HEALTH EDUCATION PROGRAMS TO ENCOURAGE HEALTHY LIFESTYLES AND PREVENT OBESITY IN CHILDREN AND ADOLESCENTS . THE DEVELOPMENT, EVALUATION AND IMPLEMENTATION PROCESS OF INTERVENTIONS TO IMPROVE EFFECTIVENESS

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HEALTH EDUCATION PROGRAMS TO ENCOURAGE HEALTHY LIFESTYLES AND PREVENT OBESITY IN CHILDREN AND ADOLESCENTS

The development, evaluation and implementation process of interventions to improve effectiveness

INTERNATIONAL THESIS

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FAIG CONSTAR que aquest treball, titulat “Health education programs to encourage healthy lifestyles and prevent obesity in children and adolescents. The development, evaluation and implementation process of interventions to improve effectiveness”, que presenta **Elisabet Llauradó Ribé** per a l’obtenció del títol de Doctor, ha estat realitzat sota la meva direcció al Departament de Medicina i Cirurgia d’aquesta universitat i que acompleix els requeriments per poder optar a títol de Doctor amb Menció Internacional.

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Les directores de la tesi doctoral

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D'aquesta tesi es deriven les següents aportacions científiques:

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2) Llauradó E, Tarro L, Aceves-Martins M, Solà R, Giralt M. Follow-up of a Healthy Lifestyle Education Program (the EdAl Study): Four Years after cessation of Intervention. (editor submitted).
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5) Llauradó E, Albar SA, Giralt M, Solà R, Evans CEE. The effect of snacking and eating frequency on dietary quality in British adolescents. (in review).

Altres comentaris sobre la qualitat de la tesi:

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

Reus, 23 de Maig de 2014
Directores de la tesi

Rosa SOLÀ ALBERICH

Montse GIRALT BATISTA

"*Research is to see what everybody else has seen,*
and to think what nobody else has thought"

Albert Szent-Gyorgyi

ABSTRACT

BACKGROUND

Obesity is one of the main determinants of avoidable disease burden. The encouragement of healthy lifestyles for obesity prevention in young people is a public health priority. However, the optimal intervention to tackle childhood and adolescent obesity remains unknown.

HYPOTHESIS

Our hypothesis is that health education programs based on lifestyle improvements to prevent childhood obesity can be effectively delivered by peer leaders as easily accessible individuals using different methodologies in the elementary school or high-school setting.

OBJECTIVES

The principal objective was to evaluate the effectiveness of health education programs, using different methodologies, to prevent childhood and adolescent obesity by encouraging healthy lifestyles.

Specific objectives

Objective 1: To assess the reproducibility of an educational intervention EdAl-2 (Educació en Alimentació) program in 'Terres de l'Ebre' (Spain) to improve lifestyles, including diet and physical activity, over 22 months.

Objective 2: To verify the maintenance of health benefits achieved at 4-year follow-up after EdAl intervention cessation program by assessing obesity prevalence, anthropometric variables, lifestyle habits and physical activity in adolescents (13-15 years of age) who had participated in the EdAl program implemented in the 2007 to 2010 academic years.

Objective 3: To design and implement an intervention to tackle adolescent obesity in Reus (Spain), named “Som la Pera” (we are cool), using social marketing and a peer-led model belonging to European Youth Tackling Obesity (EYTO) project.

Objective 4: To plan and evaluate the implementation sustainability of the “Som la Pera” intervention, a social marketing and an adolescent peer-led model to tackle adolescent obesity, to achieve optimal long-term sustained implementation beyond completion of the intervention.

Objective 5: To identify causal factors for obesity risk and the dietary quality of adolescents, including identifying the relationship between dietary quality and eating frequency, to improve dietary habits as a key component to develop future obesity prevention interventions.

METHODS

Study 1: EdAl-2 (Educació en Alimentació) programme: Reproducibility of a cluster randomised, interventional, primary school-based study to induce healthier lifestyle activities in children

Reproduction of a cluster randomized controlled trial. Two semi-rural town-group primary school clusters (690 students in total) were randomly assigned to an intervention (1 cluster, n=320) or control group (1 cluster, n=370). The student ethnicity was 78% Western European. The mean age (±SD) was 8.04 ±0.6 years (47.7% females) at baseline. The inclusion criteria for the clusters were towns from the southern part of Catalonia with a minimum of 500 children aged 7–8 years; complete data for participants, including name, gender, date and place of birth; and written informed consent from parents or guardians. The intervention focused on eight lifestyle topics covered in 12 activities (1 h/activity/ session) implemented by undergraduate university students as health promoting agents in the primary school over three academic years (2010-2011 to 2013-2014). The primary outcome was obesity prevalence, and the secondary outcomes were body mass

index (BMI) collected every year and dietary habits and lifestyles collected by parent-completed questionnaires at baseline and end-of-study.

Study 2: Follow-up of a Healthy Lifestyle Education Program (the EdAl Study): Four Years after cessation of Intervention

Adolescents (n=349, intervention; n=154, control) with baseline and 4-y follow-up data who participated in original EdAl Program were recruited. The analyses included BMI, BMI z-score, and lifestyle data such as dietary habits and physical activity practice (obtained from questionnaires).

Study 3: A youth-led social marketing intervention to encourage healthy lifestyles, the EYTO (European Youth Tackling Obesity) project: A cluster randomised controlled trial in Catalonia, Spain.

Study design of a cluster randomized controlled intervention to encourage healthy lifestyles in a socioeconomically disadvantaged adolescent population. This study was implemented in high-schools of vulnerable neighbourhoods, in which 2 high-schools were designated as the control group (180-200 high-school students) and 2 high-schools were designated as the intervention group (180-200 high-school students), over 2 academic years (2013-2014 to 2014-2015). From the intervention group, 5 adolescents with leadership characteristics, called “Adolescent Challenge Creators” (ACCs) were recruited and they received an initial 4h training session about social marketing principles and healthy lifestyles theory, following of 24 sessions (1.30h/session) divided in two academic years, to design and implement activities presented as challenges to encourage healthy lifestyles of their peers.

Study 4: The EYTO Project: Sustainability planning of “Som la Pera”, a peer-led intervention programme to encourage healthy lifestyles

European financial support has enabled the implementation of the “Som la Pera” intervention, a school-cluster randomized controlled trial to improve the lifestyles of adolescents from Spain (Reus, Catalonia) over 2 academic years (2013-2014 to 2014-2015). The main methodologies used in the intervention are social marketing

and adolescent peer-leading. Here, we report the specific planning and assessment of the sustainability of the "Som la Pera" intervention with the aim of guaranteeing its long-term sustained implementation beyond the intervention completion. The "program sustainability assessment tool", which comprises 8 domains and 40 items, was used to assess the long-term sustainability of the "Som la Pera" intervention.

Study 5: The effect of snacking and eating frequency on dietary quality in British adolescents

A sample of 884 adolescents (11-18y) in the United Kingdom (UK) National Diet and Nutrition Survey (NDNS) were included. The Diet Quality Index for Adolescents (DQI-A) was implemented. The total number of eating occasions and snacks was frequency of food or beverages consumed over 24h and the frequency of foods or beverages consumed outside of the three mealtimes respectively. Results were generated with and without low energy occasions under 210 KJ (50 kcal). Regression models were generated using the DQI-A score as the outcome variable and the number of eating occasions and snacks as predictors.

RESULTS

Study 1: EdAl-2 (Educació en Alimentació) programme: Reproducibility of a cluster randomised, interventional, primary school-based study to induce healthier lifestyle activities in children

In the EdAl-2 intervention reproduction, the obesity prevalence and body mass index values were similar in the intervention and control groups at 22 months. Relative to children in control schools, the percentage of boys in the intervention group who performed ≥4 after-school physical activity h/week was 15% higher (p=0.027), whereas the percentage of girls in both groups remained similar. Additionally, 16.6% more boys in the intervention group watched ≤2 television h/day (p=0.009), compared with controls; and no changes were observed in girls in either group.

Study 2: Follow-up of a Healthy Lifestyle Education Program (the EdAl Study): Four Years after cessation of Intervention

Between the baseline and 4-y follow-up post-cessation intervention, the OB prevalence decreased (-7.7%; p=0.02) in the boys in the intervention group compared with the control group, and the BMI z-score (-0.17 units; p<0.01) decreased in the girls (-0.33 units, p<0.01) compared with the control group. A positive trend was observed, with a 19% higher percentage of boys in the intervention group performing ≥4 hours/week after-school PA, compared with the control (p=0.06). Both groups followed a similar dietary pattern, with decreased consumption of dairy products, fruits and fish.

Study 3: A youth-led social marketing intervention to encourage healthy lifestyles, the EYTO (European Youth Tackling Obesity) project: A cluster randomised controlled trial in Catalonia, Spain

The “Som la Pera” Spanish intervention study protocol describes an intervention aimed at improving lifestyles, including nutritional habits and physical activity practice, for obesity prevention in socioeconomically disadvantaged and vulnerable adolescents. The activities of the intervention are designed by adolescent campaign creators as challenges. A total of 10 challenges (5 challenge per each academic year) were implemented over 12 weeks each academic year. During the design of the campaign, it was essential that the ACCs used the 8 social marketing principles (customer orientation, behaviour, theory, insight, exchange, competition, segmentation and methods mix) and a peer-led model. The expected primary outcomes from the Spanish intervention aimed at the following: Increases in the consumption of fruits and vegetables and physical activity practice, together with reductions in TV/computer/game console use. The secondary outcomes were as follows: Increased breakfast consumption, engagement with local recreation and reduced obesity prevalence. The outcomes will be measured by the Health Behaviour in School-aged Children Study survey at baseline and at the end-of-study in the intervention and control groups. The control group did not receive any intervention.

Study 4: The EYTO Project: Sustainability planning of "Som la Pera", a peer-led intervention programme to encourage healthy lifestyles

The sustainability assessment was performed on January 2015 and revealed a score of 5.7 out of 7 possible points. In particular, two of the 8 domains (namely, funding stability and strategic planning) require improvement to ensure that "Som la Pera", a social marketing and peer-led school-based intervention, will be sustainable.

Study 5: The effect of snacking and eating frequency on dietary quality in British adolescents

The mean (95%CI) dietary quality score was 31.1% (30.2, 32.0), ranging from -33 to 100%, where 100% is the highest possible score. The mean numbers of eating occasions and snacks were 7.5 (7.3, 7.7) and 2.6 (2.6, 2.7) times/day, respectively. When low energy occasions were excluded, the mean numbers of eating occasions and snacks decreased to 6.2 (6.1, 6.4) and 2.0 (2.0, 2.1) times/day, respectively. The dietary quality score increased by 0.74 points (0.42, 1.05; $p<0.01$) and 0.55 points (-0.08, 0.69; $p=0.17$) for total eating occasions and snacks, respectively. When low energy occasions were excluded, the dietary quality score only increased by 0.30 points (-0.84, 0.69; $p=0.13$) for each eating occasion and decreased by 1.20 points (-2.1,-0.3; $p<0.01$) for each snack.

CONCLUSIONS

1. The original EdAl school-based intervention program is feasible and reproducible by increasing after-school physical activity (to ≥4 h/week) in boys. Despite this improvement, the EdAl-2 program has no effect on BMI or the prevalence of obesity.

2. The EdAl-2 school-based intervention program induces healthy lifestyle effects (such as more physical activity and less sedentary behaviour), which can produce anti-obesity benefits in children in the near future beyond the limited length of our current study.

3. The EdAl-2 program exhibits the same pattern with respect to the improvement in healthy food-habits by increasing consumption to two fruits per day, one or more vegetables per day relative to the original EdAl school-based intervention program.

4. Four-year post-cessation intervention of the original EdAl program was associated with a lower BMI z-score and OB prevalence than the control group. The improvement in after-school PA practice was more likely to be maintained for the long-term after the cessation of the intervention, whereas encouraging healthy food habits in adolescents is a challenge.

5. In the original EdAl program, the reduction in obesity-related measurements in boys began during the intervention and continued after its cessation. Meanwhile, in girls, the decrease in obesity-related measurements requires 4-y follow-up post-cessation intervention.

6. The effect of the EdAl school-based intervention program on girls needs to be more closely studied.

7. The design of the “Som la Pera” randomized controlled social-marketing peer-led intervention to encourage healthy lifestyles in high-schools provides 10 challenges (5 challenges/year) designed by 5 adolescent coordinators and

delivered to their schoolmates to encourage healthy lifestyles, including diet and physical activity practice.

8. The “Som la pera” intervention challenges use new approaches to disseminate healthy messages, such as social media, in addition to high-schools activities and activities delivered in different places identified as stakeholders of the intervention.

9. After sustainability assessment of the ongoing program, we will invest efforts to recover funding stability and strategic planning domains for the effective and long-term implementation of the “Som la Pera” intervention.

10. After sustainability assessment of the ongoing program, we propose that every 2 years, 5 ACCs be trained by health sciences university students’ acting as HPAs to disseminate healthy lifestyles information and propose challenges to their peers according to a social marketing and peer-led model.

11. The dietary quality could result superior in adolescents with the replacement of high-energy snacks with low-energy alternatives.

12. The identification of adolescents’ dietary quality contributes to improve the design interventions to encourage healthy lifestyles.

GLOBAL CONCLUSION

The development of the EdAl (Educació en Alimentació) school-based intervention program, which focused on the prevention of childhood obesity and encouraging healthy lifestyles in children, is effective at 4-y follow-up post-cessation intervention. The EdAl decreased the prevalence of obesity and BMI z-scores and increased the practice of physical activity. Moreover, this intervention confirmed the effectiveness on the reproducibility of the program in other location; the EdAl-2 program also improved lifestyles, including improved physical activity practices and food habits, similar to the original EdAl intervention program.

The “Som la Pera” intervention is designed according to evidence-based focused on social marketing and a peer-led model to improve healthy lifestyles and prevent obesity in adolescents. The planning and early assessment of the sustainability of this intervention promises effective permanently implementation beyond the intervention completion.

Furthermore, our study identified diet quality characteristics as a basis to integrate eating frequency recommendations with new effective strategies to tackle obesity in adolescents.

PERSPECTIVES

Long-term follow-up of the EdAl-2 program participants is needed to determine the post-cessation intervention effectiveness of the EdAl school-based intervention program.

End-of-study and long-term assessment of the “Som la Pera” intervention is needed to confirm its effectiveness and implementation sustainability. Additionally, assessments of the EYTO project must be conducted on a European level.

The assessment of relationship between dietary quality, eating frequency and obesity-related outcomes could be identified in a Spanish cohort to validate this recommendation in the Spanish population.

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ABBREVIATIONS

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AAP	American Academy of Pediatrics
BMI	Body Mass Index
CDC	Centers for Disease Control and Prevention
CONSORT	CONsolidated Standards of Reporting Trials
DQ	Dietary Quality
DQI-A	Dietary Quality Index for Adolescents
EdAl	Educació en Alimentació (Nutrition Education)
EPHPP	Effective Public Health Practice Project
EYTO	European Youth Tackling Obesity
FBDG	Flemish food–based dietary guidelines
HDI	Healthy Diet Indicator
HPAs	Health Promoter Agents
KOPS	Kiel Obesity Prevention Study
METs	Metabolic Equivalent of Tasks
MVPA	Moderate-to-Vigorous Physical Activity
NSMC	National Social Marketing Centre
OB	Obesity
OW	Overweight
OCDE	Organization for Economic Cooperation and Development
PA	Physical Activity
PSAT	Program Sustainability Assessment Tool
QALYs	Quality Adjusted Life Years
RCT	Randomized Controlled Trials
SD	Standard Deviation
SES	Socio Economic Status
SM	Social Marketing
SMBC	Social Marketing Benchmark Criteria
TV	Television
WC	Waist Circumference
WHO	World Health Organization
WtHR	Waist to Height Ratio

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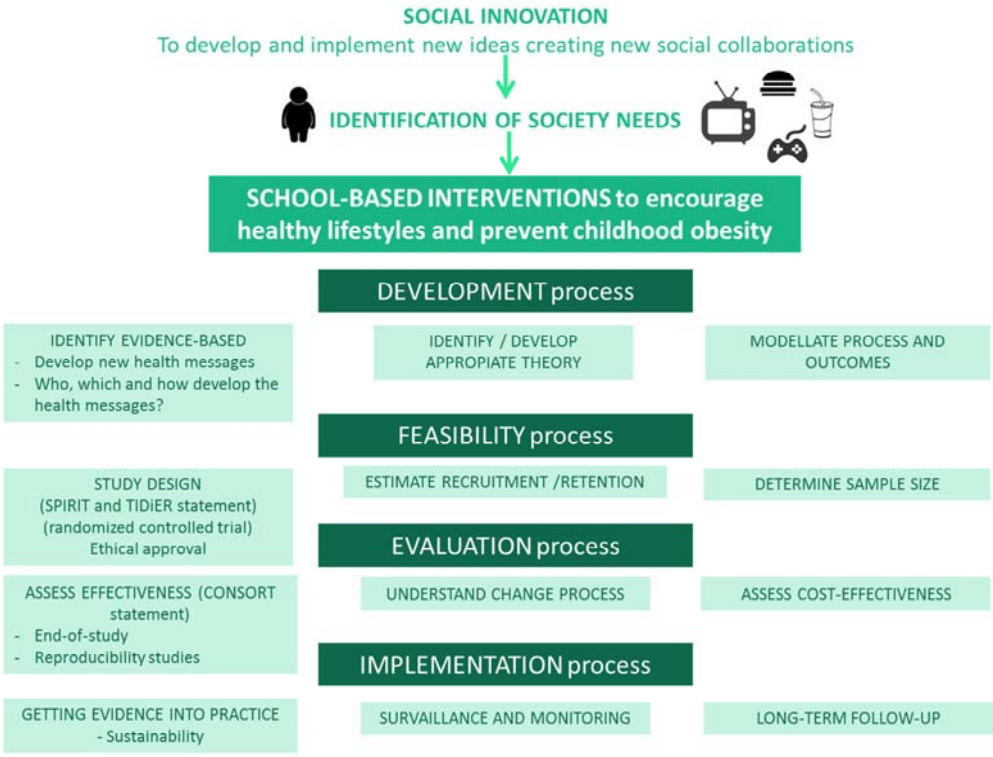
JUSTIFICATION

Currently, societies exhibit highest recorded prevalence of childhood and adolescent obesity (OB) (World Health Organization, 2010b), and the food habits and lifestyles of children and adolescents continue to deteriorate (Currie et al., 2012). The implementation of school-based interventions to encourage healthy lifestyles is essential to reduce childhood and adolescent OB which is identified as a society need (Silveira, Taddei, Guerra, & Nobre, 2013). Decrease the high prevalence of childhood OB is a society need that requires the development of social innovation, defined as "new ideas (products, services and models) that simultaneously meet social needs and create novel social relationships or collaborations" (Murray, Caulier-Grice, & Mulgan, 2010).The school-based interventions will require the creation of social innovations strategies, such as educational intervention (European Commission, 2013).

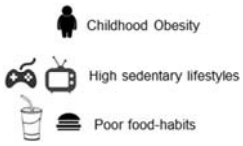
School-based interventions can be considered complex interventions involving interacting components, including: school, family and the community. Thus, the development, evaluation and implementation processes of school-based interventions are crucial to achieve high-quality outcomes, and these processes comprise different essential parts. These processes are as follows (Craig et al., 2012) (Figure 1):

- Development process: Identify evidence-based interventions and, identify and develop appropriate theory and modelling processes and outcomes.
- Feasibility processes: Study design, estimate recruitment and determine sample size.
- Evaluation processes: Assess effectiveness, understand change processes and assess cost-effectiveness.
- Implementation processes: Translate evidence into practice and promote surveillance, monitoring and long-term follow-up.

Figure 1: Diagram of new perspectives in the development, evaluation and implementation of effective school-based intervention programs.



Source: Adapted from the Medical Research Council guide on the development and evaluation of complex interventions (Craig et al., 2012)



The identification of causal factors of OB risk, including dietary quality, is the basis of the development of new health messages to improve the recommendations of school-based interventions.

Such evidence-based intervention is implemented by different methodologies that included who, what and how of message dissemination (Figure 2):

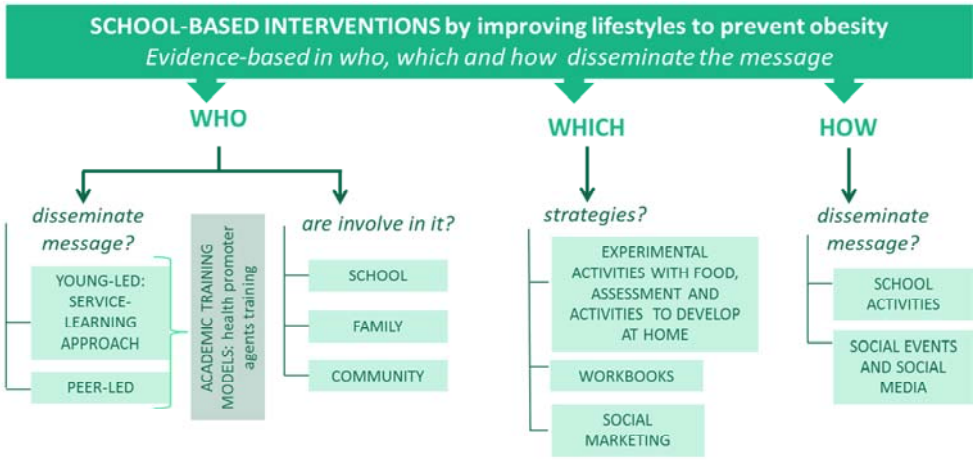
a.1) *Who disseminates the message?*: Easily accessible individuals should act as disseminators of health message. The training and responsibilities of individuals who disseminate the health messages is an important aspect to considerer.

a.2) *Who is involved in the intervention?*: The interacting components included in the intervention should be identified.

b) *Which strategies should be employed?*: Intervention strategies may include experimental activities with foods and social marketing.

c) *How should the message be disseminated?*: The procedures for the dissemination of the messages may include activities such as school activities or social media and social events.

Figure 2: Diagram of school-based intervention methodologies design: Evidence-based determination of the who, what and how of message dissemination.



Source: Elaborated by the author.

The determination of good intervention practice characteristics is another challenge in intervention design (Horodyska et al., 2015). Good practices are defined as processes or methodologies that have been proven to work well and produce good results and are recommended as a model (The Good Practices Team, 2013). Study designs can introduce these good practice characteristics to promote success (Horodyska et al., 2015) (Figure 1).

JUSTIFICATION |

Successful interventions are defined as actions that are exhibit significant effects, maintain the intervention outcomes, and are sustainably implemented when the interventions are finished (Horodyska et al., 2015). Effectiveness is assessed at the end-of-study; the challenge is to determine the effect of the intervention at the end-of-study and to determine whether the results can be reproduced in other community (Figure 1). Thus, to validate the results, the intervention should be reproduced in other locations (Wang et al., 2013), and the effectiveness should be assess in the long-term after the intervention is finished (Waters et al., 2011). Moreover, if an intervention is effective, the intervention should be permanently implemented. Therefore, the implementation process should be planned and assessed over the course of intervention (Whelan et al., 2014).

All of the above considerations must be addressed when developing high-quality school-based interventions (e.g., well defined goals and guidelines monitoring) to reduce society needs promoting healthy lifestyles in children and adolescent, and decreasing the prevalence of OB.

INTRODUCTION

CHAPTER 1: HEALTH PROMOTION AND HEALTH EDUCATION: TACKLING OBESITY AS A NEW SOCIAL NEED

1.1 Social innovation

The social innovation process starts with the identification of social needs and continues with the development of new solutions in response to social needs. Subsequently, the effectiveness of these new solutions must be evaluated with respect to social needs, and the effective social innovations must be implemented (European Commission, 2013). This new approach, called social innovation, can be defined as "new ideas (products, services and models) that simultaneously meet social needs and create new social relationships or collaborations" (Murray, Caulier-Grice, & Mulgan, 2010) and represents an essential element of the Europe 2020 Strategy to promote a smart, sustainable and inclusive economy (European Commission, 2013).

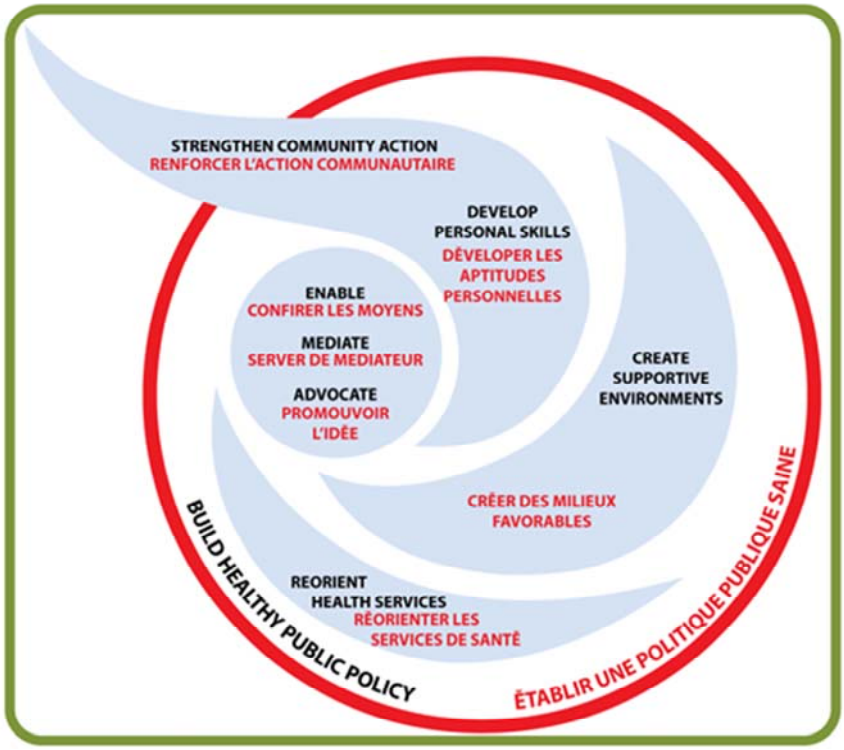
1.2 Principles of Health Promotion

Health is a value and a driver for growth (European Comission, 2011). The principal objective for Europe 2020 is to promote good health status by developing health promotion strategies (European Comission, 2011). Health promotion prepares people to increase their control over, and to improve, their health (World Health Organization, 2009) and associated health promotion spending and procedures are a useful future investment (Bloom et al., 2011). However, the current European health expenditure set aside for public health and prevention programs is only approximately 3% of health budget (Seychell & Hackbart, 2013).

The "Health Promotion Emblem" (Figure 3) created at the First International Conference on Health Promotion in Ottawa (1986) illustrated the five key action areas in Health Promotion: 1) build healthy public policies, 2) create supportive environments, 3) strengthen community action, 4) develop personal skills and 5) re-orient health services. Moreover, the enable, mediate and advocate health

promotion strategies which should be employed in the five key action areas described previously (World Health Organization, 2009).

Figure 3: Logo created at the First International Conference on Health Promotion, Ottawa, Canada, 1986.



Source: (World Health Organization, 2009)

1.3 Health promotion strategies

In 2006, 20 years after the creation of the Health Promotion Emblem, the Health in All Policies strategy was implemented, to generate a relationship between health policies and other policies (Stahl, Wismar, Ollila, Lahtinen, & Leppo, 2006). The four strategies outlined were as follows (Ollila, 2011):

a) *Health strategy*: To encourage other sectors to adopt policies that promotes health objectives. The aim is to allocate responsibility beyond the health sector.

b) *Win-Win strategy*: To facilitate a mutual beneficial strategy among different sectors. The principal aim is to achieve better health results, but social or economic gains are also important.

c) *Cooperation strategy*: To guarantee the cooperation of health sectors with other supporting sectors.

d) *Damage limitation strategy*: To amend health policy proposals that damages another sector.

Currently, in the 2020 Europe agenda, one of the main goals of the Health for Growth Action (2014-2020) is to promote good health and prevent disease, emphasizes the idea that a healthy population is critical for economic success (Seychell & Hackbart, 2013). To achieve this objective, the following actions were proposed: a) exchange information on the best practices in key-health issues (smoking prevention, alcohol and OB), b) support the prevention of chronic diseases by sharing knowledge and developing joint activities, and c) promote a health knowledge system to improve evidence-based decision-making (Seychell & Hackbart, 2013).

