lifestyle Education Program (the EdAl Study): Two Years Post-cessation of Intervention. (editor submitted)

Altres comentaris sobre la qualitat de la tesi:

Autorització del director/a o codirector/s/a/es de la tesi doctoral

I en conclusió, s'emet l'informe FAVORABLE pel tràmit de dipòsit de la tesi doctoral i posterior defensa pública.

Reus, de Maig de 2014
Directores de la tesi

Nom i cognoms. Rosa SOLÀ ALBERICH. Nom i cognoms. Montse GIRALT BATISTA

A mis padres, mi hermano Héctor y Lluís

“Nothing in life is to be feared. It is to be understood.”

— Marie Curie

ABSTRACT

Abstract

Background

Obesity (OB) is one of the main determinants of avoidable disease burden. Schools are excellent learning environments where children spend a great deal of time to apply intervention program to reduce OB. Some school-based interventions focused on 6- to 12-year-old children have shown some beneficial effects on prevention of OB prevalence. Our hypothesis is that a regular, systematic, educational intervention in primary schools improves lifestyle choices and reduces OB developed by university students acting as Health Promoter Agents (HPA). The benefits achieved are maintained for several years after intervention cessation.

Primary Objective

1. To evaluate the effects of a 28-month EdAl primary-school-based program that promotes a healthy lifestyle including dietary and PA recommendations on OB prevalence in children 7-8 years of age.

Secondary Objectives

2. To design a health promotion program, named *Educació en Alimentació* (EdAl), for implementation by university student HPAs in primary schools.

3. To implement an EdAl program by HPAs in primary schools.

4. To verify that the benefits achieved, that is, OB prevalence reduction and PA practice increase, are sustained at 2 years post-cessation of the intervention in adolescents aged 11-13 years who participated in the EdAl program.

Methods

EdAl program is a randomized, controlled, school-based program performed by university students acting as HPA. There are two clusters, (designated cluster A and cluster B) as the units of randomization. The first cluster involves 24 schools from Reus (it was intervention group), and the second cluster involved 14 schools from Cambrils, Salou and Vilaseca (it was the control group) combined in order to obtain comparable groups. Data collected include name, gender, date and place of birth, and subsequently weight, height, body mass index (BMI) and waist circumference, each year of follow-up. Questionnaires on eating and PA habits are filled-in by the parents or guardians in baseline, end-of-study and 2 years follow-up post-cessation intervention program. The intervention has a duration of 3 school-academic years and, 2-year post-cessation it has continued the assessment of EdAl participants (control and intervention group).

The intervention program is based on 8 lifestyle topics. These 8 topics are developed in 4 educational activities/year for 3 years (a total of 12 activities; 1 h/activity) performed by HPA.

Descriptive data are presented as means and 95% confidence interval (95%CI) in variables with normal distribution, and Median (Interquartile Range) in variables with no normal distribution, or percentages (95%CI). Fisher's exact test was used to analyse differences between the intervention and control pupils in relation to the prevalence of OB. The odds ratios (OR) and the 95%CI were calculated for nutritional patterns, after-school physical activity and sedentary habits based on the questionnaire. The anthropometric measurements were calculated with ANOVA analyses adjusted by age. The main analyses were performed with the modified intention-to-treat. Statistical significance was set at $p \leq 0.05$. Data were analysed using SPSS statistics 20 package.

Results

After 28 months of EdAl program, OB prevalence in boys was decreased −2.36% in the intervention group (from 9.59% to 7.23%) and increased 2.03% (from 7.40% to 9.43%) in the control group; the difference was 4.39% (95% CI 3.48 to 5.30; p=0.01). The boys in the intervention group had an effective reduction of −0.24 units in the change of BMI z-score (from 0.01 to −0.04), compared to control (from −0.10 to 0.09); 5.1% more intervention pupils undertook PA >5 hours/week than control pupils (p= 0.02). Since baseline to 2-year follow-up, in the intervention group OB prevalence was reduced (-5.5%; p<0.01) and BMI z-score (-0.25; p<0.01). At 2-y EdAl program had post-cessation, in the intervention group, change of BMI z-score had an effective reduction in both genders, -0.26 units in boys and -0.32 in girls compared to control group. A 16% higher scholars percentage who practice ≥4 after-school PA h/week in intervention group (51.7% vs. 34.9%; p<0.01), while a 5% higher who watched ≥4 television h/day was in control group (4.4% vs. 9.5%; p=0.035).

Conclusions

1. The design of the EdAl program provided 12 activities implemented by HPAs that are designed to be entertaining yet informative and that are focused on healthy lifestyle concepts that can be achieved by improving diet and PA practice.

2. Medical, Physiotherapy and Human Nutrition and Dietetics students trained as HPAs enrolled the EdAl program.

3. The HPA university program can be used to train, design, standardize and promote healthy lifestyle activities effectively in different community environments.

4. At 28 months of the EdAl program, the prevalence of OB was reduced by -4.39% in boys but not in girls compared with the control groups, and the BMI

z-scores were reduced by −0.20 units in total and by −0.24 units in boys participating in the EdAl intervention, confirming its effectiveness, as the magnitude of these changes is greater than -0.15 units related to the changes in the control group.

5. At 2-years post-cessation, the OB prevalence decreased by -5.5% in adolescents in the intervention group.

6. At 2-years post-cessation, the BMI z-scores were significantly reduced by -0.29 units in the adolescents who were included in the intervention group of the EdAl program compared to those of the control group.

7. At 28 months of the EdAl program, the percentage of intervention participants performing ≥5 hours/week of after-school PA had significantly increased to 19.7%, or 5.1% more children compared to the control group.

8. At 2-years post-cessation of the EdAl program, 13.1% more adolescents in the intervention group performed ≥4 h/week of after-school PA compared to the control group.

9. The EdAl program stimulates the practice of after-school PA in adolescent participants, with 51% of intervention participants nearly achieving the WHO recommendations of 60 minutes/day of PA that is considered moderate to vigorous.

10. At 2-years of follow up, the participation in ≥4 h/week of after-school PA and the daily consumption of fruit were protective factors against OB, whereas ≤2 h/week of after-school PA was a risk factor for OB.

Global conclusion

A regular, systematic, educational intervention that promotes a healthy lifestyle and that includes dietary and PA recommendations is an easy tool that can be implemented by HPAs as part of their university curriculum to reduce the prevalence of OB and to increase the practice of after-school PA in children with these achieved benefits sustained at 2-years post-cessation of the intervention.

Perspectives

Long-term follow-up of the EdAl participants is needed to confirm the effectiveness of the EdAl school-based intervention program.

Furthermore, the EdAl program must be reproduced to compare it with other populations and to confirm its effectiveness and feasibility.

ABBREVIATIONS

Abbreviations

OB	Obesity
OW	Overweight
BMI	Body Mass Index
Y	Year
IOTF	International Obesity Task Force
WHO	World Health Organization
CDC	Center Diseases Control
Kg	Kilogram
PA	Physical Activity
HPA	Health Promoter Agents
H	Hour

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INTRODUCTION

1. INTRODUCTION

Children represent the future, and their healthy growth should be the first objective for all societies. For children less than 10 years of age, childhood is a vulnerable period and is influenced by environmental factors, such as dietary habits and lifestyles (WHO, 2010).

Healthy lifestyles acquired in childhood may be maintained in adolescence (ages 10 to 19 years, inclusive). Most adolescents make the transition into adulthood in good health and do not fall victim to epidemic diseases, such as obesity (OB), which tends to occur later in life (WHO, 2010).

Because OB status in adulthood is predicated on childhood and adolescent weight, OB prevention should begin early in life. An educational program is a tool to prevent OB (Reinehr & Wabistch, 2011).

1.1 Health Education and Health Promotion

1.1.1 Definitions

1.1.1.1 Health

"Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO, 2013).

In 1986, the Ottawa Charter for Health Promotion defined health as an individual or group's ability to satisfy needs and to change or cope with the environment. Health is a resource for everyday life, not the objective of living. Health is a positive concept emphasizing social and personal resources as well as physical abilities (WHO, 1986).

1.1.1.2 Wellness

Wellness is the optimal state of individual and group health that involves the comprehension of the physical, psychological, social, spiritual and economic potential of each individual and their respective family, community, place of worship, workplace and other settings (figure 1) (WHO, 2012).

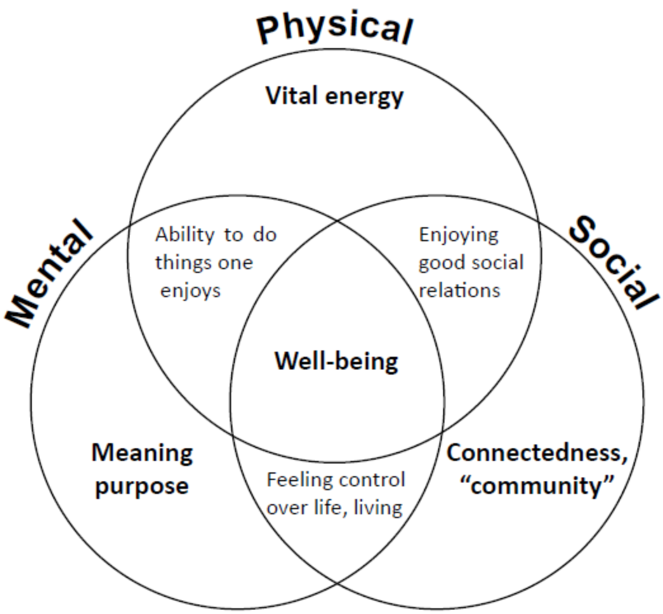

Figure 1. Source: Dimensions of health and well-being (WHO, 2012)

1.1.1.3 Health Education

Health education is any combination of learning experiences designed to help individuals and communities improve their health, according to WHO (WHO, 2012).

The WHO of Europe lends support to Member States:

- To provide technical consultancy and support to countries to improve the quality of education and the training of health professionals;
- To build national and institutional competence to introduce evidence-based approaches in education and practice;
- To advise on the Bologna Process in health professionals' education.

According to the WHO, health education is any combination of learning experiences designed to help individuals and communities improve their health by increasing their knowledge or influencing their attitudes (WHO, 2012). Furthermore, the Coalition of National Health Education Organizations and the Society for Public Health Education declared that health education is (Hanson et al., 2013):

- The social science to promote health and to prevent disease and premature death through education with voluntary behavior-change activities.
- The development of individual or group systematic strategies to improve health knowledge, attitudes, skills and behaviors.
- The influence and impact of individual or group health behaviors, besides those pertaining to living and working conditions, on health.

Health education provides information concerning healthy nutrition and physical activity (PA) using techniques such as the active participation of the target population to promote health as a process that permits people to improve their health.

Health education and promotion must assess the social determinants of health and use appropriate approaches to improve well-being.

1.1.1.4 Health Promotion

Health promotion focuses on physical, mental and social well-being, not solely with regard to disease, as in the WHO definition of health. Health promotion and education are needed when there is a behavioral risk and a link to living conditions.

Health promotion involves the improvement of influencing lifestyles, health services and environments. There are several definitions of health promotion, most of which are related to health as a general concept, involving community and individual participation. The most prominent health-promotion concept, from the Ottawa Charter (WHO, 1986), proposes a context for action that specifies five priority areas: building healthy public policies; creating supportive environments; strengthening community action; developing personal skills; and reorienting health services.

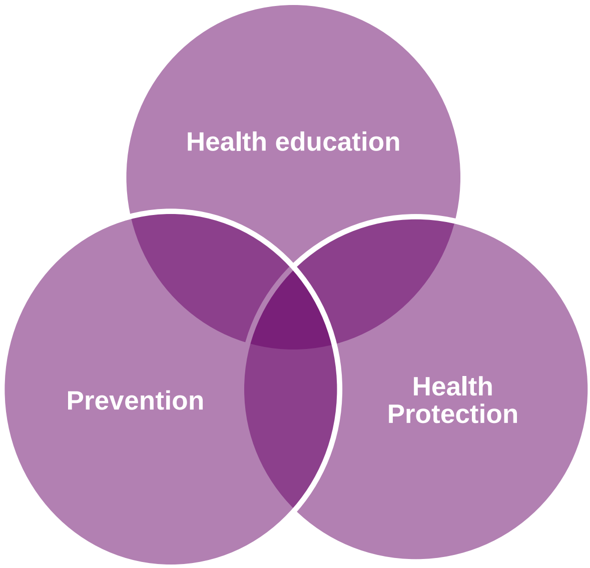

Figure 2. Model of Health Promotion (Health education: theoretical concepts, effective strategies and core competencies).

1.1.2 Service-learning

"Service-learning," which links academic coursework with community-based service, provides specific experiences and training for university students through medical and health-science courses and improves health status by increasing control over the determinants of a healthy lifestyle that have been developed and applied around the world (Doolittle et al., 2006; Porter, 2007). As a complex educational approach that involves students and communities, this training is based on several theories that reflect the active learning and the reflection of students, as demonstrated in 1938 by Dewey (Menamin et al., 2014). This learning process exhibits reciprocity between the learners and the communities (Doolittle et al., 2006; Durlak et al., 2011; McMenamin et al., 2014, McMenamin et al., 2010).

The heightened scientific rigor involved in service-learning research has been utilized within the prevention sciences (Doolittle et al., 2006).

Table 1. Service-learning provides the following educational benefits:
The application of theory to practice in the community environments,
Skill development by conveying appropriate health messages via public speaking, etc.,
Social responsibility, among other important benefits.

Table 1. Service-learning educational benefits (Azer et al., 2013)

1.1.3 Health Promoter Agents

Health Promoter Agents (HPAs) act as reference models for the general population, while the latter develop tasks and collaborations to promote health initiatives. The HPAs must maintain professionalism and a spirit of service while they acquire and assimilate bioethics.

The HPA concept has been applied in various communities under different titles, such as educator in family welfare, country doctor and medical assistant, district nurse and community health worker (Giralt et al., 2011).

Certain projects related to health have been developed for implementation by HPAs in their communities. In 2003, a project in Tanzania was developed in which young citizens (10-14 years of age) were trained as community HPAs to promote health in general and awareness of HIV/AIDS in particular (Kamo et al., 2008). The methodology of the program was to have the young people enact a light-hearted drama with serious messages about this disease. The results indicated that such a project could improve communication between adults and youth to overcome the stigma of HIV-positive status. Other habit-changing programs are important. For example, elevated levels of sugar in the diet may cause dental caries and other health problems, including more serious issues, such as metabolic derangements. Hence, dental and nutrition professionals must act as HPAs because it appears evident that interventions to change behavior have the potential to alter disease trends (Richards & Filipponi, 2011).

The MATCH project, a Mexican study (Swider et al., 2010), consisted of a multi-component community health worker-training program to disseminate the awareness of diabetes and its consequences in the community. The individuals selected as community health workers (termed "*promotoras*") received 90 h of initial training with follow-up supervision and continuous training. It is becoming increasingly clear that programs involving community HPA interventions are effective in improving health outcomes. However, more research in this field is necessary.

Students can perform self-reflection regarding the community situation before, during and after the service-learning activities (Azer et al., 2013).

1.2 School-based intervention

The school environment has the potential to introduce healthy lifestyles to children and adolescents across all socioeconomic and ethnic strata. Several programs involving lifestyle interventions at schools have been conducted, but the study results have been inconsistent (Harris et al., 2009; Zenzen & Kridli, 2009).

The implementation of effective prevention strategies at an early age are of highest importance, as school-based interventions have yielded very limited data on the effectiveness of childhood OB-prevention programs from randomized controlled trials, and no generalizable conclusions can be established (Collins et al., 2004; Verstraeten et al., 2012).

The effectiveness of school-based interventions involves several PA strategies, such as the following (Gutin, 2013):

- reducing the negative emphasis on restriction of energy intake,

- promoting adequate intervals of vigorous PA,
- assuring that the participation in vigorous PA is maintained,
- taking individual differences into account when interpreting the meaning of vigorous PA.

Two target groups have been identified for implementing school-based interventions: one group composed of all children and adolescents and the other focused on overweight children and adolescents. Usually, the results demonstrate greater success when the target group is obese or overweight (OW) because messages can be clearer and stronger than with the other target group. In the excess body weight target group, the reduction of body weight is immediately effective after the intervention program, but the evidence concerning post-cessation of the intervention is unknown (Silveira et al., 2011).

1.2.1 Age

The optimum age to implement a school-based intervention is between 7 and 8 years because children are more receptive to guidance at that age (Kuoppala et al., 2008). A recent review of school-based interventions for the prevention of OB prevalence in children found strong evidence to support the beneficial effects of excess weight prevention programs on body mass index (BMI), especially for those programs that targeted children 6 to 12 years of age (Waters et al., 2011). It might be concluded that OB prevention should begin by the age of 5-7 years because children who do not develop good health habits more easily become obese during older childhood and adolescence (Cunningham et al., 2014). Because OW and OB status in adulthood are predicated on weight during childhood and adolescence, OB prevention should commence early in life (Reinehr & Wabitsch, 2011). Moreover, a recent review showed that the risk of OW children becoming OW adults was at least twice that for normal-weight children (Singh et al., 2008).

1.2.2 The school environment

Schools are excellent learning environments where children spend a great deal of time (Lautenschlager & Smith, 2007). The school environment is regarded as a good setting for the promotion of health interventions among children because no other institution has as much contact time with the target population (Taylor et al., 2013; Wechsler et al., 2000). Schools provide an environment wherein nearly all children can be reached repeatedly and continuously, and where health education can be combined with health promoting environmental changes (Brug et al., 2010).

The large majority of childhood OB-prevention activities have occurred in primary and secondary schools (WHO, 2009).

Several studies involve comprehensive, multi-component programs with interventions targeting the school environment and that combine diet and PA (WHO, 2013).

1.2.3 Characteristics school-based interventions

To rectify the OB problem in children, The Institute of Medicine recommends a series of entry points to engage in a school-based program (Institute of Medicine, 2004):

a) To spend time performing PA in daily life.

b) To create environments for healthy foods and beverages those generate and reinforce easy choices.

c) To promote healthy messages about PA and nutrition in child and adolescent environments.

d) To prevent childhood OB in the educational environment.

The school-based interventions based on effective nutrition education and PA combined to yield both behavioral and excess weight changes (Hoelscher et al., 2013). Whereas the evidence is insufficient to conclude that school-based nutrition education interventions effectively reduce excess weight in children, the school-based PA interventions alone reduced BMI and excess weight in children by increasing PA leisure practice time and by reducing the television time. The school-based interventions that combine nutrition and PA are effective with regard to changes in BMI and demonstrate a behavioral improvement as demonstrated by increased PA and fruit and vegetable intake and decreased sedentary behaviors (American Dietetic Association, 2006).

School-based interventions can significantly reduce children's BMI, especially if they include a physical exercise component (Lavelle et al., 2012). Furthermore, several studies suggest that the combination of increasing PA and classroom curriculum (physical education) significantly decreases the prevalence of childhood OW and OB (Gonzalez-Suarez et al., 2009).

Specific strategies for promoting healthy eating and PA to prevent OW and OB in school-based interventions should include the following:

- Increased PA: In addition to providing health benefits in the general population, PA should be particularly focused on sedentary pupils and implemented in children and adolescents by the following:

    - The community
    - Individually targeted programs
    - School-based physical education
    - Interventions to provide social support for PA
    - Interventions to provide places for PA

- Increased fruit and vegetable consumption: the intake of these foods is associated with the prevention of some determinants of chronic and cardiovascular diseases and of certain cancers.

- Reduced sedentary lifestyle (television-watching, video-gaming): such behaviors can reduce the risk of OB in children and adolescents. Extended television-viewing periods may induce children to consume more high-calorie foods and snacks and may reduce their metabolic rates. Elements involved in child and adolescent health programs are described in figure 3.