1.4 Principles of Health Education

Health education is defined as “consciously constructed opportunities for learning, involving some form of communication designed to improve health literacy, including increasing of knowledge, and developing life skills, which are conductive to individual and community health” (World Health Organization, 1998). Health education is one of several key components and action areas of health promotion (World Health Organization, 2009) and is an effective tool to improve the health of a population (World Health Organization, 2012). Thus, the aim of health education is to improve the behaviour of individuals and communities using the educational process (World Health Organization, 2012).

Health Education curriculum are defined by the Centers for Disease Control and Prevention (CDC) with 15 main characteristics (Centers for Disease Control and Prevention, 2013):

1. Focuses on clear health goals and related behavioural outcomes
2. Based on research and theory-driven
3. Addresses individual values, attitudes, and beliefs
4. Addresses individual and group norms that support health-enhancing behaviour
5. Focuses on reinforcing protective factors and increasing perceptions of personal risk and harmfulness of engaging in specific unhealthy practices and behaviours
6. Addresses social pressures and influences
7. Builds personal competence, social competence and self-efficacy by addressing skills
8. Provides functional health knowledge that is basic, accurate, and directly contributes to health-promoting decisions and behaviours
9. Uses strategies designed to personalize information and engage students
10. Provides age-appropriate and developmentally-appropriate information, learning strategies, teaching methods, and materials
11. Incorporates learning strategies, teaching methods, and materials that are culturally inclusive
12. Provides adequate time for instruction and learning
13. Provides opportunities to reinforce skills and positive health behaviours
14. Provides opportunities to make positive connections with influential others
15. Includes teacher information and plans for professional development and training that enhance effectiveness of instruction and student learning

1.5 Health Promoter Agents

Human resources are the key ingredient in successful health systems. “Health promoter agent” (HPAs) and “community health worker” are among the variety of

different names around the world given to members of the community who are supported by the health system and undergo a shorter period of training than professional workers. The specific profile of HPAs is difficult to characterize, and could the title may be applied to any person who is involved in and accepted by the community. HPAs can perform a diverse range of tasks in the community environment or can be trained for a specific intervention in the community. This professional figure is historically used in low-income countries (Lehmann & Sanders, 2007).

Evidence confirms that HPAs can accomplish the following (Lehmann & Sanders, 2007):

- Exhibit a valuable contribution to community development: Undertaking actions to improve health outcomes in the community, not exclusively in the child health field
- Require appropriate selection, training and uninterruptedly support
- Should be volunteers or paid traditional workers underserved populations

In 2006, the World Health Organization (WHO) in the *Working Together for Health* report (*Working Together for Health*, 2006), strongly recommended that HPAs be involved in community programs.

HPAs are described as people closely associated with community interests, and the best way to create a close relationship between the community and HPAs involves the use of peer-led instruction. The term “peer educators” refers to people who teach interventions to people who are of a similar age or slightly younger (Mellanby, Rees, & Tripp, 2000). Peer-led instruction is effective when it is applied in school-based studies and generates more positive results in health behaviour than does adult-led instruction (Mellanby et al., 2000).

Consequently, the training and posterior work of “Health Educators” defined by WHO have the following major responsibilities (World Health Organization, 2012): 1) assess individual and community needs for health education, 2) plan effective health education programs, 3) implement health education programs, 4) evaluate

the effectiveness of health education programs, 5) coordinate the provisions of health education services, 6) act as a resource person in health education and 7) communicate health and health education needs, concerns and resources (Figure 4).

Figure 4: Major responsibilities of health educators.

Source: (World Health Organization, 2012)

CHAPTER 2: HEALTH STATUS OF CHILDREN AND ADOLESCENTS

2.1 Overweight and Obesity

Overweight (OW) and OB are defined as "abnormal or excessive body fat accumulation" (World Health Organization, 2015a). OB is a multifactorial disease caused by genetic factors, sedentary lifestyles, unhealthy lifestyles, socioeconomic and education factors, the environment and the development of new technologies (Varela Moreiras, 2013).

Currently, OB is a worldwide epidemic concern (World Obesity Federation, 2012) in spite of the diversity of strategies to tackle OB (European Commission, 2014). Nearly 2.8 million of deaths/year are attributable to the consequences of OW and OB in Europe (World Health Organization, 2011), and high childhood OB indexes are particularly alarming. In 2010, the WHO's Childhood Obesity Surveillance Initiative (COSI) estimated that approximately 1 in 3 children (6-9 years) were OW or OB in Europe (World Health Organization, 2010b). It is well established that OW and OB in children or adolescents produce consequences in adulthood, increasing the risk of physical morbidity and early mortality (Reilly & Kelly, 2011). The United States CDC suggested that the next generations may live less than their parents due to the increase of paediatric OB (Varela Moreiras, 2013).

In 2013, a worldwide consensus on the OB epidemic provided 6 guidelines to promote weight control (Figure 5) (Varela Moreiras, 2013).

Figure 5: Obesity and sedentary lifestyles in the 21st century: What can and what must be done?

Source: (Varela Moreiras, 2013)

Spain is rated 10th in the prevalence of childhood OW + OB rates of Organization for Economic Cooperation and Development (OCDE) countries (Organisation for Economic Cooperation and Development, 2014), and more than 1 in 3 children (13-14 years) exhibits OW (Organisation for Economic Cooperation and Development, 2012).

An action plan has been developed by all European stakeholders to tackle childhood OB by 2020 and involves 8 priority actions (Varela Moreiras, 2013):

I) *Support a healthy start in life*: The most important pre-natal determinants of childhood OB are maternal pre-conception weight and maternal weight gain over pregnancy. Additionally, breastfeeding is considered to be the best option, and it is important adopt a healthy lifestyle early in life. Primary prevention is critical, and evidence-based programs for childhood and adolescent OB must be developed to change the OB situation.

II) *Promote healthier environments, especially in schools and pre-schools:* Societies must implement policies to regulate access to healthy meals and snacks and assure opportunities to engage in physical activity (PA) and healthy environments. Additionally, societies should promote good habits from an early age and introduce a taste for healthier foods.

III) *Make the healthy option the easier option:* Societies should provide information on healthier products, improving the offering of these products in the supermarket and restaurants, and make these options more attractive and affordable. Parents should be educated in the appropriate portion size for their children, and water should always be provided at home and in school.

IV) *Restrict marketing and advertising to children:* Regulations are needed to reduce children and adolescent exposure to food marketing.

V) *Inform and empower families*: Parents are primarily responsible for their children and should be aware of the importance of healthy lifestyles early in

life. Regulations should be implemented with respect to nutritional labels on foods and drinks.

VI) *Encourage PA*: PA should be encouraged early in life by redesigning urban areas and providing options to be physically active throughout life.

VII*) Monitor and evaluate*: The health status and behaviour of children and adolescents should be monitored.

VIII) *Increase research*: Systematic reviews of childhood OB should be conducted to improve European Union policies and translate these policies to innovative actions.

2.2 Anthropometric measurements

2.2.1 Body Mass Index

Body Mass Index (BMI) is defined as weight in kilograms divided by the square of height in meters (World Health Organization, 2015a) and is the most frequently used metric of OB (Flegal & Ogden, 2011). However, BMI is not an accurate measure of fat mass (Flegal & Ogden, 2011) (Mei et al., 2002) and exhibits high specificity (0.93) and low sensitivity (0.73) to detect excess adiposity in children (Javed et al., 2014). Nonetheless, high BMI in the adolescent period is a risk factor for the development of OB-related disorders in adulthood (Tirosh et al., 2011).

In children between 0 to 18 years, the measurement of OB is complicated due to the difference in growth patterns for children of differences sexes and ages (Dinsdale, Ridler, & Ells, 2011). Therefore, the calculation of BMI in children relies on the use of thresholds that consider age and gender and are usually defined by a specific z-score, percentile or child growth reference (Dinsdale et al., 2011) universal criteria have not yet been developed.

2.2.2 BMI z-score

The BMI z-score is defined as the "relative weight adjusted for child age and sex" (Must & Anderson, 2006) and provides information about the standard deviation (SD) units above or below the mean (Flegal & Ogden, 2011).

The BMI z-score is calculated using an external reference (national or international) and can be used to calculate the WHO child growth reference (World Health Organization, 2007). This measure is valid and readily available for use in clinical and population-based applications (Must & Anderson, 2006). The BMI z-score is a valid means to measure annual adiposity change in primary school children (Inokuchi, Matsuo, Takayama, & Hasegawa, 2011).

2.2.3 Child growth references

Each country provides child growth references specific to the country that providing a comparison with the general population (Dinsdale et al., 2011). Table 1 describes international child growth references, which permit a better comparison of the data among countries and Spanish national data.

It is necessary agree on a unique international reference to compare the growth of school-aged children and adolescents across different countries (Wang, Moreno, Caballero, & Cole, 2006). Despite this recommendation, there is no clearly superior definition, and the appropriateness definition depends on the specific condition. Thus, it would be interesting identify the BMI cut-off values that represent the best predictors of future health risks (Flegal & Ogden, 2011).

Table 1. Description of International and Spanish Child Growth References

Child Growth References	Orbegozo Foundation (1988)	Orbegozo Foundation (2004)	Orbegozo Foundation (2008)	IOTF (2007)	WHO (2007)
Sample	600 children	6,443 children	32,064 children	192,727 children	26,985 children
Age range	0-18 years	0-18 years	0 – 24 years	2-18 years	5-19 years
Geographic areas	Spain	Spain	Spain	Brazil, Great Britain, Hong Kong, Netherlands, United States	Brazil, Ghana, Norway, India, Oman, United States
How is it measured?	Percentiles	Percentiles	Percentiles	BMI are extrapolated from the adult BMI.	BMI z-score
BMI cut-offs	90^{th} percentile = OW 97^{th} percentile = OB	85^{th} percentile = OW 95^{th} percentile = OB	85^{th} percentile = OW 95^{th} percentile = OB	16, 17 or 18.5 kg/m^2 = Thinness 25 kg/m^2 = OW 30 kg/m^2 = OB	< 2 SD = Thinness +1SD and <+2SD = OW >+ 2 SD = OB
How is it used?	Spanish population and comparison studies	Spanish population and comparison studies	Spanish population and comparison studies	International comparison and present OW/OB prevalence in a scientific journal	International comparison
References	(Hernández et al., 1988)	(Sobradillo et al., 2004)	(Carrascosa et al., 2008)	(Cole, Bellizzi, Flegal, & Dietz, 2000) (Cole, Flegal, Nicholls, & Jackson, 2007)	(World Health Organization., 2007)

2.2.4 Adiposity measures

Central fat is associated with higher health risks, including risk for cardiovascular and metabolic disease (Janssen, Katzmarzyk, & Ross, 2004) than total body fat distribution. Visceral adipose tissue is a highly active metabolic component of abdominal fat (Després, 2006).

Waist circumference (WC) (cm) and Waist-to-Height ratio (WtHR) [waist (cm) divided by height (cm)] are measures of abdominal adiposity and are associated with cardiovascular metabolic risk in children and adolescents (Lee, Huxley, Wildman, & Woodward, 2008). Skinfolds are the best predictor of adiposity, but when skinfold measurements are not available, WtHR is a better predictor of total

adiposity than BMI or WC in children and adolescents (Brambilla, Bedogni, Heo, & Pietrobelli, 2013).

WtHR increases with body fat. However, a single value such as ≥0.50 in WtHR as a cut-off point is not a good predictor of adiposity in children (Brambilla et al., 2013).

2.3 Lifestyles

2.3.1 Food habits

A healthy diet protects against the development of chronic disease such as OB, diabetes, heart disease, stroke and cancer (World Health Organization, 2015b). Suboptimal intake of some foods has been observed, including decreased intake of low energy-dense foods, such as fruits, vegetables, legumes, and whole grain cereals, in conjunction with high intake of energy-dense foods, including high-fat and high-sugars processed foods. These habits contribute to high rates of OW and OB (World Health Organization, 2003).

The Mediterranean diet is characterized by the high intake of fruits, vegetables, nuts, olive oil, and cereals, the moderate intake of fish, poultry and dairy products (cheese and yoghurt) and the low intake of red meat. Additionally, wine is consumed with meals in moderate amounts in adult population (Willett et al., 1995). Adherence to the Mediterranean diet is associated with improved health status (Sofi, Cesari, Abbate, Gensini, & Casini, 2008) and cardiovascular risk (Estruch et al., 2013). Paradoxically, children of Mediterranean countries are abandoning this type of diet in favour of increasingly western diets, which appears to be related to the high OW and OB prevalence (Tognon et al., 2014).

Fruit and vegetable consumption in children or adolescents affects adult health (Te Velde, Twisk, & Brug, 2007). In Spain, the recommended fruit and vegetable consumption is 5 portions per day (*Raciones de frutas y hortalizas en España*, 2010), significantly reducing the risk of coronary obstruction and stroke (European Heart Network, 2011). Fifty percent of children of 11 years old in Europe and in

Spain consume fruit daily, but consumption decreases by 15% in 15-year olds (Currie et al., 2012).

In addition to the Mediterranean diet, breakfast consumption has been observed to include favourable nutrients, such as dietary fibre, carbohydrates, lower total fat and cholesterol (Deshmukh-Taskar et al., 2010). Additionally, habitual breakfast consumption is independently associated with better school grades (Adolphus, Lawton, & Dye, 2013). In Europe, and particularly in Spain, 75% of children aged 11 consume daily breakfast before leaving home. However, at 15 years of age, breakfast consumption declines approximately 15%, following the same pattern as fruit and vegetable consumption (Currie et al., 2012).

Dietary quality (DQ) is an innovative concept that combines the quality and variety of the whole diet (Wirt & Collins, 2009) and can be assessed by a number of different tools to evaluate how closely food patterns adhere to the dietary recommendations of diverse populations (Marshall, Burrows, & Collins, 2014). The evaluation of DQ provides a single value to represent the complexity of human diets and takes into account the interactions between nutrients, food preparation methods and eating patterns (Vyncke et al., 2013).

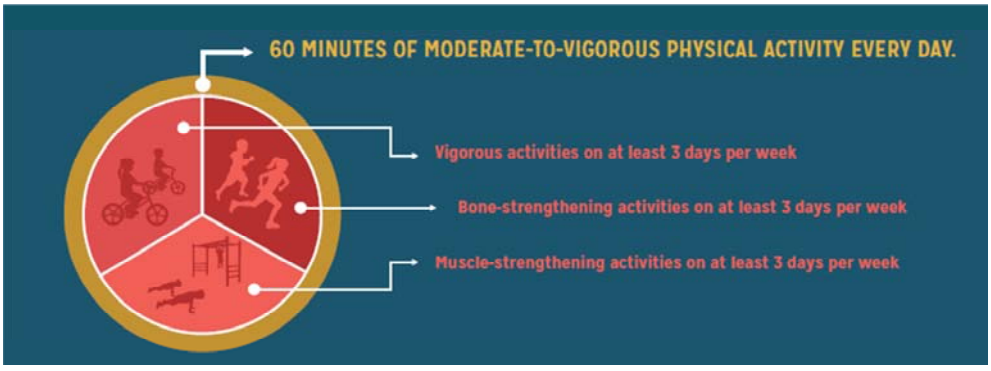
Some DQ indices are associated with health and disease outcomes and provide an alternative to studying individual nutrients or foods (Nicklas, O'Neil, & Fulgoni, 2014). Low DQ scores have been reported to be associated with higher rates of all-cause mortality in adult populations (Wirt & Collins, 2009). However, it is necessary to conduct more research on DQ indices in paediatric and adolescent populations and their relationship with health outcomes (Marshall et al., 2014).

2.3.2 Physical activity

PA is defined as "all modes of movement caused by muscle activity resulting in increased energy expenditure" (Rauner, Mess, & Woll, 2013). Exercise is considered to be a planned, structured and repetitive PA with the aim of improving or maintaining physical fitness, and sports are defined as competitive exercises based on regulations (Generalitat de Catalunya, 2007). The recommendations

suggest that children between 5-17 years should accumulate at least 60 minutes per day of moderate-to-vigorous PA (MVPA) (Figure 6). However, health benefits can be achieved in children in as little as 30 minutes per day (Janssen & Leblanc, 2010). However, children can accumulate this time sporadically, with time PA intervals shorter than 5 minutes over the day; however, this is not as beneficial as longer time intervals (Mark & Janssen, 2009). Moreover, to the addition of vigorous intensity activities, including activities strengthening muscle and bone, may be beneficial (Janssen & Leblanc, 2010). Finally, aerobic activities (cardio exercises) and activities that strengthen muscle and bone should be incorporated at least 3 days per week (Janssen & Leblanc, 2010).

Figure 6: American Physical Activity recommendations guidelines for children and youth.



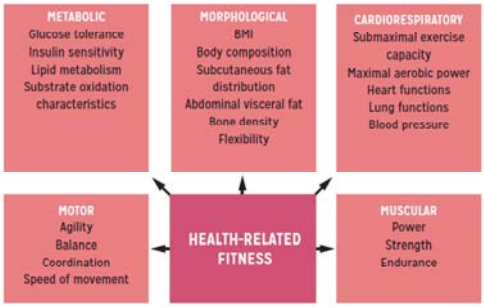
Source: (National Physical Activity Plan Alliance, 2014)

PA practice is associated with a large number of health benefits (National Physical Activity Plan Alliance, 2014):

- Increase health related-fitness, including metabolic, morphological, cardiorespiratory, motor and muscular fitness (Figure 7)

- Improvements in cardiovascular and metabolic disease risk profiles especially in higher intensity activities
- Decreased risk of cardiovascular disease in adulthood
- Decreased risk of type 2 diabetes in childhood and adulthood
- Boosts in bone health and development
- Improvements in mental health and well-being
- Enhancements in cognitive and academic performance
- Improvements in body coordination and physical functioning

Figure 7: Bouchard and Shephard model of health-related fitness, components and factors.



Source: (National Physical Activity Plan Alliance, 2014)

Despite of these benefits, only 25% of children and young people in Europe (11 years) achieved the recommended 60 minutes/day, and this proportion declining substantially at age 15. In Spain, the percentage is similar in girls, but boys are more physically active, with 40% engaging in at least 60 minutes of PA per day (Currie et al., 2012).

2.3.3 Sedentary behaviour

Sedentary behaviour was defined recently as “any waking behaviour characterized by an energy expenditure ≤1.5 Metabolic Equivalent of Tasks (METs) while in a sitting or reclining posture”, and inactive behaviour is defined as “insufficient amounts of MVPA” (Sedentary Behaviour Research Network, 2012). Sedentary behaviour includes activities performed during leisure time, such as watching

television (TV), screen games, and productive time (school or homework) (National Physical Activity Plan Alliance, 2014).

The increase sedentary behaviour time to more than 2 hours/day is related to negative health outcomes in boys and girls, including unfavourable body composition, decreased fitness, low self-steem, low social behaviour and decreased academic achievement (Tremblay et al., 2011). Additionally, sedentary behaviour increases the cardiovascular metabolic risk when combined with suboptimal levels of PA (Väistö et al., 2014). Despite sedentary time, high levels of MVPA are associated with better cardiovascular metabolic risk (Ekelund et al., 2012).

The American Academy of Pediatrics (AAP) recommends limiting television viewing and screen time to 2 hours or less per day (American Academy of Pediatrics, 2001). Despite of this recommendation, only 50% of school-aged children in Europe and in Spain (11 years) view TV or play in screen games ≤ 2 hours/day over the weekdays; this proportion decreases to 40% at 15 years old (Currie et al., 2012).

The Canadian Sedentary Behaviour Guidelines offer some tips to achieve the recommendations to reduce sedentary behaviour (*Canadian Physical Behaviour Activity Guidelines*, 2011), such as active transportation, active play and active family time (Figure 8).

Figure 8: Tips to reduce sedentary behaviour.

Source: (*Canadian Physical Behaviour Activity Guidelines*, 2011)

The Spanish Ministry of Health, Sport and Culture recommends less sedentary time in schools and suggests physically active breaks of 10 minutes (Ministerio de Sanidad, Cultura y deporte, 2014). According to different school practices, physically active breaks can include practicing numerical mathematics exercises while jumping.

CHAPTER 3: OBESITY PREVENTION INTERVENTIONS IN CHILDREN AND ADOLESCENTS

3.1 Obesity prevention interventions in childhood and adolescence

The interventions to prevent OB include all children (normal weight children and OW and OB children and adolescents) because the intervention objective is to tackle the rise in childhood OB and to combat established OB. However, programs do exist that aim to tackle OB and only include children with OW or OB. The interventions those including all children, could be classified according to the following variables:

a) The setting where the intervention is delivered (Table 2)

Table 2. Types of interventions applied to prevent childhood OB according to the setting

Type of intervention	Setting	Specifications
School-Based Intervention	Schools	Sometimes involve parents, and school community
Home-Based Intervention	Child's home	
Primary Care-Based Intervention	Office of primary-care practitioner, clinic, or health entity	
Childcare-Based Intervention	Setting were children received nonparental/noncustodial care, outside the home	
Community-Based and Environmental-Level Interventions	Interaction with community (a group of individuals that existed prior to the intervention)	Include interventions delivered by the enforcement of policies or legislation or by changes to the built environment.
Consumer Health Informatics-Based Interventions	Web-based, phone-based, video-based programs, games, and information storehouses	The intervention is delivered indirectly to the community

Source: (Wang et al., 2013)

b) The lifestyles targeted for improvement: diet intervention, PA intervention, and a combination of diet and PA intervention.

3.2 Effectiveness of obesity prevention interventions

The effectiveness of different types of OB prevention interventions depends on the setting of the intervention, the lifestyles included and the strategies used. Table 3 presents the strength of different types of OB prevention interventions depending on the setting in which they are applied and the lifestyles targeted for improvement based on a review of effectiveness published in 2013 (Wang et al., 2013). This review provides the strength of evidence, calculated using the "Methods Guide for Effectiveness and Comparative Effectiveness Review" (Owens et al., 2010) according to key questions defined by the authors. There are four categories of the strength-of-evidence: a) high: high confidence that the evidence reflects the true effect (further research is unlikely to change the confidence in the estimate of effect); b) moderate: moderate confidence that the evidence reflects the true effect (further research may change the confidence in the estimate of the effect); c) low: low confidence that the evidence reflects the true effect (further research is likely to change the confidence in the estimate of effect); and d) insufficient: evidence is unavailable (Wang et al., 2013).

It is important to take caution in interpreting these results, as high strength-of-evidence is not necessarily an effectiveness indicator.

In Table 3, it can be observed that some school-based interventions exhibit the highest strength of evidence; these are school-based interventions with home and PA components that improve OB outcomes and school-based interventions with home and community components that use PA and diet to effectively improve OB outcomes.

Table 3. Effectiveness of different types of intervention depending on the setting applied and the lifestyle used to prevent childhood OB

Type of intervention per setting	Subtype of intervention	Lifestyles to improve	Strength of the evidence in weight-related outcomes
School-Based Intervention	School-based-only	Diet	Moderate
		PA	Moderate
		Diet + PA	Insufficient
	School-home	Diet	Insufficient
		PA	High
		Diet + PA	Moderate
	School-home-community	PA	Insufficient
		Diet + PA	High
	School-community	Diet	Insufficient
		PA	Insufficient
		Diet + PA	Moderate
	School-CHI	PA	Insufficient
		Diet + PA	Insufficient
	School-home-CHI	Diet + PA	Insufficient
Home-Based Intervention	Home-based only	Diet	Insufficient
		Diet + PA	Low
	Home-PC-CHI	Diet + PA	Insufficient
	Home-school-community	Diet + PA	Insufficient
Primary Care-Based Intervention	Primary care	Diet + PA	Insufficient
Childcare-Based Intervention	Child care	PA	Insufficient
		Diet + PA	Low
Community-Based and Environmental-Level Interventions	Community-based only	PA	Insufficient
	Community-school	Diet + PA	Moderate
	Community-school-home	Diet + PA	Insufficient
	Community-home	Diet + PA	Insufficient
	Community-home-PC-CC	Diet + PA	Insufficient
	Community-school-PC-CC	Diet + PA	Insufficient
Consumer Health Informatics-Based Interventions	None	None	None

Source: Adapted from the Agency of Healthcare Research and Quality (Wang et al., 2013)
CHI: Consumer Health Informatics
CC: Childcare
PC: Primary Care
PA: Physical Activity

A recent meta-analysis concluded that school-based nutrition education interventions are effective in the reduction of BMI in children and adolescents (Silveira et al., 2013).

Children are exposed to many influences outside school. Therefore, it is important address both the school setting as well as the community or home to increase program effectiveness (Institute of Medicine, 2012).

However, the meta-analysis identified strong evidence for OB-related outcomes in school-based intervention programs focused on reducing excess weight that were performed in children between 6 to 12 years old and proposed the following (Waters et al., 2011):

- Include healthy eating, PA and body image in school curriculum
- Increase sessions of PA hours/week in school setting
- Increase the nutritional quality of foods in school canteens
- Improve environmental and cultural practices related to healthy lifestyles
- Professional support to teachers about healthy lifestyles
- Incorporate home components in school-based interventions to involve parents in the children's lifestyles

Table 4 presents 13 school-based randomized controlled studies implemented in Europe among 6 to 18 years old children published between 2009 and 2014 that, focused on preventing OB or improving PA or lifestyles.

Table 4. Description of different school-based intervention randomized controlled studies implemented in Europe among 6 to 18 years old children and adolescents (published from 2009 to 2014)

Program Name	Population	Type of Intervention	Intervention Description	Outcomes	Reference
Active for Live Year 5 (ALFY5)	South West of England (8-9y) IG (n=1064); CG (n=1157)	1-y school-based study + family component D+PA	Primary school teacher training to teach 16 lessons about sedentary behaviour, healthy nutrition, and healthy behaviour (10 with parent-child interactive homework associated)	Not effective in increasing PA levels, decreasing sedentary behaviour, and increasing fruit and vegetable consumption.	(Kipping et al., 2014)
Join the Healthy Boat	South West of German (6-8y) IG (n=954); CG (n=782)	1-y school-based, teacher-centred, intervention D+PA	Teaching material for alternative recreational activities, PA, and healthy diet; integrated in the primary-school curriculum.	Reduction of screen media use in girls and children without migration background and parents with low-education level Improve breakfast behaviour in second grade	(Kobel et al., 2014)
Enjoy being fit!	Low-income neighbourhoods in Rotterdam, Netherlands (6-12y) IG (n=1271); CG (n=1499)	1-y school-based, multi-component intervention D+PA	Three Physical Education sessions/week + sport activities outside school hours + 3 main lessons on healthy nutrition, active living and healthy lifestyle in classrooms + involvement of local sport clubs	6-9 y children: Reduce of 3% OW prevalence in intervention group compare with control; lower increase of WC and fitness in intervention group compare with control 9-12 y children: No effects.	(Jansen et al., 2011)
AVall study	City of Granollers (Spain) (5-6y) IG (n=272); CG (n=237)	2-y school-based + family component D+PA	Use educational methodology IVAC. Three hours/week in the classrooms develop activities related to healthy foods and/or PA. + Recipes/month distributed among families + Information and tools to school and families	Lower increase in BMI and OW+OB prevalence in intervention group relative to control. Increase in fruit intake and PA levels.	(Llargues et al., 2011)

Table 4. Description of different school-based intervention randomized controlled studies implemented in Europe among 6 to 18 years old children and adolescents (published from 2009 to 2014)

Program Name	Population	Type of Intervention	Intervention Description	Outcomes	Reference
Health in Adolescents (HEIA) study	Counties in South-Eastern Norway (11y) IG (n=566); CG (n=1014)	20-month school-based + multicomponent D+PA	Classrooms: 6 lessons about healthy diet and PA + 1 poster/month + fruit and vegetable break (1/week) + PA break (10 minutes/week) + sport equipment for recess activities + active commuting campaigns + pedometer + computer tailored individual advice Home/Parents: Facts sheets (monthly) + brochures School wide: Kick-off meetings in school + courses for physical education teachers + resource box for school management + committee meetings Leisure time activities: Equipment for cutting and selling fruit and vegetable	Increased overall PA of intervention group, especially girls and children with low levels of PA. Decrease BMI and BMI z-score among girls but not in boys.	(Grydeland et al., 2013) (Grydeland et al., 2014)
Reykjavik school-program	Reykjavik (Iceland) (7y) IG (n=151); CG (n=170)	2-y school based + home component D+PA	Teacher-led-daily implementation focus on PA and nutritional.	Increase PA hours and dietary habits in intervention school children. However, did not report significant changes in body composition.	(Magnusson, Hrafnkelsson, Sigurgeirsson, Johannsson, & Sveinsson, 2012)
France PA school-program	France (6-10y) IG (n=229); CG (n=228)	6-month school based PA	Two PA sessions per week in addition to standard physical education classes.	Improve anaerobic and aerobic physical fitness. However, did not report significant changes in anthropometric measures.	(Thivel et al., 2011)
KISS program	26 provinces of Switzerland (6-11y) IG (n=297); CG (n=205)	1-y school-based multicomponent PA	Two standardized PA sessions per week in addition to standard physical education classes. + 3-5 short activity breaks (2-5min/each) over academic lessons + 10min/day of PA homework	Improvement of PA and fitness and reduction of adiposity in the children in the intervention group.	(Kriemler et al., 2010)
Portugal school-based	North of Portugal cities (6-12y) IG (n=233); CG (n=231)	5-month school-based D+PA	Teachers training (72 hours) + 12 lessons to scholars about concepts of training	Attenuated the intake of low nutrient, energy-dense foods	(Rosário et al., 2013)

Table 4. Description of different school-based intervention randomized controlled studies implemented in Europe among 6 to 18 years old children and adolescents (published from 2009 to 2014)

Program Name	Population	Type of Intervention	Intervention Description	Outcomes	Reference
Italy school-based	Suburban area of Bologna, Italy (9y) IG (n=103); CG (n=106)	5-month school-based + home and environment components D+PA	Three meetings with children by experts in PA to implement new recreational physical activities + step counters for children to stimulate PA practice + a meeting of nutritional practice of breakfast + 3 motivational meetings about healthy diet and PA for parents	Modification of progressive increase in BMI, significantly lower BMI z-scores in the intervention group and changes in PA.	(Centis et al., 2012)
JuvenTUM project	Bavaria (Germany) (8y) IG (n=486); CG (n=340)	1-y school-based + home and environment components PA	Monthly lessons of 45 minutes with 3 parts: 10 min running, playing running games at high-intensity, 30 min exercise to improve body awareness and self-esteem, 5 min of relaxation Workshops and homework plus monthly newsletters. 2 training sessions for parents (3 hours) 3 training sessions for teachers (9 hours) to increase PA.	Increase in PA level (number of day/week in which children met the guideline levels) in intervention group, from 4.6±2.0 day/week to 5.1±2.0 day/week, independent of gender or socioeconomic status.	(Siegrist, Lammel, Haller, Christle, & Halle, 2013)
URMEL-ICE school-based	Regions in Southern Germany (7y) IG (n=540); CG (n=579)	1-y school-based	4 teaching training (2.5 hours/each) + 29 teaching units (30-60 min/session) + 2 short blocks of PA exercises/day (5-7 min/each) + 6 family homework lessons	No effects on children's BMI. Tendency for positive changes in subscapular skinfold thickness and WC.	(Brandstetter et al., 2012)
Educació en Alimetnació (EdAl) study	Reus, Cambrils, Salou i Vila-seca (Spain) (7-8y) IG (n=1550); CG (n=800)	3-y school-based + family and environment component D+PA	12 sessions (1 hour/each), 4 session/year, about healthy lifestyles (foods, PA and lifestyles) based on evidence. Each session had a family component, food-taste component and environment component	Reduction of OB prevalence in boys of intervention group by 4.39% and reduction of BMI z-score by -0.24 units compare with control schools. Improvement of percentage of intervention group children who perform >5 hours/week after-school PA and dietary habits (breakfast, fruit and vegetable consumption).	(Tarro, Llauradó, Albaladejo, et al., 2014)

Source: Elaboration by the author. The studies included were published between 2009 and 2014
IG = Intervention Group **CG** = Control Group
D = Diet **PA** = Physical activity

3.3 Characteristics of obesity prevention interventions

3.3.1 CONSORT (CONsolidated Standards of Reporting Trials)

Intervention trials to prevent OB need to be reported according the CONSORT statement. The transparency is an important characteristic of clinical trials (Rennie, 2001). To achieve reliable evidence in health interventions, the CONSORT guidelines are recommended (Moher et al., 2012). The guidelines report a checklist of 25 items and a flow diagram of the participants to be filled by the authors and can help researchers improve intervention designs (Schulz, Altman, & Moher, 2010). Guidelines place special emphasis on the methodology of the intervention design (randomized, intervention and control groups, parallel trials). However, there are some situations in which randomization is not possible, and it is necessary to use a cluster randomization (groups of people or schools or communities) to avoid intervention "contamination" with the control group. For this reason, an extension of the CONSORT guidelines exists specifically for use in cluster-randomized controlled trials (Campbell, Piaggio, Elbourne, & Altman, 2012).

3.3.2 Quality of obesity prevention interventions

The assessment of quality intervention design is an important matter for clinicians, researchers and policy makers (Armijo-Olivo, Stiles, Hagen, Biondo, & Cummings, 2012). One qualitative assessment tool is The Effective Public Health Practice Project (EPHPP) for quantitative studies, which allow researchers to classify the quality of the study as strong, moderate or weak. The EPHPP is composed of 8 items: 1) selection bias, 2) study design, 3) confounders, 4) blinding, 5) data collection methods, 6) withdrawals and drop-outs, 7) intervention integrity and, 8) analysis appropriate to question. From each section, the scores are summed according to the guidelines of the quality assessment tool, obtaining a global rating. Studies can be classified according to a three-grade scales: strong (four or more strong section ratings and no weak ratings), moderate (1 to 3 strong section ratings and one weak rating), or weak (two or more weak section ratings) (Effective Public Health Practice Project, 2009).

Another option is a quantitative assessment tool proposed by Cochrane (Higgins & Green, 2011). This tool is composed of 6 items: selection bias, development bias, detection bias, wear bias, notification bias and another bias.

3.3.3 Social marketing interventions

Kotler and Zaltman expressly defined social marketing (SM) in 1971 as "a social influence technology involving the design, implementation and control of programs aimed at increasing the acceptability of a social idea or practice in one or more groups of target adopters" (Kotler & Zaltman, 1971). This term was re-described by Andreasen in 1994 as "the application of commercial marketing technologies to the analysis, planning, execution and evaluation of programs designed to influence the voluntary behavior of target audiences in order to improve their personal welfare and that of their society"(Andreasen, 1994).

Doctrines and tactics from commercial marketing for social change programs can improve the strategic value of health communication and increase the likelihood that people will make healthy choices (Kotler, Roberto, Roberto, 2002).

To help strengthen the use of effective SM approaches, the Social Marketing National Benchmark Criteria (SMBC) was developed by the National Social Marketing Centre (NSMC) in the UK (National Social Marketing Centre, 2010). The purpose of this benchmark is to create support for a better understanding of core SM concepts that take into account the 8 basic SM principles described in Table 5 (NSMC, 2010):

Table 5. Social Marketing Benchmark Criteria (SMBC)

SMBC	Definition
Costumer orientation	Understand target audience
Behaviour	Influence specific behaviours
Theory	Use of behavioural theories to understand audience behaviours
Insight	Understand what motivates the target audience
Exchange	Consider costs and benefits to changing behaviour
Competition	Internal and external barriers to changing behaviour
Segmentation	Identify common characteristics of the target audience
Methods Mix	Use of primary intervention methods: inform, educate, support, design and control.

Source: (NSMC, 2010)

Some studies suggest that the use of SM strategies to modify diet and PA using an intervention (active target audience), campaign (passive target audience), or program (can englobe interventions and campaigns) can reduce the OW or OB prevalence among children and adolescents. However, the analysis and conclusions are not clear because there are very few interventions that expressly use the SM criteria (Gracia-Marco et al., 2011) (Gracia-Marco, Moreno, & Vicente-Rodríguez, 2012). One such intervention is Change4Life, a national SM program implemented in the United Kingdom to reduce OB (Mitchell, Clifford, Hardy, & Asscher, 2011). This intervention achieved increased awareness of the anti-OB campaign but had little impact on attitudes and behaviours (Croker, Lucas, & Wardle, 2012). However, EPODE *Together Let's Prevent Childhood Obesity*, is a SM coordinated, capacity-building approach aimed at reducing childhood OB through a societal process involving all community components (Borys et al., 2012). The involvement of different stakeholders represents a challenge (Pettigrew et al., 2014).

3.3.4 Social media interventions

Social media can be defined as a "variety of new sources of online information that are created, initiated, circulated and used by consumers' intent on educating each other about products, brands, services, personalities and issues" (Blackshaw & Nazarro, 2004). This social media is visible in a group of online applications: a)

collaborative projects (e.g., Wikipedia), b) blogs or microblogs (e.g., WordPress and Twitter), c) content communities (e.g., YouTube), d) social networking sites (e.g., Facebook), and e) virtual gaming or social worlds (e.g., Second Life) (Kaplan & Haenlein, 2010). These new tools and strategies can contribute to changing the communication between consumers (Mangold & Faulds, 2009).

Social media for health communications by a recent systematic review indicates that social media is a powerful tool but that the information exchanged needs to be supervised by professionals (Moorhead et al., 2013). Additionally, this systematic review proposed some keys for future on health communication research: a) determine the impact of social media for health communication in specific population groups with large sample sizes, b) use randomized controlled trials (RCTs) to determine the effectiveness of social media applications, c) determine the long-term impact of social media health communication and d) explore the potential of social media to achieve behaviour changes. However, there is a scarcity of such interventions (Maher et al., 2014).

Currently, social media are commonly used to improve diet and exercise (Williams, Hamm, Shulhan, Vandermeer, & Hartling, 2014) and are rapidly expanding in child and adolescent health (Hamm et al., 2014). However, this tool is also used as part of complex interventions. A systematic review and meta-analysis revealed no differences in adult social media interventions and recommended involving participants in the development of social media interventions to enhance their acceptance and adherence (Williams et al., 2014).

CHAPTER 4: DIFFERENT APPROACHES TO CONFIRM THE EFFECTIVENESS OF INTERVENTIONS BEYOND THE FINAL INTERVENTION ASSESSMENT

4.1 Follow-up of obesity prevention interventions

The goal of intervention studies is the long-term maintenance of the effects produced by the intervention, because their aim is to improve the health and well-being of the population. Thus, intervention studies need to conduct follow-ups beyond the cessation of the intervention to guarantee the long-term maintenance of effects (Lai et al., 2014a). Nonetheless, there is a scarcity of published follow-up post-cessation intervention studies. There are several reasons that may contribute to insufficiency of these types of publications: no success at the end-of-study, many drop-outs, large sample size that results in high economic costs, contamination and the reticence of funders to support follow-up studies (Jones et al., 2011).

Seven studies have provided evidence of follow-up of OB prevention studies (Table 6). Some of these studies reported the maintenance of results achieved at end-of-intervention. However, the Kiel Obesity Prevention Study (KOPS) only sustained the effects in an intervention subgroup, characterized by high socioeconomic level, at the 8-y follow-up (Plachta-Danielzik, Landsberg, Lange, Seiberl, & Müller, 2011). On the other hand, the EdAl Program improved the results obtained at end-of-study at 2-y follow-up (Tarro, Llauradó, Moriña, Solà, & Giralt, 2014).

Table 6. Intervention studies with follow-up post-cessation intervention

Program Name	Type of intervention	Population	Follow-up outcomes	Reference
The CATCH (Child and Adolescent Trial for Cardiovascular Health) cohort	3-y school-based, randomized controlled trial, among 3rd and 5th grade children	Scholars of public elementary schools of USA	3-y post-intervention: Maintenance of behaviours (PA and dietary) improved over the intervention	(Perry et al., 1997) (Nader et al., 1999)
The KOPS (Kiel Obesity Prevention Study)	1-y school-based, cluster randomized controlled trial, among 5-7 year-old children	Scholars of Kiel (Germany) schools	4-y post-intervention: Non-potential effects 8-y post-intervention: Sustained effects on BMI in subgroup of high SES families	(Plachta-Danielzik et al., 2007) (Plachta-Danielzik et al., 2011)
Cretan Health and Nutrition Education Program	6-y school-based, cluster randomized controlled trial, among 1st grade of primary schools children	Scholars of Iraklio, Rethimno, Hania counties (Greece)	4-y post-intervention: Maintenance of favourable effect of PA levels in intervention boys and favourable changes in serum lipids and BMI	(Manios, Kafatos, & Kafatos, 2006)(Manios & Kafatos, 2006)
CHOPPS (Christchurch obesity prevention programme)	1-y school-based, cluster randomized controlled trial, among 7-11 year old children	Scholars of southern England (United Kingdom)	2-y post-intervention: BMI z-score difference between intervention and control group, favourable to intervention and increase in OW prevalence in both groups but higher in control group	(James, Thomas, & Kerr, 2007)
The APPLE project (A Pilot Programme for Lifestyle and Exercise)	2-y community-based controlled trial, among 5-12 year old children	Scholars of 2 geographic regions of New Zealand	2-y post-intervention: Maintenance of BMI benefits in intervention children	(Taylor et al., 2008)
The Avall study	2-y School-based cluster randomized controlled trial, among 5-6 year-old children	Scholars of Granollers (Spain)	2-y post-intervention: Maintenance of BMI z-score reduction achieved at end-of-study 4-y post-intervention: BMI reduced in intervention children	(Llargués et al., 2012) (Mora, Llargués, & Recasens, 2014)
The EdAl (Educació en Alimentació)	3-y school-based, randomized, controlled, trial,	Scholars of Reus, Salou,	2-y post-intervention: Decrease in the BMI z-	(Tarro, Llauradó, Moriña, et al., 2014)

Study	among 3rd and 4rd grade children	Cambrils i Vila-seca (Spain)	score and OB prevalence, compared with control group; and increase in the number of children who engage in >4 hours/week after-school PA 4-y post-intervention: Decrease in the BMI z-score in girls and OB prevalence in boys compared with the control group; increase in >4 hours/week of after-school PA in the intervention group	(Llauradó, Tarro, Aceves-Martins, Solà, & Giralt, n.d.)

Source: Elaboration by the author.
PA: Physical activity
BMI: Body Mass Index
SES: Socio economic status
OW: Overweight
OB: Obesity

4.2 Reproducibility of obesity prevention interventions

Interventions to prevent OB in the school setting have demonstrated radical improvements (Brown & Summerbell, 2009). However, successful studies need to be reproducible, especially those improving healthy lifestyles (e.g., after-school PA) to confirm best childhood practices. To standardize a method, it is essential to be able to reproduce appropriate levels of an intervention, especially one that involves behavioural changes. The effectiveness of intervention study need to be demonstrated with the reproduction of the intervention in other localities and with other children (Boutron, Moher, Altman, Schulz, & Ravaud, 2008). Owing to the complexity, such interventions are difficult to rationalize, standardize, reproduce and administer consistently to all participants. Therefore, publication of reproducibility studies is rare. A recent review proposed assessing interventions in other settings to verify their effectiveness in reducing OB (Wang et al., 2013).

In the KOPS study, the results demonstrated the efficacy and feasibility of implementing new nutritional concepts (Danielzik, Pust, & Müller, 2007). The study demonstrated that nutritional knowledge was increased as a result of the intervention in the two cohort studies (KOPS 1 and KOPS 2) (Danielzik et al.,

2007). However, the study did not describe differences in OB-related outcomes or lifestyles between the cohorts.

Some multicentre studies attempted to reproduce the methodological aspects of interventions conducted in different countries or different populations. However, although multicentre studies are usually implemented concurrently; reproducibility involves the applicability of the intervention at different sites and/or different times to validate the initial findings. One example of this is the Pro Children Study (Te Velde et al., 2008), which, as a multicentre study, had been applied in different countries simultaneously and demonstrated its efficacy and feasibility.

4.3 Sustainability of interventions

Sustainability has been defined as "the long-term ability of an organizational system to mobilize and allocate sufficient and appropriate resources for activities that meet individual or public health needs and demands" (Olsen, 1998). The sustainability planning and assessment of health programs are increasingly necessary for the policy-makers, practitioners, and funders of health systems to distribute resources efficiently and effectively. However, many health programs do not focus on the prediction of long-term sustainability. Intervention assessment (Gruen et al., 2008) is essential to determine whether a health program maintains effective health benefits once the intervention is over (Luke, Calhoun, Robichaux, Elliott, & Moreland-Russell, 2014). Moreover, sustainability is a key element in the OB prevention strategies in children (World Health Organization, 2010a) (Whelan et al., 2014).

The Program Sustainability Assessment Tool (PSAT) is a tool to predict the sustainability of health intervention programs. This new instrument comprises 8 domains (Luke et al., 2014):

- *Environmental support:* Internal and external climate support
- *Funding stability:* Consistent financial base
- *Partnership:* Stakeholders and program connections

- *Organizational capacity:* Effective program management with sufficient resources and internal support
- *Program Evaluation:* Assess and collect data about program
- *Program Adaptation:* Take action to assure the effectivity of the program
- *Communications:* Inform stakeholders and general public of the development of the program
- *Strategic Planning:* Guide your program using goals and strategies

Each of these domains comprises 5 items (40 items in total). The PSAT is a reliable and ready-to-use tool that is designed to assess a program's capacity for long-term sustainability (Luke et al., 2014).

4.4 Cost-effectiveness of interventions

The cost-effectiveness analysis of interventions to prevent OB and improve lifestyles can help policy-makers, practitioners and funders determine which intervention should be implemented in their community. This type of analysis is defined as the quantification of intervention costs and outcomes achieved over the implementation of the intervention (Tilson et al., 2006). Unfortunately, the resources allocated to prevention interventions are limited; for this reason, it is necessary demonstrate both the effectivity as well as the cost-effective of each intervention (Wang, Yang, Lowry, & Wechsler, 2003).

A cost-effective intervention is defined as one with a cost-utility ratio less than 30,000 dollars per quality adjusted life years (QALYs) saved, but there is no consensus on this definition (Wang et al., 2003).

Cost-effectiveness analysis is a laborious task involves a numerous steps: calculate the costs of the intervention, estimate the cases of adulthood OW prevented, estimate the medical costs averted per case of adulthood OW prevented, and calculate the QALYs saved per case of adulthood OW prevented (Wang et al., 2003).

CHAPTER 5: EdAl (Educació en Alimentació) program

5.1 EdAl (Educació en Alimentació) program

The EdAL (Educació en Alimentació) study is a long-term, nutrition educational, primary-school-based program designed to prevent OB by promoting a healthy lifestyle that includes dietary recommendations and PA.
The aims were as follows: 1) to design a health-promotion program to be implemented by health-promoter agents (university students) in primary schools and 2) to evaluate the effects of a 3-y school-based life-style improvement program on the prevalence of OB in an area of the northwest Mediterranean (Giralt et al., 2011).

To encourage healthy lifestyles using a win-win strategy, undergraduates in medical and health-science university students were trained as HPAs to increase their communication skills in two university courses as part of the EdAl program to respond the challenge of childhood OB. The aim of this study was to describe the curricula of the university courses training HPAs for school interventions in the EdAl program. Twenty undergraduate students per year were enrolled in 2 courses of 45 h/course/year for a total of 90 h of training coursework/year. The 1st course develops a methodological basis for promoting health, and the 2nd course focuses on strategies for designing, standardizing, implementing and evaluating 12 activities (1 h/activity/session) that address 8 healthy lifestyle topics based on nutrition and PA. From 2006 to 2010, 60 HPAs formed without extra costs implemented 12 activities associated with a reduced BMI and an increase in the hours/week of after-school PA in 1550 pupils of primary school-based EdAl program (Tarro et al., n.d.). In conclusion, the HPA courses are an effective, innovative, standardized, and economical tool to meet society's current needs.

Two school clusters were randomly assigned to the intervention (24 schools, 1,222 pupils) or control (14 schools, 717 pupils); 78% of the pupils were Western European. The mean age (±SD) was 8.4±0.6 years (49.9% females) at baseline.

Generalized linear mixed models were used to analyse differences in primary outcomes between both groups. The data collected included BMI every year. Dietary habits and lifestyle questionnaires were filled in by the parents at baseline and at the end-of-study. The interventions focused on eight lifestyle topics covered in 12 activities (1 hour/activity/session) implemented by HPAs over 3 school academic years. At 28 months, OB prevalence in boys 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 in BMI z-score (from 0.01 to −0.04) relative to the control (from −0.10 to 0.09); 5.1% more intervention pupils undertook >5 hours/week of after-school PA than control pupils (P = 0.02). Fish consumption was a protector (odds ratio 0.39; 95% CI 0.23 to 0.67) and “fast-food” consumption was a risk factor for childhood OB (odds ratio: 2.27; 95% CI 1.08 to 4.77). Our school-based program, conducted by HPAs students, successfully reduced childhood OB prevalence in boys.

The continued benefit after cessation of EdAl program is unknown. We assessed the changes in OB prevalence and healthy lifestyle in 11- to 13-year-old adolescents, the age group that had complete inclusion data available 2-y after the EdAl program’s conclusion. At 2-y follow-up, the EdAl program induced a decrease in the BMI z-scores and OB prevalence compared with the control group. After-school PA practice can be stimulated in the primary school as part of a healthy lifestyle and maintained subsequently despite cessation of the intervention program.

HYPOTHESIS AND OBJECTIVES

HYPOTHESIS

Our hypothesis is that health education programs based on lifestyle improvements to prevent childhood obesity can be effectively delivered by peer leaders as easily accessible individuals using different methodologies in the elementary school or high-school setting.

OBJECTIVES

The principal objective was to evaluate the effectiveness of health education programs, using different methodologies, to prevent childhood and adolescent obesity by encouraging healthy lifestyles.

Specific objectives

Objective 1: To assess the reproducibility of an educational intervention EdAl-2 (Educació en Alimentació) program in 'Terres de l'Ebre' (Spain) to improve lifestyles, including diet and physical activity, over 22 months.

Objective 2: To verify the maintenance of health benefits achieved at 4-year follow-up after EdAl intervention cessation program by assessing obesity prevalence, anthropometric variables, lifestyle habits and physical activity in adolescents (13-15 years of age) who had participated in the EdAl program implemented in the 2007 to 2010 academic years.

Objective 3: To design and implement an intervention to tackle adolescent obesity in Reus (Spain), named "Som la Pera" (we are cool), using social marketing and a peer-led model belonging to European Youth Tackling Obesity (EYTO) project.

Objective 4: To plan and evaluate the implementation sustainability of the "Som la Pera" intervention, a social marketing and an adolescent peer-led model to tackle adolescent obesity, to achieve optimal long-term sustained implementation beyond completion of the intervention.

Objective 5: To identify causal factors for obesity risk and the dietary quality of adolescents, including identifying the relationship between dietary quality and eating frequency, to improve dietary habits as a key component to develop future obesity prevention interventions.

METHODS AND RESULTS

Study 1

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

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

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ABSTRACT

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

Design: Reproduction of a cluster randomised controlled trial.

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

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

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

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

Results: At 22 months, the OB prevalence and BMI values were similar in intervention and control groups. Relative to children in control schools, the percentage of boys in the intervention group who performed ≥4 after-school PA h/week was 15% higher (p=0.027), whereas the percentage of girls in both groups remained similar. Also, 16.6% more boys in the intervention group watched ≤2 television (TV) h/day (p=0.009), compared to controls; and no changes were observed in girls in both groups.

Conclusions: Our school-based intervention is feasible and reproducible by increasing after-school PA (to ≥4 h/week) in boys. Despite this improvement, there was no change in BMI and prevalence of OB.

Trial registration number: Clinical Trials NCT01362023.

Strengths and limitations of this study

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

BACKGROUND

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

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

The Organization for Economic Co-operation and Development (OECD) has predicted an

increase of 7% in excess weight prevalence in adulthood over the period spanning 2010 to 2020.[8] The WHO proposes the prevention and control of OB prevalence as key in the updated 'Action Plan 2008–2013' in which effective health promotion is considered as the principal strategy.[9]

Since excess weight status in adulthood is almost invariably predicated on childhood and adolescent weight, OB prevention should start early in life.[10] The optimum age to start an intervention is between the ages of 7 and 8 years because children are more receptive to guidance.[11] The school is an ideal place for the promotion of healthy nutrition and lifestyle habits[12] and, as some studies have shown, such interventions have inspired changes in nutritional habits and body mass index (BMI) status[13 14]; the message is received by all schoolchildren, irrespective of ethnic and socioeconomic differences.[9] The effectiveness of an intervention is when educational strategies and environmental factors such as healthy nutrition and physical activity (PA) habits coincide since both aspects are essential in preventing childhood OB.[15] Currently, European children spend more of their leisure time in sedentary activities such as watching television (TV), video games or on the internet. These activities represent a decrease in physical movement and lowering of energy expenditure and, as such, are risk factors for OB.[16]

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

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

There has been one study in the literature that has reproduced its programmes in other locations. Described as the Kiel Obesity Prevention Study (KOPS), the results demonstrated the efficacy and feasibility of implementing new nutritional concepts.[20] We tested the reproducibility of the EdAl programme in a geographical area (Terres de l'Ebre) about 80 km away from where the original EdAl programme was designed and implemented. We designed a cluster (town group) randomised controlled trial, the rationale being that since good communications exist between the schools of the same town, this could contribute to schools of the intervention group 'contaminating' those of the putative control group.

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

METHODS

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

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

Study population

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

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

towns around Amposta. The children in this study are in the second and third grades of primary education (7–8-year-olds). Schoolchildren were enrolled in May 2011 (children born in 2002–2003) and followed up for three school academic years (2012–2013). The study was completed in March 2013.

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

Intervention program

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

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

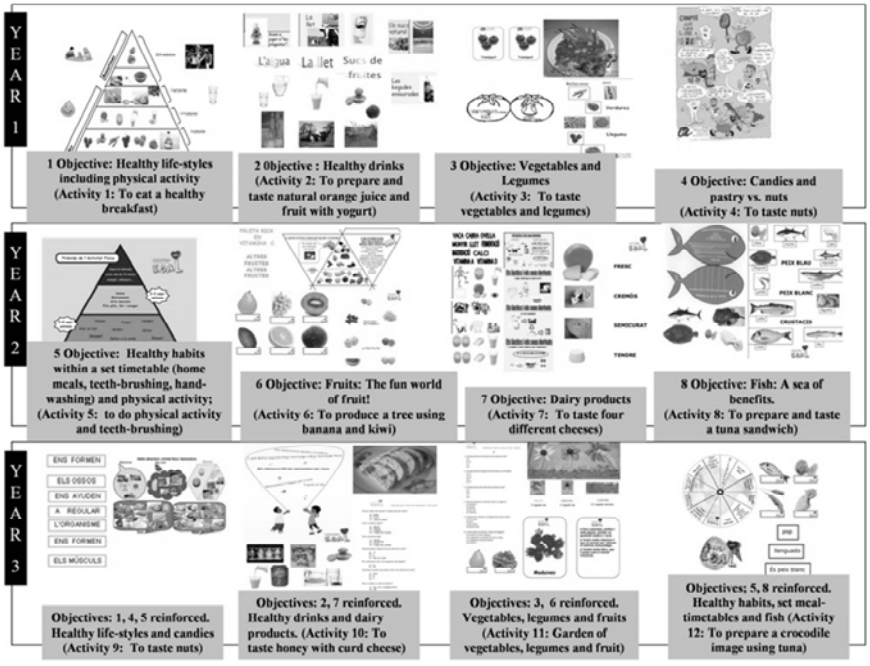

Figure 1 Eight topics of educational intervention activities. This figure shows the eight topics of 12 educational intervention activities of the EdAl programme.