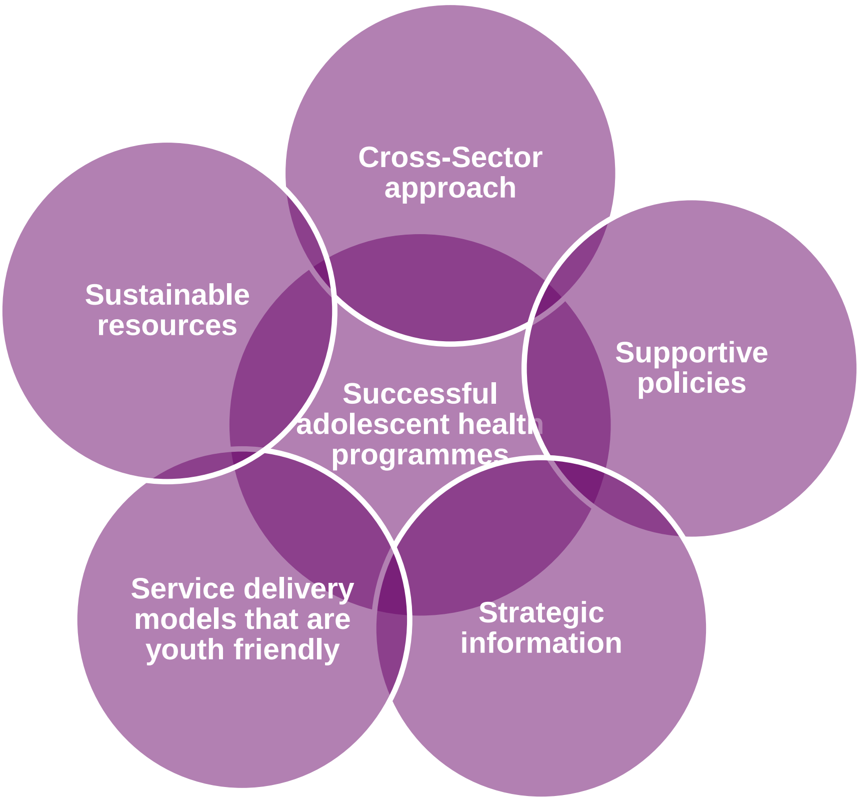

Figure 3. Children and adolescent health programs require different elements for participant involvement (WHO, 2012).

1.2.4 Effectiveness of school-based interventions

School-based interventions have been demonstrated to be effective in decreasing the prevalence of OW and OB but not in reducing BMI in treatment groups compared to the control groups (Gonzalez-Suarez et al., 2009). However, because BMI is not the most precise assessment, another measure of adiposity is needed (Pérez-Farinós et al., 2013; Pigeot et al., 2004; Silveira et al., 2011). The effectiveness of school-based intervention programs may be influenced by the duration of the program, the type of intervention, the age of the participants, the participation of parents, the school environment, socioeconomic factors, etc. Several studies have demonstrated the effectiveness of the programs that were implemented for more than 1 year and which at minimum demonstrated more successful results than interventions of less than 6-months' duration (Gonzalez-Suarez et al., 2009).

School-based programs published since 2007 (the initiation time of our school-based program) that have included PA, food tasting, and healthy lifestyles promotion as intervention criteria in childhood populations and their control groups are represented in table 2.

Table 2. School-based programs published from 2007 in children.

Program	N	Duration	Intervention	Conclusions	Reference
KOPS	1744 children aged 6-10-year	48 months	Health education and promotion in school program.	The program has sustainable effects on nutritional knowledge and remission of overweight being most pronounced in girls.	(Danielzik, Pust, & Müller, 2007)
School Nutrition Policy initiative	774 children aged 11-year	21 months	Education, policy, social marketing and agents.	It can be effective in preventing the development of OW among children in urban public schools.	(Foster et al., 2008)
School Fruit Tuck Shops	1612 children aged 10-11-year	12 months	School environment.	Fruit tuck shops were not effective in changing children's snacking behaviour in schools.	(Moore & Tapper, 2008)

Table 2. School-based programs published from 2007 in children.

Program	N	Duration	Intervention	Conclusions	Reference
Fruit and vegetables distribution program	436 children aged 8-year	12 months	Free school fruit and vegetable distribution, curriculum, food provision, communication and community.	A free distribution program and a multicomponent program can increase children's fruit consumption over time.	(Reinaerts et al., 2008)
AVall Study	725 children 5-6-year	24 months	Promotion of healthy eating habits and PA by means of the educational methodology Investigation, Vision, Action and Change (IVAC).	The educational intervention in healthy eating habits and PA in the school could contribute to lessen the current increase in child OB.	(Llargues et al., 2011)
Project Energize	1352 children aged 5-10-year	23 months	Energizer educated through information regarding replacing sugary drinks with water and importance of eating breakfast. Promotion of PA.	It has shown minor improvements in the health outcomes over 2 years, its potential long-term benefits cannot be ignored.	(Rush et al., 2012)

Table 2. School-based programs published from 2007 in children.

Program	N	Duration	Intervention	Conclusions	Reference
CHANGE: Creating Healthy, Active and Nurturing Growing-Up Environments	432 children 8-9-year	24 months	Educational curriculum. Providing 5 different fruit and vegetable options weekly.	The CHANGE study enhanced some aspects of rural students' dietary intake.	(Cohen et al., 2013)
"Healthy Schools" project	178 children aged 10-12-year	48 months	PA intervention curriculum.	Favourable effects on lower prevalence of OW/OB.	(Sigmund & Sigmundová, 2013)
The JuvenTUM project	724 children 8-9-year	12 months	Physical education program on PA, fitness, health, and promote healthier food availability and choices. Curriculum	It was increase PA and fitness but the influence is small, and this effect seems to be primarily favourable in those at risk such as obese children.	(Siegrist, Lammel, Haller, Christle, & Halle, 2013)

Table 2. School-based programs published from 2007 in children.

Program	N	Duration	Intervention	Conclusions	Reference
School-Based Intervention of Enhanced Physical Education in the Primary School	497 children 8-9-year	24 months	Improving physical abilities and influencing physical behaviour in PA education in three environments have been identified, the gym, classroom, and schoolyard.	No changes in the school curriculum are necessary (2 hours a week of lessons in the gym and the extra 30 minutes of daily PA) can be obtained during recreation time.	(Sacchetti et al., 2013)
Si! Program	2062 children 3-5-year	1-school-year (9 months)	. Promote cardiovascular health through the acquisition of healthy behaviours, dietary habits, PA patterns, human body and management of emotions.	It has demonstrated as an effective strategy for increasing knowledge and improving lifestyle habits in preschool children but needs to follow-up.	(Peñalvo et al., 2013)
A Novel Approach for Increasing Fruit Consumption in Children	218 children aged 9-year	12 months	Fruit intake, using teachers as the exposure vehicle, curriculum.	It can induce changes in fruit intake. The role of teachers improves healthy behaviours.	(Perikkou et al., 2013)

Table 2. School-based programs published from 2007 in children.

Program	N	Duration	Intervention	Conclusions	Reference
KISS Program	289 children aged 6.9-year	36 months	Physical education lessons per week and additional PA lessons. Motor skills tasks.	Improved body composition with less body fat and lower cardiovascular risk scores immediately after the intervention.	(Meyer et al., 2014)

1.2.5 Post-cessation follow-up of school-based interventions

Post-cessation intervention evaluations are a challenge because it is necessary to determine the sustainability and effectiveness of the intervention program on the reduction in the prevalence of OB and on improving healthy lifestyle habits in a school setting (Muckelbauer et al., 2009) (Reinaerts et al., 2008). There are few post-cessation intervention follow-up studies.

The CATCH study achieved a reduction in daily energy intake. The three-year post-cessation follow-up demonstrated that this reduction was maintained together with greater self-reported daily vigorous PA, whereas a non-significant difference in BMI was noted in the intervention compared to the control group (Nader et al., 1999).

The Cretan Health and Nutrition Education Program intervention at 4-year follow-up post-cessation showed higher levels of moderate-to-vigorous PA in boys in the intervention group compared to the control group, whereas no differences in OB prevalence were detected between the two groups (Manios et al., 2006). The benefits may be further maintained over time, but few studies provide examples of participant follow-up for longer than 4 years (Manios et al., 2006).

One of the first Spanish post-cessation follow-up studies of school-based interventions was the AVall study (Llargués et al., 2012). The AVall population was followed for 2 years post-cessation of the intervention in schools in Granollers (Spain), and the results showed a significantly greater increase in BMI in the control group compared to the intervention group, whereas the excess weight (OW plus OB) prevalence increased 8.5% in the control group and 1.8% in the intervention group (Llargués et al., 2012).

Post-cessation follow-up studies provide an important tool in the analysis of the long-term effects of school-based interventions. Additionally, such studies are useful for determining the optimal length, intensity, and long-term effectiveness of lifestyle interventions (Ho et al., 2012; Ortega Anta et al., 2013; Simon et al., 2008).

1.3 OW and OB

OW and OB are defined as the fat mass that may be unhealthy for people and that may contribute to the development of cardiovascular disease risk factors (WHO 2012, WHO 2003).

Childhood OB is associated with a higher chance of OB, premature death and disability in adulthood. In addition to increased future risks, obese children experience breathing difficulties, an increased risk of fractures, hypertension, early markers of cardiovascular disease, insulin resistance and psychological effects (WHO, 2013).

The assessment of OW and OB in children and adolescents is difficult because a standard definition does not exist, although international and national reference curves and tables may be used.

1.3.1 Measuring OW and OB

Because the bodies of children and adolescents undergo a number of physiological changes during growth, it is difficult to develop one simple index for the measurement of OW and OB in these groups. Depending on the individual's age, different methods are available to determine a healthy weight (WHO, 2010).

The definition of excess weight in children and adolescents based on BMI (Rolland-Cachera, 2011) is recommended for use by the International Obesity Task Force (IOTF) and WHO criteria to assess the prevalence of childhood and adolescence OW, OB and underweight.

1.3.1.1 BMI

BMI is the ratio: weight (in kg) / recumbent length or standing height (in m^2)

In adults, weight status is easier to calculate using BMI as described in table 3.

Table 3. Classification of adult underweight, OW and OB according to BMI

Status	BMI (kg/m^2)	Chronic disease risk
Underweight	<20	Low (but increase mortality and morbidity from other causes)
Normal weight	20-24.9	Average
OW	25-29.9	Increased
OB	>30	Moderate-very severe

Table 3. WHO BMI classification (WHO, 2013)

Nevertheless, the BMI of children and adolescents is not assessed by the same method as adults, and different methods have been proposed:

a) WHO

The WHO Multicentre Growth Reference Study was undertaken between 1997 and 2003 to generate new growth curves for assessing the growth and development of infants and young children (WHO, 2006). Approximately 8500 children were studied, with a focus on ages 0-5 and 5-19 years (or 61-228 months) and who represented widely different ethnic backgrounds and cultural settings (Brazil, Ghana, India, Norway, Oman and the USA) (WHO, 2006).

These growth curves provide an international standard that represents the best description of physiological growth for all children from birth to 18 years of age. These measurements were obtained before 2003 and thus were prior to the large increase of excess weight in children (de Onis, 2003).

b) IOTF

The IOTF collected data from 1963 to 1993, including information from approximately 97,876 males and 94,851 females from birth to 25 years of age. With its focus on references for children 2 to 18 years of age, the IOTF used the BMI information from six countries: United Kingdom, USA, Netherlands, Brazil, Singapore and Hong Kong. Centile curves were drawn such that age 18 passed through the widely used criteria of 25 and 30 kg/m^2 for adult OW and OB. These curves were used to construct country-specific centile curves along BMI 25 for OW and 30 for OB, and 16, 17 and 18.5 for thinness grades (1, 2 and 3) at age 18. The curves obtained represented an average of the countries by age with specific gender curves for each cut-off point (Cole et al., 2000; Cole & Lobstein, 2012).

c) Centers for Disease Control and Prevention (CDC)

The US 2000 Centers for Disease Control and Prevention (CDC) BMI charts were developed between 1963 and 1994 and focused on ages 2 to 20 years. The CDC uses percentile curves developed in two stages: empirical percentiles with parametric and non-parametric procedures and parameters obtained by final curves and z-scores (CDC, 2014). The limitation is that the CDC population base is from the US.

d) National Tables: Orbegozo Foundation

Growth curves and cut-off points are important in excess weight calculations. In Spain, various tables that were published by the Faustino Orbegozo

Foundation are frequently used in routine clinical practice to define BMI categories.

d.1) Hernandez et al., 1988: Data were obtained from 3 groups of 600 children, boys and girls (ages 0.5-9 years) who were followed for 9 years. The cut-off points were as follows:

- OW = percentile ≥90-91
- OB = percentile ≥97-98

d.2) Sobradillo et al., 2004: Data were obtained from 2 different studies: first, a cross-sectional study was performed to assess the precise characteristics of the child compared to the general population of his/her age and gender; and second, a longitudinal study was conducted to follow-up on the child's growth. The cut-off points were as follows:

- OW =percentile 85
- OB = percentile 95

When these data were obtained, both the BMI and the prevalence of excess weight were increasing. These data were used by the ALADINO study, a recent cross-sectional Spanish study with the aim of determining the prevalence of OW and OB in Spanish children aged 6-9 years in 2011-2013 (Pérez-Farinós et al., 2013).

d.3) Carrascosa et al., 2008: Data from 4 cross-sectional studies of 32,064 children, adolescents and adults (ages 0-24 years) were analyzed. The BMI values according to Carrascosa were higher than those in other older studies because there was an increase in OB prevalence, as demonstrated by a normal weight value that was greater (that is, closer to excess weight) than the older values. The cut-off points were as follows:

- OW = percentile 85
- OB = percentile 95

The WHO recommends using OW corresponding to BMI values between the 85^{th} and 95^{th} percentiles and OB corresponding to values greater than the 95^{th} percentile, with Spanish references citing the same percentiles but adapted to their own BMI population tables (Fundación Faustiono Orbegozo, 2011).

As described, several criteria have been used in studies that investigated childhood and adolescent OW, including OB, although currently no gold-standard criteria define OW and OB in this population. Furthermore, studies suggest that the IOTF criteria have poor sensitivity for OB. Using the IOTF criteria, an estimate of the magnitude of the childhood OB epidemic would be likely to be far less than when using country-specific analyses (Lang et al., 2011; Rolland-Cachera, 2011). However, the IOTF might be used because it was based on a larger sample size than other international references and it provides more opportunities to obtain prevalence comparisons between other studies that use this international reference (Cole et al., 2000; Cole & Lobstein, 2012; WHO, 2006). Universal cut-off points for BMI and waist circumference are not appropriate for worldwide use as they must take into account the ethnic or population-specific differences in the disease risk for any particular anthropometric measure.

The use of two international methods, the IOTF and WHO, to define OW and OB in children and adolescents generates uncertainty regarding different outcomes (Lang et al., 2011; Monasta et al., 2011; Rolland-Cachera, 2011; Walton et al., 2014). However, it has been recommended to use international references, such as those of the IOTF or the WHO, and one or more country-specific standards (Walton et al., 2014).

1.3.1.2 BMI z-score

The z-score is the deviation of an individual's value from the median value of a reference population, divided by the standard deviation of the reference population (or transformed to normal distribution). In children and adolescents (5-19 years of age), the WHO defines OW and OB as the proportion of adolescents with a BMI value for each age above + 1 z-score and above +2 z-scores, respectively, relative to the 2007 WHO growth reference median (de Onis et al., 2007).

The use of the BMI z-score appears to be preferable to the use of absolute BMI in describing values of each population (Lavelle et al., 2012).

1.3.1.3 Waist circumference

In 2011, the WHO established a guide for adults' waist circumference, as abdominal OB can increase the risk of metabolic complications and disease (table 4) (WHO, 2011).

Table 4. Circumference (cm)		
Risk of metabolic complications	**Men**	**Women**
Increased	≥94	≥80
Substantially increased	≥102	≥88

Table 4. WHO classification

Measures of abdominal OB are better predictors of cardiovascular risk than BMI, although combining BMI with waist circumference can improve the predictive accuracy in children and adults. Using waist circumference or the waist–hip ratio, the absolute risk of diabetes or hypertension (risk factors for cardiovascular disease incidence) is higher in some population groups than in Caucasian adults. Universal cut-off points for BMI and waist circumference are not appropriate for worldwide use because they must take into account the ethnic or population-specific differences in disease risks for any particular anthropometric measure.

Moreover, excessive abdominal fat in children and adolescent is defined as the following:

a) Waist-to-height ratio >0.50 cm/cm (a measure that has been related to cardiometabolic risk in children and adolescents (Schröder et al., 2014).

b) Equal to or greater than the gender- and age-specific 90th percentile of waist circumference.

c) Gender- and age-specific waist circumference cut-off values associated with increased trunk fat, as measured by dual-energy X-ray absorptiometry (Schröder et al., 2014).

However, a waist-to-height ratio of 0.50 has not yet been established as the optimal threshold for all populations and ethnicities; therefore, there is a need to establish population-specific waist to height ratio thresholds (Schröder et al., 2014). In fact, two studies in different populations have reported different waist to height ratio thresholds associated with cardiometabolic risk in children (Schröder et al., 2014).

Abdominal OB is highly prevalent in children and adolescents in Spain (Schröder et al., 2014). The need exists to incorporate waist circumference into routine clinical practice in addition to traditional measurements of weight and height.

1.3.2 OB and OW prevalence in children and adolescents

Childhood and adolescence are critical periods for the development of OW and OB conditions because approximately one half of OW adolescents and over one-third of OW children become obese adults (Franks et al., 2010; Wang & Lobstein, 2006). Furthermore, excess body weight (OW plus OB) in children before puberty or during puberty is a risk factor for excess weight in adulthood (Lanigan et al., 2010; Pelone et al., 2012; Singh et al., 2008).

Approximately 20% of children are affected by excess body weight across all countries, and in Greece, the United States and Italy, the percentage is closer to 30%, whereas in China, Korea and Turkey, less than 10% of children carry excess body weight (OECD, 2012). In most countries, boys have higher rates of OW and OB than girls (OECD, 2012).

The OB incidence (new cases per year) in the United States is 11.9% in children and adolescents 5-14 years of age, whereas boys have an OB prevalence of nearly 25% and nearly 18% in girls (age 11-18 years) (Cunningham et al., 2014). Between 1976-1980 and 2009-2010, there was a doubling in the prevalence of OB in children 2-5 years of age and a three-fold increase of OB in children 9-11 years-old and adolescents 12-19 years-old (Odgen et al., 2014).

In 2013, the WHO European Commission confirmed that in Spanish children 6-9 years of age, the OW prevalence was approximately 26.2% and that the OB prevalence approximately 18.3% (WHO, 2013), as described in the ALADINO study (Pérez-Farinós et al., 2013).

Considering the different regions of Spain and with a focus on children 2-17 years of age, it has been noted that Ceuta has the greatest prevalence of OB (24.7%), followed by the Canary Islands (13.9%), Murcia (12.6%) and Andalucía (11.7%). With regard to the prevalence of OW, the Balearic Islands have the highest percentage at 26.5%, followed by the Basque Country (25.5%), Galicia (23.8%) and Andalucía (21.3%). Furthermore, when the prevalence of OW and OB are considered together, 35.5% of the youth population of the Balearic Islands is overweight or obese, followed by Galicia at 34.6%, the Canary Islands at 34.5% and Andalucía at 33% (Instituto Nacional de Estadística, 2012). However, this increasing tendency towards excess weight in childhood and adulthood (Branca et al., 2007) observed in some countries (United Kingdom, France, Korea, United States and Spain) is stable despite the absolute rates being a cause for concern (OECD, 2012). The OB prevalence in children and adolescents is higher in the southern regions of Europe (Ahrens et al., 2011; Brug et al., 2012).

These studies demonstrate the importance of further research and interventions to understand the factors associated with the expansion and prevention of OW and OB in the youth population.

1.3.3 Determinants of OB

The multiple influences on a child's growth with regard to adequate nutrition, plentiful PA, and training and education for the development of healthy behavior patterns can be shaped by policies at the community, national and international levels to avoid OB.

Changes in lifestyle habits may be the principal cause of the increased OB prevalence in the general population as well as in children (Capewell & O'Flaherty, 2011; WHO, 2003).

Certain factors that may influence OB are described below.

1.3.3.1 Sleep time

Several studies have suggested that sleep time is an important factor in the prevalence of OB. Children who sleep <8 hours per day have a higher probability of developing OB (Garaulet et al., 2011).

The National Sleep Foundation recommends that children sleep 9 hours per night. Sleeping longer in older childhood (9.4 years of age) and younger adolescence (11.4 years of age) has been observed to be associated with higher BMIs. Thus, sleep appears to represent an important prevention opportunity in that sleep is modifiable (El-Sheikh et al., 2014). In Spain, the mean sleep time is 9.2 hours/day for boys and girls aged 5-14 years (Instituto Nacional de Estadística, 2012). The youth population that does not adhere to this sleep-time average might be at risk for OB.

Moreover, less sleep or poor sleep continuity were also associated with an increased OB risk, suggesting that a relationship between sleep loss and specific unhealthy eating behaviors exists and may be a risk factor for OB later in life (Burt et al., 2014).

1.3.3.2. PA

Physical inactivity is the fourth leading risk factor for global mortality (6% of deaths) for all individuals. Inactive people should begin with small amounts of PA and gradually increase the duration, frequency and intensity over time. In 2013, the WHO Member States agreed to reduce physical inactivity by 10% by 2025 in the framework of the "Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-2020" (WHO, 2013).

It is recommended that children and adolescents ages 5-17 should practice 60 minutes of moderate to vigorous PA daily to avoid the accumulation of excess body weight and the development of OB-related chronic diseases (Vander Ploeg et al., 2014; WHO, 2014). PA is essential for short- and long-term positive health outcomes (Zanotti et al., 2012).

The main aim of PA practiced for 60 minutes daily is achievable by school-based interventions in children and adolescents when practiced for longer than 1 year, producing effective beneficial impacts beyond PA improvement (Brown & Summerbell, 2009).

1.3.3.3 Sedentary habits

As previously noted, lifestyles have become increasingly sedentary, leading to physical inactivity. Console game-playing and television-viewing time has dramatically replaced PA and participation in organized sports (Burke et al., 2006; Garaulet et al., 2011).

a) Television in the bedroom: The high prevalence of bedroom televisions, independent of the time spent watching TV, is an excess weight risk factor among children and adolescents (Gilbert-Diamond et al., 2014). This association suggests that the effect of more television-viewing time is the reduction in children's sleep time.

1.3.3.4 Dietary habits

Since 2002, the Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases has recommended the consumption of at least 400 grams of fruits and vegetables per person per day (approximately equivalent to five servings). The preferred recommendation is to consume approximately 600 grams of fruit and vegetables per person per day.

A high intake of fruit and vegetables is associated with reduced cardiovascular disease (Bazzano et al., 2002; Evan et al., 2012; Hung et al., 2004; Woodside et al., 2013), some cancers (Boeing et al., 2012; Hung et al., 2004) and risk of mortality-morbidity (Bazzano et al., 2002; Capewell & O'Flaherty, 2011).

Children who do not consume adequate fruit and vegetable may be at risk for inadequate nutrient intake (Fildes et al., 2014; Skinner et al., 2002).

Furthermore, eating breakfast before going to school is inversely associated with childhood OB, and skipping breakfast is associated with higher BMI in adolescents and adults, whereas breakfast consumption can prevent OB in later years (Antonogergos et al., 2012).

Although the consumption of a Mediterranean diet has been demonstrated to have several health benefits, such as the prevention of chronic diseases and a lower BMI in the general population (Chrysohoou et al., 2004; Corella & Ordovás, 2014; Estruch et al., 2013; Schwingshackl & Hoffmann, 2014; Sofi et al., 2008), the specific effects of a Mediterranean diet on OB are unknown.

According to the consensus statement from the American Heart Association titled "Dietary recommendations for children and adolescents: a guide for practitioners", 8 healthy lifestyle topics were cited to improve and reinforce nutritional habits and healthy lifestyles (Gidding et al., 2006):

1. Healthy lifestyle: Taste (knowledge of previously unknown food items)

2. Healthy drinks

3. Vegetables and legumes

4. Candies and pastry vs. nuts

5. Healthy habits: Timetable (home meals preferably) and physical activity

6. Fruits

7. Dairy products

8. Fish

1.3.3.5 Socioeconomic level

Low socioeconomic levels are associated with excess weight prevalence in children and adolescents. In the United Kingdom, children and adolescents of low-income families have been associated with excess weight (Walton et al., 2014). Findings from other countries, such as the United States, Mexico, and Germany, suggest that low socioeconomic and low cultural levels are associated with excess weight in children and adolescents. Some studies have observed that educated mothers are associated with lower excess weight among their children (Mak et al., 2012; O'Dea et al., 2014).

1.3.3.6 Breastfeeding

Breastfeeding is a normal way of providing young infants with the nutrients they need for healthy growth and development. All mothers can breastfeed, provided they are offered accurate information and the support of their family, the health care system and society at large (WHO, 2003).

The WHO recommends exclusive breastfeeding for six months, with the introduction of age-appropriate and safe complementary foods at six months, and continued breastfeeding for up to 2 years or beyond (WHO, 2006; WHO, 2003).

In 2003, in Geneva, the WHO concluded that there is increased evidence of an association of lower blood pressure levels in childhood, a lower risk of developing OB, lower risk factors for cardiovascular disease and a lower risk for several chronic diseases (e.g., type 1 diabetes, celiac disease, some childhood cancers and inflammatory bowel disease) with breastfeeding than for feedings with milk formulas (WHO, 2003).

Several studies have demonstrated associations between breastfeeding and protective factors for child and adolescent OB (WHO, 2006).

1.3.3.7 Ethnicity

Commonly used cut-off points for waist circumference and waist–hip ratio are based on studies undertaken predominantly in populations of European origin (Fernández-Alvira et al., 2013). The importance of considering ethnic differences in the amount of body fat associated with waist circumference or the waist–hip ratio at different BMI levels was a primary motivation for an expert consultation upon which were based the findings of the 2002 WHO Expert Consultation on Appropriate BMI for Asian Populations and Its Implications for Policy and Intervention Strategies (WHO, 2004).

1.3.3.8 Gender

Gender differences in body composition of fat are evident at the fetal stage and become much more pronounced during puberty (Wells, 2007). After adjusting for differences in height, men have greater total lean mass and bone mineral mass and a lower fat mass than women; these differences continue throughout adult life. Women have more total adipose tissue than men, and these whole-body sex differences are complemented by major differences in tissue distribution.

Gender differences in body composition are primarily attributable to the action of sex steroid hormones, which drive the dimorphisms during pubertal development. In men, a reduction in free testosterone levels is associated with an increase in fat mass and a reduction in muscle mass, and both total and free testosterone levels are inversely associated with OB (Derby et al., 2006).

1.3.3.9 Cardiovascular Risk

Excess weight and the accumulation of fat tissue in childhood cause an increase of disease risk in childhood as well as in adulthood and are associated with chronic diseases, some types of cancer, diabetes mellitus and cardiovascular diseases (Barton, 2012; Estruch et al., 2013; Franks et al., 2010; Wojcicki & Heyman, 2010; Woodside et al., 2013). The development of cardiovascular risk is related to behavioral components that should be initiated by health promotion programs at an early age, when behaviors are first developed.

1.4 EdAl program

Considering all of the evidence presented within this framework, we designed the EdAl (Education in Alimentation) program, a regular systematic educational intervention in primary schools and implemented by university students acting as HPAs during 3 academic years with a 2-year post-cessation follow-up of the intervention program.

HYPOTHESIS AND OBJECTIVES

2. HYPOTHESIS AND OBJECTIVES

2.1 Hypothesis

Our hypothesis is that a regular, systematic, educational intervention in primary schools improves lifestyle choices and reduces OB. The benefits achieved are maintained for several years after intervention cessation.

2.2 Objectives

2.2.1 Primary objective:

1. To evaluate the effects of a 28-month EdAl primary-school-based program that promotes a healthy lifestyle including dietary and PA recommendations on OB prevalence in children 7-8 years of age (article 1).

2.2.2 Secondary objectives:

2. To design a health promotion program, named *Educació en Alimentació* (EdAl), for implementation by university student HPAs in primary schools (article 2).

3. To implement an EdAl program by HPAs in primary schools (article 2).

4. To verify that the benefits achieved, that is, OB prevalence reduction and PA practice increase, are sustained at 2 years post-cessation of the intervention in adolescents aged 11-13 years who participated in the EdAl program (article 3).

ARTICLES

3. ARTICLES

3.1 ARTICLE 1

A primary-school-based study to reduce the prevalence of childhood obesity – EdAl (Educació en Alimentació) study: a randomized controlled trial

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TRIALS

RESEARCH Open Access

A primary-school-based study to reduce the prevalence of childhood obesity – the EdAl (Educació en Alimentació) study: a randomized controlled trial

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Abstract

Background: Obesity is one of the main determinants of avoidable disease burden.
To implement a program by university students acting as "health promoting agents" (HPAs) and to evaluate the effects on obesity prevalence of the primary-school-based program that promotes healthy lifestyle, including dietary and physical activity recommendations over 28 months.

Methods: Two school clusters were randomly assigned to intervention (24 schools, 1,222 pupils) or control (14 schools, 717 pupils); 78% of pupils were Western European. Mean age (±SD) was 8.4 ± 0.6 years (49.9% females) at baseline. Generalized linear mixed models were used to analyze differences in primary outcome between both groups. Data collected included body mass index (BMI) every year. Dietary habits and lifestyle questionnaires were filled in by the parents at baseline and at the end of the study. The interventions focused on eight lifestyle topics covered in 12 activities (1 hour/activity/session) implemented by HPAs over 3 school academic years.

Results: At 28 months, obesity prevalence in boys was decreased −2.36% in the intervention group (from 9.59% to 7.23%) and increased 2.03% (from 7.40% to 9.43%) in the control group; the difference was 4.39% (95% CI 3.48 to 5.30; $P = 0.01$). The boys in the intervention group had an effective reduction of −0.24 units in the change of BMI z-score (from 0.01 to −0.04), compared to control (from −0.10 to 0.09); 5.1% more intervention pupils undertook physical activity >5 hours/week than control pupils ($P = 0.02$).
Fish consumption was a protector (odds ratio 0.39; 95% CI 0.23 to 0.67) while "fast-food" consumption was a risk factor for childhood obesity (odds ratio: 2.27; 95% CI 1.08 to 4.77).

Conclusions: Our school-based program, conducted by HPA students, successfully reduced childhood obesity prevalence in boys.

Trial registration: International Standard Randomized Controlled Trial Number: ISRCTN29247645.

Keywords: Childhood obesity, Healthy lifestyle, Obesity prevention, Intervention program, Health promoting agent

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Background

Obesity is one of the main determinants of avoidable disease burden [1-4]. The adverse effects of obesity on health status are not fully reversible and so a stronger focus on the prevention of obesity has been advocated [5]. Since overweight status and obesity in adulthood are predicated on childhood and adolescent weight, obesity prevention should start early in life [4].

Treatment to decrease childhood obesity, addressing different areas and focusing on behavioral changes towards healthier lifestyles, has been a means of reducing morbidity and mortality from non-communicable diseases [6]. Lifestyle has become increasingly sedentary. Playing console games and watching television [7] have dramatically replaced physical activity and participation in organized sports [8]. The consequence is a relationship between overweight and television viewing hours as part of a sedentary lifestyle. However, non-school computer use and reading were not part of this relationship [9-11].

One important target group is the child of school-age, especially when old enough to understand and young enough to be influenced (that is, the age-group around pre-adolescence) [12]. Schools are excellent learning environments where children spend a great deal of time [13]. Some school-based interventions focused on 6- to 12-year-old children have shown some beneficial effects on overweight prevalence, or percentage obesity [14,15]. A recent review of interventions for the prevention of obesity in children found strong evidence to support beneficial effects of obesity prevention programs on body mass index (BMI), specifically those programs targeting children aged 6 to 12 years [16].

Intervention duration, preferably 3 years, and parental involvement as a primary target of intervention, can help to reduce obesity [17]. However, the causes of failure of school intervention to prevent obesity still need investigating [4,18]. Waters and colleagues [16] suggested that it may no longer be justified to test short-term (3 months to 1 year), behaviorally-focused school-based interventions for 6- to 12-year-old children.

Our study (EdAl; *Educacio en Alimentacio*; Education in Alimentation) is a program that can reach most school children in our population [19]. Routinely, teachers have many tasks to perform and, perhaps, are too busy with new educational challenges. An alternative we proposed was to involve young students from medical and health science departments of the local university who, as part of their new curriculum, receive health education oriented towards school-based interventions. Hence, we designed the EdAl program with defined experimental activities to be conducted by university students given specific instruction aimed at training them to become "health promoting agents" (HPAs) as part of their undergraduate science/medical curriculum.

A recent meta-analysis recommends that research be encouraged to test innovative interventions which exploit new technologies, behavioral theories, and methodologies, including system science [20]. Hence, we proposed a program for the prevention of childhood obesity by implementing healthy lifestyle choices. The innovative design involved the use of university students as HPAs in local schools.

Our hypothesis was that a regular, systematic, educational intervention in primary school improves lifestyle choices and reduces obesity. The interventions were based on eight nutritional and physical activity objectives.

The aims of the study were: 1) to design a health promotion program for implementation by HPAs in primary schools; and 2) to evaluate the effects of a 3-year school-based program of lifestyle improvement, including diet and physical activity over a period of 28 months, on the prevalence of obesity.

Methods

The protocols, rationale, randomization, and techniques of study have been published in *Trials* [19]. This study was approved by the Clinical Research Ethical Committee of the Hospital Universitari Sant Joan of Reus, Universitat Rovira i Virgili (Catalan ethical committee registry #20; ref: 08-07-24/07aclproj1). The protocol conformed to the Helsinki Declaration and Good Clinical Practice guides of the International Conference of Harmonization. This study followed the CONSORT criteria (see the Additional file 1).

University program

The training and standardization of educational intervention activities to promote healthy lifestyles in schools were carried out over two university courses (basis of health education and behavior; strategy design, implementation, health program evaluations) carried out in the same university academic year for undergraduates from medical and health-science departments, and included training and standardization for each activity as well as the implementation of these activities in schools (45 hours per academic course as described in [19]) leading to the title of HPA. These two courses are taught in each of the three university undergraduate basic-science academic years. HPA students implemented the activities for which they had been training and standardizing in the second course. Hence, the university HPA in the first year of training implemented, in the first school academic year, the four activities focusing on four of the eight lifestyle topics. The following year, the second university HPA group developed four new training and standardization activities focusing on the other four of the eight lifestyle topics for implementation in the second school academic year. The third university HPA group implemented, in the third school academic year, four new training and standardization activities to reinforce the previous eight lifestyle topics.

Study population

The coordinating center in Reus developed a randomization scheme in which the schools in Reus were designated as Group A (intervention) and the schools in the three other towns of Cambrils, Salou and Vila-seca were designated as Group B (control). The socio-demographic indicators in all the towns surrounding Reus were similar. Children attending the schools in both groups (intervention and control) live in close proximity within each school's catchment area. Hence, after randomization, Reus schools were chosen for intervention, while the surrounding schools were the control population to avoid crossover of intervention details.

The research team arranged to meet all the schools in the proposed intervention group (Reus) and, following the explanation of the objectives, each school decided whether or not to take part in the study. The directors of the EdAl program explained the sequence of events of the EdAl activities and, subsequently, the EdAl coordinator arranged a meeting with every school that opted to participate. Intervention institutions were 24 schools involving 36 classrooms and 1,550 pupils in Reus. Control institutions consisted of 14 schools involving 39 classrooms and 800 pupils in the three surrounding towns of Cambrils, Salou and Vila-seca. The imbalance in enrollment was due to the high number of schools in the intervention group that were keen and enthusiastic to enter the EdAl program; we did not place any limit on the number of schools that wished to participate.

All strategies focused on children between 7 and 8 years of age. The program targeted the whole school community, including parents, pupils, staff and teachers. To be representative of the child population, the schools selected needed to have at least 50% of the children in the classrooms volunteer to participate. We offered the program to all schools, whether public (funded by the government and termed "charter" schools) or private.

Inclusion criteria were name, gender, date, place of birth and parental consent. These data were registered at the start of the program, while weight, height, body mass index, and waist circumference variable (identified set of anthropometric measures) were recorded in each of the 3 years. For logistic reasons, the first group of school children was enrolled in 2006 (children born in 1998–1999) and followed-up for 3 school academic years (2006–2009). A second group of school children was enrolled in 2007 (children born in 2000–2001) and also followed-up for 3 school academic years. Hence, the measurements were performed each school academic year between the years 2006 and 2010. In the intervention group, all children of the selected classrooms were exposed to the intervention, and the control group did not receive any type of intervention. The data were collected on all children, but only the data from individuals who provided written informed consent signed by parents or guardians in each academic year were included in the final analyses.

Questionnaires regarding eating habits (Krece Plus) developed by Serra Majem and colleagues [21], and physical activity, level of parental education and their lifestyles (AVall) developed by Llargués and colleagues [22] were filled in by the parents at baseline and at the end of the study.

Intervention program

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

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

Each of the eight topics was integrated within educational intervention activities of 1 hour/activity, prepared and standardized by the HPAs and then implemented in children's classrooms. In the first school academic year, we focused on four topics: 1) to improve healthy lifestyle; 2) to encourage healthy drinks intake (and avoidance of unhealthy carbonated/sugared beverages); 3) to increase vegetables and legumes consumption; and 4) to decrease candies and pastries while increasing the intake of fresh fruits and nuts. These corresponded to four standardized activities (1 hour/activity). In the second year, the remaining four of the eight selected lifestyle topics were addressed: 5) to improve healthy habits within a set timetable (home meals, teeth-brushing, hand-washing) and physical activity participation; 6) to increase fruit intake; 7) to improve dairy product consumption; and 8) to increase fish consumption. These corresponded to four standardized activities. Finally, in the third school academic year, four standardized activities were introduced that reinforced the eight lifestyle topics implemented in the previous 2 academic years. Thus, the intervention program was based on eight lifestyle topics incorporated in 12 activities which were disseminated over 12 sessions (1 hour/activity/session), and prepared, standardized and implemented as four activities per school academic year by the HPAs in the school classrooms. The activities or sessions were implemented every 2 weeks over a 2-month period, each academic year. All 12 activities or sessions were conducted over a period of 28 months (3 school academic years).

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

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

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

Outcomes

Primary outcomes included overall prevalence of obesity, as well as prevalence segregated by gender, according to the International Obesity Task Force [24] recommendations for better international comparisons of data. Secondary outcomes were changes (overall and segregated by gender) in measures of adiposity such as BMI z-score and waist circumference, and incidence and remission of excess weight (overweight + obesity), as well as changes in lifestyles such as eating habits and physical activity. Weight, height and waist circumference were obtained as described previously [19]. The prevalence of underweight was analyzed according to Cole and colleagues [25] using 17 kg/m^2 as the cut-off point. BMI z-score was analyzed according to the World Health Organization Global InfoBase [26].

Statistical analyses

Descriptive data are presented as means ± SD or percentages (and 95% CI). General linear mixed models were used to analyze differences between the intervention and control pupils with respect to the prevalence of obesity.

We estimated that, with a sample of 700 pupils per group, the study would have 83.5% power to detect a difference of 5 percentage points (range: expected 9% of obesity prevalence in intervention group and 14% in control group) between the intervention and control schools, with respect to the primary outcome (prevalence of obesity).

Anthropometric measurements were conducted at baseline when the pupils were second-third graders (7 or 8 year olds), the following year, and at the end of the study when they were fourth-fifth graders (10 or 11 year olds). Lifestyle questionnaires were filled in at baseline and the end of the third year of the study.

The numbers of subjects with any specific dietary habit were expressed as percentages of the total number of individuals being evaluated. In order to evaluate risk and protective factors for childhood obesity, logistic regression analyses were performed at baseline, with no distinction between control group and intervention group. The odds ratio (ORs) and the 95% CI were calculated for dietary patterns and lifestyles based on the Krece Plus Questionnaire [21] and the AVall Questionnaire [22], respectively. The main analyses were performed with the modified intention-to-treat population (that is, subjects with at least one post-baseline measurement of weight and height). The analysis did not use any imputation missing method, the implication being that missing data were random.

Results

University program

There were 60 HPAs enrolled in the program to conduct the 12 standardized activities.

Enrollment

Figure 1 shows the recruitment and flow of pupils in the intervention and control groups over the course of the study. The modified intention-to-treat population in the intervention group and the control group were 1,222 and 717 pupils, respectively. The rate of parental consent was 92%.

Tables 1 and 2 summarize the baseline characteristics of study participants. BMI, calculated as weight in kilograms divided by the square of the height in meters (mean ± SD), was 17.69 ± 3.19 kg/m^2 in the intervention group and 17.09 ± 2.93 kg/m^2 in the control group, while the medians (P25 to P75) were 16.90 (15.50 to 19.22) and 16.37 (15.15 to 18.40), respectively.

Table 2 also contains breastfeeding characteristics and parental education levels, which were similar in both groups.