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

Process evaluation

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

Outcomes

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

Sample size

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

Statistical analyses

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

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

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

RESULTS

Enrolment

Figure 2 shows the recruitment and flow diagram of pupils in the intervention and control groups over the course of the study. The mITT population in the intervention and control groups was 320 and 370 pupils, respectively. At 22 months, the mean age was 9.67 (95% CI 9.60 to 9.73) in the intervention group (9.68 years in boys and 9.65 years in girls) and 9.86 (95% CI 9.79 to 9.91) in the control group (9.85 years in boys and 9.84 years in girls). The differences in age were not significant in relation to gender.

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

Attrition rate

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

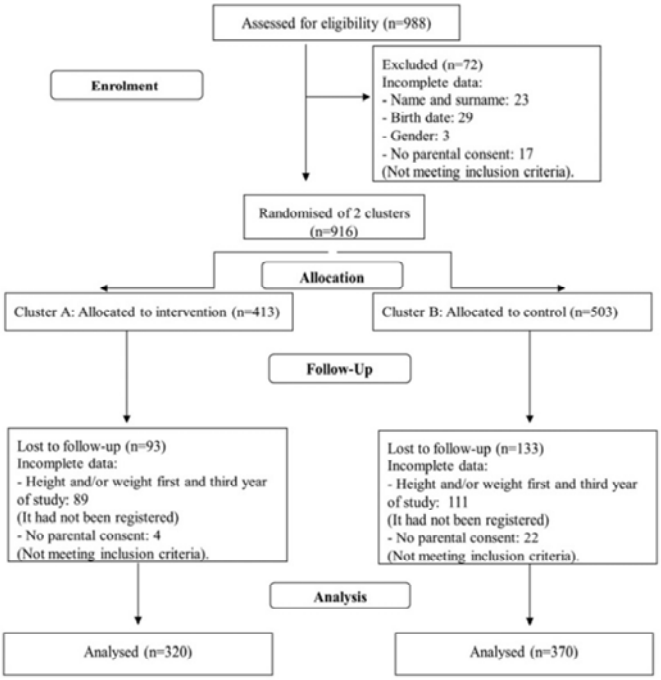

Figure 2 Flow of participants through the study. Incomplete height and/or weight (measures of the first and/or third academic year); No parental consent signed (first, second or third academic year).

pupils assessed at the beginning of the study, 690 (75.3%) pupils (73.6% of those allocated to the control group and 77.5% of those allocated to the intervention group) were reassessed three academic courses later, and valid measurements were obtained. The rate of parental consent was 95.7%. Dropouts in both groups are assumed to be missing at random.

Primary outcome: prevalence of OB

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

Secondary outcomes

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

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

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

Lifestyle evaluation

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

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

	Intervention group			Control group					
	Mean (95% CI)			Mean (95% CI)			Intervention vs control; p value* Boys	Intervention vs control; p value* Girls	Intervention vs control; p value* Total
	Boys (n=165)	Girls (n=155)	Total (n=320)	Boys (n=196)	Girls (n=174)	Total (n=370)			
Age, years	8.01 (7.91 to 8.12)	7.97 (7.88 to 8.07)	7.99 (7.92 to 8.06)	8.11 (8.03 to 8.19)	8.06 (7.97 to 8.15)	8.09 (8.03 to 8.15)	0.105	0.153	0.967
Weight, kg	30.35 (29.22 to 31.48)	29.86 (28.81 to 30.91)	30.11 (29.34 to 30.88)	31.29 (30.26 to 32.33)	31.35 (30.36 to 32.34)	31.32 (30.60 to 32.04)	0.226	0.043	0.024
BMI, kg/m^2	17.40 (16.93 to 17.86)	17.42 (16.97 to 17.88)	17.41 (17.09 to 17.73)	17.70 (17.28 to 18.13)	17.94 (17.51 to 18.37)	17.82 (17.51 to 18.12)	0.340	0.104	0.073
Height, m	1.32 (1.30 to 1.33)	1.30 (1.29 to 1.31)	1.31 (1.30 to 1.32)	1.32 (1.31 to 1.33)	1.32 (1.31 to 1.33)	1.32 (1.31 to 1.33)	0.242	0.045	0.027
Fat mass, kg	6.71 (5.99 to 7.42)	7.11 (6.50 to 7.72)	6.90 (6.42 to 7.38)	6.44 (5.78 to 7.09)	7.70 (7.12 to 8.27)	7.03 (6.59 to 7.47)	0.584	0.167	0.638
Lean mass, kg	23.99 (23.34 to 24.64)	22.86 (22.32 to 23.39)	23.44 (23.02 to 23.87)	24.88 (24.28 to 25.47)	23.71 (23.21 to 24.22)	24.33 (23.93 to 24.73)	0.049	0.022	0.003
Waist circumference, cm	60.97 (59.68 to 62.27)	59.91 (58.67 to 61.15)	60.46 (59.56 to 61.36)	64.37 (63.18 to 65.56)	65.17 (64.00 to 66.34)	64.75 (63.91 to 65.58)	<0.001	<0.001	<0.001

The results are expressed as mean (95% CI).
*p Value: GLM statistic.
BMI, body mass index; GLM, general linear model.

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

Differences between intervention and control pre–post intervention programme.

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

Impact of certain additional factors on OB

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

DISCUSSION

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

As proposed by Kain *et al*, designing a new school-based intervention study needs to have some critical aspects considered. These include the following: the random allocation of schools, although methodologically desirable, is not always possible; participation of parents is very limited; OB is not recognised as a problem; and increasing PA and implementing training programmes for teachers is difficult due to an inflexible curriculum and lack of teachers' time. Unless these barriers are overcome, OB prevention programmes will not produce positive and lasting outcomes.[27] As such, our programme of HPA-implemented intervention activities in classrooms is an attractive alternative that circumvents lack-of-teacher-time.

The EdAl-2 programme confirmed that after-school PA (in terms of h/week) can be stimulated in primary school as part of a healthy lifestyle. As we had observed in the original EdAl programme[18] at 28 months of intervention, there was an increase of up to 19.7% of children dedicating >5 h/week to extra-curricular physical activities.[18]

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

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

The results are expressed as % (n).
*p Value: McNemar's test.
†p Value: Fisher's exact test.
BMI, body mass index; OB, obesity; OW, overweight; IOTF, International Obesity Task Force.

Further, the after-school PA was maintained despite cessation of the intervention programme.[28] The effect of the EdAl programme during its implementation and after the official cessation indicated an impact on PA, whereas modification towards healthy food choices occurred according to the site of the programme's implementation, and was not consistent.

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

Reproducibility of studies is rare because of the complexity of trying to replicate a programme. To standardise a method, it is essential to be able to reproduce appropriate levels of an intervention, especially one that involves behavioural changes. The feasibility of our intervention was confirmed in two different towns and over two different timecourses (the first in Reus over 28 months, and the second in Amposta over 22 months).

Also, it is important to assess treatment adherence in order to evaluate reproducibility and feasibility.[19] For example, the KOPS study[20] demonstrated that nutritional knowledge was increased as a result of the intervention in the two cohort studies (KOPS 1 and KOPS 2).[20] However, the study was unable to show whether there were differences in OW outcomes, weight categories or lifestyles between the two cohorts. Some multicentred studies have

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

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

Differences between intervention and control preintervention versus postintervention.
*p Value: mixed models repeated measures.
†p Value: analysis of variance (ANOVA) model.
BMI, body mass index.

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

	Intervention group			Control group			Intervention vs control
	Baseline, % (n)	End of study, % (n)	p Value*	Baseline, % (n)	End of study, % (n)	p Value†	p Value‡
Krece Plus Questionnaire							
Breakfast							
Boys	98.4 (125)	98.3 (119)	1	97.5 (154)	92.2 (153)	0.092	0.635
Girls	98.4 (123)	99.2 (120)	1	98.7 (148)	93.8 (135)	**0.016**	0.453
Total	98.4 (248)	98.8 (239)	1	98.1 (302)	92.9 (288)	**0.003**	1
Dairy product at breakfast							
Boys	94.5 (121)	93.5 (116)	1	93.6 (147)	92.3 (155)	1	1
Girls	94.3 (116)	93.4 (113)	0.508	94.0 (141)	89.7 (131)	**0.039**	0.325
Total	94.4 (237)	93.5 (229)	0.481	93.8 (288)	91.1 (286)	0.167	0.574
Cereals at breakfast							
Boys	65.6 (82)	66.4 (81)	0.864	59.1 (88)	54.6 (89)	0.743	0.706
Girls	61.5 (75)	49.6 (58)	**0.036**	59.7 (86)	60.0 (87)	0.880	**0.031**
Total	63.6 (157)	58.2 (139)	0.098	59.4 (174)	57.1 (176)	1	0.225
Pastry at breakfast							
Boys	15.8 (19)	23.5 (28)	**0.027**	22.5 (33)	12.3 (20)	**0.001**	**0.002**
Girls	20.5 (24)	15.5 (18)	0.383	15.9 (22)	12.4 (18)	0.210	0.260
Total	18.1 (43)	19.6 (46)	0.441	19.1 (55)	12.3 (38)	**<0.001**	**0.002**
Daily fruit or natural juice							
Boys	73.4 (94)	76.2 (93)	0.523	74.8 (116)	76.0 (127)	1	0.535
Girls	66.7 (82)	70.0 (84)	0.690	79.9 (119)	73.5 (108)	0.243	0.549
Total	70.1 (176)	13.1 (177)	0.382	77.3 (235)	74.8 (235)	0.443	0.472
Fruit, 2nd per day							
Boys	39.7 (50)	41.2 (49)	0.581	44.5 (69)	34.1 (56)	**0.006**	0.141
Girls	26.4 (32)	47.5 (56)	**0.000**	44.8 (64)	39.0 (57)	0.281	**<0.001**
Total	33.2 (82)	44.3 (105)	**0.001**	44.6 (133)	36.5 (113)	**0.004**	**<0.001**
Dairy product, 2nd per day							
Boys	87.2 (109)	78.5 (95)	**0.029**	80.0 (124)	69.5 (116)	0.174	0.194
Girls	80.5 (99)	79.8 (95)	1	71.6 (106)	75.5 (111)	0.749	0.460
Total	83.9 (208)	79.2 (190)	0.161	75.9 (230)	72.3 (227)	0.51	0.384
Vegetables, daily							
Boys	65.6 (84)	74.4 (90)	**0.043**	71.1 (113)	70.8 (119)	1	0.473
Girls	71.7 (86)	77.5 (93)	0.169	68.7 (101)	63.3 (93)	0.152	**0.017**
Total	68.5 (170)	75.9 (183)	**0.011**	69.9 (214)	67.3 (212)	0.374	**0.028**
Vegetables, >1 per day							
Boys	19.3 (23)	29.1 (34)	**0.017**	28.7 (43)	20.7 (34)	**0.009**	**0.001**
Girls	25.4 (31)	34.5 (40)	0.052	30.3 (43)	23.1 (33)	0.110	0.149
Total	22.4 (54)	31.8 (74)	**0.001**	29.5 (86)	21.8 (67)	**0.002**	**0.001**
Fish, regularly							
Boys	73.2 (93)	76.6 (95)	0.608	70.0 (112)	70.1 (115)	0.851	0.058
Girls	71.8 (92)	71.4 (85)	0.307	74.5 (111)	71.0 (103)	1	0.662
Total	74 (185)	74.1 (180)	0.896	72.2 (223)	70.6 (218)	0.791	0.312
Fast food, >1 per week							
Boys	6.3 (8)	7.4 (9)	1	7.1 (11)	4.9 (8)	0.227	0.106
Girls	3.3 (4)	10.1 (12)	0.109	4.2 (6)	2.8 (4)	0.219	**0.013**
Total	4.8 (12)	8.8 (21)	0.21	5.7 (17)	3.9 (12)	**0.049**	**0.003**
Legumes, >1 per week							
Boys	70.3 (90)	71.1 (86)	0.648	67.5 (106)	65.9 (110)	1	0.555
Girls	72.8 (91)	73.3 (88)	0.815	62.8 (145)	76.2 (112)	**0.001**	**0.013**
Total	71.5 (181)	72.2 (174)	1	65.2 (251)	70.7 (222)	**0.025**	**0.027**
Candy, >1 per day							
Boys	14.3 (18)	12.6 (15)	1	17.2 (27)	18.2 (30)	1	0.367
Girls	12.9 (16)	12.0 (14)	1	18.7 (26)	11.1 (16)	0.078	1
Total	13.6 (34)	12.3 (29)	1	17.9 (53)	14.9 (46)	0.262	0.479
Pasta or rice daily							
Boys	63.8 (81)	67.5 (83)	0.839	69.0 (109)	67.9 (114)	0.871	0.708
Girls	59.2 (74)	64.7 (77)	0.377	68.0 (100)	69.4 (102)	0.618	0.724
Total	61.5 (155)	66.1 (160)	0.35	68.5 (209)	68.6 (216)	0.561	1

Continued

Table 4 Continued

	Intervention group			Control group			Intervention vs control
	Baseline, % (n)	End of study, % (n)	p Value*	Baseline, % (n)	End of study, % (n)	p Value†	p Value‡
Cooking with olive oil at home							
Boys	97.7 (126)	98.4 (122)	1	98.1 (157)	98.8 (167)	1	0.636
Girls	98.4 (125)	99.2 (120)	0.623	97.3 (145)	98.0 (145)	1	0.628
Total	98 (251)	98.8 (242)	0.5	97.7 (302)	98.4 (312)	0.754	0.476
AVall questionnaire							
Before leaving home							
Dairy products							
Boys	90 (117)	87.3 (110)	0.065	83.6 (133)	95.3 (139)	1	0.074
Girls	87.3 (110)	87.8 (108)	0.503	83 (122)	76.4 (110)	**0.004**	0.235
Total	90.9 (227)	87.6 (218)	0.071	86.2 (255)	81.1 (249)	**0.044**	0.836
Pastry							
Boys	4 (5)	2.4 (3)	1	0.7 (1)	1.4 (2)	1	0.610
Girls	0.8 (1)	1. 7 (2)	1	0.7 (1)	0 (0)	1	1
Total	2.5 (6)	2 (5)	1	0.7 (2)	0.7 (2)	1	0.606
Cereals							
Boys	33.9 (43)	36.8 (46)	0.711	30.7 (46)	35.0 (55)	0.608	1
Girls	32.2 (38)	26.2 (32)	0.405	25.2 (37)	26.2 (37)	0.458	0.297
Total	33.1 (81)	31.6 (78)	0.89	27.9 (83)	30.9 (92)	0.314	0.409
Fresh fruit or natural juice							
Boys	18.4 (23)	24.6 (31)	0.189	17.0 (26)	21.2 (32)	1	0.537
Girls	14.2 (17)	24.6 (30)	0.064	18.5 (27)	23.6 (33)	0.541	0.332
Total	16.3 (40)	24.6 (61)	**0.016**	17.7 (53)	22.3 (65)	0.560	0.256
Sandwich							
Boys	6.6 (8)	17.7 (22)	0.115	17.3 (26)	21.1 (32)	0.458	1
Girls	0.3 (12)	19.7 (24)	**0.049**	14.9 (21)	18.4 (26)	0.572	1
Total	8.4 (20)	18.7 (46)	**0.008**	16.2 (47)	19.8 (58)	0.289	0.889
Juice package/soft drinks							
Boys	6.7 (8)	7.4 (9)	0.754	8.7 (13)	7.1 (11)	1	0.756
Girls	7.7 (9)	5.0 (6)	0.508	8.6 (12)	10.8 (15)	1	0.507
Total	7.2 (17)	6.2 (15)	0.359	8.6 (25)	8.9 (26)	0.845	0.483
Break (midmorning)							
Dairy products							
Boys	16.0 (20)	20.0 (24)	0.824	15.3 (22)	14.4 (21)	1	0.819
Girls	8.7 (10)	9.6 (11)	0.388	10.7 (15)	8.4 (11)	1	0.595
Total	12.5 (30)	15 (35)	0.367	13.0 (37)	11.6 (32)	1	0.488
Pastry							
Boys	4.1 (5)	0.8 (1)	0.625	4.1 (6)	2.1 (3)	1	1
Girls	0.9 (1)	0.9 (1)	1	1.5 (2)	2.3 (3)	1	0.480
Total	2.5 (6)	0.9 (2)	0.687	2.8 (8)	2.2 (6)	0.687	1
Cereals							
Boys	3.3 (4)	5.9 (7)	0.727	5.7 (8)	4.9 (7)	1	1
Girls	3.5 (4)	3.4 (4)	1	4.3 (6)	6.9 (9)	0.180	0.544
Total	3.4 (8)	4.7 (11)	0.804	5 (14)	5.9 (16)	0.238	0.659
Fresh fruit or natural juice							
Boys	16.3 (20)	10.1 (12)	0.804	19.5 (30)	14.5 (22)	0.189	0.787
Girls	15.5 (18)	16.8 (20)	0.424	20.1 (29)	20.3 (28)	0.815	1
Total	15.9 (38)	13.4 (32)	0.856	19.8 (59)	17.2 (50)	0.522	0.721
Sandwich							
Boys	28.3 (36)	37.7 (46)	0.087	43.2 (67)	41.6 (67)	0.701	0.080
Girls	24.8 (30)	33.6 (41)	0.064	29.7 (44)	41.1 (58)	**0.016**	0.860
Total	26.6 (66)	35.7 (87)	**0.008**	36.6 (111)	41.4 (125)	0.185	0.299
Juice package/soft drinks							
Boys	7.4 (9)	9.1 (11)	0.344	12.2 (18)	12.6 (19)	1	1
Girls	7.8 (9)	6.1 (7)	0.727	12.1 (17)	13.2 (18)	1	0.233
Total	7.6 (18)	7.7 (18)	0.815	12.2 (35)	12.9 (37)	1	0.543

Bold typeface indicates p<0.05.
*p Value: McNemar's test (changes in the intervention group).
†p Value: McNemar's test (changes in the control group).
‡p Value: Fisher's exact test.

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

	Intervention			Control			Intervention vs control
	Baseline, % (n)	End of study, % (n)	p Value*	Baseline, % (n)	End of study, % (n)	p Value†	p Value‡
TV and/or video games							
0–2 h/day							
Boys	49.2 (62)	45.2 (57)	0.268	32.5 (51)	27.0 (43)	0.627	0.71
Girls	48.4 (60)	51.2 (63)	1	44.0 (66)	49.7 (71)	0.43	0.287
Total	48.8 (122)	48.2 (120)	0.464	38.1 (117)	37.7 (114)	0.91	0.697
3–4 h/day							
Boys	46.0 (58)	50.0 (63)	0.542	62.4 (98)	63.5 (101)	1	0.874
Girls	43.5 (54)	44.7 (55)	0.86	54.0 (81)	47.6 (68)	0.349	0.71
Total	44.8 (112)	47.4 (118)	0.489	58.3 (179)	56.0 (169)	0.606	0.632
>4 h/day							
Boys	4.8 (6)	4.8 (6)	0.375	5.1 (8)	9.4 (15)	0.607	0.393
Girls	8.1 (10)	4.1 (5)	0.453	2.0 (3)	2.8 (4)	1	1
Total	6.4 (16)	4.4 (11)	1	3.6 (11)	6.3 (19)	0.481	0.462
After-school PA							
0–2 h/week							
Boys	26.2 (34)	14.5 (18)	0.013	21.5 (34)	19.0 (31)	0.286	0.354
Girls	35.2 (43)	33.6 (41)	0.701	34.5 (50)	36.6 (52)	1	0.557
Total	30.6 (77)	24.0 (59)	**0.049**	27.7 (84)	27.2 (83)	0.435	0.254
2–4 h/week							
Boys	29.2 (38)	24.2 (30)	0.418	38.0 (60)	3.1 (54)	0.78	0.602
Girls	36.9 (45)	32.0 (39)	0.377	32.4 (47)	31.0 (44)	1	0.155
Total	32.9 (83)	28.0 (69)	0.188	35.3 (107)	32.1 (98)	0.764	0.135
>4 h/week							
Boys	44.6 (58)	61.3 (76)	**0.006**	40.5 (64)	47.9 (78)	0.243	0.643
Girls	27.9 (34)	34.4 (42)	0.136	33.1 (48)	32.4 (46)	0.868	0.598
Total	36.5 (92)	48.0 (118)	**0.002**	37.0 (112)	40.7 (124)	0.272	0.485

Bold typeface indicates p<0.05.
*p Value: McNemar's test (changes in the intervention group).
†p Value: McNemar's test (changes in the control group).
‡p Value: Fisher's exact test.
PA, physical activity; TV, television.

attempted to reproduce methodological aspects in interventions conducted in different countries or different populations. However, while multicentred studies are usually implemented concurrently, reproducibility involves the applicability of the intervention at different sites and/or different times in order to validate the initial findings. One example of this is the Pro Children Study,[30] which, as a multicentred study, had been applied in different countries simultaneously and had demonstrated its efficacy and feasibility.

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

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

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

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

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

There are several limitations to our study. First, we evaluated dietary habits via a questionnaire that did not take into account the quantities of the different types of food items consumed. These data would be important in

addressing the quantity versus quality debate in OB or OW prevalence. Second, assigning control groups according to towns surrounding the intervention town could be a limitation. However, schools in the same town have good relationships and communications with each other and this could entail a possible contamination between schools if assigned to intervention or control status within the same town. This cross-contamination would be minimised if the schools themselves were assigned to intervention or control. Third, the significant difference in Latin American ethnicity between the two groups of the study at baseline could be a limitation. However, there were no significant differences in distributions of OB and/or OW. Also, no differences were observed in terms of response to the intervention study in relation to ethnicity. Fourth, when asked about fast-food consumption, the participants interpreted this as pertaining only to fast-food outlets such as burger shops, and did consider other concepts such as frozen pizza consumed at home. Finally, another limitation could be the proportion of females who may have started puberty in the course of the study. This implies changes in body composition. However, both study groups (intervention and control) had a similar proportion of females with a similar age, and this could cancel out the effect.

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

CONCLUSION

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

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

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Study 2

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

Follow-up of a Healthy Lifestyle Education Program (the EdAI Study): Four Years after cessation of Intervention

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Abstract

Importance: An important challenge of school-based, childhood obesity (OB) intervention programs is understanding the maintenance of effects after cessation of intervention. In our case, over 28 months, the EdAl (Educació en Alimentació) program, which was conducted with primary-school children (2007-2010 academic years), lead to reductions in the body mass index (BMI) z-score and prevalence of OB in boys along with an increase in after-school physical activity (PA). At 2-year post- intervention cessation, the first follow-up showed a lower BMI z-score and OB prevalence in these children and an increase in after-school PA relative to the control group. At 4-year follow-up post-intervention cessation, the second follow-up is evaluated in this study.

Objective: To assess the OB-related variables and lifestyles in 13- to 15-year-old adolescents in 2014, 4-year after EdAl intervention cessation.

Design: Four-year follow-up study after cessation of a school-based randomized controlled intervention.

Setting: High schools in Reus (intervention group) and Salou, Cambrils and Vila-seca (control group).

Participants: Adolescents (n=349, intervention; n=154, control) with baseline and 4-year follow-up data.

Intervention: The EdAl intervention was finished at 2010.

Main outcomes measures: BMI, BMI z-score, OB prevalence according to World Health Organization and International Obesity Task Force criteria and lifestyle data (obtained from questionnaires).

Results: From baseline (2007) to the 4-year follow-up post-intervention cessation (2014), the BMI z-score was reduced (-0.33 units, $p<0.01$) in intervention girls compared with control girls. OB prevalence was reduced (-7.7%; $p=0.02$) in intervention boys compared with control boys. More boys in the intervention group (19% increase; $p=0.059$) showed ≥ 4 h/week after-school PA compared with control boys. A decrease in the consumption of dairy products, fruits and fish was observed in intervention and control groups.

Conclusions and relevance: Four-year post-intervention cessation of the EdAl program, the intervention girls had a lower BMI z-score and intervention boys had a lower OB prevalence, compared with control group. The improvement in after-school PA was more likely to be maintained for long-term after the cessation of the intervention, whereas healthy food habits need to be encouraged in adolescents.
Trial Registration: ISRCTN29247645

Word Count: 336 /350

At a glance

- Four years after the EdAl program cessation, the BMI z-score in girls and the obesity prevalence in boys were lower in the intervention group than in the control group, presenting different gender responses.

- Four years after the EdAl program cessation, after-school physical activity was higher compared to the control group.

- Four years after the EdAl program cessation, dietary habits should be encouraged because they were maintained only up to 2 years post-intervention cessation.

Childhood obesity (OB) is a public health challenge. [1] The most recent data show that approximately one in five children in The Organisation for Economic Co-operation and Development (OCDE) area are overweight (OW) or obese. [2] In Spain, this trend has increased modestly or remained approximately stable, as in Canada, England, Italy, Korea, and the United States. [2] However, Spanish childhood OW and OB are high in comparison with the OCDE countries, [3] with OB at a prevalence of 6.7% in the adolescent population (14-17 y), as calculated by the International Obesity Task Force (IOTF). [4]

Effective interventions that reduce OB over the long-term after the cessation of an intervention are challenging. A Cochrane review of interventions for preventing OB in children and adolescents highlighted that education may make it possible to prevent OB whereas long-term effects of an intervention should be assessed. [5]

Few school-based programs have been evaluated post-intervention cessation because of economic concerns, the loss of the original participants and logistical problems. [6-13] Some studies, such as The Child and Adolescent Trial for Cardiovascular Health (CATCH) cohort, [6,7] the Cretan Health and Nutrition Education Program, [8,9] the CHristchurch Obesity Prevention Programme in Schools (CHOPPS) study, [10] the A Pilot Programme for Lifestyle and Exercise (APPLE) project [11] and The Intervention in Eating Habits and Physical Activity in Schoolchildren: the AVall study, [12,13] have demonstrated sustained effects over the long-term after-cessation intervention.

We have previously shown that the effects of the primary school-based EdAl program applied in a Spanish area that was aimed at decreasing the prevalence of OB resulted in successfully reduced the prevalence of childhood OB in boys by 4.39%, yielding an effective reduction of -0.24 units in the BMI z-scores compared with the controls. Notably, 5.1% more pupils in the intervention group engaged in >5 h/week of after-school physical activity (PA) compared with the controls during the 28 months of intervention that ended in 2010. [14] Furthermore, in 2012, at the 2-year follow-up post-intervention cessation, these patterns had been maintained, as indicated by the lower BMI z-scores, lower OB prevalence, and increase in after-school PA in both genders compared with the control group. [15] In 2014, the aim of present study is to verify the sustainability of the benefits achieved 4-year post-

cessation of the EdAl intervention, we assessed the prevalence of OB, anthropometric variables, lifestyle habits and PA in adolescents (13-15 years of age) who had participated in the EdAl program that was implemented between 2007 and 2010.

METHODS

The protocol, rationale, randomization, and techniques of the EdAl program (trial registration number ISRCTN29247645) as well as the results at the conclusion of the program have been published in Trials. [14,16] Additionally, the results at the 2-year follow-up post-intervention cessation in 2012 have been published in the Journal of Adolescent Health. [15] The current study, conducted at the 4-year follow-up post-intervention cessation in 2014, 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 collected on the adolescents, who had provided written informed consent (signed by the parents or guardians) prior to their participation in the follow-up study, were analyzed. The 4-year follow-up post-intervention cessation of the EdAl program was an observational study and is described according to the STROBE Statement. [17]

Study population

EdAl intervention program and results achieved up to 2010

Briefly, the EdAl program consisted of 12 educational intervention activities [14,16] focusing on 8 lifestyle topics that were implemented over 28 months, ending in 2010. These 8 topics were selected on the basis of 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, the overall adoption of behaviors that encourage PA

(walking to school, playground games), and the avoidance of sedentary behavior. These topics were covered in 12 activities (1 h/activity/session) in 7- to 8-year-old children and implemented by health promoting agents (HPAs) over 28 months during 3 academic years.

The present study reports on the 4-year follow-up (2014) post-intervention cessation of the EdAl program.

Outcomes

Weight and height were obtained as described in the protocol. [16] Primary outcome was OB prevalence measured as BMI according to IOTF [18] and World Health Organization (WHO) criteria.[19] Secondary outcomes were OB-related variables such as BMI z-score, waist circumference, hip circumference, BMI, incidence and remission (i.e., the participant's change from OB status to OW or normal weight) of excess weight (OW + OB). Additionally, changes in eating habits using the Krece Plus questionnaire [20] and the level of PA (as measured on the AVall questionnaire) were recorded. [21] Both questionnaires were completed at baseline (2007-2008) and at the 4-year follow-up post-intervention cessation. BMI z-score was analyzed according to the WHO Global InfoBase [22] that defines children with BMI z-score >2 as OB. [19,22]

Statistical Analyses

The descriptive data are presented as means or percentages and 95% confidence intervals (95%CIs) or ± standard deviations (±SDs) for the variables that followed normal distributions. General linear models (GLMs) were used to analyze the differences between the continuous values for the intervention and control groups in relation to the prevalence of OB. The anthropometric data were analyzed using an ANOVA adjusted for age. Repeated measures GLMs were used to analyze the trend in the BMI z-scores between baseline and the 4-year follow-up post-intervention cessation. The number of subjects with specific data on the TV h/day watched and the h/week of after-school PA were expressed as percentages of the

total number of individuals being assessed. The McNemar's test was used to calculate the differences among the changes from the baseline to the 4-year follow-up post-intervention cessation in each group and to analyze the change over time in food habits, after-school PA h/week and TV h/day in the intervention and control groups.

The anthropometric data were analyzed using an ANOVA adjusted for age.

The primary analyses were performed with the modified intention-to-treat (mITT) population, i.e., the subjects with at least baseline and 4-year follow-up post-intervention cessation measurements of weight and height. The analysis did not use any imputation missing method, with the assumption that any missing data were random.

The statistical significance was set at $p \leq 0.05$. The data were analyzed using SPSS software (version 22).

RESULTS

Participants

At the 4-year follow-up post-intervention cessation, 349 of 421 in the intervention group and 154 of 198 in the control group of the 2-year follow-up post-intervention cessation were included in the analysis. [14] These participants consisted of 674 of 1222 children in the intervention group and 330 of 717 children in the control group that completed the original EdAl study and were born between 1999 and 2000. [14]

The retention rates at the 4-year follow-up post-intervention cessation were 349 of 421 (82.29%) in the intervention group and 154 of 330 (77.7%) in the control group regarding the 2-year follow-up post-intervention cessation participants analyzed. However, calculating the retention rate among children that completed the EdAl yielded 349 of 966 (36.12%) in the intervention group and 154 of 413 (37.28%) in the control group. The adolescents included in the 4-year follow-up post-intervention cessation analysis had consent forms signed by their parents and, at a minimum, their weight and height measurements at baseline, 2-year follow-up and

4-year follow-up post-intervention cessation (**Figure 1**). The dropouts observed were not more prevalent among either the OW or OB adolescents.

At the 4-year follow-up post-intervention cessation, the mean (±SD) age was 15.6 ±0.53 years in the intervention group and 14.9±0.36 years in the control group ($p<0.01$).

Analysis of the anthropometric characteristics of the adolescents at the 4-year follow-up post-intervention cessation showed that the BMI and waist circumference were greater in the boys in the intervention group than boys in the control group. In contrast, the girls in the control group presented with 2.45 kg more fat mass compared with girls in the intervention group (15.47 kg vs. 13.02 kg; $p=0.008$) (**Table 1**).

The BMI z-score in the intervention group was reduced by -0.58 units, whereas in the control group, it was reduced by -0.41 units, with a significant difference of -0.17 units ($p=0.003$). By gender, the BMI z-score of the girls in the intervention group was reduced by -0.65 compared with a reduction of -0.32 of the girls in the control group, with a significant difference of -0.33 units ($p=0.003$) (**Table 2**).

From baseline to 4-year follow-up post-intervention cessation, using the WHO criteria, a decrease in the prevalence of OW in the girls in the intervention group was observed (from 22.2% to 7%; $p<0.001$). Additionally, the prevalence of OB decreased in the boys in the intervention group (from 13.5% to 1.7%; $p<0.001$) and in the girls in the intervention group (from 6.4% to 2.3%; $p=0.039$) over this period, whereas no significant differences were observed in the control group. Therefore, at the 4-year follow-up post-intervention cessation, the OB prevalence by WHO criteria compared with the baseline prevalence was reduced by -11.8% in boys in the intervention group and -4.1% in the boys in the control group, with a difference of -7.7% ($p=0.019$) in favor of intervention group (**Table 3**).

Conversely, at the 4-year follow-up post-intervention cessation, the OW prevalence (using the IOTF criteria) decreased in girls in the intervention group (from 17.5% to 6.4%; $p=0.002$) and girls in the control group (from 20.9% to 10.5%; $p=0.022$). However, there were no differences in the OW prevalence and OB prevalence changes between the groups (Table 3).

Although no firms conclusions can be made due to the small sample size, the OB remission number of 23 of 24 (95.8%) between baseline and the 4-year follow-up post-intervention cessation in the boys in the intervention group was significantly greater than the 2 of 5 (40%; p=0.019) in the control group; this result indicates that the weight status of the participants in the intervention group changed to a better category, either OW or normal weight. There were no significant differences in the incidence of OB or excess weight between the groups.

At the 4-year follow-up post-intervention cessation, no differences between groups were observed in the number of hours of TV and video games engaged in per day (**Table 4**).

Furthermore, from baseline to the 4-year follow-up post-intervention cessation, we observed an increase in the number of participants with ≥4 h/week of after-school PA of 26.8% (p<0.001) in the boys and 16% (p=0.004) in the girls in the intervention group, whereas there was an increase of 12.3% (p=0.388) in the boys and 12.2% (p=0.049) in the girls in the control group. More boys of the intervention group (increase of 19%; p=0.059) performed ≥4 h/week of after-school PA compared with boys of the control group, whereas in girls were not significant. Additionally, 3.5% (p=0.035) more adolescents in the control group performed 0-1 h/week of after-school PA than those in the intervention group (Table 4).

The 4-year follow-up post-intervention cessation showed deteriorating food behaviors based on the 15 food items in the Krece Plus questionnaire related to the consumption of dairy products, fruit and fish in both the intervention and control groups, primarily in the girls (**Supplementary file 1**). However, we observed a decrease in pastry consumption in girls in the intervention group (13.4% to 9.0%; p=0.064) compared with girls in the control group (8.8% to 19.1%; p=0.109), with a difference between the groups of 14.7% (p=0.024). In contrast, we detected a >1/day reduction in vegetable consumption in boys in the intervention group (28.7% to 20.8%; p=0.150) compared with boys in the control group (13.2% to 29.3%; p=0.109), with a difference between groups of 24% (p=0.042). However, considering the dietary items on the AVall questionnaire, we observed an increase of 11.1% (p=0.039) in sandwich consumption for breakfast before leaving home in the control group compared with the intervention group. In the intervention group,

we observed a decrease in midmorning breakfast consumption of pastries (p=0.029), juice and soft drinks compared with the control group (p=0.009). Additionally, the consumption of fruit decreased in the intervention group compared with the control group (p=0.024) (Supplementary file 1).

DISCUSSION

This study reports the long-term effects of the EdAl school-based OB intervention program at the 4-year follow-up post-intervention cessation, showing a significant reduction of -0.33 units in the BMI z-score of the girls in the intervention group relative to girls in the control group and a reduction of -7.7% in the prevalence of OB in the boys in the intervention group compared with the those in the control group.

In the present study, at the 4-year follow-up post-intervention cessation, the effectiveness of the OB prevention program was evidenced by the overall reduction of -0.17 in the BMI z-score units, with a -0.33 reduction in the BMI z-score in the girls. Considering reductions of -0.15 units in BMI z-scores between the pre- and post-intervention group changes relative to the control group these reductions are effective. [5] The decrease in OB-related variables in boys of the EdAl program began during implementation and continued after cessation of the intervention, whereas the effects in girls were only apparent at the 4-year follow-up following the cessation of intervention. While BMI z-score considers standard deviation units above or below the mean [23] in the present study according to WHO population standard, and OB prevalence only considers changes from OB to other weight status. These data suggest that the EdAl program was effective post intervention with respect to OB-related variables in both genders, in girls the decreasing BMI z-score was nearer to the mean of the WHO population standard and, in boys the weight status decreased to a healthier category.

Furthermore, it is necessary to measure the beneficial effects of interventions in terms of a healthy lifestyle over the long-term [24] to serve as indicators of when a new intervention is needed. According to our knowledge, there are six follow-up

studies that were performed after intervention cessation, including 3 studies that observed the effects at the 4-year follow-up post-intervention cessation, [9, 13, 25] as in the EdAl study.

The AVall study achieved a 3.6% reduction in the prevalence of OB in the intervention schoolchildren and a 0.5% increase in OB prevalence in the control schoolchildren at the 2-year post-intervention follow-up, [12] and at the 4-year follow-up post-intervention cessation, the BMI in the intervention group had been reduced by 1.13 kg/m2. [13] Moreover, the Cretan study demonstrated that the intervention group presented a lower increase in BMI at the 4-year follow-up post-intervention cessation relative to the control group. [8] In addition, the KOPS study showed a sustainment in OW incidence and remission over time, with both being higher in families of high socioeconomic status; however, there was no change in OB-related variables at the 4-year follow-up post-intervention cessation. [25] The EdAl program collected no data related to family socioeconomic status, and this variable may contribute as an OB confounder. [26] The 4-year follow-up post-intervention cessation studies showed similarities with respect to beneficial changes in OB-related variables; however, it is difficult make comparisons among these studies due to the different measures used. The data argue in favor of the measurement of additional OB-related variables of schoolchildren to enable comparisons among different interventions.

Furthermore, there is no consensus regarding the best way to identify OB in children and adolescents, which has contributed to some limitations because approaches differ with respect to BMI reference criteria, pubertal stages, and racial/ethnic differences. [27] A recently published meta-analysis reported that the BMI criteria have high specificity but low sensitivity for identifying pediatric OB. [27] According to Inokuchi et al., the BMI z-score is the optimal measure of annual adiposity change for elementary school children. [28] From OB-related variables already described, determining the optimal measure that evaluates the effectiveness to tackle obesity, is needed in adolescents. Based in our results, we proposed the BMI z-score as the ideal variable for the consideration of BMI changes and, an specific evaluation in gender differences to elucidate the reason of OB-related variables over intervention and at long-term.

The present study showed an increase of PA at the 4-year follow-up post-intervention cessation. Of 3 studies that reported data from a 4-year follow-up post-intervention cessation, only one of them provided data on PA variables. The Cretan study [9] reported a maintenance of moderate-to-vigorous levels of PA min/week in boys of the intervention group of students compared with the control group. Similarly, the EdAl study demonstrated an increase in after-school PA h/week in boys of the intervention group. Therefore, it is important to identify strategies to motivate girls to be physically active.

In contrast, the CATCH study showed that the PA levels of intervention students declined after the cessation of the intervention, while PA levels in this group were higher than those of the control group at the 3-years follow-up post-intervention cessation. [7]

Although school-based intervention follow-up post-intervention cessation studies for the prevention of OB have included data on OB-related variables and PA practice, the subjects' food habits have not been reported for the long-term follow-ups post-intervention cessation; [6-13] therefore, further research is needed.

At the 4-year follow-up post-intervention cessation of the EdAl study, the food habits followed a similar pattern between the intervention and control groups, showing a reduction in the consumption of healthy foods such as dairy products, fruit and fish, suggesting that the improvements in food-related habits established during the program are lost over time. This finding leads us to recommend that healthy dietary habits be encouraged at the 2-year follow-up post-intervention cessation to maintain healthy food intake.

Some factors that may contribute to the low number of follow-up publications on school-based interventions are: [29] a) a lack of success at the end of the intervention, b) a high rate of participant dropout that induces low attrition, influencing study power, risk of bias and generalizability, [30] c) high economic costs associated with the demand for a large sample size, d) risk of contamination of the control group, which may arise due to the initiation of healthy lifestyles in the absence of any specific intervention, and e) a lack of funding to support follow-up studies.

Several limitations to our study were identified. First, despite the acceptable retention rates between the 2-year follow-up and the 4-year follow-up after cessation of the intervention, with 82.29% retained in the intervention group and 77.7% retained in the control groups, substantial dropout rates at the 2-year follow-up post-intervention were observed. [15] The low retention rates at the 2-year follow-up post-intervention cessation observed in this study might be explained by the emigration phenomenon observed in Spain in 2013, in which approximately 30,000 children between 10 and 16 years emigrated with their parents. [31] Moreover, the low retention rates might partially be due to the high rate of parental decision to not provide consent and the rate of adolescents themselves deciding to not participate in the program. Similarly, most other follow-up post-intervention cessation studies have described high dropout rates as major limitation. [9,10,12] However, the retention rate of the present study was higher than 25%, which may mean that the dropout rate did not significantly affect our results. [32] Moreover, dropouts were not differentially prevalent among the OW or OB adolescents, avoiding risk of bias. [26] Second, there was an age difference between intervention and control groups because most of the individuals in one group were born at the start of the year and most in the other group were born at the end of the year. Third, there was a ratio of 2:1 in favor of the intervention groups, which requires that our results be interpreted with caution.

As generalizability, the original EdAl program is an easy-to-apply tool that can be implemented in primary schools to prevent childhood OB and improve lifestyles, with effects that extend from childhood to adolescence. The implementation of the EdAl program could be maintained by university students designated as HPA, with educational activities implemented in the schools of intervention area. In addition, such university students could form HPA programs in other localities to spread the program over a larger region.

In conclusion, four-years after intervention cessation of the EdAl program, the intervention group had a lower BMI z-score and OB prevalence than did the control group. The improvement in after-school PA was more likely to be maintained for the long-term after the cessation of the intervention, whereas healthy food habits need to be encouraged in adolescents.

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Disclosure of any potential conflict of interest

The authors have declared that no competing interests exist.

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Figure Legends

Figure 1: Flow diagram of participants through the study

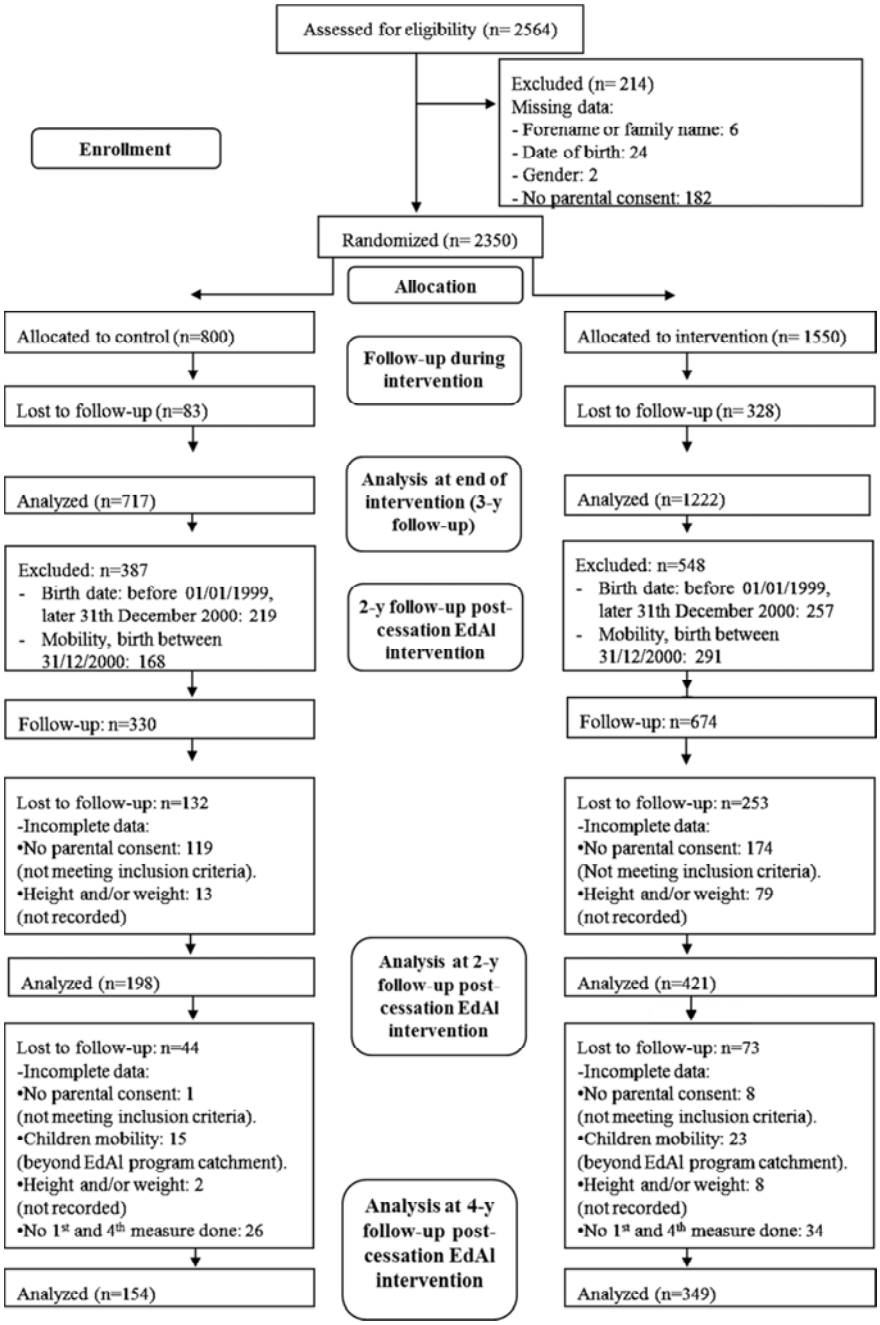

Table 1
Anthropometric characteristics of pupils at 4-year follow-up in intervention and control groups

	Intervention Group (n = 349)			Control Group (n = 154)			p-value interventi on versus control	p-value intervention versus control	p-value intervention versus control
	Boys	Girls	Total	Boys	Girls	Total	Boys	Girls	Total
Weight; Kg[a,b]	57.87 (56.10 to 59.65)	52.44 (50.94 to 53.93)	55.17 (53.99 to 56.35)	55.24 (52.12 to 58.36)	54.44 (52.22 to 56.67)	54.89 (52.99 to 56.79)	0.178	0.169	0.819
Height; cm[a,b]	167.6 (166.4 to 168.8)	160.9 (159.9 to 161.9)	164.3 (163.4 to 165.1)	167.7 (165.6 to 169.9)	161.5 (160.1 to 163.0)	164.4 (163.0 to 165.8)	0.944	0.496	0.911
BMI[c]; Kg/m[a,e]	20.50 (20.05 to 20.95)	20.31 (19.86 to 20.76)	20.41 (20.09 to 20.72)	19.44 (18.59 to 20.30)	20.60 (19.90 to 21.30)	20.09 (19.54 to 20.64)	**0.020**	0.475	0.294
BMI z-score[a,e]	-0.10 (-0.27 to 0.08)	-0.21 (-0.36 to -0.06)	-0.15 (-0.27 to -0.04)	-0.37 (-0.66 to -0.09)	-0.01 (-0.23 to 0.21)	-0.17 (-0.35 to 0.00)	0.100	0.139	0.846
Fat mass; Kg[a,d,e]	8.24 (7.55 to 8.93)	13.02 (12.12 to 13.92)	10.58 (9.96 to 11.19)	7.92 (6.48 to 9.35)	15.47 (13.66 to 17.28)	12.11 (10.79 to 13.44)	0.653	**0.008**	**0.018**
Lean mass; Kg[a,d]	49.65 (48.35 to 50.96)	39.82 (39.09 to 40.56)	44.78 (43.88 to 45.66)	47.87 (45.57 to 50.17)	40.97 (39.87 to 42.07)	44.20 (42.75 to 45.66)	0.217	0.111	0.538
Waist circumference; cm[a,b]	74.15 (72.88 to 75.43)	69.88 (68.73 to 71.02)	72.06 (71.17 to 72.94)	71.57 (69.36 to 73.78)	71.15 (68.98 to 73.31)	71.33 (69.80 to 72.87)	**0.043**	0.261	0.401
Hip circumference;cm[a]	84.01 (82.65 to 85.37)	82.92 (81.72 to 84.12)	83.46 (82.56 to 84.37)	81.76 (79.12 to 84.41)	85.09 (83.12 to 87.07)	83.66 (82.04 to 85.27)	0.162	0.082	0.848

Notes to Table 1:
a Results are expressed by mean (95%CI)
bWeight, height, lean mass and hip circumference; values adjusted by age, using analysis of covariance (ANCOVA).
cBody mass index (BMI) calculated as weight (kg) divided by height in square meters
dFat and lean mass calculated using a standard beam balance (Tanita TBF-300 Body Composition Analyzer)
eBMI, BMI z-score and fat mass, waist circumference, not adjusted by age, but using analysis of variance (ANOVA)

Table 2
Baseline and 4-year follow-up measurements of BMI categorized as OW and OB

		Baseline, n (%)	4-y follow-up post-cessation intervention, n (%)	p-value Baseline to 4-y follow-up[a]	p-value Intervention vs. Control[b]
WHO Criteria[c]					
OW					
Intervention	Boys	39 (21.9)	31 (17.4)	0.322	0.314
	Girls	38 (22.2)	12 (7.0)	**0.000**	0.602
	Total	77 (22.1)	43 (12.3)	**0.000**	0.238
Control	Boys	8 (11.8)	6 (8.8)	0.774	
	Girls	18 (20.9)	12 (14.0)	0.286	
	Total	26 (16.9)	18 (11.7)	0.229	
OB					
Intervention	Boys	24 (13.5)	3 (1.7)	**0.000**	**0.019**
	Girls	11 (6.4)	4 (2.3)	**0.039**	0.560
	Total	35 (10.0)	7 (2.0)	**0.000**	0.205
Control	Boys	5 (7.4)	3 (4.4)	0.500	
	Girls	6 (7.0)	2 (2.3)	0.289	
	Total	11 (7.1)	5 (3.2)	0.109	
IOTF Criteria[d]					
OW					
Intervention	Boys	39 (21.9)	30 (16.9)	0.163	0.238
	Girls	30 (17.5)	11 (6.4)	**0.002**	0.581
	Total	69 (19.8)	41 (11.7)	**0.001**	0.244
Control	Boys	6 (8.8)	3 (4.4)	0.375	
	Girls	18 (20.9)	9 (10.5)	**0.022**	
	Total	24 (15.6)	5 (3.2)	**0.008**	
OB					
Intervention	Boys	4 (2.2)	1 (0.6)	0.375	0.578
	Girls	8 (4.7)	4 (2.3)	0.289	0.430
	Total	12 (3.4)	5 (1.4)	0.092	0.186
Control	Boys	3 (4.4)	3 (4.4)	1.000	
	Girls	1 (1.2)	2 (2.3)	1.000	
	Total	4 (2.6)	5 (3.2)	1.000	

Notes to Table 2:

BMI = body mass index; IOTF = International Obesity Task Force; OW = overweight; OB = obesity; WHO = World Health Organization.
Bold text indicates significant values.
a Fisher exact test
b McNemar test
c WHO criteria cutoff points (2007) was used for BMI classification
d IOTF criteria cutoff points (Cole, 2000) was used for BMI classification

Table 3
BMI z-score at baseline and 4-y follow-up in intervention and control groups

		Baseline[c]	Four-year follow-up	Change Baseline[c] to 4-y follow-up	Baseline[c] versus 4-year follow-up	Intervention versus control
		Mean (95%CI)	Mean (95%CI)	Mean (95%CI)	p-value[b]	p-value[d]
BMI Z-score[a]						
Intervention						
	Boys	0.57 (0.40 to 0.74)	-0.09 (-0.25 to 0.08)	-0.67 (-0.80 to -0.54)	**0.000[e]**	0.282
	Girls	0.44 (0.26 to 0.61)	-0.23 (-0.39 to -0.07)	-0.65 (-0.78 to -0.51)	**0.000[e]**	**0.003**
	Total	0.51 (0.38 to 0.63)	-0.15 (-0.27 to -0.04)	-0.58 (-0.75 to -0.56)	**0.000[e]**	**0.003**
Control						
	Boys	0.16 (-0.12 to 0.44)	-0.37 (-0.66 to -0.09)	-0.54 (-0.72 to -0.35)	**0.000[e]**	
	Girls	0.30 (0.08 to 0.53)	-0.01 (-0.23 to 0.21)	-0.32 (-0.45 to -0.18)	**0.000[e]**	
	Total	0.24 (0.06 to 0.42)	-0.17 (-0.35 to 0.00)	-0.41 (-0.53 to -0.30)	**0.000[e]**	

Notes to Table 3:
BMI = body mass index; CI = confidence interval; WHO = World Health Organization
Bold text indicates significant p values.
a BMI z-score was calculated as "Growth reference 5-19 years" WHO tables
b General Linear Mixed models of repeated measures
c Baseline (2007-2008)
d Fisher exact test
e Repeated measures of General Linear Mixed Models

Table 4
Physical and leisure activities assessed at baseline and 4-year follow-up in intervention and control group

		Intervention group			Control group			
		Baseline, n (%)	4-year follow-up, n (%)	p-value baseline to follow-up[b]	Baseline, n (%)	4-year follow-up, n (%)	p-value baseline to follow-up[b]	p-value intervention versus control changes[c]
TV and/or video games, hours/day								
0-1hour/day	Boys	77 (58.3)	60 (38.2)	**0.000**	23 (54.8)	27 (38.3)	0.238	0.367
	Girls	80 (62.5)	69 (43.7)	**0.008**	37 (54.4)	29 (43.3)	0.180	0.438
	Total	157 (60.4)	129 (41.0)	**0.000**	60 (54.5)	52 (40.9)	0.050	1.000
2-3 hours/day	Boys	51 (38.6)	77 (49.0)	**0.036**	18 (42.9)	32 (53.3)	0.648	0.676
	Girls	45 (35.2)	70 (44.3)	0.134	27 (39.7)	36 (53.7)	0.077	0.578
	Total	96 (36.9)	147 (46.7)	**0.009**	45 (40.9)	68 (53.5)	0.090	0.889
≥4 hours/day	Boys	4 (3.0)	20 (12.7)	**0.013**	1 (2.4)	5 (8.3)	0.375	1.000
	Girls	3 (2.3)	19 (12.0)	0.057	4 (5.9)	2 (3.0)	0.625	0.110
	Total	7 (2.7)	39 (12.4)	**0.001**	5 (4.5)	7 (5.5)	1.000	0.275
After-school physical activity, hours/week								
0-1 hour/week	Boys	25 (18.9)	31 (19.5)	1.000	11 (26.8)	18 (30.0)	1.000	0.297
	Girls	36 (28.8)	55 (35.0)	0.618	23 (34.8)	32 (46.4)	0.210	0.098
	Total	61 (23.7)	86 (27.2)	0.716	34 (31.8)	50 (38.8)	0.256	**0.035**
2-3 hours/week	Boys	66 (50.0)	36 (22.6)	**0.000**	20 (48.8)	20 (33.3)	0.405	0.206
	Girls	62 (49.6)	43 (27.4)	**0.002**	30 (45.5)	15 (21.7)	**0.005**	1.000
	Total	128 (49.8)	79 (25.0)	**0.000**	50 (46.7)	35 (27.1)	**0.005**	0.490
≥4 hours/week	Boys	41 (31.1)	92 (57.9)	**0.000**	10 (24.4)	22 (36.7)	0.388	0.111
	Girls	27 (21.6)	59 (37.6)	**0.004**	13 (19.7)	22 (31.9)	**0.049**	0.852
	Total	68 (26.5)	151 (47.8)	**0.000**	23 (21.5)	44 (34.1)	**0.024**	0.174

Notes to Table 4:
Bold text indicates significant p values.
a Physical activity and TV hours were analyzed at baseline and at 4-year follow-up
b McNemar's test
c Fisher exact test. Difference between intervention and control changes