Attrition rate

Figure 1 shows the recruitment and retention of pupils in the intervention and control schools. Among the 2,350 pupils assessed at the beginning of the second or third grade, 1,939 (82.5%) pupils (89.6% of those allocated to the control group and 78.8% of those allocated to the intervention group) were reassessed when they were in the fifth or sixth grade, and valid measurements

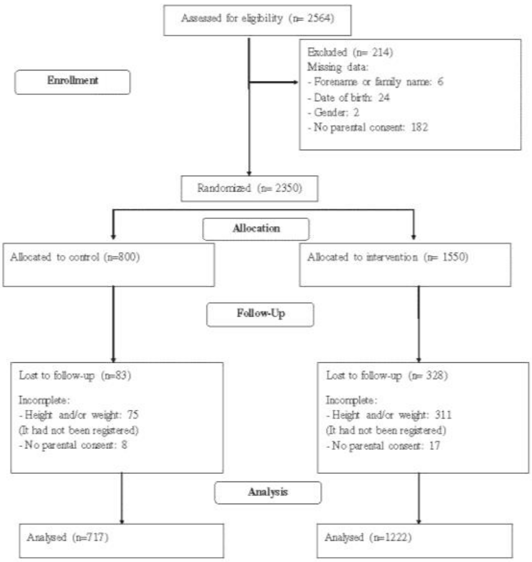

Figure 1 Flow of subjects through the study. Incomplete height and/or weight (measured in the second and/or third academic year) and no parental consent signed (second or third academic year) were two criteria that included the participants who moved to another school that was not taking part in the *Educacio en Alimentacio* (EdAl) study.

were obtained. Drop-outs in both groups are understood to be missing at random.

Primary outcome: prevalence of obesity

At 28 months, there was a significant difference of −4.39% in obesity prevalence in boys between the intervention and control groups ($P = 0.02$; that is, reduction from the first to the third year in the intervention group of −2.36% (9.59% to 7.23%) while in the control group this increased by 2.03% (7.40% to 9.43%) (Table 3)).

Secondary outcomes

BMI z-score, waist circumference, incidence and remission of excess weight (overweight plus obesity)

At 28 months of the study, BMI z-score was significantly lower in the intervention group compared to controls (overall: −0.03 vs 0.01, $P < 0.001$; in boys: −0.04 vs 0.09, $P < 0.001$; and in girls: −0.01 vs −0.03, $P < 0.001$). For pre- versus post-intervention, the BMI z-score increase was significant only in boys in the control group (−0.10 to 0.09, $P = 0.015$; Table 4). Waist circumference changed

Table 1 Baseline anthropometric characteristics of pupils: intervention group and control group

	Intervention group (n = 1,222)			Control group (n = 717)		
	Mean ± SD			Mean ± SD		
	Boys	Girls	Total	Boys	Girls	Total
Weight (kg)	31.26 ± 7.11	30.71 ± 7.26	30.99 ± 7.19	29.3 ± 6.75	29.53 ± 7.23	29.42 ± 7
Body mass index (kg/m^2)	17.73 ± 3.16	17.65 ± 3.22	17.69 ± 3.19	17 ± 2.77	17.17 ± 3.07	17.09 ± 2.93
Height (m)	132.3 ± 6.27	131.4 ± 6.53	131.9 ± 6.41	130.7 ± 6.73	130.4 ± 6.82	130.6 ± 6.78
Fat mass (kg)	6.44 ± 4.49	6.67 ± 4.15	6.55 ± 4.33	5.43 ± 3.42	6.47 ± 4.92	5.97 ± 4.3
Lean mass (kg)	24.71 ± 3.62	23.76 ± 3.09	24.26 ± 3.41	23.89 ± 3.97	23.31 ± 3.42	23.59 ± 3.7
Waist circumference (cm)	60.69 ± 7.85	58.98 ± 7.33	59.85 ± 7.64	59.8 ± 7.18	60.04 ± 8.28	59.93 ± 7.77

Body mass index was calculated as weight (kg)/height squared (m^2). Fat and lean mass were calculated using a Standard Beam Balance (Tanita TBF-300 Body Composition Analyzer; Tanita Corporation of America, Inc. 2625 South Clearbrook Drive, Arlington Heights, Illinois 60005, USA).

Table 2 Baseline characteristics of pupils: intervention group and control group

	Intervention group (n = 1,222)	Control group (n = 717)
	Total (%)	Total (%)
Ethnicity		
Western European	76.2	80.4
Eastern European[a]	4.2	4.3
Latin American	7.4	10.7
North African (Arab origin)	10.6	2.7
Sub-Sahara African	0.4	0.1
East Asian (Chinese origin)	1.1	1.3
Indian	0.1	0.4
North American	0.0	0.1
Breastfeeding[b]		
0–1 month	66.5	65.2
1–3 months	7.9	6.9
3–6 months	12.5	12.7
>6 months	13.1	15.3
Father's education level[b]		
Less than high school	3.3	1.2
High school	42.3	36.5
Technical training	36.5	38.9
Non-university higher education	1.3	1.4
University degree	16.6	22.1
Mother's education level[b]		
Less than high school	3.1	1.6
High school	38.7	31.6
Technical training	37.1	39.6
Non-university higher education	1.1	2.2
University degree	20.1	24.9

[a]Eastern European includes Russia and newly independent states (former USSR). [b]Data on maternal breastfeeding were solicited as this could be a possible confounding variable, as was the level of parental education.

significantly between the first and third year of the study in the intervention and control groups ($P = 0.043$).

At 28 months, BMI was not statistically different in the intervention and control groups ($P = 0.381$).

The incidence of excess weight was significantly higher in the control group (51/414, 12.3%, $P = 0.021$) than in the intervention group (57/709, 8%), particularly in boys in the control group (35/207, 16.9%, $P = 0.011$) compared to boys in the intervention group (33/352, 9.4%). Girls did not present significant differences between the control and intervention groups. Remission of excess weight was not significantly different between the intervention and control groups, nor in relation to gender.

Lifestyle evaluation (including eating habits and physical activity)

Tables 5 and 6 summarize dietary and lifestyle habits, including time spent doing physical exercise, watching television and playing video games and other leisure-time activities. In the intervention group, the percentage of pupils having a cereal breakfast (68.3% vs 72.9%; $P = 0.01$), a second fruit per day (38.3% vs 42.6%, $P = 0.03$), at least one vegetable a day (68.9% vs 72.6, $P = 0.04$), and vegetables more than once a day (25.7% vs 32.0%, $P = 0.001$) increased. Conversely, the percentage of legumes consumed more than once a week decreased in the control group (76.9% vs 70.9%, $P = 0.01$).

Physical activity change (from baseline to 28 months) analyzed by gender showed that the percentage of pupils that perform >5 hours/week physical activity in the intervention group were: boys 14.9 to 24.1%, $P < 0.001$; girls 8.2 to 15.5%, $P = 0.005$. In the control group the corresponding values were: boys 17.4 to 17.8%, $P = 0.860$; girls 9.6 to 11.9%, $P = 0.804$. There were no differences between groups in relation to gender.

Of these intervention pupils, more boys involved themselves in >5 hours/week physical activity than did the girls (24.1% vs 15.5%, $P = 0.001$), but this gender difference did not exist in the control group.

In the intervention group, the percentage of pupils consuming pastry before setting off for school decreased from 3.9% to 2.4% ($P = 0.005$), and in the mid-morning break decreased from 3.8% to 1.7% ($P < 0.001$). In the control group, the percentage of pupils consuming pastries in the mid-morning break also decreased (4.1% vs 2.2%, $P = 0.002$) while the consumption of fruit or natural juice increased (12.2% vs 15.5%, $P = 0.05$). There were no significant differences between groups with respect to other nutritional habits.

Furthermore, in the intervention group at the end of study, a higher percentage of boys than girls consumed dairy products for breakfast (94.1% vs 90.5%, $P = 0.038$) including a second dairy product daily (84.1% vs 77.4%, $P = 0.010$). The only differences between genders we observed were in relation to these two aspects of dairy products consumption.

It is interesting to note that the percentage of mothers dedicating >3 hours/week to sporting activities increased in the intervention group (22.1% vs 26.1%, $P < 0.001$).

We observed a larger reduction of BMI z-score in children who performed >4 hours/week physical activity (−0.07), whereas BMI z-score reduction was less in children who performed <4 hours/week physical activity (−0.03). This indicates that children who perform more hours of physical activity per week have a tendency to reduce their BMI z-score, albeit without achieving statistical significance in our present study ($P = 0.171$).

Table 3 Baseline and end of study measurements of categorized body mass indices in the intervention and control groups

Body mass index classification			Baseline (% (n))	End of study (% (n))	Change (%)	Baseline vs end of study (P value)	Intervention vs control (P value)
Underweight	Intervention	Boys	1.65 (10)	1.20 (8)	−0.45	0.636	0.768
		Girls	0.69 (4)	1.42 (9)	0.73	0.270	0.014
		Total	1.18 (14)	1.31 (17)	0.13	0.857	0.030
	Control	Boys	0.89 (3)	0.34 (1)	−0.55	0.627	
		Girls	2.43 (9)	1.87 (6)	−0.56	0.795	
		Total	1.69 (12)	1.13 (7)	−0.56	0.490	
Normal weight	Intervention	Boys	66.78 (404)	67.47 (449)	0.69	0.811	<0.001
		Girls	70.81 (410)	71.36 (451)	0.55	0.849	0.385
		Total	68.75 (814)	69.37 (899)	0.62	0.761	<0.001
	Control	Boys	80.77 (273)	67.00 (199)	−13.77	< 0.001	
		Girls	72.43 (268)	69.78 (224)	−2.65	0.450	
		Total	76.41 (541)	68.45 (423)	−7.96	0.0013	
Overweight	Intervention	Boys	21.98 (133)	24.10 (160)	2.12	0.386	0.001
		Girls	20.03 (116)	20.41 (129)	0.38	0.886	0.292
		Total	21.03 (249)	22.30 (289)	1.27	0.465	0.001
	Control	Boys	10.95 (37)	23.23 (69)	12.28	< 0.001	
		Girls	17.57 (65)	21.81 (70)	4.24	0.178	
		Total	14.41 (102)	22.49 (139)	8.08	< 0.001	
Obese	Intervention	Boys	9.59 (58)	7.23 (48)	−2.36	0.155	0.016
		Girls	8.46 (49)	6.80 (43)	−1.66	0.280	0.762
		Total	9.04 (107)	7.02 (91)	−2.02	0.075	0.047
	Control	Boys	7.40 (25)	9.43 (28)	2.03	0.390	
		Girls	7.57 (28)	6.54 (21)	−1.03	0.657	
		Total	7.49 (53)	7.93 (49)	0.44	0.836	

Prevalence of obesity and overweight were categorized using the cut-off criteria proposed by the International Obesity Task Force [24]. Prevalence of underweight was analyzed according to Cole *et al.* [25] using 17 kg/m^2 as the cut-off point. Categorical outcomes were analyzed using generalized linear models. Analyses were performed with the modified intention-to-treat analysis.

A lower prevalence of obesity of 3.9% was associated with a higher level of maternal education. A higher prevalence of 11.5% was associated with a lower educational level ($P < 0.01$). The same trend was observed in relation to paternal education level, although the differences were less statistically evident. In summary, after 28 months of the EdAl intervention the children's parents increased their involvement with their children's activities to >3 hours/week (29.5% vs 35.1%, $P < 0.001$ for fathers; 22.1% vs 26.1%, $P < 0.001$ for mothers), whereas in controls the increase in physical activity occurred only in fathers (34.4% vs 36.5%, $P = 0.01$) (Table 6). No significant differences were observed between groups with respect to hours per day devoted to television and/or video games.

Impact of some additional factors on obesity

At baseline with one obese parent, the child obesity prevalence was 9.06% while, with neither parent being obese, the prevalence was 5.91%. However, there were no significant differences between those children with, and those without, obese parents ($P = 0.214$) in relation to the intervention outcomes.

Figure 2 summarizes the ORs of obesity related to some of the more relevant dietary habits. For example, fish consumption was found to be a protective factor against obesity whereas fast-food consumption ≥1/week increased the risk of obesity.

Adverse events

Adverse events were not systematically collected in the questionnaire. However, no such effects were reported by the children or their parents/guardians.

Discussion

The hypothesis of our study was that an intervention focusing on lifestyle improvement that included diet and physical activity can reduce the prevalence of obesity in children. Our study sample is representative of current

Table 4 Secondary outcomes (body mass index z-score, waist circumference and body mass index) at baseline and at the end of the study in the intervention and control groups

			Baseline (mean (95% CI))	End of study (mean (95% CI))	Baseline vs end of study (*P* value)	Intervention vs control (*P* value)
Body mass index z-score	Intervention	Boys	0.01 (−0.07, 0.10)	−0.04 (−0.11, 0.04)	0.367	<0.001
		Girls	0.00 (−0.08, 0.08)	−0.01 (−0.09, 0.06)	0.755	<0.001
		Total	0.05 (−0.01, 0.11)	−0.03 (−0.08, 0.03)	0.388	<0.001
	Control	Boys	−0.10 (−0.20, 0.00)	0.09 (−0.03, 0.21)	0.015	
		Girls	−0.02 (−0.12, 0.08)	−0.03 (−0.14, 0.08)	0.941	
		Total	−0.11 (−0.18, -0.04)	0.01 (−0.07, 0.09)	0.105	
Waist circumference (cm)	Intervention	Boys	60.69 (60.07, 61.30)	67.44 (66.73, 68.16)	<0.001	0.269
		Girls	58.98 (58.39, 59.57)	65.96 (65.24, 66.67)	<0.001	0.108
		Total	59.85 (59.42, 60.28)	66.72 (66.21, 67.22)	<0.001	0.043
	Control	Boys	59.80 (59.04, 60.57)	66.39 (65.39, 67.38)	<0.001	
		Girls	60.04 (59.20, 60.88)	66.10 (65.10, 67.10)	<0.001	
		Total	59.93 (59.36, 60.50)	66.24 (65.54, 66.94)	<0.001	
Body mass index (kg/m^2)	Intervention	Boys	17.73 (17.48, 17.97)	18.86 (18.60, 19.13)	<0.001	0.442
		Girls	17.65 (17.39, 17.91)	18.76 (18.49, 19.04)	<0.001	0.596
		Total	17.69 (17.51, 17.87)	18.82 (18.63, 19.01)	<0.001	0.381
	Control	Boys	17.00 (16.71, 17.30)	18.48 (18.10, 18.86)	<0.001	
		Girls	17.17 (16.85, 17.48)	18.28 (17.92, 18.64)	<0.001	
		Total	17.09 (16.87, 17.30)	18.38 (18.12, 18.64)	0.001	

Continuous outcomes were analyzed through mixed models of repeated measures. Analyses were performed with the modified intention-to-treat analysis.

Spanish society with respect to economic, social and ethnic distributions. Our hypothesis was partially fulfilled in that the data showed a reduction in prevalence of obesity of 4.39% in boys, but not in girls. There were also significantly greater reductions in BMI z-scores in boys of the intervention group compared to the control group of boys. Waters and colleagues [16] stated that an intervention may be effective in reducing, relative to the change in the control group, the size of the change in BMI z-score pre- to post-intervention by −0.15 units. Specifically, a change of −0.20 units in total and −0.24 units in boys participating in the EdAl intervention reveals that the intervention was effective. However, BMI and waist circumference measurement were not statistically different between groups at 28 months. Further, the intervention group had less new cases of excess weight than the control group. This highlights the efficacy of our program in preventing (or reducing) childhood obesity.

Some studies, such as the AVall study [27], have shown BMI not to be reduced despite changes in lifestyle, albeit the intervention group having a lower increase in BMI than the control group. However, the control group also showed changes in lifestyle and physical activity. Nevertheless, the prevalence of overweight and obesity increased less in the intervention group than in control group [27,28]. Kriemler and colleagues [29] proposed applying a multi-component program, including increased physical activity, over the period of 1 school year. The target outcomes were physical and psychological health in young school children around 7 years of age. The results indicated a reduction in adiposity but not BMI; obesity *per se* had not been evaluated [29].

Schools have been proposed as the ideal places to conduct obesity prevention programs, to prevent weight gain or to reduce the prevalence of overweight and obesity [20]. Half of the published school-based interventions reported statistically significant beneficial effects compared with the control in at least some of the body-weight-related indices. These included BMI, BMI z-score, overweight and obesity prevalence, waist circumference, skinfold thickness, and percentage body fat [20].

The study by Wang and Lobstein [30] predicted 0.5% increase/year in childhood obesity prevalence in Mediterranean Europe. In our control group, the rate of obesity was shown to rise from 7.4% in year 1 to 9.4% in year 3 of the study; an increase of 2% in 3 years (that is, greater than the 1.5% predicted by Wang and Lobstein). Conversely, in the intervention group, obesity was reduced from 9.6% in year 1 to 7.2% in year 3 of the study, a reduction of 2.4% in obesity prevalence. At 3 years of intervention, obesity in the girls was reduced by −1.7%, and by −1.0% in the control group (that is, no statistically significant difference between the

Table 5 Food habits assessed at baseline and at the end of the study in the intervention and control groups

	Intervention group			Control group			
	Baseline (%)	End of study (%)	*P* Value	Baseline (%)	End of study (%)	*P* value	Intervention vs control (*P* value)
Krece plus questionnaire							
Breakfast	99.2	98.2	0.11	99.8	99.2	0.18	0.50
Dairy product at breakfast	91.9	92.3	0.72	95.4	93.0	0.08	0.09
Cereals at breakfast	68.3	72.9	0.01	74.8	74.5	0.89	0.13
Pastry at breakfast	17.5	15.3	0.17	16.2	15.1	0.62	0.70
Daily fruit or natural juice	70.9	72.9	0.30	78.1	78.9	0.95	0.59
Fruit, second per day	38.3	42.6	0.03	38.4	37.6	0.78	0.14
Dairy product, second per day	81.9	80.6	0.43	85.9	84.2	0.4	0.81
Vegetables, daily	68.9	72.6	0.04	72.7	73.8	0.67	0.42
Vegetables, >1 per day	25.7	32.0	0.001	23.2	26.9	0.13	0.50
Fish, regularly	73.9	74.8	0.65	76.10	74.3	0.4	0.35
Fast food, >1 per week	7.9	8.9	0.41	7.9	8.7	0.63	0.92
Legumes >1 per week	75.5	75.2	0.85	76.9	70.9	0.01	0.06
Candy >1 per day	12.9	12.0	0.52	11.6	9.9	0.32	0.68
Pasta or rice, daily	57.3	57.9	0.80	59.9	62.2	0.37	0.58
Cooking with olive oil at home	96.6	97.4	0.32	97.1	97.9	0.38	0.85
AVall questionnaire							
Before leaving home							
Dairy products	84.3	82.4	0.20	86.6	83.8	0.15	0.65
Pastry	3.9	2.4	0.005	2.8	2.6	0.15	0.50
Cereals	37.6	38.2	0.87	38.4	39.7	0.83	0.94
Fresh fruit or natural juice	20.9	20.6	0.07	18.8	18.5	0.21	0.93
Sandwich	23.9	25.2	0.45	19.1	22.1	0.93	0.69
Juice packaged/soft drinks	9.6	7.2	0.93	8.4	8.9	0.32	0.46
Break (Midmorning)							
Dairy products	17.3	12.7	0.79	13.7	10.1	0.29	0.51
Pastry	3.8	1.7	<0.001	4.1	2.2	0.002	0.95
Cereals	6.5	5.6	0.68	5.2	4.7	0.45	0.71
Fresh fruit or natural juice	12.5	12.7	0.59	12.2	15.5	0.05	0.18
Sandwich	45.5	49.2	0.09	43.3	48.3	0.08	0.71
Juice packaged/soft drinks	11.4	6.1	0.67	9.9	12.8	0.48	0.41

The parent or guardian completed a self-reported form at school, which included Krece Plus Questionnaire regarding nutritional habits [21] and AVall Questionnaire regarding lifestyles [22]; this included food items consumed at breakfast (before leaving home and midmorning). This questionnaire was filled in by parents twice during the study (at baseline and at the end of the study).

two groups). Furthermore, at baseline, the subgroup of obese and overweight represents 30.07% in the intervention group and 21.9% in the control group while, at the end of the study, the obese and overweight subgroup represents 29.32% and 30.42%, respectively (that is, in the intervention group the proportion remained almost the same while, in the control group, this proportion was increased by almost 8.5%).

The duration of the intervention program to reduce overweight and obesity is another factor that can influence the outcomes [16]. The present study suggests that a notable decrease in the prevalence of obesity and improvement in lifestyle in children to avoid overweight and obesity can be achieved in 28 months (that is, 3 school academic years).