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

	Intervention group			Control group			
	Baseline n (%)	End of study n (%)	p-value baseline to follow-up[b]	Baseline n (%)	End of study n (%)	p-value baseline to follow-up[b]	p-value intervention versus control changes[c]
Krece plus questionnaire							
Breakfast							
Boys	76 (58)	157 (98.1)	-	39 (97.5)	57 (95.0)	1.000	**0.000**
Girls	96 (75.6)	146 (93.0)	**0.000**	67 (98.5)	65 (97.0)	1.000	**0.000**
Total	172 (66.7)	303 (95.6)	**0.000**	106 (98.1)	122 (96.1)	0.687	**0.000**
Dairy product at breakfast							
Boys	129 (95.6)	141 (88.1)	0.092	40 (97.6)	54 (90.0)	0.063	0.512
Girls	122 (93.1)	121 (76.1)	**0.004**	67 (98.5)	57 (85.1)	0.125	1.000
Total	251 (94.4)	262 (82.1)	**0.000**	107 (98.2)	111 (87.4)	**0.004**	0.823
Cereals at breakfast							
Boys	99 (74.4)	118 (73.8)	0.500	34 (81.0)	39 (67.2)	0.267	0.601
Girls	94 (71.8)	98 (62.8)	0.154	46 (69.7)	38 (57.6)	0.118	0.594
Total	193 (73.1)	216 (68.4)	0.644	80 (74.1)	77 (62.1)	**0.036**	0.267
Pastry at breakfast							
Boys	15 (11.7)	25 (16.1)	0.263	7 (19.4)	8 (14.0)	0.727	1.000
Girls	17 (13.4)	14 (9.0)	0.064	6 (8.8)	13 (19.1)	0.109	**0.024**
Total	32 (12.5)	39 (12.6)	0.749	13 (12.5)	21 (16.8)	0.481	0.188
Daily fruit or natural juice							
Boys	107 (79.9)	108 (67.5)	**0.036**	33 (78.6)	41 (70.7)	0.388	0.741
Girls	97 (74.0)	96 (60.8)	**0.006**	57 (83.8)	38 (57.6)	**0.041**	1.000
Total	204 (77.0)	204 (64.2)	**0.000**	90 (81.8)	79 (63.7)	**0.020**	0.831
Fruit, second per day							
Boys	41 (30.6)	56 (35.7)	1.000	10 (25.6)	23 (39.7)	0.219	1.000
Girls	53 (41.1)	50 (31.8)	0.119	25 (36.8)	19 (28.4)	0.549	0.222
Total	94 (35.7)	106 (33.8)	0.241	35 (32.7)	42 (33.6)	1.000	0.284

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

	Intervention group			Control group			
	Baseline n (%)	End of study n (%)	p-value baseline to follow-up[b]	Baseline n (%)	End of study n (%)	p-value baseline to follow-up[b]	p-value intervention versus control changes[c]
Dairy product, second per day							
Boys	119 (88.8)	127 (79.4)	0.087	34 (81.0)	43 (72.9)	0.388	0.512
Girls	106 (82.8)	97 (61.8)	**0.001**	57 (82.6)	40 (58.8)	**0.012**	1.000
Total	225 (85.9)	224 (70.7)	**0.000**	91 (82.0)	83 (65.4)	**0.007**	0.823
Vegetables, daily							
Boys	100 (75.2)	101 (63.9)	0.052	28 (70.0)	36 (64.3)	0.227	0.709
Girls	92 (70.8)	108 (69.2)	1.000	41 (60.3)	45 (65.2)	0.180	0.663
Total	192 (73.0)	209 (66.6)	0.215	69 (63.9)	81 (64.8)	1.000	0.446
Vegetables, >1 per day							
Boys	37 (28.7)	33 (20.8)	0.150	5 (13.2)	17 (29.3)	0.109	**0.042**
Girls	28 (22.6)	33 (21.0)	0.864	13 (19.4)	14 (21.2)	0.791	0.813
Total	65 (25.7)	66 (20.9)	0.215	18 (17.1)	31 (25.0)	0.152	0.138
Fish, regularly							
Boys	108 (80.6)	111 (68.9)	0.058	30 (76.9)	36 (61.0)	0.070	0.302
Girls	99 (75.0)	100 (63.3)	**0.050**	52 (75.9)	45 (66.2)	0.189	0.404
Total	207 (77.8)	211 (66.1)	**0.004**	82 (75.9)	81 (63.8)	**0.024**	0.830
Fast food, >1 per week							
Boys	12 (9.0)	21 (13.0)	0.503	4 (9.5)	7 (11.9)	1.000	0.554
Girls	9 (6.8)	15 (9.5)	1.000	3 (4.3)	5 (7.5)	0.375	0.490
Total	21 (7.9)	36 (11.3)	0.597	7 (6.3)	12 (9.5)	0.424	0.499
Legumes >1 per week							
Boys	99 (74.4)	117 (73.1)	0.652	30 (71.4)	41 (68.3)	1.000	1.000
Girls	94 (71.2)	105 (66.0)	0.736	49 (71.0)	50 (74.6)	1.000	0.811
Total	193 (72.8)	222 (69.6)	0.500	79 (71.2)	91 (71.7)	0.856	0.865
Candy > per day							
Boys	13 (9.7)	21 (13.1)	0.481	3 (7.3)	10 (16.9)	0.180	0.142
Girls	15 (11.5)	16 (10.2)	0.143	12 (17.6)	12 (17.9)	0.289	1.000
Total	28 (10.6)	37 (11.7)	0.736	15 (13.8)	22 (17.5)	1.000	0.349
Pasta or rice daily							
Boys	79 (58.5)	102 (63.4)	1.000	28 (68.3)	37 (62.7)	1.000	0.289
Girls	60 (45.8)	92 (58.2)	0.104	39 (56.5)	42 (62.7)	1.000	0.232
Total	139 (52.3)	194 (60.8)	0.284	67 (60.9)	79 (62.7)	1.000	0.110

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

	Intervention group			Control group			
	Baseline n (%)	End of study n (%)	p-value baseline to follow-up[b]	Baseline n (%)	End of study n (%)	p-value baseline to follow-up[b]	p-value intervention versus control changes[c]
Cooking with olive oil at home							
Boys	134 (99.3)	158 (98.8)	1.000	41 (97.6)	58 (96.7)	-	1.000
Girls	128 (97.0)	158 (99.4)	0.375	66 (95.7)	66 (97.1)	0.500	1.000
Total	262 (98.1)	316 (99.1)	0.453	107 (96.4)	124 (96.9)	1.000	1.000
Avall questionnaire							
Before leaving home							
Dairy products							
Boys	117 (86.7)	131 (82.4)	0.378	37 (88.1)	53 (88.3)	0.513	1.000
Girls	115 (88.5)	106 (66.7)	**0.001**	61 (91.0)	43 (62.3)	**0.028**	0.366
Total	232 (87.5)	237 (74.5)	**0.001**	98 (89.9)	96 (74.4)	0.091	0.785
Pastry							
Boys	2 (1.8)	7 (4.4)	0.706	1 (2.5)	1 (1.7)	0.867	1.000
Girls	4 (3.6)	4 (2.5)	0.427	1 (1.5)	4 (5.8)	0.613	0.333
Total	6 (2.7)	11 (3.5)	0.401	2 (1.9)	5 (3.9)	0.700	0.248
Cereals							
Boys	52 (41.3)	62 (39.2)	0.214	20 (50.0)	24 (40.0)	0.892	0.807
Girls	51 (41.8)	44 (27.7)	**0.000**	21 (30.9)	15 (22.1)	**0.025**	0.807
Total	103 (41.5)	106 (33.4)	0.109	41 (38.0)	39 (30.5)	0.100	0.862
Fresh fruit or natural juice							
Boys	20 (18.0)	28 (17.8)	0.695	6 (15.0)	11 (18.3)	0.688	0.724
Girls	21 (18.1)	28 (17.8)	0.966	15 (22.4)	10 (14.5)	0.182	0.753
Total	41 (18.1)	56 (17.8)	0.796	21 (19.6)	21 (16.3)	0.737	1.000
Sandwich							
Boys	31 (27.7)	45 (28.5)	0.143	7 (17.9)	21 (35.6)	0.105	0.225
Girls	25 (21.6)	28 (17.8)	0.310	15 (22.4)	18 (26.1)	0.129	**0.049**
Total	56 (24.6)	73 (23.2)	0.084	22 (20.8)	39 (30.5)	**0.042**	**0.039**
Juice package/soft drinks							
Boys	8 (7.0)	11 (7.1)	0.988	1 (2.5)	2 (3.4)	0.706	1.000
Girls	6 (5.4)	5 (3.2)	0.101	6 (9.1)	6 (8.7)	0.567	0.261
Total	14 (6.2)	16 (5.2)	0.608	7 (6.6)	8 (6.3)	0.732	0.757
Break (Midmorning)							

Table 5

Foods habits assessed at baseline and at the end of the study in the intervention and control groups

	Intervention group			Control group			
	Baseline n (%)	End of study n (%)	p-value baseline to follow-up[b]	Baseline n (%)	End of study n (%)	p-value baseline to follow-up[b]	p-value intervention versus control changes[c]
Dairy products							
Boys	22 (21.4)	13 (8.4)	**0.008**	3 (8.1)	6 (10.5)	0.572	0.377
Girls	21 (18.9)	6 (3.8)	**0.000**	11 (16.4)	3 (4.5)	**0.005**	1.000
Total	43 (20.1)	19 (6.1)	**0.000**	14 (13.5)	9 (7.3)	**0.006**	0.493
Pastry							
Boys	5 (4.7)	5 (3.3)	-	1 (2.4)	2 (3.4)	0.846	0.283
Girls	3 (2.7)	0 (0.0)	-	1 (1.5)	3 (4.4)	0.056	0.110
Total	8 (3.7)	5 (1.6)	-	2 (1.9)	5 (4.0)	0.103	**0.029**
Cereals							
Boys	5 (4.8)	6 (3.9)	0.566	0 (0.0)	2 (3.5)	-	1.000
Girls	2 (1.8)	6 (3.8)	**0.000**	0 (0.0)	2 (2.9)	**0.025**	1.000
Total	7 (3.2)	12 (3.9)	**0.000**	3 (2.9)	4 (3.2)	**0.012**	1.000
Fresh fruit or natural juice							
Boys	9 (8.9)	8 (5.2)	0.109	2 (5.4)	9 (16.1)	0.308	0.274
Girls	6 (5.5)	4 (2.5)	**0.004**	6 (8.8)	5 (7.5)	0.250	**0.043**
Total	15 (7.1)	12 (3.9)	**0.001**	8 (7.6)	14 (11.4)	0.086	**0.024**
Sandwich							
Boys	57 (49.1)	123 (76.9)	**0.000**	14 (36.8)	45 (73.8)	**0.023**	0.172
Girls	58 (48.7)	109 (69.0)	**0.030**	30 (44.1)	53 (77.9)	**0.003**	0.124
Total	115 (48.9)	232 (73.0)	**0.000**	44 (41.5)	98 (76.0)	**0.000**	0.053
Juice package/soft drinks							
Boys	12 (11.4)	17 (11.0)	0.569	2 (5.0)	8 (13.8)	**0.021**	0.368
Girls	9 (8.3)	7 (4.6)	0.304	6 (9.0)	16 (24.2)	0.160	**0.003**
Total	21 (9.8)	24 (7.8)	0.480	8 (7.5)	24 (19.4)	**0.011**	**0.009**

Study 3

A youth-led social marketing intervention to encourage healthy lifestyles, the EYTO (European Youth Tackling Obesity) project: A cluster randomised controlled trial in Catalonia, Spain.

A youth-led social marketing intervention to encourage healthy lifestyles, the EYTO (European Youth Tackling Obesity) project: A cluster randomised controlled trial in Catalonia, Spain.

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Abstract

Background: The encouragement of healthy lifestyles for obesity prevention in young people is a public health priority. The European Youth Tackling Obesity (EYTO) project is a multicentric intervention project with participation from the United Kingdom, Portugal, the Czech Republic and Spain. The general aim of the EYTO project is to improve lifestyles, including nutritional habits and physical activity practice, and to prevent obesity in socioeconomically disadvantaged and vulnerable adolescents. The EYTO project works through a peer-led social marketing intervention that is designed and implemented by the adolescents of each participating country. Each country involved in the project acts independently. This paper describes the “Som la Pera” intervention Spanish study that is part of the EYTO project.

Methods/Design: In Spain, the research team performed a cluster randomised controlled intervention over 2 academic years (2013-2015) in which 2 high-schools were designated as the control group and 2 high-schools were designated as the intervention group, with a minimum of 121 schoolchildren per group.

From the intervention group, 5 adolescents with leadership characteristics, called “Adolescent Challenge Creators” (ACCs), were recruited. These 5 ACCs received an initial 4 h training session about social marketing principles and healthy lifestyle theory, followed by 24 sessions (1.30 h/session) divided in two academic years to design and implement activities presented as challenges to encourage healthy lifestyles among their peers, the approximately 180-200 high-school students in the intervention group. During the design of the intervention, it was essential that the ACCs used the 8 social marketing criteria (customer orientation, behaviour, theory, insight, exchange, competition, segmentation and methods mix). The expected primary outcomes from the Spanish intervention will be as follows: increases in the consumption of fruits and vegetables and physical activity practice along with reductions in TV/computer/game console use. The secondary outcomes will be as follows: increased breakfast consumption, engagement with local recreation and reduced obesity prevalence. The outcomes will be measured by the Health Behaviour in School-aged Children Study (HBSC) survey at baseline and at the end of the intervention.

METHODS and RESULTS |

In the control group, no intervention was implemented, but the outcome measurements were collected in parallel with the intervention group.
Discussion: This study described a new methodology to improve lifestyles and to address adolescent obesity.

Trial Registration: ClinicalTrials.gov: NCT02157402. Registered 03 June 2014.

Keywords: adolescents, youth, peer-led, healthy lifestyles, obesity, social marketing, study protocol

Background

Obesity is an important global public health problem, and its long-term consequences are well documented [1-3]. The prevalence of excess weight and obesity in childhood is increasing in different countries. In Europe, the prevalence of excess weight, including overweight and obesity, is 19-49% in boys and 18-43% in girls, whereas the obesity prevalence is 6-26.6% in boys and 5-17% in girls [4]. In developed countries, obesity is also related to socioeconomic status: obesity rates follow a social gradient in which the highest rates are present in racial/ethnic minorities and socioeconomically disadvantaged populations [5, 6].

Once obesity is established, it is difficult to treat, highlighting the urgent need for successful strategies and policies to revert trends in weight gain, sedentary lifestyles and inadequate nutritional habits, especially in vulnerable youth populations [6-8].

The improvement of healthy lifestyles through modification of eating habits, daily physical activity practice and avoiding sedentary behaviour are the principle modifications that can prevent or reduce the risk of obesity [9]. Specific recommendations based on expert opinion or supported by clinical studies are proposed [10]. These recommendations are the periodic surveillance of obesity status of children and adults, education of children and families about healthy lifestyles, community enrolment in health advice and health education, assure a balanced nutrition and breastfeeding in early infancy and perinatal period, school-based interventions on health education focused on healthy eating and physical activity, home-based interventions, and support of health authority and registration. The authorities should contribute in encouraging people in disadvantaged areas to eat healthier by improving the availability, quality and pricing of healthy food in these localities [11] and encouraging them to perform more physical activity by providing access to sport grounds and green spaces [12].

Nutrition and healthy lifestyle education for adolescents have to be planned differently than for other educational ages because the cognitive and social developmental processes, such as the shifts towards abstract thinking and problem-solving skills, questioning adult authority, increased autonomy from parents, and an increased reliance on peers as a source of identity, support, and

normative behaviour, develop during this life period [13-20]. This age period presents both a challenge and an opportunity to offer new learning and teaching strategies to engage adolescents and motivate them to make healthy food choices [13-14]. The influence of peers on young people´s health behaviours is acknowledged [16-19], and interventions using a peer-led model for health promotion have shown positive effects [20].

Social marketing when it is conscientiously applied, has been identified as a possible strategy to change behaviours [21]. Kotler and Zaltman expressly defined social marketing in 1971 as "a social influence technology involving the design, implementation and control of programs aimed at increasing the acceptability of a social idea or practice in one or more groups of target adopters" [22]. This term was re-described by Andreasen in 1994 as "the application of commercial marketing technologies to the analysis, planning, execution and evaluation of programs designed to influence the voluntary behaviour of target audiences in order to improve their personal welfare and that of their society"[23].

Doctrines and tactics from commercial marketing for social change programs can improve the strategic value of health communication and increase the likelihood that people will make healthy behavioural choices [22-25].

To help strengthen the use of effective social marketing approaches, the Social Marketing National Benchmark Criteria (SMBC) was developed by the National Social Marketing Centre (NSMC) in the United Kingdom [26]. The purpose of this benchmark is to create support for a better understanding of social marketing that takes into account the 8 basic SMBC principles: customer or participant orientation, behaviour, theory, insight, exchange, competition, segmentation and methods mix, as well as the promotion of a consistent approach to review and evaluate projects [26].

Some studies suggest that the use of social marketing strategies to modify behaviour, lifestyles and other aspects of diet and physical activity through an intervention (target audience played an active role) or a campaign (target audience played a passive role) can reduce the overweight or obesity prevalence among children and adolescents. There are some social marketing campaigns that demonstrate positive attitude and behaviour effects in children, such as the VERB

social marketing campaign to increase physical activity among youth [27], Canada's ParticipACTION national physical activity mass media campaign targeting parents of elementary school-aged children [28] and an intervention focused on improving the snacking habits of pre-school children [29]. By contrast, "The 5,4,3,2,1 go! Intervention" [30] demonstrated effects on parental behaviour and did not affect children [31]. The Change4Life campaign, a national social marketing program implemented in the United Kingdom to reduce obesity [32], demonstrated positive effects on awareness but little impact on attitudes and behaviours. However, the effectiveness of these campaigns requires further research on behaviour modification using randomised, controlled intervention studies to determine the appropriate number of criteria and the key social marketing criteria that will have the greatest impact on achieving the intervention objectives.

The European Youth Tackling Obesity (EYTO) project looks to contribute the description and evaluation of interventions to tackle obesity in adolescents by recruiting young people to design and implement peer-led social marketing interventions that promote healthy eating and physical activity among young people aged 13-16 years with low income who are vulnerable to obesity. The general aims of the EYTO project are to improve lifestyles, such as nutritional habits and physical activity practice, and to prevent obesity in socioeconomically disadvantaged and vulnerable adolescents. The secondary aims are to reduce the modifiable causes of obesity amongst disadvantaged young people; to improve health, education and social outcomes for young people who are obese; to contribute to a reduction in health inequalities among young people; and to increase the participation of young people in the development of interventions to address obesity.

This paper describes the "Som la Pera" Spanish intervention study design of the EYTO project, which proposed performing a school cluster randomised controlled trial.

Methods

European study design

This is a multicentric peer leadership intervention involving the participation of the United Kingdom, Spain, Portugal and the Czech Republic. Five selected adolescents (in each country) are tasked with designing and implementing a social marketing intervention, using the SMBC as a basis for the design, for 180-200 schoolmates. The selection of 5 ACCs per country was done as an easy and rapid way to design and prepare the challenges. The intervention should encourage healthy lifestyles among their peers of the same age in disadvantaged neighbourhoods; the adolescent peer-led model is more effective at achieving positive results in health behaviour than the adult-led models applied in school-based studies [33]. Adolescent peer-led interventions use the youth empowerment theory based on engaging young people in the decision-making process to improve their health and well-being [34]. Because the EYTO is a multicentric project in which each country acts autonomously and because the design and implementation of the interventions are directed by different adolescents in the participating countries, this protocol only reports the description of the Spanish study design.

The procedures and progress reports of work deliverables will be led by the Spanish management team according to the schedule's National Children's Bureau (NCB) to the European Commission, with a frequency of 6 months.

The communication of the results to the participants, healthcare professionals, and the public will be performed via publication, reporting in a results database, and other data-sharing arrangements. Authorship eligibility is in accordance with the best practices and ethical guidelines. If necessary, we will guarantee public access to the full protocol, participant database and statistical code.

Spanish study design

The "Som la Pera" intervention is a school cluster randomised controlled trial. The participating Spanish city was Reus (Catalonia). Local authorities have already identified public high-schools that they agree serve low-income neighbourhoods that are considered disadvantaged areas. From the 9 public high-schools identified in these neighbourhoods, 4 high-schools were randomly selected. The

randomisation code was computer generated. The high-schools were assigned to the control or intervention arm at a ratio of 1:1 via an interactive electronic response system hosted by the Nutrition and Health Technology Centre (CTNS) in Reus, Spain. The unit responsible for the randomisation took no further part in the study. Because the researchers know the names of the four high-schools, allocation concealment was not performed. The project consists of five main phases, as shown in Figure 1. The first phase included the randomisation and allocation of the high-schools in the disadvantaged area into the two intervention and two control high-schools. High-school teachers from the randomised intervention group selected the five adolescents according to their knowledge of the students by considering leadership characteristics and English level (because the students will participate in EYTO European meetings), 2 adolescents from one high-school and 3 from the other high-school. These 5 adolescents will be referred to in this protocol as the Adolescent Challenge Creators (ACCs). The study characteristics are summarised in Table 1.

Participants and Professional experts

The inclusion criteria were as follows: participants were between 13 and 16 years of age, attended one of the four randomised high-schools and had an informed consent signed by their parents or legal guardians. In addition, the five ACCs selected in the intervention group were included if they fulfilled the inclusion criteria mentioned previously, displayed leadership characteristics, had at least a working knowledge of the English language (for the International EYTO meetings) and were highly motivated and committed to the study. The lack of any inclusion criteria was the first and only exclusion criterion.

The professional experts who participate in “Som la Pera” intervention are:

a. Physicians: physicians specialist on health education and promotion led the implementation of the study from the recruitment process to the end of the experimental protocol by meetings with stakeholders like high-schools’ director or local policy-makers and health and educators administrators. They were in charge of designing, performing and revising the evaluation process throughout the study

b. Nutritionists: nutritionists with expertise on health education and health promotion led the high-school recruitment process by meetings with parents and adolescents explaining the project, recollected the informed consent of parents and adolescent to participate in the study and, coordinated the logistical issues of the study. They contributed to support the evaluation of primary and secondary outcomes through the validated questionnaire in high-schools computer classrooms to solve adolescents' questions of lifestyles and behaviour evaluation questionnaire. The nutritionists were responsible for the dietary and healthy lifestyle training of the 5 ACCs.

c. Managers: The managers coordinated the Spanish intervention among the participating countries. They supervised all of the scientific work, from the intervention trial design to the scientific data interpretation.

d. Publicists and Journalists: publicists and journalists experts on health communication were responsible for the communication training of the 5 ACCs. Even though the 5 ACCs were in charge of the communication and dissemination campaign (lifestyles messages and intervention challenges), publicists and journalists are in charge to disseminate the general information of this intervention and European project to general population through local, national and international newspapers and television media.

Intervention

a) Training process

The 5 ACCs received a 4 h initial training session about social marketing principles and the healthy lifestyle theory from a university specialist in health and communication. Moreover, the 5 ACCs received 1.30 h of training every week over 12 weeks (1st academic year) and 1.30 h of training every week over 12 weeks (2nd academic year), a total of 12 sessions/academic year, leading to a total of 24 sessions (1.30 h/session), also performed by a university specialist. The aims of the sessions were to train the 5 ACCs on health promotion, health education, communication and social media so that they could design the challenge activities for their peers. The university specialists educated the 5 ACCs about the primary

and secondary objectives of the intervention, and the ACCs then had to design the challenges for their schoolmates to accomplish the defined objectives.

The 5 ACCs designed social marketing activities proposed as challenges based on 8 SMBCs: 1) customer orientation, 2) behaviour, 3) theory, 4) insight, 5) exchange, 6) competition, 7) segmentation and 8) methods mix (Table 2). These 5 ACCs were recruited separately from two different high-schools. Then, the 5 ACCs, as peer-led instructors, identified the possible lifestyle components that they and their peers should improve, selected the easiest and most common communication channels among them, and determined which challenges should be designed and implemented for their peers.

b) Design and implementation process

The ACCs chose the name “Som la Pera” for the Spanish intervention. This name is a Catalan idiom that literally means “we are a pear” but figuratively means “we are cool”. The ACCs designed and implemented the following challenges: gymkhanas (an activity inside high-schools in which adolescents were divided by teams and competed among themselves in different sport and food tasting competitions, such as goal scoring, racing, or discerning foods with one’s eyes closed) and cooking ability and lifestyle knowledge competitions (high-school cooking competition to prepare healthy dishes simulating cooking TV show or quiz show), as well as pop-up events that included healthy cooking contests and lifestyle knowledge competitions. The 5 ACCs had to be in touch with community stakeholders to obtain some resources free of charge. For example, Central Mercat de Reus gave them food to develop cooking competitions and run the gymkhana, and local government provided local community spaces to develop challenges. Moreover, material costs for items such as posters, flyers, etc. were paid for by the project budget. The ACCs chose Facebook as the main channel of communication with their peers (https://www.facebook.com/somlapera). The intervention designed by the Spanish ACCs was launched in Reus, Spain, in May 2014.

The 5 challenges designed by the ACCs over the first year in the intervention high-schools were implemented for a period of 12 weeks (second phase Figure 1). At the end of this phase, there was an EYTO project meeting in London (UK) at which

the 5 ACCs from the 4 participating countries came together to exchange experiences and ideas so they could revise, maintain or add new components to their second-year design intervention. The costs of this meeting were included in the project funding (third phase Figure 1). Five new challenges designed by the ACCs were implemented during the second academic year, for a period of 12 weeks (fourth phase Figure 1). And finally, last European EYTO meeting in Spain to conclude the participation of the ACCs were done to exchange intervention experiences across participating countries (fifth phase Figure 1).

In the control group, no intervention will be implemented, but the outcome measurements were collected in parallel with the intervention group.

Evaluation process

Primary and secondary outcomes

The expected primary outcomes of the Spanish intervention were as follows: increases in the consumption of fruits and vegetables and physical activity practice, along with reductions in TV/computer/game console use. The secondary outcomes were as follows: increased breakfast consumption, engagement with local recreation and reduced obesity prevalence. The outcomes of the Spanish intervention were measured by the Health Behaviour in School-aged Children Study (HBSC) Survey 2009-2010 [35] to evaluate the adolescents' lifestyles at baseline and at the end of the intervention as presented in Table 3. The HBSC study is a validated cross-sectional survey of school students that collects data every four years on 11-, 13- and 15-year-old adolescents [36]. The baseline measurements from the intervention and control groups were performed in the second phase, and the end-of-study measurements were performed in the fourth phase (Figure 1). Analyses and evaluations of each country's intervention and global project will be performed in phase 5 (Figure 1) so that the project can be concluded.

Statistical Analysis Plan

We estimated that with a sample size of 121 adolescent schoolmates per group, the study will have 90% power to detect a difference of a 0.5 portion of vegetables

or fruits between the intervention and control groups, setting the bilateral level of statistical significance at 5%. We anticipate a loss of follow-up rate of 30%.

Analyses of the results will be performed on an intent-to-treat (ITT) basis, defined as a participant who had at least baseline efficacy data.

The descriptive results are expressed as the means ± standard deviations and the 95% confidence intervals for quantitative variables or as frequency distributions for qualitative variables. Generalised linear mixed models are used to analyse differences between the intervention and control groups and changes in primary and secondary outcomes from baseline to the end of the intervention. For the rest of the efficacy variables, we will use Fisher's exact test for the categorical variables and Student's t-test for the continuous variables. The significance level is fixed at a bilateral level of 5%.

All statistical analyses are performed with SPSS version 22.0 (SPSS, Inc., IBM, Armonk, NY, USA).

Ethical approval and trial registration

The study has the approval of the Ethical Committee of the Hospital Universitari Sant Joan de Reus (ref: 14-04-24/4proj2), and the trial was registered with clinicaltrials.gov (NCT02157402).

The protocol is in accordance with the Helsinki Declaration and the good clinical practice guidelines of the International Conference of Harmonization (ICH GCP). This randomised trial was conducted according to the extended cluster CONSORT 2010 guidelines.

Additional information

This study followed the SPIRIT [37] and TIDieR protocol description recommendations [38] as presented in Additional File 1 and Additional File 2. The participation, schedule of enrolment, interventions and assessment are presented in Table 4. Finally, a cluster CONSORT checklist and flow diagram were used to summarise the description of study when the study and analysis were completed [39].