In our study, the percentage obesity in girls remained relatively unchanged during the study. Physiological differences between boys and girls at around 10 to 11 years of age could explain these findings. Certainly, the differences in age-of-onset of puberty between girls and boys could

Table 6 Physical activity and leisure activities assessed at baseline and at the end of the study in the intervention and control groups

	Intervention group			Control group			
	Baseline (%)	End of study (%)	*P* value	Baseline (%)	End of study (%)	*P* value	Intervention vs control (*P* value)
Television and/or video games							
0–1 hours/day	7.9	6.8		8.2	9.4		
1–2 hours/day	42.4	40.5		46.0	42.8		
2–3 hours/day	33.3	34.1		33.3	32.1		
3–4 hours/day	10.4	12.7		7.7	11.1		
4–5 hours/day	3.9	3.5		3.8	3.4		
>5 hours/day	1.9	2.5	0.06	1.1	1.3	0.39	0.59
After-school physical activity							
0–1 hours/week	24.9	18.8		21.2	20.8		
1–2 hours/week	9.3	11.4		10.2	9.6		
2–3 hours/week	25.2	20.8		24.4	22.1		
3–4 hours/week	17.9	16.4		19.5	18.8		
4–5 hours/week	11.2	12.9		11.0	14.1		
>5 hours/week	11.4	19.7	<0.001	13.2	14.6	0.21	0.02
Leisure-time activity							
Park or garden, daily	61.4	62.7	0.63	61.7	64.6	0.24	0.52
Park or garden, weekend	52.9	52.6	0.94	44.2	45.9	0.44	0.51
Sport with father >3 hours/week	29.5	35.1	<0.001	34.4	36.5	0.01	0.47
Sport with mother (>3 hours/week	22.1	26.1	<0.001	26.3	28.9	0.06	0.43

The AVall Questionnaire is about lifestyles, and includes hours of television watched, physical activity after school and leisure-time activities [22]. This questionnaire was filled in by parents twice during the study (at baseline and at the end of the study).

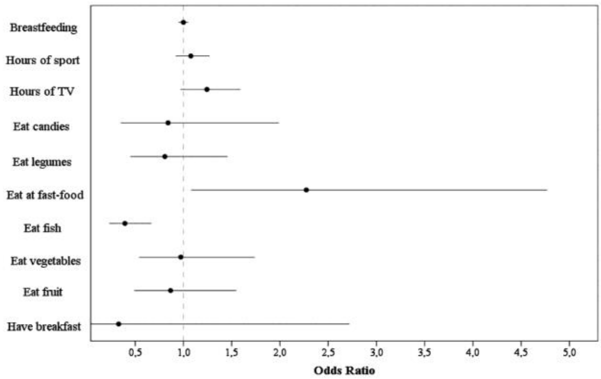

Figure 2 Obesity prevalence risk factors. These risk factors are listed in order of appearance in the questionnaires: breastfeeding, sporting activity time, hours watching television (TV) or video games, sweetened snacks and beverages, consumption of legumes, fast-food, fish, vegetables, fruit and having breakfast. The results showed that eating fish is a protector against childhood obesity while eating fast-food is a risk factor. These risk factors are measured as odds ratios.

explain some of the variation in BMI response observed in our study. Gortmaker and colleagues [31] observed obesity prevalence changes in girls, but not in boys; however, Planet Health had a duration of 2 years in which educational sessions were incorporated within the curricula by primary school teachers [31]. The present study had a duration of 3 years and the educational sessions were not part of the curriculum [19]. As outcomes, the incidence was different between the group of boys in EdAl, but not in Planet Health. On the other hand, Planet Health presented differences in girls in terms of remission, while the EdAl study does not. Thus, while the EdAl study has prevented childhood obesity cases, Planet Health has reduced the initial cases of obesity, both interventions inducing positive benefits in the intervention group of children. The findings of differences in outcomes indicate that, since mediators of anthropometric changes are different between males and females, future interventions need to be specifically tailored to gender [32].

We used the International Obesity Task Force [24] criteria for better international comparisons of data. The prevalence of obesity at baseline in our study was 9.0% in the intervention group, and 7.5% in the control group. The EnKid Study by Serra Majem and colleagues [21] in northeast Spain (conducted between 1998 and 2000) indicated 9.8% obesity at the same age as the participants in the present study. In Spain, using the same obesity definition criteria [24] as the present study, measurements made in 2012 by Sánchez-Cruz and colleagues showed 25.3% as overweight and 9.6% obesity prevalence in children between 8 and 13 years of age [33]. As such, the obesity prevalence in 2012 in the Sánchez-Cruz study is similar to the control groups of both genders and also girls in the intervention group in the EdAl study, whereas the boys in the intervention group of the present study showed the lowest obesity prevalence.

The observed efficacy of our intervention, with respect to BMI-related outcomes, may be due to our approach that focused on the nutritional quality of food intake, and included increasing the physical activity of the pupils in conjunction with their parents. At 28 months of intervention, an increase of up to 19.7% of children dedicated >5 hours/week to extra-curricular physical activities. The percentage of parents participating in the children's sporting activities of >3 hours/week also increased, and has led to a lifestyle change that has become characteristic of our intervention program.

The tendency towards a reduction in BMI z-score when children perform >4 hours/week physical activity needs to be confirmed in other long-term studies.

Our results showed that fish consumption was a protective factor against childhood obesity. A high proportion of fish in the diet is characteristic of the Mediterranean diet, but which children, in general, do not find very palatable. Recently, results from a study conducted in 1,764 healthy children and adolescents aged 6 to 19 years attending Seventh Day Adventist schools in the USA [34] indicated that the frequencies of consumption of grains, nuts, vegetables and low nutrient-dense foods were inversely related to the risk of being overweight, while dairy products increased the risk.

In the present study, weekly consumption of fast-food was identified as a risk factor for childhood obesity, despite the low percentage (<9%) of our pupils who consumed ≥1 fast-food items per week. A study involving 6,740 school-aged children aged 7 to 18 years in Xi'an in China indicated that sedentary lifestyles that included watching television, playing video games, and using computers are risk factors for obesity [35].

The Kiel Obesity Prevention Study showed that children from high Socio Economic Status families had some favorable, and sustained, effects with respect to BMI changes over an 8-year study period [36]. Furthermore, the PANACEA study concluded that parents' academic level was inversely associated with overweight and obesity prevalence, together with better adherence to the Mediterranean diet [37]. As such, these articles follow the same direction of trends as our current study. Nevertheless, long-term studies would be necessary to evaluate whether parental education levels have an influence on sustained effects post-intervention.

More specific investigation is required to establish the factors underlying obesity in girls at this age. The type of intervention that would be effective across the childhood population is eagerly sought. The cost-effectiveness of our type of obesity-prevention program is associated with social involvement by a public university. The feasibility of our program is based on offering course credits within the academic curriculum as an inducement for HPAs to participate in these educational interventions in schools. The dissemination of this program depends on selecting personnel who can undertake these activities in children. In a well-constructed program, the economic cost of obesity is reduced while social interaction between generations of young people is improved.

Concerning the limitation of the study in the school setting, there are possible sources of "contamination" of the control group. For example, if a school in the control group acquired some information deployed in the intervention group as a result of chatting among parents and school friends, this can motivate control students and families to adopt the intervention recommendations and, thus, they do not behave as controls should. Further, we believe that lifestyles and physical activity measured by self-reporting (parents of children) provide only a limited validity of these measures. Hence, it is necessary to assess the feasibility, effectiveness, and sustainability of this intervention study, as well as its reproducibility in the context of other schools, before the results can be generalized.

Conclusions

In conclusion, our primary-school-based program performed by HPAs reduces, within 28 months, the prevalence of obesity in boys by 4.39%, but not in girls.

Additional files

Additional file 1: CONSORT criteria was considered for this study.

Additional file 2: Booklets designed for teachers to address the same lifestyle topics as the educational intervention activities to scholars.

Abbreviations

BMI: body mass index; EdAl: *Educacio en Alimentacio*; (Education in Alimentation); HPA: health promoting agent; OR: odds ratios.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

MG, RA, LT, VA and RS designed the research (project, conception, development of overall research plan, and study oversight). MG, RA, LT, EL and RS conducted the research (hands-on conduct of experiments and data collection). RA, LT, MG, EL, VA and RS provided essential reagents, or provided essential specialist materials (applies to authors who contributed by providing constructs and databases necessary for the research). DM analyzed data and performed statistical analysis. RS, LT, EL, MG, and DM wrote the manuscript (authors who made a major contribution). The final manuscript was read and approved by all co-authors. RS and MG had primary responsibility for the study, and manuscript content. All authors read and approve the final manuscript.

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3.2 ARTICLE 2

A primary-school-based study to reduce the prevalence of childhood obesity in Catalunya (Spain) – EdAl-Educació en Alimentació: study protocol for a randomized controlled trial.

Giralt *et al. Trials* 2011, **12**:54
http://www.trialsjournal.com/content/12/1/54

TRIALS

STUDY PROTOCOL | Open Access

A primary-school-based study to reduce prevalence of childhood obesity in Catalunya (Spain) - EDAL-Educació en alimentació: study protocol for a randomised controlled trial

Montse Giralt[1], Rosa Albaladejo[2*], Lucia Tarro[2], David Moriña[3], Victoria Arija[4], Rosa Solà[5]

Abstract

Background: The EdAL (***Ed****ucació en* ***Al****imentació*) study is a long-term, nutrition educational, primary-school-based program designed to prevent obesity by promoting a healthy lifestyle that includes dietary recommendations and physical activity.
The aims are: 1) to evaluate the effects of a 3-year school-based life-style improvement program on the prevalence of obesity in an area of north-west Mediterranean 2) To design a health-promotion program to be implemented by health-promoter agents (university students) in primary schools.

Methods/Design: 1) The intervention study is a randomised, controlled, school-based program performed by university-student health-promoter agents. Initial pupil enrolment was in 2006 and continued for 3 years. We considered two clusters (designated as cluster A and cluster B) as the units for randomisation. The first cluster involved 24 schools from Reus and the second involved 14 schools from surrounding towns Cambrils, Salou and Vilaseca combined in order to obtain comparable groups. There are very good communications between schools in each town, and to avoid cross influence of the programs resulting from inter-school dialogue, the towns themselves were the unit for randomisation. Data collected included name, gender, date and place of birth at the start of the program and, subsequently, weight, height, body mass index (BMI) and waist circumference every year for 3 years. Questionnaires on eating and physical activity habits are filled-in by the parents at the start and end of the study and, providing that informed consent is given, the data are analysed on the intention-to-treat basis.
The interventions are based on 8 nutritional and physical activity objectives. They are implemented by university students as part of the university curriculum in training health-promoter agents. These 8 objectives are developed in 4 educational activities/year for 3 years (a total of 12 activities; 1 h/activity) performed by the health-promoter agents in primary schools. Control pupils follow their usual activities.
2) Courses on education and promotion of health, within in the curriculum of medicine and health sciences for university students, are designed to train health-promoter agents to administer these activities in primary schools.

Discussion: This controlled school-based intervention will test the possibility of preventing childhood obesity.

Trial registration number: ISRCTN: ISRCTN29247645

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Background

Obesity is one of the main determinants of avoidable disease burden [1-3]. *In lieu* of affordable, non-invasive, effective obesity treatment over the long-term, and because the adverse effects of obesity on health status are not fully reversible, a stronger focus on the prevention of obesity has been advocated [4]. Since overweight status and obesity in adulthood are predicated on childhood and adolescent weight, obesity prevention should start early in life. One important target group is the child of school-age i.e. the age-group around adolescence [5]. Although genetic factors may influence the susceptibility of individuals to weight gain [6], there is a consensus that changes in lifestyle activities have driven the current obesity epidemic [7]. Therefore, obesity prevention among school children should target dietary habits as well as physical activity and sedentary behaviour [4].

The school environment is regarded as a good setting for the promotion of health interventions among children because no other institution has as much contact time with the target population [8]. Schools provide an environment where almost all children can be reached repeatedly and continuously, and where health education can be combined with health promoting environmental changes [5]. The development of personal skills and coping practices involves the promotion of healthier behaviour, particularly with respect to nutrition and physical activity, and this can be achieved by health education. Health education attempts to provide information regarding healthy diets and physical activity by means of active participation of the target population and, in soliciting a response, to promote health as the process of enabling people to increase control over, and to improve, their health [9]. Officially, teachers are preoccupied with academic activities and an option may be to involve young students from medical and health science departments of the local university who, as part of their new curriculum, receive health education oriented towards school-based interventions.

Although some school-based interventions have had positive effects on overweight and/or obesity [10-12] most, particularly those involving large cohorts [13-15], have not.

The effects of a long-term school-based intervention on improving diet and increasing physical activity and reducing obesity in the north-west Mediterranean area are, as-yet, unknown. Our hypothesis is that a regular systematic educational intervention in primary school improves lifestyle choices and reduces obesity.

As such, the aims of the study are: 1) To evaluate the effects of a 3-year school-based program of lifestyle improvement, including diet and physical activity, on the prevalence of obesity; 2) To design a health promotion program for implementation by university students acting as "health promoting agents" (HPA) in primary schools.

Methods/Design

University program

The training focuses on promoting a healthy lifestyle via activities designed to reduce obesity, and to prepare the HPA to implement these educational interventions in schools.

The intervention approach combines constructs from education- and nutrition-based evidence.

Two courses are proposed:

Course #1: Methodology for the promotion of health in schools

Description of the course

Bases of health education and health behaviour

Theory and program planning: A study of determinants of health behaviour, factors influencing health behaviour, health behaviour theories and application of methodology are examined.

Health education curriculum and instruction: Research methods in health education; principles of evidence-based nutrition.

12 lectures of 1 h duration each, delivered over 15 weeks per academic year. Eight topics in nutrition are chosen for scientific evidence to improve consumption of some foods. Increased physical activity and healthy habits such as teeth-brushing and hand-washing are highlighted.

The objectives are:

1. Healthy lifestyle. Taste (knowledge of previously-unknown food items)
2. Healthy drinks
3. Vegetables and legumes
4. Candies and pastry *vs.* nuts
5. Healthy habits: timetable (home meals preferably) and physical activity
6. Fruits
7. Dairy products
8. Fish

Course #2. Interdisciplinary implementation of health education in schools

This course provides a careful examination of strategies of design, implementation, and health program evaluations, including training and standardisation of each activity as well as the performance of these activities in schools.

In the activity training, the primary school teachers are included in the jury to assess the performance of the HPA in the primary schools.

4 lectures of 1 h duration each; in 12 h for training and standardisation and 12 activities (1 h/activity/classroom) over 15 weeks per academic year

Schools

The school-based lifestyle modification program is designed as an interdisciplinary health promotion program performed by HPA.

All strategies are focused on children aged between 7 and 8 years. The program targets the whole school community including parents, pupils, staff and teachers within the school environment. The schools for the program needed to be representative of the child population. We offered the program to all schools whether public (funded by the government and termed "charter" schools) or private. To maintain independence between intervention and control schools, we selected schools from Reus (a town with about 100,000 citizens) to represent the intervention group, with Cambrils, Salou and Vilaseca (3 towns on the outskirts of Reus with about 70,000 citizens in total) to represent the control group. There are very good communications between schools within each town and, hence, to avoid cross influence between control schools that were masked with respect to intervention, the towns themselves were the units for randomisation.

The coordinating Centre developed a randomization scheme in which the schools in Reus (designated as group A) and the schools in the three others towns of Cambrils, Salou and Vilaseca (designated as group B) had similar pupil populations.

Randomisation defined A group as the intervention and B as the control group.

In our area of Spain, each classroom contains approximately 25 children (at most 27 children and, occasionally, 20-22 children). When the numbers of children exceed the state-recommended level, a new classroom at the same education level is opened in the school. Thus, there could be 2 or more classrooms for any specific level; some schools may even have 3 classrooms per level with 25-27 children per classroom. All classes are co-educational

Participating intervention institutions consist of 24 schools involving 36 classrooms (97% public or state funded "charter" schools and 3% private) involving at least 700 pupils in Reus. Participating control institutions consist of 14 schools involving 39 classrooms (96% public or state funded "charter" and 4% private) involving at least 700 pupils in the 3 surrounding towns of Cambrils, Salou and Vilaseca. The ethnic origin of control and intervention pupils are: 83.2% of Western European descent (mainly from Catalunya) and 16.8% are non- European; 7.8% from Latin America, 5% of North-African Arab descent, 3% recent immigrants from Eastern Europe (mainly Rumanian) and from other countries from the Asian Far East (such as China).

For a school to be included in the study, at least 50% of the children in the classrooms needed to have volunteered to participate. In the intervention group, all children of the selected classroom are exposed to the intervention. For logistics reasons, the first scholastic group was enrolled in 2006 and followed-up for 3 years (2006-2009), and a second scholastic group was enrolled in 2007 and also followed-up for 3 years. Thus the final measures are performed in the year 2010. The data are collected on all the children, but only the data from individuals (and their parents) who provided informed consent are included in the final analyses.

Name, gender, date and place of birth are recorded at the start of the program, while weight, height, body mass index (BMI) and waist circumference variables (identified set of anthropometric measures) are recorded in each of the 3 years of the study. The measurements were performed in May of the years 2006, 2007, 2008, 2009, and 2010.

Body weight was measured to the nearest 0.05 kg using a standard beam balance (Tanita TBF-300 Body Composition Analyzer, Brooklyn NY, USA). The set of anthropometric measurements was performed three times each academic year. The mean values were used in all subsequent statistical analyses.

To assess intra-observer variability, the anthropometric measurements were repeated in 20 children (10 boys and 10 girls). To assess inter-observer variability, all 5 observers conducted the 5 anthropometric measurements in 10 children. The standardisation of observers was performed in each year of the study [16].

If the child is lost to follow-up (the child is relocated to a different school, or the parents move to a different area) we are able to contact the child/parents via the name and date of birth; data that are held in the records of the local education authority. If the child moves to a school that is participating in the study, he/she is identified and followed-up within the new school. If, instead, the children move to another city outside the study area, they are lost to the study and are not replaced. We anticipate a loss of about 20% of pupils which, by chance, would be similar in intervention and control schools. The assumption would be that all losses are, also, by chance and the statistical methods used are robust enough to accommodate for randomly-produced missing values.

Questionnaires regarding eating habits (Krece-Plus) developed by Serra-Majem et al [17] and physical activity as well as the level of parental education and their habits [18] are filled-in by the parents at the start and conclusion of the study.

Intervention program

The intervention program consisted of three components:

1. Classroom practice by HPA to highlight healthy lifestyle habits

2. Teaching practice by HPA using books designed to include the nutritional objectives

3. Parental activities included with their children

In each of 12 activities (1 h/activity), the classroom practice consisted of three components:

1. Experimental development of activities regarding each healthy lifestyle habit

2. Assessment of activity performed in classroom

3. An activity developed for use at home

Approval

This study was approved by the Clinical Research Ethical Committee of the Hospital Universitari Sant Joan of Reus, Universitat Rovira i Virgili (Catalan ethical committee registry #20; ref: 08-07-24/07aclproj1). The protocol conformed to the Helsinki Declaration and Good Clinical Practice guides of the International Conference of Harmonization (ICH GCP). This trial is registered with International Standard Randomised Controlled Trial Register, number ISRCTN29247645.

Statistical Analyses

We estimated that with a sample of 700 pupils per group, the study would have 83.5% power to detect a difference of 5 percentage points between the intervention and control schools (9%-14%), with respect to the primary outcome (prevalence of obesity), setting the bilateral level of statistical significance at 5%.

Descriptive data are presented as means ±SD (95%CI) or percentages. Generalised linear mixed models were used to analyse differences between the intervention and control pupils with respect to the primary outcome.

Measurements were conducted at baseline when the pupils are 2^{nd}-3^{rd} graders (6 or 7 year olds) and at the end of the study when they are 4^{th}-5^{th} graders (9 or 10 year olds).

Primary outcomes include obesity (BMI $\geq 95^{th}$ percentile) and overweight (BMI $\geq 85^{th}$ percentile) based on the 1988 BMI tables of Hernandez [19]. We analysed obesity and overweight and a measure of thinness according to the Cole criteria [20,21] as well as other measures of adiposity such as BMI z score and waist circumference. The numbers of subjects having a particular dietary habit are expressed as percentages of the total number of individuals being evaluated.

Discussion

Developing personal skills and coping practices involving the promotion of healthier behaviours or habits can be induced by health education, particularly with respect to nutrition and physical activity. Nutrition and health education programs attempt to inculcate nutritional values or healthy diets by means of active participation of the target population, often involving person-to-person interactions.

Although genetic factors may influence the susceptibility of individuals to weight gain [6], there is growing awareness that recent changes in lifestyle habits underlie the current obesity epidemic [7].

We chose BMI as the measure of obesity and the changes in BMI as the effectiveness of the education program. Although waist circumference (WC) or skinfold thickness, particularly tricipital, or BMI z score can be used as the measure of obesity, BMI values are acceptable.

We proposed 3 evaluation methods based on the tables of Hernández et al and Cole et al [18,19] and the EnKid study of 2003 [22] because each one has advantages and inconveniences. Hernandez is the oldest, and the values of BMI are the lowest corresponding to data before the increase in prevalence of overweight and obesity. The Enkid study contains BMI values from 1998-2000, which are ten years more recent than that of Hernández [18], and describe the increase in BMI in a youth population. Obesity is defined as BMI $\geq 95^{th}$ percentile and overweight by BMI $\geq 85^{th}$ percentile in order to compare the results of United States guidelines [23]. The tables from Cole et al [19,20] enable comparisons to be made with European studies.

We standardised intra- and inter-observer variation to assure quality in the anthropometric measurements.

The results expected are the reduction of obesity prevalence based on improving lifestyle habits. Wang et al [24] had proposed that 1% increase/year in childhood obesity in Mediterranean Europe would induce an estimated 11.5% obesity and 30.2% overweight prevalence by the year 2010 and, as such, increase in prevalence of obesity and overweight will have an important health effect.

The lifestyle interventions in the program implemented by the university students being trained as HPA include experimental activities using natural food in the habitual diet, and increasing physical activity in the schools. Multi-component foods, physical education, class curricula, behavioural knowledge and skills, communications and social marketing, and the acceptability of healthy behaviour have been proposed as means of reducing BMI. However, the efficacy observed has been inconsistent. Evidence for effectiveness on anthropometrical obesity-related measures is lacking [25].

The challenge is to identify and to develop a cohesive hypothesis which combines educational and health promotion, to examine the effects of the intervention with valid and reliable measurements of the outcomes.

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Authors' contributions

MG participated in the conception and design of the study and its final approval, drafting and revising the manuscript. RA participated in designing the study, drafting and revising the manuscript. DM participated in designing the biostatistical methods of the study, drafting and revising the manuscript. RS participated in designing the study, drafting and revising the manuscript.

Competing interests

The authors declare that they have no competing interests.

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3.3 ARTICLE 3

Follow-up of a Healthy Lifestyle Education Program (the EdAl Study): Two Years Post-cessation of Intervention

Follow-up of a Healthy Lifestyle Education Program (the EdAl Study): Two Years Post-cessation of Intervention

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Disclosure of any potential conflict of interest

The authors have declared that no competing interests exist.

Clinical Trial Register: ISRCTN29247645Abstract

Abstract

Purpose: The EdAl (Educació en Alimentació) program conducted over 28 months in primary-school children reduced obesity (OB) prevalence in boys and increased voluntary physical activity (PA). The continued benefit post-cessation of EdAl is unknown. We assessed the changes in OB prevalence and healthy lifestyle in 11-13 year-old adolescents, the age group that had complete inclusion data available 2 years after the EdAl program's conclusion.

Methods: Adolescents (n=421 intervention; n=198 control) with data at baseline and at 2-year follow-up were recruited. Analyses included body mass index (BMI), BMI z-score, and lifestyle data (from questionnaires).

Results: Between baseline and 2-year follow-up, OB prevalence was reduced (-5.5%; p<0.01) and BMI z-score (-0.29; p<0.001) in intervention compared to control group. BMI z-score was effectively reduced in intervention in both genders: -0.26 units in boys and -0.32 in girls, compared to control group. The ≥4 h/week after-school PA was increased significantly by 13.1% in adolescents of intervention group, compared to control group (p=0.023), a tendency towards increased PA in intervention girls was observed (p=0.062).

At 2-year follow up, participating in ≥4h/week after-school PA (OR: 0.240; p=0.002) and daily fruit consumption (OR: 0.447; p=0.025) were protective factors against OB, while ≤2h/week after-school PA was a risk factor for OB.

Conclusions: At 2-year follow-up, the EdAl program induced a lowering of BMI z-score and OB prevalence, compared to control group. After-school PA practice can be stimulated in primary school as part of a healthy lifestyle, and maintained subsequently despite cessation of the intervention program.

Word Count: 247

Key Word: adolescents, prospective study, cohort studies, obesity, physical activity, follow-up studies

Abbreviations

OB: Obesity

OW: Overweight

PA: Physical Activity

BMI: Body Mass Index

mITT: modifying Intention-to-Treat

MANUSCRIPT

Implications and contribution

At 2-year follow-up, BMI z-score and OB prevalence were lower and the percentage of adolescents who practiced ≥4 h/week after-school PA was higher in intervention than control group. Benefits from a healthy lifestyle (including after-school PA) can be maintained following implementation of intervention in primary school.

[Word count = 46]

Introduction

Obesity (OB) prevalence in children has increased over the past decade and approaches epidemic levels (1). High levels of excess weight, such as overweight (OW) and OB, have been observed in southern European countries (2), such as Spain (3) where it remains high, at about 40% (4).

Most of the beneficial effects of intensive long-term interventions do not usually persist once the program is completed (5), and evaluating the long-term effect post-intervention is a challenge (6). Of the studies that have tested the effectiveness after cessation of the intervention (7-8), the CATCH study achieved a reduction in energy intake. This reduction was maintained together with a higher, self-reported, daily vigorous physical activity (PA). A non-significant difference in body mass index (BMI) was noted at 3 years of follow-up (7). Similarly, in the Cretan Health and Nutrition Education Program, higher levels of moderate-to-vigorous PA in boys occurred in intervention group at 4 years of follow-up (8), while no differences were detected in OB prevalence between intervention and control groups (9).

Long-term evaluation is necessary to determine the sustainability and effectiveness of intervention programs to reduce OB prevalence and to improve healthy lifestyle habits in a school setting (10). In our case, after 28 months of commencing the EdAl program, there was a significant difference of -4.4% in OB prevalence in the intervention group and a favorable reduction in BMI z-score (from 0.01 to -0.04), but only in boys. Furthermore, a significant 5.1% more boys and girls in the intervention group practiced ≥5 h/week after-school PA than the control group (11). To verify the sustainability of the benefits achieved, the present study sought to assess OB prevalence, anthropometric variables, healthy lifestyle habits, and PA in adolescents (11-13 years of age) who had participated in the EdAl program which was implemented between 2007/2008 and 2009/2010.

METHODS

The protocol, rationale, randomization, and techniques of EdAl program (trial registration number ISRCTN29247645) as well as the results at the conclusion of the program have been published in Trials (11, 12). The current study at 2-year follow-up post-cessation of intervention was approved by the clinical research ethical committee of the Hospital Universitari Sant Joan de Reus, Universitat Rovira i Virgili (Catalan ethical committee registry #20; ref: 12-03-29/3proj2).

The protocol conformed to the Helsinki Declaration and Good Clinical Practice guidelines of the International Conference of Harmonization (ICH GCP). The data were collected on adolescents who provided written informed consent (signed by parents or guardians) prior to the participation in the follow-up study. This 2-year follow-up post-cessation of the EdAL program is an observation study, and is described according to the STROBE Statement (13).

Study population

At 2-year follow-up, we analyzed the anthropometric and lifestyle choices of the original EdAl participants (now 11-13 year-olds). The present study covered 18 education centers in Reus (primary- and high-schools) and included 1222 adolescents. The control group was from 20 education centers in the surrounding towns of Salou, Cambrils and Vila-seca (schools and high-schools) and included 717 adolescents. With permission of the local education and health authorities, the original EdAl participants (born between 1st January 1999 and 31st December 2000 and who had participated in the original EdAl program in 2007/2008 academic course) were contacted to participate in the follow-up program conducted in 2012. The inclusion criterion was the availability of a data set that included, at least, name, gender, date and place of birth, weight and height in each adolescent between 11 to 13 years of age who had participated in EdAl program at baseline, whether in the intervention or in the control group. Exclusion criteria were EdAl participants that were not aged between 11-13 years, and who lacked one or other of the inclusion criteria. Each participant maintained the same identification number in the 2-year follow-up as in the original EdAl program. The current analyses include those children on whom complete anthropometric data were available from baseline (2007/2008) and at the 2-year follow-up.

EdAl intervention program and results achieved up to 2010

The EdAl program consisted of interventional activities of educational value (11,12) focusing on 8 lifestyle topics. These topics are based on scientific evidence indicating the value of improving nutritional food-item selection (and perhaps more importantly, the avoidance of certain other items), healthy habits such as teeth-brushing and hand-washing and, overall, adoption of activities that encourage physical activity (walking to school, playground games), and avoidance of sedentary behavior. These topics were covered in 12 activities (1h/activity/session) in 7-8 year old children, and implemented by health-promoter agents (HPAs) over 3 school academic years. The intervention carried-out in the primary-schools of Reus successfully reduced childhood OB prevalence in boys by 4.39%; an effective reduction of -0.24 units in BMI z-scores compared to controls. Of note was that there were 5.1% more pupils in the intervention group who practiced ≥5 h/week PA after school compared to the controls (11).

Outcomes

Weight and height were obtained as described in the protocol (12). Primary outcome was OB prevalence as measured as BMI according to the International Obesity Task Force (IOTF; 14) and WHO criteria (15). Secondary outcomes were adiposity measurement changes in BMI z-score, waist circumference and BMI, incidence and remission (i.e. the participant's change from OB status to OW or to normal weight) of excess weight (OW + OB). Also recorded were changes in eating habits using the Krece Plus questionnaire (16). This included 15 habitual food items such as dairy product at breakfast, cereals at breakfast, pastry at breakfast, daily fruit or natural juice, second fruit per day, second dairy product per day, daily vegetables, >1 vegetables per day, fish eaten regularly, fast food >1 per week, legumes >1 per week, candy >1 per day, daily pasta or rice, cooking with olive oil (16) and the level of PA (as measured on the AVall questionnaire) (17). Both questionnaires were filled-in at baseline (2007/2008) and at the 2-year follow-up. BMI z-score was analyzed according to the WHO Global InfoBase (18) which defines children with BMI z-score >2 as OB (15, 18).

Statistical Analyses

Descriptive data are presented as means or percentages and 95% confidence intervals (95%CI) or standard deviation (SD) for variables that follow normal distributions. General Linear Mixed Models (GLM) was used to analyze differences between the intervention and control group values in relation to OB prevalence. Repeated measures of GLM were used to analyze the trend of BMI z-score between baseline and 2-year follow-up. The number of subjects with specific data on TV h/day watched and h/week after-school PA were expressed as percentages of the total number of individuals being assessed. To evaluate risk- and protective-factors for childhood OB, logistic regression analyses were performed with the 2-year follow-up data, with no distinctions made between control group and intervention group. The odds ratios (OR) and the 95%CI were calculated for after-school PA and TV patterns based on the AVall Questionnaire (17).

Anthropometric data were analyzed using ANOVA adjusted for age.

The main analyses were performed with the modified intention-to-treat (mITT) population i.e. subjects with at least baseline and 2-year follow-up measurements of weight and height. The analysis did not use any imputation missing method; the implication being that missing data were random.

Statistical significance was set at $p \leq 0.05$. Data were analyzed using the SPSS software (version 20).

RESULTS

Participants

The children who completed the original EdAl study numbered 1222 and 717 in intervention and control group, respectively. Focusing on follow-up of EdAl participants, 674 adolescents in the intervention and 330 adolescents in the control group, born between 1st January 1999 and 31st December 2000, were identified as potential participants in the current follow-up study. Of these, 421 in the intervention group and 198 in the control group were analyzed. The retention rates were 421/674 in intervention (62.5%) and 198/330 (60%) in controls i.e. these had provided consent forms signed by the parent for the 2-year post-cessation of the intervention program and had, at least, weight and height measurements at baseline and at 2-year follow-up.

At the 2-year follow-up, the mean (±SD) age was 12.51 ± 0.52 years in intervention and 11.88 ± 0.35 years in control group.

Table 1 presents the anthropometric characteristics of the adolescents at 2-year follow-up. There were no significant differences between the two groups.

At 2-year follow-up, the OW prevalence (using IOTF tables) decreased (from 20.2% to 18.3%; p=0.020) while OB prevalence remained unchanged in intervention group.

Further, no significant differences were observed in OW and OB prevalence between the two groups (Table 2). However, using the WHO criteria (17), OB prevalence decreased in boys by 7.2% (p=0.006) and in girls by 3.8% (p=0.039) in the intervention group (Table 2) while no statistically significant differences were observed in the control group. At 2-year follow-up, the OB prevalence compared to baseline was reduced by -10% (p<0.01) in boys and was not statistically significantly different in girls of intervention group, relative to control group (Table 2).

Between baseline and 2-year follow-up, the OB remission was significantly higher in intervention group; 31 of 50 (62%) participants changed their OB status to best category OW, or normal weight, compared to the control group in which only 3 of 14 (21%) adolescents had changed their OB status. The difference in remission) in OB status between the two groups was statistically significant (p=0.014). Focusing on gender, adolescents with greater remission from OB to a better status such as OW or normal weight, were boys in intervention group (10/18 =55.6%) compared to boys of control group (0/8 = 0%) (p=0.001). In girls, there were no statistically significant differences between groups. The incidence of OB (according to WHO classification) was higher in girls of control group than in intervention group (5/100 = 5% vs. 2/191 = 1%, respectively; p=0.049).

Between baseline and 2-year follow-up, we observed: a ≥4h/week after-school PA increase of 29.5% in boys (p<0.001) and 20.7% in girls (p=0.004) in the intervention group while there was an increase of 12.9% in boys (p=0.049) and 2.8% in girls (p=0.664) in the control group. Thus, at 2-year follow-up, 13.1% more adolescents in the intervention group performed ≥4h/week after-school PA compared to control group (p=0.023).

By gender, there were no significant differences in boys or girls between groups with respect to ≥4h/week after-school PA, albeit a tendency towards increased PA in intervention girls was observed (p=0.062).

Normal-weight subjects in the intervention group increased their ≥4h/week after-school PA; rising to 31.8% in boys (p<0.001) and to 21.1% in girls (p=0.020), while no statistically significant differences were found in the control group. Furthermore, at 2- year follow-up, 5% more of ≥4 h/day TV was watched by the adolescents of the control group, compared to intervention group (p=0.013) (Table 4).

BMI z-score in intervention group was reduced by -0.25 units whereas control group had an increase of 0.04 units (p<0.001) difference of -0.29 units. By gender, the intervention boys decreased -0.21 while control boys increased 0.05 (p=0.004). Also, intervention girls decreased -0.29 and control girls increased 0.03 (p<0.001) (Table 3 and Figure 2). Of the 15 food items of the Krece Plus questionnaire (16), the only significant change was a 24% increase in mid-morning snack consumption (usually a mini-sandwich) in boys in the intervention group compared to boys in the control group (p=0.008).

Participation in ≥4h/week after-school PA (OR: 0.240; p=0.002) and daily fruit consumption (OR: 0.447; p=0.025) were protective factors against OB, whereas performing ≤ 2 h/week after school PA was a risk factor for OB.

DISCUSSION

At 2- year follow-up, the EdAl school-based intervention prospective cohort study showed a significant reduction of -0.29 units in BMI z-score and -5.9 % of OB prevalence in adolescents in the intervention group, compared with control group. The practice of ≥4 h/week after-school PA was increased significantly by 16.8% in adolescents of intervention group, compared to control group with a trend that was borderline non-significant in intervention girls. These results are similar to that achieved in the original intervention EdAl program in which a significantly greater number (5.1%) of boys and girls performed ≥5 h/week after-school PA than the control group (11). These data suggest that EdAl program has a beneficial effect in promoting PA in childhood, and was maintained over 2-year follow-up, even after cessation of the intervention.

In the adolescents of EdAl follow-up study, the prevalence of OB observed in adolescents was 10% less than that observed in the ENERGY project that described BMI distributions of 10 to 12 year-old participants from different European countries, including Spain (19). In the ENERGY project using WHO criteria, OW prevalence was higher; up to 37.6% in boys and 30.8% in girls. Our EdAl follow-up study observed 10% more OW in boys and in girls. OB prevalence was similar in the ENERGY and EdAl studies (18), albeit the EdAl adolescents had 2% less OB prevalence.

The BMI z-score has been proposed as an appropriate measure to verify the long-term beneficial effects of an intervention (5, 6), such as the EdAl program. As proposed by Waters et al (20), an intervention may be considered effective when the magnitude of the change in BMI z-score pre- to post-intervention is of the order of -0.15 units, relative to the change in the control group. Thus, in the present study, a change of -0.24 units in boys and -0.33 units in girls indicated that the EdAl intervention was effective in the long-term in both genders. Other long-term measures of intervention effectiveness have been proposed, such as OB prevalence. For example, as with our present study, the AVall study (21) observed a similar reduction of -3.6% in OB prevalence in the intervention group of school children. Similarly, a meta-analysis by Ho et al (22) showed that the most healthy lifestyle interventions produced a significant weight-loss in the intervention group (as measured by BMI and BMI z-score) but the post-treatment effect on BMI at 1 year from baseline was not maintained.

Our 2-year follow-up study showed a significant improvement of 24.9% in participants who performed ≥4 h/week after-school PA (26.8% at baseline change to 51.7% at 2-year post-cessation follow-up) in the intervention group. Further, these adolescents have obligatory 2h/week PA as part of their curriculum when they reach high school. Hence, these 51.7% of adolescents, practice at least 6 h/week PA. These results are in accord with the overall PA observed to be effective in prevention programs to reduce OW in adolescents (23). Further, in our 2-year follow-up, the increase in the numbers of adolescents in the intervention group who performed ≥4 h/week after-school PA with normal-weight at baseline, suggest that the intervention is effective not only in a primary-school healthy population, but is also effective in preventing OB over the longer-term because of PA practice being maintained. Also, in the present study, participation in ≥4h/week after-school PA is a protective factor against OB, while performing ≤ 2 h/week after school PA appears to be a risk factor for OB.

On the other hand, the mid-morning snack consumption (usually a mini-sandwich) increased significantly to 24% of boys in the intervention group compared to control group. Daily fruit consumption was a protective factor against OB. The association between different aspects of dietary intake and the development of OB in adolescents is controversial (24). Ortega et al found that missing breakfast and having lunch at home was a risk factor for childhood obesity in a Spanish population (25), but the study did not find any association with fruit intake.

Thus, the EdAl intervention program, which focused on healthy lifestyle (such as dietary choices and practice of extra-school PA) in primary-school children, continues to be effective as the children grow into adolescence.

Follow-up of children over several years is beset with difficulties regarding appropriate sample size acquisition, mainly because children move between primary- and high-schools. In this 2-year follow-up study, 291 adolescents of the intervention and 168 adolescents of the control group were excluded for reasons of mobility. From 2010 (end of the original intervention program) to 2012 (the current follow-up study) the emigration phenomenon observed was higher than usual in Spain. Due to economic difficulties in Spain, approximately 20,000 children between the ages of 10-14 years moved with their parents from Spain to another country in 2011, with particular impact in our area (26). This would seem to be reflected in the movement of our study children beyond the catchment area of the EdAl program, and could be a result of parental preference or geographic convenience i.e. when children finish primary-school they move to high-school that can be in a totally different locality, or even country. Also, the low retention rate around 61.7% can be explained by a high rate of parental decision not to provide consent and, as well, the decision of the children themselves not to participate in the program.

Follow-up studies constitute an important tool to analyze the long-term effects of school-based interventions. Also, they are useful in determining the long-term effectiveness of lifestyle interventions (22,23).

There are several limitations to our study: 1) we employed a 2-year follow-up evaluation focusing only on adolescents of 11-13 years of age because, in our data collection, they represented the age group in which we had the most sets of complete data (an inclusion criterion). This improved our sample size but, adolescents of other ages need to be studied; 2) after-school PA was evaluated with a questionnaire. Perhaps a more accurate method than questionnaires, such as using an accelerometer (27) needs to be used to evaluate PA; 3) in the absence of a consensus to define childhood OB, several alternative criteria should be included (28). WHO criteria (18) have been proposed because they combine more sensitivity and specificity than the alternative methods to determine BMI (29,30); 4) socio-economic status of the parents or guardians of participants was not determined. This is a potential confounder of OB and not having been measured constitutes a limitation of our study (31).

The generalizability of results from this study is that the original EdAl program was applied to entire schools (12). It is an easy-to-apply tool for implementation in primary-schools so that the amount of PA can be increased, as with other beneficial choices within the context of an overall healthy lifestyle. This intervention program can be applied equally in other cultures, providing specifics of the intervention are adapted to the habits and customs of the population in which it is to be applied.

CONCLUSION

At 2-year follow-up, the EdAl program induced a lowering of BMI z-score and OB prevalence, compared to control group. After-school PA practice can be stimulated in primary-school as part of a healthy lifestyle, and maintained subsequently, despite cessation of the intervention program.