Discussion

This paper describes an intervention aimed at improving lifestyles, such as nutritional habits and physical activity practice, for obesity prevention in socioeconomically disadvantaged and vulnerable adolescents.

Based on the worldwide current high rates of childhood and adolescent obesity [9], the fight against adolescent OB is a significant public health objective. This focus indicates the necessity of new methodologies to achieve adolescent behaviour changes [40]. Social marketing nutrition interventions were strongly and equally effective at influencing nutrition behaviour, knowledge and psychosocial variables, suggesting that social marketing interventions can produce changes across different behaviours [41]. There is growing evidence that interventions using social marketing approaches can contribute to encouraging healthier lifestyles and, as a result, can prevent obesity [21].

An important problem in the field of social marketing research is that there are some interventions that use social marketing principles in their study design without being aware of that fact [42]. Additionally, few interventions that use the principles consciously publish the obtained results. One such intervention is Change4Life, a national social marketing program, implemented in the United Kingdom to reduce obesity [35]. This intervention achieved increased awareness of the anti-obesity campaign but had little impact on attitudes and behaviours. The peer-led model is effective when it is applied in school-based studies and generates more positive results in health behaviour than adult-led instruction [33]. Also, key principles to create new approaches that fight obesity are set to guide the development of strategies to address unhealthy diets and physical inactivity, and should include: best available scientific evidence, comprehensiveness, multisectoral and multidisciplinary approaches, a life course perspective, addressing poverty, gender and culture sensitivities, and the accountability of all stakeholders to achieve success [43].

Despite their considerable complexity, it is crucial to assess the outcomes achieved in interventions that employ social marketing principles. In this way, the public health sector of the government will be able to distribute its efforts to address adolescent obesity more efficiently [40].

List of abbreviations
EYTO: European Youth Tackling Obesity
ACCs: Adolescent Campaign Creators
HBSC: Health Behaviour in School-aged Children Study
SMBC: Social Marketing National Benchmark Criteria

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
MG, RS, EL, MA-M, and LT were responsible for the study's conception and design. They led the implementation of the study from the recruitment process until the end of the experimental protocol. They were also in charge of designing, performing and evaluating the nutritional and clinical aspects throughout the study. Additionally, they were responsible for the dietary and healthy lifestyle training.
IP, FP and LA were responsible for substantial contributions to conception and design, and they coordinated the Spanish intervention among the participating countries. In addition, they supervised all of the scientific work, from the intervention trial design to the scientific data interpretation.
JP, MM, and CMM were responsible for substantial contributions to conception and design and the communication training. They also led the global communication and dissemination of the project.
MG, RS, EL, MA-M, and LT participated in writing the manuscript and designing the study's biostatistics methods.
MG, RS, EL, MA-M, LT, IP, FP, LA, JP, MM and CMM participated in the manuscript revision.

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This research project has been developed as an EYTO component, and the National Children's Bureau of the United Kingdom is responsible for the general data analysis of the four EYTO project participating countries; however, the Spanish data will be analysed by our research team. We appreciate the enthusiastic support of our European partners: Komunikujeme (Czech Republic), Companhia de Ideias (Portugal) and the National Children's Bureau (United Kingdom).
The Spanish research project has been supported by Central Market of Reus, Spain (Mercat Central de Reus), which provides fresh food for the intervention, and the Municipality of Reus, Spain [Ajuntament de Reus, Spain].
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Figure Legends

Figure 1: Spanish Intervention Schedule of the European Youth Tackling Obesity (EYTO) Project

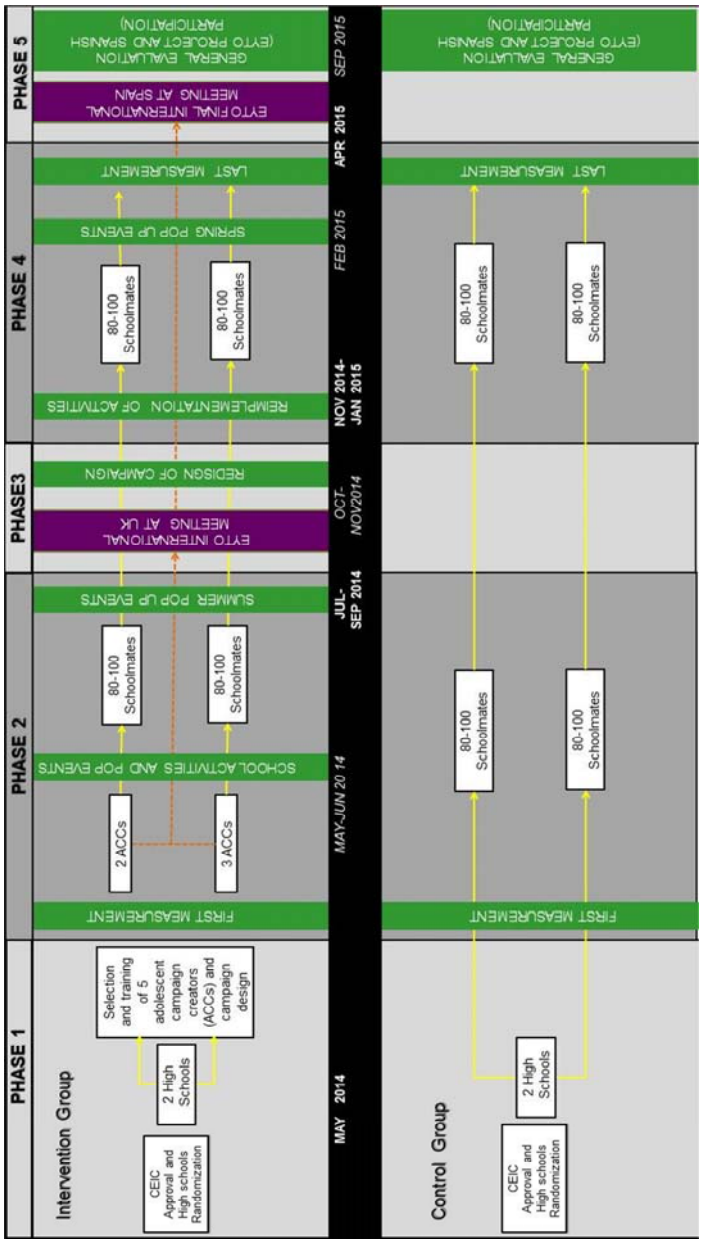

Table 1. General study characteristics.

Arm	High-schools information	Assigned interventions	Population	Primary and secondary outcomes
Intervention Group The intervention group received challenges designed by ACCs that promote healthy lifestyles.	<u>High-school A</u> Economic disvantatged Size: 3 classes/level Public Reus	The intervention group will receive an intervention consisting of challenges designed by 5 ACCs. These activities must have social marketing criteria.	<u>High-school A</u> Students from high schools from low-income neighbourhoods, who are 13 to 16 years old: a) 3 to 5 ACCs b) 80-100 adolescents	Primary outcome: consumption of fruits and vegetables, physical activity practice, and TV/computer/game console use. Secondary outcomes: breakfast consumption, engagement with local recreation and obesity prevalence
	<u>High-school B</u> Economic disvantatged Size: 4 classes/level Public Reus		<u>High-school B</u> Students from high schools from low-income neighbourhoods, who are 13 to 16 years old: a) 2 to 5 ACCs b) 80-100 adolescents	
Control Group The control group no received challenges to promote healthy lifestyles.	<u>High-school A</u> Economic disvantatged Size: 3 classes/level Public Reus	No intervention is assigned for this group.	<u>High-school A</u> Students from high schools from low-income neighbourhoods, who are 13 to 16 years old: b) 80-100 adolescents	The same outcomes were measured with the same tools and over the same time frame as in the intervention group.
	<u>High-school B</u> Economic disvantatged Size: 4 classes/level Public Reus		<u>High-school B</u> Students from high schools from low-income neighbourhoods, who are 13 to 16 years old: b) 80-100 adolescents	

Table 2. Use of SM in the intervention

Research group	Adolescent Challenge Creators (ACCs)	Research group and Adolescent Challenge Creators (ACCs)
1.*Customer Orientation*: Focuses on the audience to help understand their lives, behaviours and issues. The peer-led model attracts the motivation of adolescents to participate and interact in the intervention, because adolescents prepare activities directed to adolescents. In this way, it have in mind their motivations and behaviours.	2. *Behaviour*: Aims to change people's actual behaviours. Aims to improve the consumption of fruit and vegetable, PA practice, breakfast consumption, and decrease the TV, PC and videogames behaviour.	3. *Theory*: Uses behavioural theories to understand behaviour and to inform the intervention. It used the conductual behavioural change framework, taking into account the "Behaviour Change Wheel" (Michie, van Stralen, & West, 2011).
5. *Exchange*: Considers the benefits and costs of adopting and maintaining a new behaviour. The perceived cost can be social, economic, or physical. The consideration of cost-effectiveness of the intervention will be evaluated at the end-of-intervention.	4. *Insight*: Develop a deep understanding of target audience. The peer-led model attracts the motivation of adolescents to participate and interact in the intervention, because adolescents prepare activities directed to adolescents. In this way, it have in mind their motivations and behaviours.	6. *Competition*: Seeks to understand the possible barriers for the audience's time, attention, and inclination to behave in a particular way. The 5 adolescent's coordinators discussed about enablers and barriers that adolescents have to achieve behavioural changes. From this debate, it proposed some changes to improve it including stakeholders.
8. *Methods Mix*: Uses a mix of methods to bring about behavioural change. Does not rely solely on raising awareness. It contributed to inform using social media, educate using activities designed by adolescent coordinators and social media, support using visual material in high-schools and social media, and the design and control will be applied with the suggestions provided by 5 adolescent coordinators.		7. *Segmentation*: Identifies audience "segments" that have common characteristics and then tailors interventions appropriately. The intervention is focused on adolescents from 13-16y old, who attend the participant high-schools accomplishing low socioeconomically characteristics.

Social Marketing National Benchmark Criteria (SMBC) developed by the National Social Marketing Centre (NSMC) UK. (23)

Table 3. Outcomes measurements in the Health Behaviour in School-aged Children Study (HBSC) Survey

Health Behaviour in School-aged Children Study Items	Outcome measured	Question	Possible answers
Eating habits (primary outcomes)	Nutritional behaviour. Fruit, vegetable and water consumption.	How many times a week do you usually eat or drink (fruits, vegetables, sweets, coke or other soft drinks that contain sugar)…?	Never, less than once a week, once a week, 2-4 days a week, 5-6 days a week, once a day, every day, every day more than once every day.
	Breakfast quantity and quality	How often do you usually have breakfast (more than a glass of milk or fruit juice)?	*Weekdays* (I never have breakfast, one day, two days, three days, four days, five days).
			Weekends (I never have breakfast during the weekend, I usually have breakfast on only one day of the weekend (Saturday OR Sunday), I usually have breakfast on both days (Saturday AND Sunday)).
Physical activity (primary outcomes)	Physical activity practice	Over the past 7 days, on how many days were you physically active for a total of at least 60 minutes per day?	0 days, 1 day, 2 days, 3 days, 4 days, 5 days, 6 days, 7 days.
		Outside school hours: How often do you usually exercise in your free time so much that you get out of breath or sweat?	Every day, 4-6 times a week, 2-3 times a week, once a week, once a month, less than once a month, never.
		Outside school hours: How many hours a week do you usually exercise in your free time so much that you get out of breath or sweat?	None, about half an hour, about 1 hour, about 2 to 3 hours, about 4 to 6 hours, about 7 hours or more.

Table 3. Outcomes measurements in the Health Behaviour in School-aged Children Study (HBSC) Survey

Health Behaviour in School-aged Children Study Items	Outcome measured	Question	Possible answers
Sedentary behaviour (primary outcomes)	Sedentary behaviour	About how many hours a day you usually watch television (includes DVD and videos) in your free time?	Weekdays: None at all, about half an hour a day, about 1 hour a day, about 2 hours a day, about 3 hours a day, about 4 hours a day, about 5 hours a day, about 6 hours a day, about 7 or more hours a day.
			Weekends: None at all, about half an hour a day, about 1 hour a day, about 2 hours a day, about 3 hours a day, about 4 hours a day, about 5 hours a day, about 6 hours a day, about 7 or more hours a day.
		About how many hours a day do you usually play games on a computer or games console (PlayStation, Xbox, GameCube, etc.) in your free time?	Weekdays: None at all, about half an hour a day, about 1 hour a day, about 2 hours a day, about 3 hours a day, about 4 hours a day, about 5 hours a day, about 6 hours a day, about 7 or more hours a day.
		About how many hours a day do you usually use a computer for chatting on-line, internet, emailing, homework, etc in your free time?	Weekends: None at all, about half an hour a day, about 1 hour a day, about 2 hours a day, about 3 hours a day, about 4 hours a day, about 5 hours a day, about 6 hours a day, about 7 or more hours a day.
Self-confidence (secondary outcomes)	Weight control and body image	At the present, are you on a diet or doing something else to lose weight?	No, my weight is fine; No, but I should lose some weight; No, because I need to put on weight; Yes.
Body mass index (secondary outcomes)	Perceived obesity and overweight prevalence	How much do you weigh without clothes?	Free space for answer.
		How tall are you without shoes?	Free space for answer.

Items obtained from the Health Behaviour in School-Aged Children (HBSC) 2009/2010. Ref (20)

Table 4. Spanish EYTO Project Participation, schedule of enrolment, interventions and assessment.

	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					
	Phase 1				Phase 2			Phase 3
TIMEPOINT**	$-t_1$ **May 2014** (after CEIC approval) *High-Schools of low income in Reus are included in this phase.* *Randomization is performed.*	a0 **May 2014** *4 high-school are randomized chose, 2 in intervention and 2 in control group*	t_1 **May 2014** *Control High-schools meeting, separately intervention high-school meeting and 5 ACCs selection*	t_2 **May 2014** *Social marketing, health promotion and communication formation to 5 ACCs* *Design of the intervention.* *Information and sign consent informed*	t_3 *May 2014* *Each participant answered the HBSC Survey.* *Implementation by 5 ACCs to their peers in high-school for 12 weeks*	t_4 *September 2014* *Implementation of challenges by the 5 ACCs with help of stakeholders to their peers.*	t_5 *September 2014* *Preparation of the 5 ACCs presentation of first academic Spanish intervention to EYTO meeting in London*	t_6 *October 2014* *Meeting of 5 ACCs from the 4 EYTO project participating countries in London to pool designed activities and exchange ideas. Successful intervention activities can be re-implemented*
ENROLMENT:	360-400 adolescents of low income neighbourhoods.							
Eligibility screen	x							
Informed consent			x					
[List other procedures]								
Allocation	180-200 from intervention group, and 180-200 from control group							

Table 4. Spanish EYTO Project Participation, schedule of enrolment, interventions and assessment.

Intervention			Training of 5 ACCsto design activities		HBSC Survey Implementation of activities during 12 weeks	Implementation of social events challenges in the community and local markets for their peers		Expose the activities performed during 12 weeks (1st academic year)
Control			This group wasn't received any intervention		HBSC Survey			
ASSESSMENTS: *List baseline variables*	X	X	X				X	X
List primary and secondary outcome variables at 200 participants in intervention and 200 participants in control group			Fruit and vegetable consumption Physical activity Practice. Sedentary behaviours					

Table 4. Spanish EYTO Project Participation, schedule of enrolment, interventions and assessment.

STUDY PERIOD						
	Post-allocation					Close-out September 2015
	Phase 4			Phase 5		
TIMEPOINT**	***t_7* November 2014** *Activities re-implementation by 5 ACCs to their peers in the intervention group high-schools during 12 weeks duration (2nd academic year)*	***t_8* February 2015** *Challenges designed by the 5 ACCs for their peers with stakeholders help*	***t_9* Mar 2015** *Preparation of presentation of Spanish intervention to EYTO meeting in Spain*	***t_{10}* Sept 2015** *Meeting of 5 ACCs from the 4 EYTO project participating countries in Reus Spain.*	***t_{11}* Sept 2015** *Report of intervention challenges to pooling 4 countries EYTO challenges and its web presentation and analysis of data.*	***t_{12}* Sept 2015** *EYTO Final report including intervention challenges and Results of lifestyles outcomes*
INTERVENTIONS:						
Intervention	mplementation of activities during 12 weeks (2nd academic year)	HBSC Survey Intervention mplementation				
Control		HBSC Survey				
ASSESSMENTS:			X	X		
List primary and secondary outcome variables at 200 participants in intervention and 200 participants in control group		February 2015, at the end of ntervention		End of the participation of the 5 ACCs	Fruit and vegetable consumption. Physical activity Practice Sedentary behaviours.	

Additional files

- **Additional File 1**.pdf: The TIDieR (Template for Intervention Description and Replication) Checklist.
- **Additional File 2**.pdf: Standard Protocol Items: Recommendations for interventional trials (SPIRIT) 2013 Checklist

Study 4

The EYTO project: Sustainability planning of "Som la Pera", a peer-led intervention programme to encourage healthy lifestyles

The EYTO Project: Sustainability planning of "Som la Pera", a peer-led intervention programme to encourage healthy lifestyles

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Abstract

Background: The sustainability prediction and assessment of health programmes is increasingly important for the policy-makers, practitioners, and funders of health systems to distribute the appropriate resources efficiently and effectively.

Findings: European financial support has enabled the implementation of the “Som la Pera” intervention, a school-cluster randomized controlled trial to improve the lifestyles of adolescents from Spain (Reus, Catalonia), for 2 academic years (2013-2014 to 2014-2015); the main methodologies used in the programme are social marketing and adolescent peer-leading. Here, we report on the specific planning and assessment of the sustainability of the “Som la Pera” intervention with the aim of guaranteeing its long-term sustained implementation beyond 2 years.

Results: The “program sustainability assessment tool”, which comprises 8 domains and 40 items, was used to assess the long-term sustainability of this intervention. The sustainability assessment was done at January 2015, and provided a score of 5.7 out of 7 possible points. In particular, two of the 8 domains (namely, funding stability and strategic planning) require improvement every 2 years to ensure that “Som la Pera”, a social marketing and peer-led school-based intervention, will be sustainable. We propose that every 2 years, 5 adolescent campaign creators be trained by health sciences university students to disseminate information and activities to their adolescent mates according to a social marketing and peer-led methodology.

Conclusion: We will invest efforts to recover funding stability and strategic planning domains for the effective and long-term implementation of “Som la Pera”.

Keywords: sustainability, health programme, peer-led intervention, lifestyles, adolescents

FINDINGS

BACKGROUNG

Sustainability has been defined as "the long-term ability of an organizational system to mobilize and allocate sufficient and appropriate resources for activities that meet individual or public health needs and demands" [1]. The sustainability planning and assessment of health programmes are increasingly necessary for the policy-makers, practitioners, and funders of health systems to distribute the resources efficiently and effectively [2]. However, many health programmes do not focus on the prediction of long-term sustainability. Intervention assessment [3] is essential to determine whether a health programme maintains effective health benefits once the intervention is over [4]. Moreover, sustainability is a key element in the World Health Organization (WHO) guidelines [5]; e.g., in obesity prevention interventions [2].

For this reason, we propose to plan and evaluate the sustainability of the "Som la Pera" intervention at baseline to determine the possible gaps and shortcomings of the domains that are necessary to achieve optimal long-term sustained implementation as soon as the intervention is finished and to determine whether the programme is effective at encouraging healthy adolescent lifestyles.

METHODS

Overview of the "Som la Pera" Intervention

The "Som la Pera" intervention [6] is part of a multicentre European peer-led intervention project named European Youth Tackling Obesity (EYTO) project, which is being developed simultaneously in the United Kingdom, the Czech Republic, Portugal and Spain over the academic years 2013-2014 and 2014-2015. The intervention is designed differently in each country [7]. The interventions were designed by 5 adolescents of each country using peer-leading methodology and address activities that are aimed at improving the lifestyles of adolescents; social marketing criteria were used in the design of the intervention.

In particular, the Spanish intervention "Som la Pera" is a school-cluster randomized controlled trial; this trial is described in detail in the programme's protocol [6].

Participants

The "Som la Pera" intervention programme is being implemented in 4 high schools in Reus (Spain); 2 high-schools are considered the intervention group and receive the intervention that is designed by 5 adolescent campaign creators (ACCs), and 2 high-schools are considered the control group and do not receive any type of intervention.

The included participants are 13- to 16-year-old adolescents who attend one of the four randomized high-schools and who provided informed consent, which was signed by their parents or legal guardians. In addition, the five ACCs selected to comprise the intervention group were included if they fulfilled the inclusion criteria mentioned previously, displayed leadership characteristics, had at least moderate knowledge of the English language (to attend International EYTO meetings), and were highly motivated and committed to the programme. Adolescents were excluded from participation if they failed to meet any of the inclusion criteria.

Instruments and procedures

The sustainability of the "Som la Pera" intervention programme was planned using the "programme sustainability assessment tool (PSAT)" [4]. This new instrument comprises 8 domains (political support, funding stability, partnerships, organisational capacity, programme evaluation, programme adaptation, communications and strategic planning), each of which comprises 5 items (40 items in total). PSAT is a reliable and ready-to-use tool that is designed to assess a programme's capacity for long-term sustainability [4]. The collection of data was made over the first academic year and on January 2015. The analysis of this data was performed on January 2015.

This study protocol was approved by the Ethical Committee of the Hospital Universitari Sant Joan de Reus (ref: 14-04-24/4proj2), and the trial was registered with Clinical Trials (NCT01562080).

RESULTS

The sustainability planning was developed using 8 PSAT [4] domains and used an electronic application, which is available at www.sustaintool.org. **Table 1** described assessment of each 8 domains.

The sustainability assessment was performed by 9 researchers, staff and stakeholders of the "Som la Pera" intervention. We obtained a realistic score by working with a wide range of professionals who are participating in this project. The project was scored 5.7 out of 7 points. **Figure 1** shows the sustainability capacity based on 8 domains; based on the figure, it is clear that the funding stability and strategic planning domains require improvement. The team in charge of these domains intends to improve both domains.

DISCUSSION

This article demonstrates the sustainability prediction and assessment of the "Som la Pera" intervention, which was conducted during the 2013-2014 and 2014-2015 academic years in Spain with the purpose of achieving a permanent implementation of the intervention beyond the first 2 years. No minimum score was used to assess the sustainability capacity. However, a higher value of the intervention sustainability capacity suggests a higher ability to implement the programme permanently. Lower scores indicate that the programme needs improvement in certain domains. We plan to improve two domains that presented lower scores (namely, funding stability and strategic planning) over the course of the intervention implementation and before the final assessment to guarantee that the intervention will be permanently implemented.

The sustainability of some health programmes is analysed at the end of the programme [8]. However, we suggest that predicting the sustainability capacity before starting the intervention would be beneficial in terms of solving possible problems while the intervention is ongoing. Thus, if some domains are not satisfied, the sustainability plan can be adapted to achieve the main goal.

Moreover, if the peer-led school-based intervention programme is effective, it will be sustainable over the long term.

It is necessary to plan and assess sustainability capacity before, during, and after (including the long term) the start of an intervention to reinforce all domains and ensure the permanent implementation of the programme.

Limitations

Nowadays, the funding for school-based interventions is limited, for this reason, knowing that the funding stability domain is our first limitation; we need work to improve it.

CONCLUSION

We will attempt to improve the funding stability and strategic planning domains during the “Som la Pera” implementation because if the intervention is effective, it might be implemented permanently.

List of Abbreviations used

WHO: World Health Organization

EYTO: European Youth Tackling Obesity

ACC: Adolescent Campaign Creator

PSAT: Programme Sustainability Assessment Tool

Competing interests

The authors declare no conflict of interest.

No-financial disclosures were reported by the authors of this paper.

Authors' contributions

All authors must have contributed substantially to the conception and design or analysis and interpretation of the data, drafting or revision of content, and approval of the final version.

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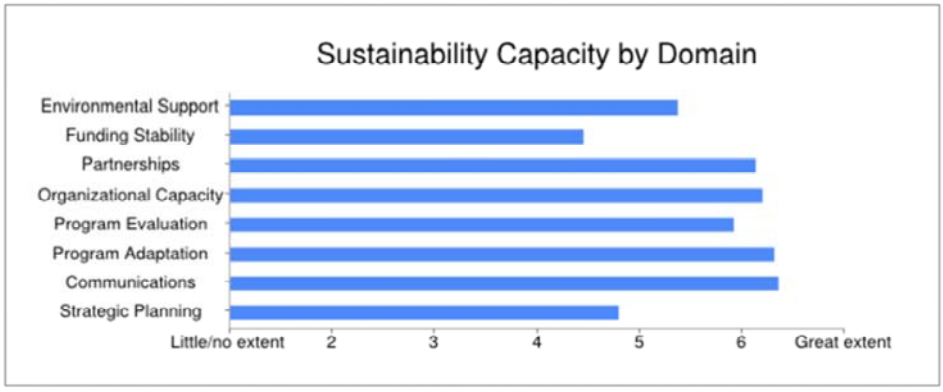
FIGURE LEGENDS

Fig 1 Sustainability capacity range by eight domains



TABLES

Table 1 Sustainability capacity range by eight domains

Domain	Assessment of each sustainability domain
Environmental support	Stakeholder analysis was performed to determine the engagement of various sectors and population. The stakeholders supporting this project include adolescent participants, the families of these adolescents, Reus high-schools, local businesses, local and national policy makers, local institutions, the general population, Universitat Rovira i Virgili and The Nutrition and Health Technology Centre (CTNS). The official Facebook platform has approximately 450 followers; however, more followers are needed.
Funding stability	The funding plan was designed to ensure that the project could be maintained over the long term by the CTNS project manager; the 5 adolescent creators of the intervention also contributed to it. Currently, the programme is supported by the Executive Agency of Health Consumers of the European Union, and we need new stable, flexible, and sustained funding to achieve a permanent implementation of the programme.
Partnership	A wide range of communities and organizations are involved in the programme and collaborate in the attempt to achieve the intervention goals. The 5 ACCs (community leaders) of the intervention are passionately committed to the project. The peer-led methodology used reaches a devoted population of adolescent participants. Nevertheless, it would be beneficial to have more community engagement in the development of the programme goals.
Organizational capacity	We designed an organizational capacity plan to attempt to sustain the programme when the European funding expires. This programme was based on health promotion and on the communication training of the 5 ACCs involved in the intervention. The 5 ACCs are selected by university experts. Then, the 5 ACCs disseminate the intervention message to their adolescent colleagues. To guarantee a long-term sustained implementation beyond 2 years, we proposed that 5 ACCs should be trained by health sciences university students every 2 years to disseminate the programme message and activities to their adolescent colleagues.
Programme evaluation	The programme will report the intermediate and short-term outcomes, and this assessment will be continued after the financial support ends. This assessment could be performed using an online survey because high-schools are inclined to collaborate in this way. The outcomes focus on adolescent lifestyles, stakeholder commitment, and the implementation plan.

	The results will be presented to the stakeholders and the community in meetings and at conferences that are coordinated by the communication team and will also be presented to the scientific community at conferences or in scientific journals, as coordinated by the health promotion team.
Programme adaptation	The health promotion team constantly reviews new evidence regarding lifestyle recommendations and adapts the messages and activities of the intervention in response. Simultaneously, the 5 ACCs design the intervention while considering the resources available at the moment and the motivation and suggestions of their colleagues. When a proposed activity does not achieve sufficient success, it is cancelled, and the activity is improved for use in the next implementation.
Communications	A communication team manages the communication and social marketing strategies and are responsible for generating press releases to inform the general public about the development of the intervention with the aim of generating community interest. Additionally, this team is responsible for informing the 5 ACCs about popular and available communication platforms. The adolescents upload events, activities and health messages to the most popular adolescent communication channels, such as Facebook and Instagram.
Strategic planning	Funding and resources planning is necessary to ensure the long-term sustained implementation of the project. The sustainability plan explained in this paper is an example of sustainable programme planning. Transparency with stakeholders is important for communication regarding programme development and current necessities and is achieved by communicating via e-mail, telephone calls or at stakeholder conferences.

Study 5

The effect of snacking and eating frequency on dietary quality in British adolescents

The effect of snacking and eating frequency on dietary quality in British adolescents

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ABSTRACT

Purpose: To describe the effects of number of eating occasions and snacks on dietary quality (DQ), defined as adherence to dietary recommendations.