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TABLE 1: Anthropometric characteristics of pupils at 2-yearfollow-up: Intervention and Control group

	Intervention Group (n = 421)			Control Group (n = 198)			p-value Intervention vs. Control	p-value Intervention vs. Control	p-value Intervention vs. Control
	Boys	Girls	Total	Boys	Girls	Total	Boys	Girls	Total
Weight¹; Kg	46.64 (45.27; 48.01)	46.44 (45.07; 47.81)	46.54 (45.57; 47.51)	44.31 (42.07; 46,54)	47.16 (45.15; 49.17)	45.85 (44.36; 47.35)	0.102	0.586	0.478
Height¹; cm	154.7 (153.6; 155.8)	154.6 (153.6; 155.6)	154.7 (153.9; 155.4)	153.2 (151.4; 155.0)	154.9 (153.5; 156.4)	154.1 (153.0; 155.3)	0.167	0.737	0.438
BMI¹; Kg/m²	19.34 (18.91;19.77)	19.29 (18.83; 19.75)	19.31 (19.00; 19.63)	18.70 (18.00; 19.40)	19.57 (18.90; 20.25)	19.18 (18.69; 19.66)	0.154	0.522	0.672
BMI z-score¹	0.39 (0.23; 0.55)	0.19 (0.04; 0.34)	0.29 (0.18; 0.40)	0.27 (0.02; 0.52)	0.33 (0.12; 0.54))	0.30 (0.14; 0.46)	0.412	0.281	0.901
Fat mass¹; Kg	7.79 (7.12; 8.38)	11.48 (10.72; 12.25)	9.65 (9.14; 10.17)	7.18 (6.28; 8.08)	10.74 (9.67; 11.81)	9.12 (8.37; 9.87)	0.267	0.264	0.249
Lean mass¹; Kg	38.84 (37.91; 39.77)	35.31 (34.66; 35.96)	37.04 (36.46; 37.62)	37.22 (35.70; 38.73)	35.82 (34.86; 36.78)	36.49 (35.60; 37.39)	0.267	0.264	0.249
Waist circumference; cm	73.04 (71.80;74.29)	71.69 (70.41; 72.98)	72.35 (71.46; 73.24)	71.26 (69.23; 73.29)	71.72 (69.82; 73.62)	71.54 (70.16; 72.92)	0.167	0.984	0.365
Hip circumference¹;cm	79.40 (78.33; 80.47)	81.36 (80.20; 82.52)	80.40 (79.60; 81.20)	77.89 (76.14; 79.64)	81.11 (79.40; 82.82)	79.62 (78.39; 80.86)	0.175	0.821	0.334

Notes to Table 1:

[1]Mean (95%CI)

[2]Weight, height, lean mass, waist circumference and hip circumference; values adjusted by age, using ANCOVA analysis

[3]Body mass index (BMI) calculated as weight (kg) ÷ height in m^2; values adjusted by age, using ANCOVA analysis

[4]Fat and lean mass calculated using a standard beam balance (Tanita TBF-300 Body Composition Analyzer)

[5]BMI z-score and fat mass not adjusted by age, but using ANOVA analysis

TABLE 2: Baseline and 2-year post-cessation: BMI (OW and OB) categorized by WHO and IOTF criteria

				Baseline % (n)	Follow-up % (n)	Baseline to Follow-up % change	p-value Baseline to Follow-up[3]	p-value Intervention vs. Control[4]
WHO Criteria[1]	OVERWEIGHT	**Intervention**	Boys	20.6 (43)	26.3 (55)	5.7 (12)	0.111	0.139
			Girls	22.4 (47)	20.8 (44)	-1.6 (-3)	0.636	0.655
			Total	21.6 (91)	23.5 (99)	1.9 (8)	0.456	0.141
		Control	Boys	12.2 (11)	18.0 (16)	5.8 (5)	0.267	
			Girls	23.1 (25)	17.9 (19)	-5.2 (-6)	0.286	
			Total	18.2 (36)	17.7 (35)	-0.5 (-1)	1.000	
	OBESITY	**Intervention**	Boys	15.3 (32)	8.1 (17)	-7.2 (-15)	**0.006**	1.000
			Girls	8.5 (18)	4.7 (10)	-3.8 (-8)	**0.039**	0.312
			Total	11.9 (50)	6.4 (27)	-5.5 (-23)	**0.000**	0.607
		Control	Boys	8.9 (8)	8.9 (8)	0 (0)	1.000	
			Girls	5.6 (6)	7.4 (8)	1.8 (2)	0.727	

Notes to Table 2

[1] WHO (World Health Organization) criteria cut-off points (2007) was used for BMI classification

[2] IOTF (International Obesity Task Force) criteria cut-off points (Cole, 2000) was used for BMI classification

[3] Fisher's exact test

[4] Differences between intervention and control pre-post intervention

TABLE 3: Baseline and 2-year post-cessation: BMI z-score in Intervention and Control group

			Baseline Mean (95%CI)	2-y Follow-up Mean (95%CI	Change Baseline to 2-y Follow-up Mean (95%CI)	Baseline *vs*. 2-y Follow-up p-value[4]	Intervention *v.s* control p-value[5]
BMI Z-score	**Intervention**	Boys	0.60 (0.44; 0.76)	0.39 (0.23; 0.55)	-0.21 (-0.33; -0.09)	**0.000²**	**0.004**
		Girls	0.49 (0.33; 0.64)	0.19 (0.04; 0.34)	-0.29 (-0.40; -0.18)	**0.000²**	**0.000**
		Total	0.54 (0.43; 0.66)	0.29 (0.18; 0.40)	-0.25 (-0.33; -0.17)	**0.000²**	**0.000**
	Control	Boys	0.22 (-0.03; 0.46)	0.27 (0.02; 0.52)	0.05 (-0.08; 0.19)	0.454²	
		Girls	0.30 (0.08; 0.52)	0.33 (0.12; 0.54)	0.03 (-0.08; 0.14)	0.555²	
		Total	0.26 (0.10; 0.43)	0.30 (0.14; 0.46)	0.04 (-0.04; 0.13)	0.341²	

Notes to Table 3:

[1] BMI z-score was calculated as "Growth reference 5-19 years" WHO tables

[2] Repetead Measures of GLM

[3] Baseline (2007-2008)

[4] Mc Nemar's test

[5] Fisher's exact test. Differences between intervention and control pre-post intervention.

TABLE 4: Physical and leisure activities assessed at baseline and 2-year post-cessation; Intervention and Control Group

		Intervention group			Control group			
		Baseline % (n)	**Follow-up %(n)**	**p-value Baseline to Follow-up [3]**	**Baseline % (n)**	**Follow-up % (n)**	**p-value Baseline to Follow-up [2]**	**p-value [3] Intervention vs. Control evolution**
TV and/or video games, h/day								
0-1h/day	**Boys**	60.0 (90)	46.5 (67)	**0.014**	54.9 (28)	36.8 (32)	**0.007**	0.116
	Girls	62.9 (95)	47.7 (72)	0.104	55.7 (44)	49.0 (50)	0.332	0.658
	Total	61.5 (185)	47.1 (139)	**0.005**	55.4 (72)	43.4 (82)	**0.007**	0.214
2-3h/day	**Boys**	37.3 (56)	49.3 (71)	**0.035**	43.1 (22)	55.2 (48)	0.143	0.392
	Girls	35.1 (53)	47.7 (72)	0.360	39.2 (31)	40.2 (41)	1.000	0.653
	Total	36.2 (109)	48.5 (143)	**0.029**	40.8 (53)	47.1 (89)	0.324	1.000
≥4h/day	**Boys**	2.7 (4)	4.2 (6)	0.625	2 (1)	8.0 (7)	0.219	0.148
	Girls	2.0 (3)	4.6 (7)	0.375	5.1 (4)	10.8 (11)	0.125	0.051
	Total	2.3 (7)	4.4 (13)	0.180	3.8 (5)	9.5 (18)	**0.022**	**0.013**

		Intervention group			Control group			
		Baseline % (n)	Follow-up %(n)	p-value Baseline to Follow-up [3]	Baseline % (n)	Follow-up % (n)	p-value Baseline to Follow-up [2]	p-value [3] Intervention vs. Control evolution
After-school physical activity, h/week								
0-1h/week	**Boys**	20.7 (31)	15.4 (22)	0.263	24.0 (12)	21.3 (19)	1.000	0.498
	Girls	29.7 (44)	28.5 (43)	1.000	31.2 (24)	37.9 (39)	0.307	0.107
	Total	25.2 (75)	22.1 (65)	0.382	28.3 (36)	30.2 (58)	0.500	0.051
2-3h/week	**Boys**	48.0 (72)	23.8 (34)	**0.005**	44.0 (22)	33.7 (30)	0.152	0.692
	Girls	48.0 (71)	28.5 (43)	**0.010**	45.5 (35)	35.9 (37)	0.136	0.872
	Total	48.0 (143)	26.2 (77)	**0.000**	44.9 (57)	34.9 (67)	**0.027**	0.617
≥4h/week	**Boys**	31.3 (47)	60.8 (87)	**0.000**	32.0 (16)	44.9 (40)	**0.049**	0.381
	Girls	22.3 (33)	43.0 (65)	**0.004**	23.4 (18)	26.2 (27)	0.664	0.062
	Total	26.8 (80)	51.7 (152)	**0.000**	26.8 (34)	34.9 (67)	0.073	**0.023**

Notes to Table 4

[1] Physical activity and TV hours were analyzed at baseline and at 2-year follow-up

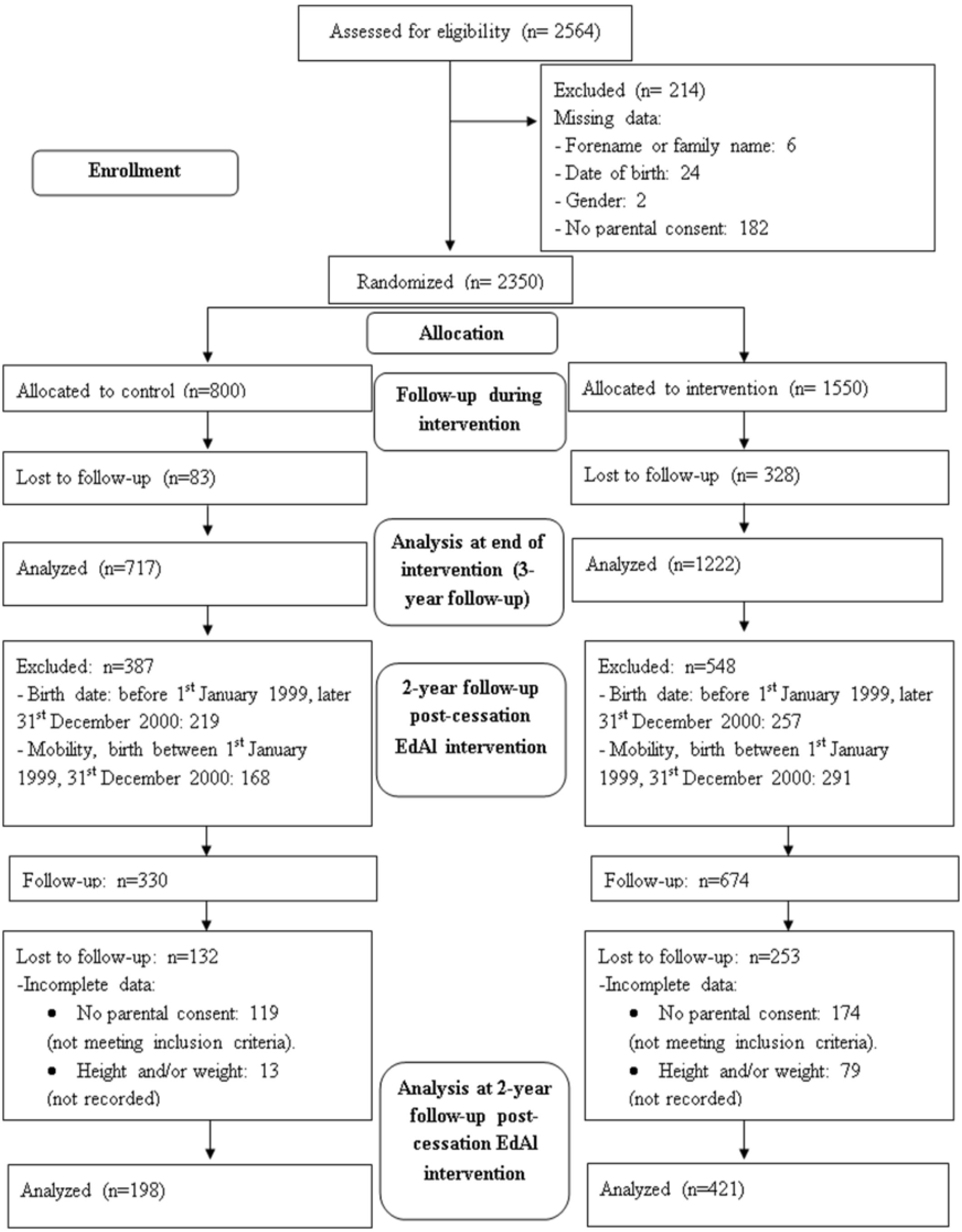
[2] McNemar's test

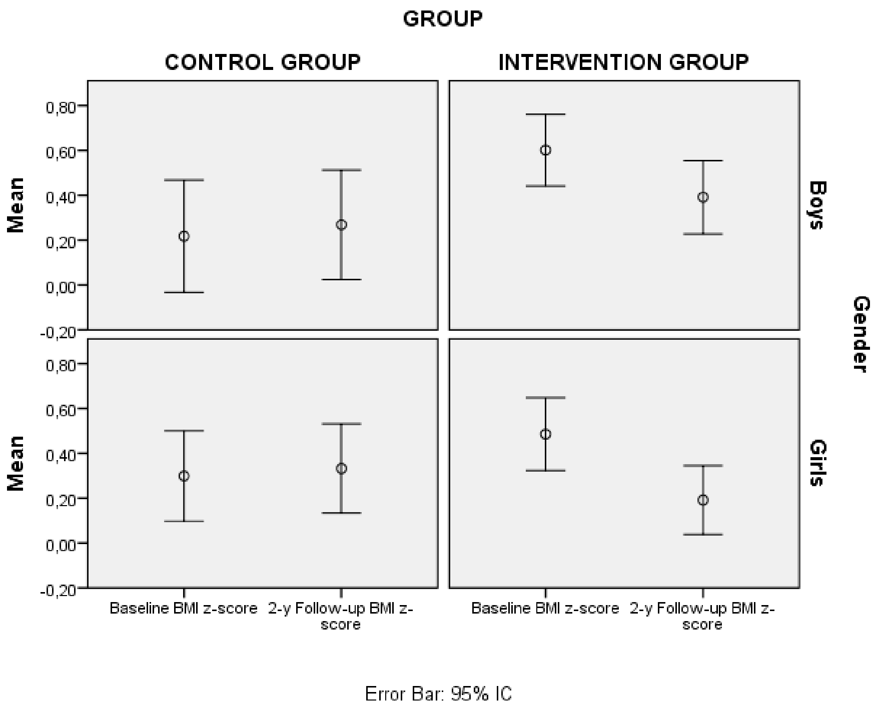
[3] Fisher's exact test. Differences between intervention and control pre-post intervention.

Figure Legends

Figure 1: Flow diagram of participants through the study

Figure 2: BMI z-score changes


Assessed for eligibility (n= 2564)
Excluded (n= 214)
Missing data:
- Forename or family name: 6
- Date of birth: 24
- Gender: 2
- No parental consent: 182
Enrollment
Randomized (n= 2350)
Allocation
Allocated to control (n=800)
Follow-up during intervention
Allocated to intervention (n= 1550)
Lost to follow-up (n=83)
Lost to follow-up (n= 328)
Analyzed (n=717)
Analysis at end of intervention (3-year follow-up)
Analyzed (n=1222)
Excluded: n=387
- Birth date: before 1st January 1999, later 31st December 2000: 219
- Mobility, birth between 1st January 1999, 31st December 2000: 168
2-year follow-up post-cessation EdAl intervention
Excluded: n=548
- Birth date: before 1st January 1999, later 31st December 2000: 257
- Mobility, birth between 1st January 1999, 31st December 2000: 291
Follow-up: n=330
Follow-up: n=674
Lost to follow-up: n=132
-Incomplete data:
• No parental consent: 119 (not meeting inclusion criteria).
• Height and/or weight: 13 (not recorded)
Lost to follow-up: n=253
-Incomplete data:
• No parental consent: 174 (not meeting inclusion criteria).
• Height and/or weight: 79 (not recorded)
Analysis at 2-year follow-up post-cessation EdAl intervention
Analyzed (n=198)
Analyzed (n=421)


GROUP
CONTROL GROUP
INTERVENTION GROUP
Mean
0,80
0,60
0,40
0,20
0,00
-0,20
Boys
Girls
Gender
Baseline BMI z-score
2-y Follow-up BMI z-score
Error Bar: 95% IC

RESULTS AND DISCUSSION

4. RESULTS AND DISCUSSION

Our hypothesis that a regular, systematic, educational intervention focused on lifestyle improvement reduces the prevalence of OB in boys and increases after-school PA practice in children and that the benefits achieved are sustained at 2 years follow-up post-cessation of the EdAl program intervention is verified.

Our study sample is representative of current Spanish society with respect to economic, social and ethnic distributions.

In 2010, at 28 months of intervention, the EdAl program showed a reduction in OB prevalence of 4.39% in boys. The OB prevalence among girls also decreased; however, the difference compared to the control group was not significant. A significantly greater reduction was observed in the BMI z-scores of boys in the intervention group compared to the control group. Waters and colleagues (Waters et al., 2011) stated that an intervention might be effective when the magnitude of the change in the BMI z-score pre- to post-intervention is approximately -0.15 units relative to the change in the control group. In our study, we observed a change of −0.20 units in total and −0.24 units in boys participating in the EdAl intervention program, thus revealing that the intervention was effective. However, BMI and waist circumference measurements were not significantly different between the groups at 28 months. We also observed that the intervention group had fewer new cases of excess weight as OB plus OW than the control group. This result highlights the efficacy of our program in preventing (or reducing) childhood OB.

With regard to the incidence and remission of OB, the incidence of excess weight was significantly higher in the control group (51/414; 12.3%) than in the intervention group (57/709; 8%), particularly in control boys (35/207; 16.9%) compared to boys in the intervention group (33/352; 9.4%). The girls, conversely, did not present significant differences in excess weight incidence between the groups. The remission of excess weight was not significantly different between the groups.

Some studies, such as the AVall study (Llargues et al., 2011), have shown that BMI was not reduced despite changes in lifestyle, although the intervention group demonstrated a lower increase in BMI than the control group. Nevertheless, in the AVall study, the prevalence of OW and OB increased less in the intervention group than in the control group (Llargues et al., 2011).

In our study, the percentage of OB in girls remained relatively unchanged during the study. Physiological differences between boys and girls at approximately 10-11 years of age might explain these findings. Differences in the age-of-onset of puberty between girls and boys might explain some of the variation in BMI response observed in the EdAl program. The Planet Health program (Gortmaker et al., 1999) observed OB prevalence changes in girls but not in boys.

Furthermore, Planet Health (Gortmaker et al., 1999) presented differences in girls in terms of remission, while the EdAl program does not. Thus, while the EdAl program prevented OB among boys in the intervention group, Planet Health reduced the OB prevalence in girls, with both interventions inducing positive benefits in the intervention groups of children, albeit with gender differences.

These differences in the outcomes indicate that because mediators of anthropometric changes are different between males and females, future interventions need to be specifically tailored to gender (He et al., 2010).

At the 2-year follow-up post-cessation of the intervention in the EdAl participants in 2012, we observed a significant reduction of -0.29 units in BMI z-score in the intervention group compared to the control group, as well as a significant reduction by -5.5% in OB prevalence among adolescents of the intervention group (-0.24 units in boys and -0.33 units in girls by BMI z-score compared to the control groups). This result indicated that the EdAl intervention was effective long term in both genders, according to a magnitude of change in the BMI z-score of at least -0.15 units relative to the change in the control group (Waters et al., 2011).

As in the EdAl program, the AVall intervention 2 years post-cessation (Llargués et al., 2012) demonstrated a reduction of -3.6% in OB prevalence in the intervention group of school children. These data correspond to a meta-analysis by Ho et al (Ho et al., 2012) that showed that the most healthy lifestyle interventions produced a significant weight loss in the intervention group as measured by BMI and BMI z-scores but that the post-treatment effect on BMI from baseline was not maintained at 1 year.

In the EdAl program, the prevalence of OB at baseline, corresponding to the academic year 2007-2008, was 9.0% in the intervention group and 7.5% in the control group. The EnKid Study by Serra Majem and colleagues (Serra et al., 2003) in northeast Spain (conducted between 1998 and 2000) indicated an OB prevalence of 9.8% in children of the same age as the participants in the present study (7-9 years). In Spain, using the same OB definition criteria (Cole et al., 2000) as the EdAl program, measurements made in 2012 by Sánchez-Cruz et al (Sánchez-Cruz et al., 2013) showed an OB prevalence of 9.6% in children between 8 and 13 years of age.

Thus, in 2012, the OB prevalence in the Sánchez-Cruz study was similar to the baseline values (2006 and 2007) obtained in the EdAl program, indicating a stabilization of childhood OB prevalence in Spain (OECD, 2012).

At the 2-year follow-up of the EdAl program in 2012, the prevalence of excess weight and OB were 21.6% and 3.3%, respectively. These results were quite similar to those observed in the ENERGY project, which described BMI distributions of 10- to 12-year-old participants from different European countries, including Spain (Brug et al., 2012).

At the 2-year follow up, participation in ≥4 h/week of after-school PA (OR: 0.240) and the daily consumption of fruit (OR: 0.447) were found to be protective factors against OB, whereas ≤2 h/week of after-school PA was a risk factor for OB.

The observed efficacy of our intervention with respect to BMI-related outcomes may be due to our approach, which focused on the nutritional quality of food intake and the increase in the PA of the pupils.

In 2010, at 28 months of the EdAl program, the performance of ≥5 hours/week PA increased significantly to 19.7% in the intervention group of boys as well as girls. Also significantly different was the increase of 5.1% more children performing ≥5 hours/week PA compared to the control group. The ENERGY project found significant associations between television-viewing time and computer use with BMI and waist circumference, whereas participation in sports was associated with low BMI and low waist circumference (Fernández-Alvira et al., 2013).

In 2012, at the 2-year follow-up post-cessation of the EdAl program, a significant improvement of 24.9% was observed among participants who performed ≥4 h/week of after-school PA in the intervention group (26.8% at baseline to 51.7%), with 13.1% more adolescents demonstrating improvement compared to the control group.

Furthermore, at the 2-year follow-up post-cessation of the EdAl program, the increase in the number of adolescents in the intervention group who performed ≥4 h/week of after-school PA who were normal-weight at baseline suggests that the intervention is effective not only in a primary-school healthy population but also in preventing OB over the longer term with the maintenance of PA. The tendency towards a reduction in BMI z-scores when children performed ≥4 hours/week PA in the EdAl program needs to be confirmed in other long-term studies.

According to the WHO, children and adolescents should practice 60 minutes/day of moderate to vigorous PA because it provides additional health benefits by reducing excess-weight prevalence, cardiovascular and chronic diseases and some types of cancer (AAPA, 2014; Vander Ploeg et al., 2014; WHO, 2014).

At the 2-year follow-up post-cessation of the EdAl program in 2012, half of our EdAl participants (51.7%) spent ≥4 hours/week involved in after-school PA. Additionally, they had obligatory 2 h/week PA practice as part of their high school curriculum, yielding a total of ≥6 h/week PA. In our geographical area, after-school PA is devoted to football, basketball, athletics, etc., which are considered moderate or vigorous in intensity. Thus, 51% of adolescents and 13.1% more adolescents in the intervention group performed ≥4 h/week of after-school PA compared to the control group, which nearly fulfills the WHO recommendation of 60 minutes/day of PA considered as moderate to vigorous in intensity. These results agree with the overall PA observed to be effective in prevention programs to reduce OB in adolescents (Simon et al., 2008).

We used the IOTF (Cole et al., 2000) criteria for optimal international comparisons of the data. However, when we designed the study protocol, 3 evaluation methods were proposed based on Hernandez et al, the EnKid study and IOFT (Cole et al., 2000; Serra et al., 2003; Fundación Faustiono Orbegozo, 2011) because each one had advantages and disadvantages. The values of Hernández in 1988 (Hernández et al., 1988) corresponded to data obtained before the increase of OW and OB prevalence in Spain, which should not be used for international comparisons that do not meet these criteria. The Spanish values in the EnKid study (Serra et al., 2003) (1998-2000) are 10 years more recent than those of Hernández. BMI values in the former are higher than those of Hernández because the worldwide increase in BMI and OB prevalence occurred during this period.

However, the selection of one of the various international methods to determine OB prevalence is controversial. Studies suggest that the IOTF criteria have poor sensitivity for OB because it was designed in 2000, when the OB problem was increasing around the world. It included a larger population sample than other international references, thereby providing more opportunities for OB prevalence comparisons with other studies that use this international reference (Cole et al., 2000; Cole & Lobstein, 2012; WHO 2006).

The use of BMI z-scores, another measure of weight status, appears preferable to the use of absolute BMI (Lavelle et al., 2012) because the former provides more sensitivity and specificity than BMI (Martinez-Costa et al., 2013; Reilly, 2010).

In 2010, at 28 months of the EdAl program with its focus on dietary habits, the percentage of pupils in the intervention group who consumed pastry before going to school significantly decreased from 3.9% to 2.4%. Moreover, the consumption of pastries at the mid-morning break significantly decreased from 3.8% to 1.7%. In the control group, the percentage of pupils consuming pastries during the mid-morning break also decreased (4.1% to 2.2%), while the consumption of fruit or natural juices increased (12.2% to 15.5%). There were no significant differences between the groups with respect to other nutritional habits. Of considerable note is that breakfast consumption increased in the intervention group (68.3% to 72.9%). Consuming more than three meals per day is associated with lower rates of OW or OB, especially if breakfast is not skipped (Antonogeorgos et al., 2012). Furthermore, Ortega et al (Ortega Anta et al., 2013) found that skipping breakfast was a risk factor for childhood OB in a Spanish population.

At the 2-year follow-up post-cessation of the EdAl program in 2012, the dietary habits of our intervention group demonstrated a significantly greater number of girls (15%) consuming more fruit and vegetables than was observed in the control group. This healthy habit is associated with a reduction of cardiovascular disease determinants (Bazzano et al., 2002; Evans et al., 2012; Hung et al., 2004; Woodside et al., 2013), certain cancers (Boeing et al., 2012; Hung et al., 2004) and mortality-morbidity risk (Bazzano et al., 2002; Capewell & O'Flaherty, 2011).

Several school-based programs show successful improvements in nutritional habits at the end of the intervention (Eilat-Adar et al., 2011; Reinaerts et al., 2008; Taylor et al., 2013; Zenzen & Kridli, 2009). The majority of these school-based programs modify the curriculum of children and actively involve the teachers. Had the activities of our intervention been included in our children's curriculum, they would have had to replace another academic task. The EdAl program's interventional activities are extra-curricular tasks, and because teachers already have many tasks to perform and are occupied with new educational challenges, we thus proposed HPAs for the implementation of these interventional activities. Planet Health (Gortmaker et al., 1999) lasted 2 years, during which educational sessions were incorporated into the curricula by primary school teachers and in which OB prevalence changes were observed in participant girls.

Some educational aspects of the EdAl program were developed in educational sessions that were implemented in the classroom but were not part of the curriculum. The intervention program was based on eight lifestyle topics that were established according to scientific evidence (Gidding et al., 2006). The program incorporated 12 activities that were disseminated over 12 sessions (1 h/activity/session). These sessions were prepared, standardized and implemented as four activities per school academic year by university students acting as HPAs in the school classrooms (figure 4). The 4 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 academic school years).

Each session was composed of experimental development activities related to healthy lifestyle habits using a food-item selection (free food items were provided by local producers) for the children to experience the organoleptic quality of the items, which may or may have not been new to them (figure 4). Evidence from longitudinal studies suggests that food preferences are established in childhood and adolescence and persist into adulthood; therefore, interventions to increase fruit and vegetable consumption should be developed in children (Skinner et al., 2002; Lytle et al., 2000; Mikkilä et al., 2004). For this reason, the EdAl children tasted different types of food. At the 2-year follow-up post-cessation of the EdAl program, the nutritional habits achieved were maintained in the adolescent participants of the intervention group.

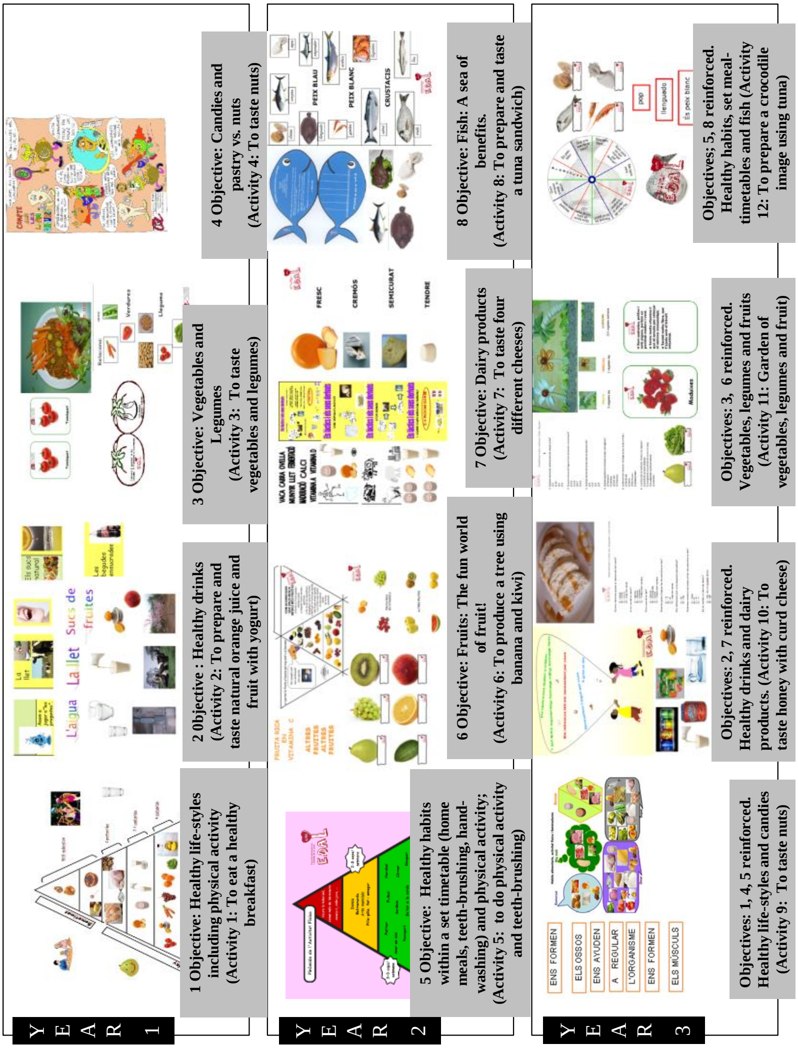


Figure 4 Schedule of standardized activities

Another aspect of the intervention program was to involve parents in activities with their children. This parental intervention involved the same educational nutritional activities that were directed towards the children by the HPAs. The intention was to have parents and their children interact in making healthy nutrition and lifestyle choices. Parents experienced the same experimental activities and tasted the specific foods identical to the children's sessions. Young children's dietary intake is also influenced by parents and by factors such as parental fruit and vegetable consumption. Parental modeling and the involvement of children in food selection contribute to more than half of the variance in children's fruit and vegetable consumption (Taylor et al., 2013). Nutritional education for parents is necessary to change children's nutritional habits (Skinner et al., 2002), supporting the importance of parental roles on child nutritional habits, as was conducted in the EdAl program.

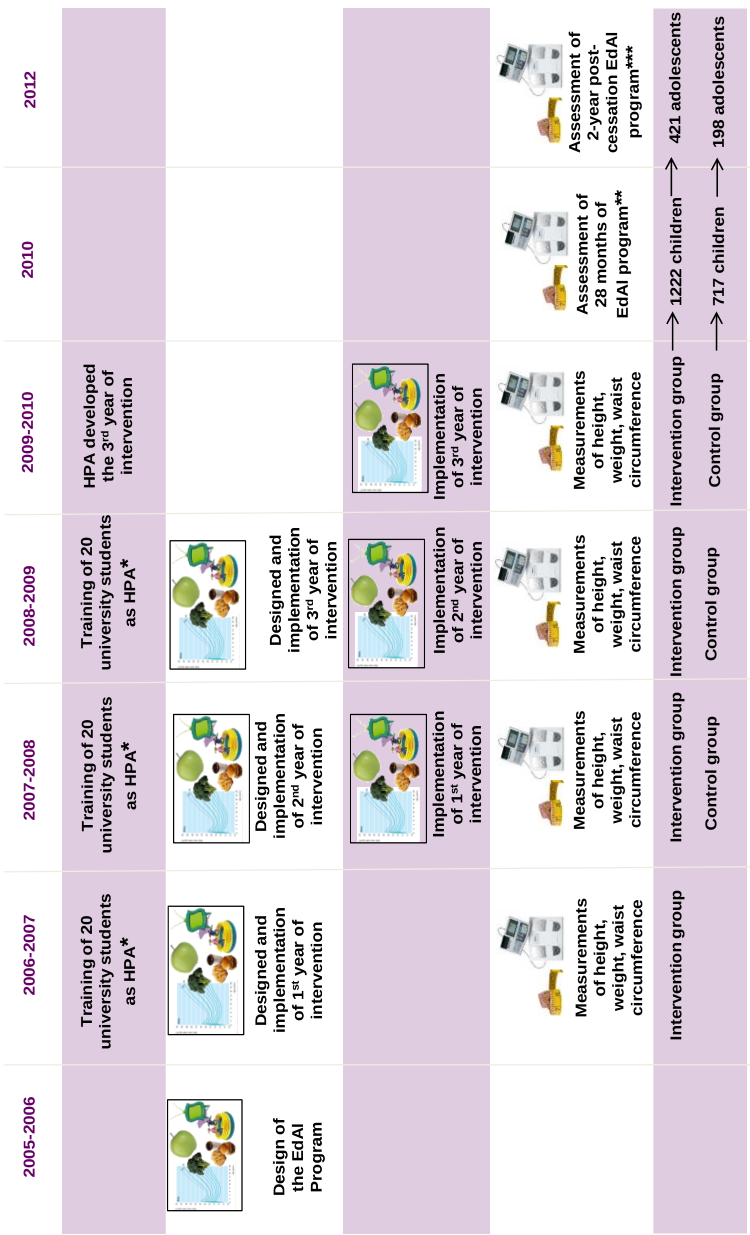
The age of the HPAs (approximately 20 years) was closer to that of the child participants and the scholars than to that of the professors. Moreover, children were more susceptible to the health message implemented by the HPAs because it was delivered by a person external to their closed environment, i.e., that of parents and teachers.

The HPA university education is designed and implemented through 2 courses in health promotion and health education within the academic degrees of Medicine, Physiotherapy, and Human Nutrition and Dietetics. We aim to train students as HPAs to implement education and the promotion of health in different sectors of the community, beginning with the primary schools in the EdAl program.

Course #1 is concerned with methodology for the promotion of health in schools and theory focusing on eight topics to improve food item selection, PA and healthy habits (14 h of lectures, 5 h of teamwork, 22 h of tutorials, 4 h of oral evaluation; total of 45 h over 15 weeks). Course #2 involves the interdisciplinary implementation of health education in schools and is focused on strategies of design, implementation, evaluation and activity definitions for each topic (4 h of lectures; 12 h of teamwork, lesson plan design and teaching materials, 2 h of oral evaluation of HPA performance with schoolteachers as the jury, 12 h of training involving 4 standardized final activities, 15 h of activities implemented in schools; total of 45 h over 15 weeks).

In summary, we trained and standardized educational intervention activities in schools to promote a healthy lifestyle. The interventional activities implemented over 3 university academic years resulted in a reduction of OB prevalence in children (albeit only in boys) participating in the EdAl program. Of considerable benefit is that the HPA university program can be used to train, design, and promote healthy lifestyle activities effectively in different environments or sites within the community (including primary schools, high schools, community centers or homes for the elderly).

A school-based program with characteristics similar to the EdAl program must involve people of the target population environment. In total, the EdAl program involved 60 university students who became HPAs, 6 university professors, 5 school teachers that assessed the intervention sessions, the community as local producers, 1550 children 7-8 years of age who received the intervention (1222 children were assessed) and 717 children 7-8 years of age in the control group. At the 2-year follow-up post-cessation of the EdAl program, focusing only on adolescents 11-13 years of age who participated in the program previously, there were 421 youths in the intervention group and 198 in the control group. Figure 5 shows the follow-up for all of the EdAl program years.



* School teacher evaluated the activities of EdAl program designed by university students and university professor trained the university students as HPA.
** Criteria: name, birth, weight and height
*** Criteria: name, birth, weight and height and born between 1999-2000

Figure 5 EdAl program since 2005 to 2012

Limitations in the follow-up of children over several years created difficulties regarding the appropriate sample size acquisition, which resulted mainly from children moving between primary and high schools and movement with their parents to other parts of town or even other parts of the country. Follow-up studies constitute an important tool to analyze the long-term effects of school-based interventions. Additionally, they are useful for determining the optimal length, intensity, and long-term effectiveness of lifestyle interventions (Gonzalez-Suarez et al., 2009; Ho et al., 2012; Simon et al., 2008).

There are several possible limitations to our study. In the school setting of various cities, there are possible sources of “contamination” of the control group. For example, if a school in the control group acquired information that was given to the intervention group as a result of chatting among parents and school friends, this might have motivated control students and families to adopt the intervention recommendations and thus not behave as true controls.

We used a 2-year follow-up post-cessation EdAl program evaluation that was focused only on adolescents 11-13 years of age because in our data collection, they represented the age group with more inclusion data sets. This inclusion improved our sample size, although adolescents of other ages clearly need to be studied.

Furthermore, after-school PA was evaluated by a questionnaire. However, a more accurate method than using questionnaires, such as using an accelerometer (Hallal et al., 2013), may also be used to evaluate PA.

In the absence of a consensus to define childhood OB, several alternative criteria should be included (Rolland-Cachera, 2011). We proposed the use of the BMI z-score criteria (WHO, 2006) because these criteria provide more sensitivity and specificity than the alternative methods to determine BMI (Martinez-Costa et al., 2013; Reilly, 2010).

The generalizability of our results is that the EdAl program is focused on a healthy lifestyle intervention and can be applied by university students trained as HPAs in primary schools. It is an easy-to-apply tool for implementation in primary schools to increase the practice of after-school PA, improve nutritional habits and reduce OB prevalence within the context of an overall healthy lifestyle.

GLOBAL CONCLUSIONS

5. GLOBAL CONCLUSIONS

1. The design of the EdAl program provided 12 activities implemented by HPAs that are designed to be entertaining yet informative and that are focused on healthy lifestyle concepts that can be achieved by improving diet and PA practice.

2. Medical, Physiotherapy and Human Nutrition and Dietetics students trained as HPAs enrolled the EdAl program.

3. The HPA university program can be used to train, design, standardize and promote healthy lifestyle activities effectively in different community environments.

4. At 28 months of the EdAl program, the prevalence of OB was reduced by -4.39% in boys but not in girls compared with the control groups, and the BMI z-scores were reduced by −0.20 units in total and by −0.24 units in boys participating in the EdAl intervention, confirming its effectiveness, as the magnitude of these changes is greater than -0.15 units related to the changes in the control group.

5. At 2-years post-cessation, the OB prevalence decreased by -5.5% in adolescents in the intervention group.

6. At 2-years post-cessation, the BMI z-scores were significantly reduced by -0.29 units in the adolescents who were included in the intervention group of the EdAl program compared to those of the control group.

7. At 28 months of the EdAl program, the percentage of intervention participants performing ≥5 hours/week of after-school PA had significantly increased to 19.7%, or 5.1% more children compared to the control group.

8. At 2-years post-cessation of the EdAl program, 13.1% more adolescents in the intervention group performed ≥4 h/week of after-school PA compared to the control group.

9. The EdAl program stimulates the practice of after-school PA in adolescent participants, with 51% of intervention participants nearly achieving the WHO recommendations of 60 minutes/day of PA that is considered moderate to vigorous.

10. At 2-years of follow up, the participation in ≥4 h/week of after-school PA and the daily consumption of fruit were protective factors against OB, whereas ≤2 h/week of after-school PA was a risk factor for OB.

Global conclusion

A regular, systematic, educational intervention that promotes a healthy lifestyle and that includes dietary and PA recommendations is an easy tool that can be implemented by HPAs as part of their university curriculum to reduce the prevalence of OB and to increase the practice of after-school PA in children with these achieved benefits sustained at 2-years post-cessation of the intervention.

Perspectives

Long-term follow-up of the EdAl participants is needed to confirm the effectiveness of the EdAl school-based intervention program.

Furthermore, the EdAl program must be reproduced to compare it with other populations and to confirm its effectiveness and feasibility.

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