Methods: A sample of 884 adolescents (11-18y) in the UK National Diet and Nutrition Survey (NDNS) were included. The Diet Quality Index for Adolescents (DQI-A) was implemented. The total number of eating occasions and snacks was frequency of food or beverages consumed over 24h and frequency of foods or beverages consumed outside of the three mealtimes respectively. Results were generated with and without low energy food under 210KJ (50kcal). Regression models were generated with DQ score as the outcome variable and number of eating occasions and snacks as predictors.

Results: The mean(95%CI) DQ score was 31.1%(30.2, 32.0). The mean number of eating occasions and snacks was 7.5(7.3, 7.7) and 2.6(2.6, 2.7) times/day respectively. When low energy events were excluded, mean number of eating occasions and snacks reduced to 6.2(6.1, 6.4) and 2.0(2.0, 2.1) times/day respectively. DQ score increased by 0.74 points (0.42, 1.05; $p<0.01$) and 0.55 points (-0.08, 0.69; $p=0.17$) for total eating occasions and snacks respectively. When low energy events were excluded, DQ score increased by 0.30 points (-0.84, 0.69; $p=0.13$) for each eating occasion and decreased by 1.20 points (-2.1,-0.3; $p<0.01$) for each snack.

Conclusion Eating more frequently improves dietary quality especially if some eating occasions, are low in energy. A focus on replacing high-energy snacks with low-energy alternatives rather than reducing the number of eating occasions may result in improved dietary quality in adolescents.

Keywords: adolescents • dietary quality • snacking • eating occasions • cross-sectional data

INTRODUCTION

Childhood obesity increases the risk of health problems such as cardiovascular disease, hypertension, some cancers and asthma [1]. In the UK the most recent data show that since 2004, prevalence of overweight in childhood has been decline, however the levels of obesity remain relatively high [2]. In 2013, prevalence of excess weight among 3-17y was higher than 20% in the UK [3]. In consequence, efforts to identify causal factors for obesity risk, including diet, are necessary [3]. In 2011, data published from the National Diet and Nutrition Survey (NDNS) 3y rolling programme (2008-2011) indicated that many children and adolescents follow a poor diet [4]. Dietary quality (DQ) is an innovative concept which combines quality and variety of the whole diet [5] and can be assessed by a number of different tools to evaluate how closely food patterns adhere to dietary recommendations of different populations [6,7]. Evaluation of dietary quality provides a single value to represent the complexity of human diets, having taken into account the interactions between nutrients, food preparation methods and eating patterns [8].

Some dietary quality indices are associated with health and disease outcomes [8,9] and provide an alternative to studying individual nutrients or foods [8, 10]. Low dietary quality scores have been reported to be associated with higher rates of all-mortality in adult population [5] however, it is necessary to conduct more research on dietary quality indices in paediatric and adolescent populations and their relation to health outcomes [6]. In 1990, the Healthy Diet Indicator (HDI) has been developed by Huijbregts et al [11] to quantify the diet adherence to World Health Organization (WHO) guidelines for the prevention of chronic disease. The WHO-DI tool characterises dietary quality, according to dietary intake and some food groups and was designed for adults, but can also be applied to children [6]. Recently, in 2013, the HELENA study validated a tool to assess dietary quality in European adolescents [8] called the Diet Quality Index for Adolescents (DQI-A). It was described in 1997, and it is an adapted version of the previously validated Diet

Quality Index (DQI) [11] for pre-school children according to Flemish food–based dietary guidelines (FBDG).

Many dietary habits may have an impact on dietary quality [12] such as snacking and consumption of sugar-sweetened beverages which are very popular among adolescents [13]. Definition of the term "snack" is ambiguous and different classification systems exist with no universally agreed definition [5]. Snacks generally refer to the foods consumed between mealtimes, which often comprise energy dense foods [5]. Snacking patterns have changed over the last two decades in UK adolescents; in 1997 snacking involving non-diet carbonated drinks was lower than in 2005, and these snacks provided a higher energy intake due to larger portion sizes of energy dense foods [13]. During this period of time, intakes of high-energy carbonated and soft drinks, tea and coffee consumption have increased and vegetable consumption has decreased [13]. Snacks are reported to contribute proportionally more sugar but less protein and fat than mealtimes [14]. Snacking has also been found to contribute to increased intakes of specific micronutrients such as vitamin C, vitamin E, dietary folate, dietary fibre, iron, calcium, magnesium, and sodium; and higher consumption of specific foods such as fruit and oils [12, 15].

Specific snacking patterns have been related to overall dietary quality in US adults [17] ,children and adolescents[18], with each additional snack consumed decreasing the overall dietary quality. However, the energy content of a snack is also likely to be important. In the UK population, the effect of snacks on dietary quality is less clear with a paucity of published data available. Eating occasions are considered as the main meals occurring at morning (breakfast), mid-day (lunch) or evening (dinner) [16] as well as snacks consumed between meals. However, some studies define an eating event when a minimum of 210kJ (50Kcal) have been consumed in order to exclude eating events where only water or tea has been consumed [16].

The hypothesis of this research is that snacks and eating occasions particularly with higher-energy options may reduce overall dietary quality in UK adolescents.

Thus, the aim of the present study is to describe the dietary quality of a representative population of UK adolescents, and to examine the effect of frequency of eating occasions and snacks on dietary quality as a measure of adherence to dietary recommendations of UK adolescents.

METHODS

Study Design and Participants

The NDNS is a cross-sectional survey administered and analysed by a consortium of three organisations: the National Centre for Social Research (NatCen), MRC Human Nutrition Research, and the department of Epidemiology and Public Health at the University College London Medical School. The NDNS survey was conducted according to the guidelines laid down in the Helsinki's Declaration and all procedures involving human subjects were approved by the Oxfordshire Research Ethics Committee.

The NDNS consists of dietary and nutritional data as well as anthropometric information assessing nutritional status of a representative population of the UK (England, Wales, Scotland and Northern Ireland) aged 1.5 and older living in private households. The current available data of the 4y rolling programme involves data collected each year among 2008 to 2012. A list of all addresses of the UK was randomly assigned from each Primary Sampling Unit. The selected addresses received information about the survey and then a face-to-face visit recruit participants.

The survey design and data-collection methods are described in detail elsewhere [19]. The inclusion criteria in this analysis were adolescents aged 11-18y recruited among 2008 to 2012. The exclusion of the analysis was a lack of inclusion criteria. Finally, the sample used in this study included 884 participants.

Dietary measures

Dietary data were collected on consecutive days using a 3-d or 4-d semi weighted dietary record [19]. Briefly, each subject received a food diary and was asked to keep a record of everything they ate and drank over the four days, inside and outside the home. Participants of 16y and older described portion sizes and could use photographs of ten frequently consumed foods using an adult food diary meanwhile younger adolescents used a food photograph atlas using a child diary. Although the food diaries are different, they collected the same dietary information. The food-diary was explained to the participant at 1st visit by the interviewer. At second or third day of recording, interviewers visit or telephone the participants to improve recording for the remaining days. In the 2nd visit, the interviewer reviewed the completion of the food-diary and fill in the gaps with the participant no later than 3 days after the final day of recording where interviewers check that at least 3-d were recorded [20].

Eating occasions and snacks

The NDNS database provides information on the exact time of the day that a food was consumed, and this information is necessary in order to classify each eating occasion as a meal, or a snack. Meal categories were defined as food consumed within three specific time frames according to Northern Ireland classification [13]. These time frames are 06.00 to 08.59 hours (breakfast), 12.00 to 13.59 hours (lunch) and 17.00 to 19.59 hours (evening meal) while eating occasions outside of these time frames were categorised as snacks.

Frequency of eating occasions is defined as the total number of times foods or beverages are consumed each day, both at mealtimes and at snacks [12]. Frequency of snacks is defined as the total number of foods or beverages consumed between mealtimes each day. If two foods were consumed with a difference of more than 15 minutes it was counted as a separate eating occasion or snack. The number of eating occasions and snacks were calculated using two different methods; firstly, for each time that a participant consumed one or more

foods or beverages, and secondly, for each time that a participant consumed one or more foods or beverages, excluding those containing fewer than 210kJ (50Kcal) [16, 20]. Data from weekend days were excluded in this analysis due to the fact that eating patterns and timing of meals at weekends are different to week days [21].

Overall Dietary Quality

Dietary quality was measured using the DQI-A score, [8] a validated version of the DQI used in the HELENA study in adolescents from Ten European Cities [12]. DQI-A is based on the mean of three components: the DQ component (DQc), the dietary diversity component (DDc) and the dietary equilibrium component (DEc), comprised of two subcomponents: the Diet Adequacy sub-component and the Diet Excess sub-component. In addition, the relationship of each component with dietary quality was analysed separately, to understand more about dietary quality.

The DQI-A score is calculated as a percentage for each day with the mean percentage of at least 3-d dietary records calculated for each participant and then reported as an overall percentage for the whole sample. A higher percentage indicates a better dietary quality score and the possible range is from -33% to 100%, with higher scores reflecting a higher dietary quality [8]. More detailed information on the technical aspects has been provided elsewhere [12].

Dietary Quality component (DQc)

DQc is based on optimal food quality choices within a food group which reflect dietary recommendations. The daily amount consumed of each food group was multiplied by different factors: “1” if it belonged to a preference food or healthy food group, “0” if it belonged to an intermediate food group and “-1” if it belonged to a low-nutrient energy-dense food group. The Supplementary Table presents the classification by “preference”, “intermediate” and “low-nutrient or energy-dense” food groups based on the criteria established by Vyncke [8].

These values are summed together, divided by the total amount of food (in grams) eaten per day and multiplied by 100. The methods were followed according to previous published research [8] apart for a small number of exceptions which took into account regional eating patterns. These exceptions were the following: beverages dry weight was not included in the analysis because powdered beverages are not sold in the UK, green beans were classified as vegetables rather than legumes, alternative milk products and ice cream that were not milk based were deleted from the milk products group and excluded from the analysis. The low fat rice puddings and custards were classified in the intermediate milk group, and whole milk rice puddings and custards were included in the energy-dense group in line with their nutritional profile. Also, fromage-frais was included as an intermediate milk product. These changes were agreed by members of the research team.

Dietary Diversity component (DDc)

DDc expresses the variation in the diet and was calculated by assigning one point for each serving consumed for each of the 9 recommended food groups which included: 1) water, 2) bread and cereal, 3) potatoes and grains, 4) vegetables, 5) fruits, 6) milk products, 7) cheese, 8) meat, fish and substitutes, and 9) fat and oils[8].

All the points were summed together and divided by 9 (food groups) and then, multiplied by 100%. DDc score ranged from 0 to 100%. The servings of each food group used were the portion sizes recommended by the British Dietetic association [22]: 1) water (250ml), 2) bread and cereal (35 g), 3) potatoes and grains (180g), 4) vegetables (80g), 5) fruit (80g), 6) milk products (170 g), 7) cheese (30 g), 8) meat, fish and substitutes (100g) and, 9) fat and oils (4.5g).

Dietary Equilibrium component (DEc)

Lastly, the DEc expressed how well minimum and maximum recommended intakes of each food group were met based on the DQI-A information [8]. The intake of foods groups were divided into two categories a) 9 recommended foods groups

and b) 2 non-recommended food groups which were: 10) snacks and candy, and 11) sugared drinks and fruit juice as proposed by Flemish food–based dietary guidelines [23].

It was calculated by taking the difference of the diet adequacy subcomponent (percentage of minimum recommended intake in 9 recommended food groups) and the diet excess subcomponent (percentage of intake exceeding the upper level recommendation in 9 recommended food groups and 2 non-recommended food groups), and each of them were multiplied by 100%.

Statistical Analysis

The statistical analysis was performed using STATA statistical software version 12 (Stata Corporation). Statistical significance was assigned to P value < 0.05 for all tests. Descriptive data were presented using means and 95% Confidence Intervals (CI) or percentages and 95% CI. Unpaired T-test analyses were carried out to analyse differences between population characteristics by gender.

Multiple regression analyses were carried out with dietary quality score as the outcome variable and eating occasions and snacking events as predictors in different models. The distribution of dietary quality was checked to ensure it was broadly normally distributed. The analyses were carried out twice for each model, once with total number of eating occasions and total number of snacks and secondly with low energy eating occasions and snacks excluded. A low energy eating event was defined as a meal or snack with fewer than 210Kj (50Kcal) such as water or small pieces of fruit. The results were reported as the change in dietary quality score with each single unit increase in the number of eating occasions or snacking events. Results included 95% confidence intervals and p values. All reported models were adjusted for age and sex. Regression models were also carried out to determine the effect of increasing eating occasions and snacks on energy intake.

Regression models were also carried out with total number of eating occasions and snacks, and eating occasions and snacks as categorical variables. Frequency of

eating occasions was grouped into five approximately equal categories based on quintiles according to the two different definitions of total eating occasions: a) Considering all foods and beverages: 1 to 5 eating occasions/day, ≥5 to <6 eating occasions/day, ≥6 to <7.5 eating occasions/day, ≥7.5 to <9.5 eating occasions/day and ≥9.5 eating occasions/day; b) Excluding eating occasions less than 50kcal: 1 to 4.5 eating occasions/day, ≥4.5 to <5.5 eating occasions/day, ≥5.5 to <6.5 eating occasions/day, ≥6.5 to <8 eating occasions/day and ≥8 eating occasions/day. Frequency of snacking occasions was grouped into the same four groups for both definitions: <1.5 snacks/day, ≥1.5 to <2.5 snacks/day, ≥2.5 to <3.5 snacks/day, and ≥3.5 snacks/day. Results were reported as the difference in dietary quality score for each category compared with the reference category which was the lowest number of eating or snacking occasions together with 95% confidence intervals and p values. All reported models were adjusted for age and sex.

RESULTS

Sample characteristics

Participants of the NDNS, surveyed from 2008 - 2012, included a total of 884 adolescents aged between 11-18y, all with at least, 3 d-dietary records completed. The adolescents had a mean (95% CI) age of 14.5y (14.4, 14.7) and 50.3% were male. The mean total daily energy intake was 1786 kcal/day (95% CI 1751, 1820), boys had higher energy intake than girls 1984 kcal/day (95% CI 1934, 2034) and 1584 kcal/day (95% CI 1545, 1623) respectively, (P<0.01).

Dietary quality

The dietary quality evaluated by DQI-A is described in Table 1, with the different components of this score; DQc, DDc and DEc comprised of the Diet Adequacy sub-component and the Diet Excess sub-component. The mean score of the DQI-A was 31.1% (95% CI 30.2, 32.0), 31.4% in girls, and 30.8% in boys with no significant gender differences.

Eating occasions and Snacks

The mean number of eating occasions, considering all food and beverages, was 7.5 times/day, with a minimum of 1 eating occasion/day and a maximum of 18.5 eating occasions/day. The mean number of eating occasions when low-energy eating events containing fewer than 210Kj (50Kcal) were excluded was 6.2 times/day, with a minimum of 1 eating occasion/day and a maximum of 18 eating occasions/day. There were no differences between genders for either result.

The mean number of snacks, considering all food and beverages, was 2.6 times/day, with a minimum of zero snacks/day and a maximum of 9.3 snacks/day. The mean number of snacks, when low-energy snacks containing fewer than 210kJ (50Kcal) were excluded, was 2 times/day, with a minimum of zero snacks/day and a maximum of 9 snacks/day. There were no significant differences between genders for either result.

There was a positive association between daily energy intake and eating occasions: a) for each 1 extra eating occasion/day (considering all food and beverages) the daily energy intake increased by 21 kcal (95% CI 9, 33; $p<0.01$) and; b) for each 1 extra eating occasion/day (considering all food and beverages excluding meals containing fewer than 210kJ (50Kcal)) the daily energy intake increased by 52 kcal (95% CI 39, 66; $p<0.01$). There was also a positive association between daily energy intake and snacks: a) for each 1 extra snack/day (considering all food and beverages), the daily energy intake increased by 141 kcal (95%CI 114, 169; $p<0.01$).; b) for each 1 extra snack/day (considering all food and beverages excluding snacks containing fewer than 210kJ (50Kcal), the daily energy intake increased by 216 kcal (95%CI 189, 244; $p<0.01$).

Relationship between eating occasions and dietary quality

The analysis of the effect of number of eating occasions on dietary quality, defining eating occasions by the first method which considered all food and beverages showed a positive relationship between dietary quality and eating occasions/day. An increase of one eating occasion/day was associated with an increase in the

dietary quality score of 0.74 points (95% CI 0.42, 1.05; p<0.01). If low energy eating occasions less than 210KJ (50kcal) were excluded the positive association was attenuated. In this case, each increase of one eating occasion increased the dietary quality score by 0.30 points (95% CI-0.08, 0.69; p=0.13). The regression analysis with dietary quality as the outcome variable and eating occasions in 5 categories (1 to <5, ≥5 to <6, ≥6 to <7.5, ≥7.5 to <9.5, >9.5) indicated that two categories were associated with improved dietary quality compared with the reference category of 1 to <5 eating occasions/day. Reporting ≥7.5 to <9.5 eating occasions/day was positively associated with dietary quality, increasing the score by 4.6 points (95% CI 1.7, 7.5; p<0.01) and reporting more than 9.5 eating occasions/day was positively associated with dietary quality, increasing the score by 4.9 points (95% CI 1.8, 8.0; p<0.001) (Fig 1) compared with the reference group. However, none of the categories were significantly different from the reference category in terms of dietary quality when eating occasions of less than 210KJ (50kcal) were excluded (Fig 1).

In the DQI-A, 3 components were positively associated with frequency of eating occasions. For each extra eating occasion the DQc score increased by 1.0 points (95% CI 0.4, 1.7; p<0.01), DDc score increased by 0.7 points (95% CI 0.4, 0.9; p<0.01), and DEc increased by 0.5 points (95% CI 0.3, 0.7; p<0.01). The relationship between the 3 components of DQI-A and number of eating occasions based on the second method excluding eating events containing fewer than 210kJ(50Kcal), revealed no significant associations (data not shown).

Relationship between snacks and dietary quality

The analysis of the effect of snacks on dietary quality, defining snacks by the first method which considered all food and beverages showed a positive relationship between dietary quality and number of snacks/day. An increase of one snack/day increased the dietary quality score by an average of 0.55 points (95% CI -2.24, 1.33; p=0.17), although this was not statistically significant. If low energy snacks less than 210KJ (50kcal) were excluded, the positive association was reversed. In this case, each increase of one snack decreased the dietary quality score by 1.2

points (95%CI -2.06,-0.26; p=0.01). Furthermore, specific associations were observed with components of the DQI-A: a) the DQc score; which assesses the optimal food quality choices within food groups reflecting dietary recommendations, was negatively associated with number of snacks/day considering snacks containing more than 210KJ (50kcal). For each extra snack the DQc score decreased by -5.0 points (95% CI -7.0, -3.1; p<0.01), b) The DDc; which expresses the variation in the diet by adherence to the 9 recommended food groups, was positively associated with snacks/day using both definitions. However, the DEc, which assesses the achievement in obtaining the minimum and the maximum recommended intakes of each food group, was not associated with number of snacks/day. The regression analysis with dietary quality as the outcome variable and snacks in 4 categories (<1.5, ≥1.5 to <2.5, ≥2.5 to <3.5, ≥3.5) indicated that two categories (considering all food and beverages definition) were associated with improved dietary quality compared with the reference category of <1.5 snacks/day. Reporting ≥1.5 to <2.5 snacks/day was positively associated with dietary quality, increasing the score by 4.1 points (95% CI 1.2, 7.1; p<0.01) and reporting more than 3.5 snacks/day was positively associated with dietary quality, increasing the score by 3.5 points (95% CI 0.4, 6.6; p=0.03) (Fig 2) compared with the reference group. However, considering only snacks with more than 50kcal, two categories were associated with a worse dietary quality compared with the reference category of <1.5 snacks/day. Reporting ≥2.5 to <3.5 snacks/day was negatively associated with dietary quality, decreasing the score by 2.8 points (95% CI -5.4, -0.3; p=0.03) and reporting more than 3.5 snacks/day was negatively associated with dietary quality, decreasing the score by 3.6 points (95% CI -7.0, 0.3; p=0.03) compared with the reference group (Fig 2).

The ten foods and beverages most often consumed in different snacking occasions are represented by the name of the food (frequency and percent of adolescents who consume this snack) : tap water (n=406, 45.9%), white bread (not high fibre, not multi-seed bread) (n=397, 44.9%), savoury sauces such as gravy (n=392, 44.3%), semi skimmed milk (n=373, 42.2%), biscuits (n=311, 35.2%), crisps and savoury snacks (n=310, 35.1%), soft drinks not low calorie (n=286, 32.4%), other

chicken/turkey including homemade recipes dishes (n=268, 30.3%), chocolate confectionary (n=251, 28.4%) and sugar (n=238, 26.9%).

DISCUSSION

This analysis of cross-sectional data reveals that the dietary quality score in UK adolescents is 31% on a scale of -33 to 100%, which reflects an intermediate adherence to dietary recommendations. Analysis of data on the frequency of eating occasions and snacks revealed interesting associations with dietary quality. Results from the analysis of all eating occasions, including low energy meals or snacks, indicated that increasing the number of eating occasions improved dietary quality; however when low energy events were excluded this improvement was attenuated and no longer statistically significant. For snacks, analysis of all snacks had no significant association with dietary quality; however when low energy snacks were excluded the association was negative with each extra snack reducing the dietary quality score by approximately 1 point. The number of eating occasions associated with the highest dietary quality score was more than 7.5 per day; but this was only the case if all eating events were included and was no longer important if low energy eating events were excluded.

Comparing the dietary quality of UK adolescents with European adolescents indicated that UK adolescents have a poor quality diet. A score of 31% is 18% lower than the mean dietary quality score of Central and Northern European adolescents (Germany, Belgium, France, Hungary, Sweden and Austria) which was reported to be 49%; and 30% lower than Southern European Adolescents (Greece, Italy and Spain) which was reported to be 61% on average [24]. These results suggest that considerable differences exist between European countries [24] and dietary improvements are particularly needed in British adolescents [7].

There are many indices to assess dietary quality [7] which provide a single value to represent the complexity of human diets, having taken into account the interactions between nutrients, food preparation methods and eating patterns [8]. There is no

universally agreed gold standard and significant variations exist in the calculation of dietary quality, although these differences do not result in large inconsistencies in the predictions of health-related outcomes [6]. Nevertheless, it is necessary to validate an international dietary quality index as a dietary quality assessment tool that is able to compare between different populations is currently unavailable. As well as including the composition of the adolescents' diet, the DQI-A also incorporates the dietary variation in food groups throughout the day, and the balance between healthy and unhealthy food groups which are strengths of this index [8].

The number of snacks was negatively associated with the DQc of the DQI-A tool, and UK adolescents who snacked frequently were more likely to have a lower dietary quality, which suggests that the quality of food between meals is worse than at mealtimes. This was also clear from the type of food adolescents were most likely to consume as snacks. However, a higher frequency of snacks was positively associated with the DDc of the DQI-A tool, indicating that when adolescents increased the number of snacks eaten, they ate a more varied diet over the whole day. Consequently, it seems to be easier for adolescents to achieve the minimum recommended intake of each food group with a higher snacking intake. Furthermore, dietary quality and daily energy intake were negatively associated, suggesting that adolescents with excessive energy intakes did not necessarily obtain a higher dietary quality score [8].

Snacking is observed at any time of the day in adults, children or adolescents in various parts of Europe and the USA [25]. Data from Northern Ireland and Britain indicate that energy intake and portion size of snacks have increased between 1997 and 2005, but not the frequency [13]. The number of eating occasions is reported to be associated with some specific nutrients and with some adiposity measures in children and adolescents [20, 26]. A recent review and meta-analysis concluded that more frequent eating occasions are associated with lower body weight status in children and adolescents, although this was mainly in boys [26] while energy provided by snacks was not recommended. However, a recent study with NDNS data (collected in 1997) showed that a higher number of eating

occasions was associated with a higher Body Mass Index (BMI), BMI z-score and lower HDL-cholesterol concentrations in British adolescents [20]. When restricted to the adult population, research has shown that a higher number of eating occasions is positively associated with BMI and waist circumference [27], and beneficially associated with cardiovascular risk factors and subclinical atherosclerosis [28]. One study that analysed the relationship between number of snacks and dietary quality in an American adult population concluded that the number of snacks was associated with a more nutrient dense diet, and a positive association with dietary quality [17], as we observed in the present study when all snacks were included. Another study in American adolescents reported a negative relationship between dietary quality and number of snacks and discussed the autonomy of adolescents in choosing unhealthy snack foods [18]. In this present study, the negative effects of snacks on dietary quality were only apparent when low energy snacks were excluded pointing to the importance of the type of snack consumed. Many (but not all) of the snacks consumed by this population are energy-dense foods such as savoury snacks and confectionery [13]. However, our findings suggest that eating more often than three times per day improves dietary quality, provided nutrient rich foods are consumed both at and between meals and when some low energy snacks are consumed such as fruit, vegetables or water. These findings do not provide strong evidence of a benefit in recommending that adolescents increase their frequency of snacks and eating occasions in a day as high-fat, high-sugar snacks could cause a negative effect on dietary quality and body adiposity [25].

The present study has some limitations. First of all, the lack of universally accepted definitions of snacks and eating occasions, make it difficult to precisely calculate these figures, thereby complicating the interpretation of the results; both those obtained in our study as well as those of other studies used for comparison [12]. The definition of a snack is particularly ambiguous as some people consume snacks at times that might be regarded as mealtimes. Alternatively, some people have meals outside traditional meal occasions; in fact adolescents may be more likely to have a chaotic eating pattern [29]. The fact that the NDNS survey did not

report the classification of eating events as meals or snacks, is a limitation for our study. However, many eating events may be difficult to define, even by participants themselves, and therefore this information would not necessarily have reduced bias. Furthermore, although the DQI-A is a validated tool applicable in large populations of different ethnicities it did present some issues. The lack of information on particular foods such as soya products, battered fish, and other foods commonly consumed in the UK could represent a limitation. The DQI-A score is composed of three separate components. The DDc is calculated by taking the serving definition into consideration and the recommended serving for various foods varies between European countries which could reduce its validity in certain populations. Furthermore, limitations exist with the NDNS which is cross-sectional data. Under-reporting is a problem with all dietary assessment tools and is likely to be considerable in this sample [30]. Also, the NDNS data does not include information on physical activity known to be an important confounder for energy. Stronger evidence for the presence or absence of an association between snacks and dietary quality or BMI could be obtained from longitudinal cohort rather than cross-sectional data in order to compare with current studies in similar populations [31].

Despite these limitations, there are very few published studies in adolescents reporting the relationships between frequency of eating and snacking on dietary quality. The data used in this analysis included dietary data from a large and nationally representative sample of British adolescents. These findings therefore provide much needed information on dietary patterns in adolescents which could be used to shape policy interventions for the adolescent population in the UK. These results suggest that replacing high energy snacks with fruit or other low energy alternatives may result in a better dietary quality for adolescents.

CONCLUSION

In summary, British adolescents have some of the worst quality diets in Europe. Analysis of national data revealed that increases in eating occasions improved

dietary quality when these eating occasions included low energy eating events. However an increase in snacking when snacks contained more than 210KJ (50Kcal) reduced dietary quality. More prospective studies are needed to confirm the associations between number of eating occasions and snacks on dietary quality in this age group. Nevertheless it is likely that replacing higher energy snacks with lower-energy alternatives will result in a higher quality diet in British adolescents. In order to improve dietary quality, adolescents need encouragement to choose, purchase and consume healthier snacks and beverages. This will require changes in the environment through local and national policies in order to improve availability, access and pricing of healthier foods.

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CONFLICT OF INTEREST

On behalf of all authors, the corresponding author states that there is no conflict of interest.

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FIGURE LEGENDS

Fig 1 Relationship between Diet Quality Index for Adolescents (DQI-A) and eating occasions by categories using two definitions: a) including all foods and beverages, and b) deleting eating occasions with <50kcal) compared with the reference group * P<0.05

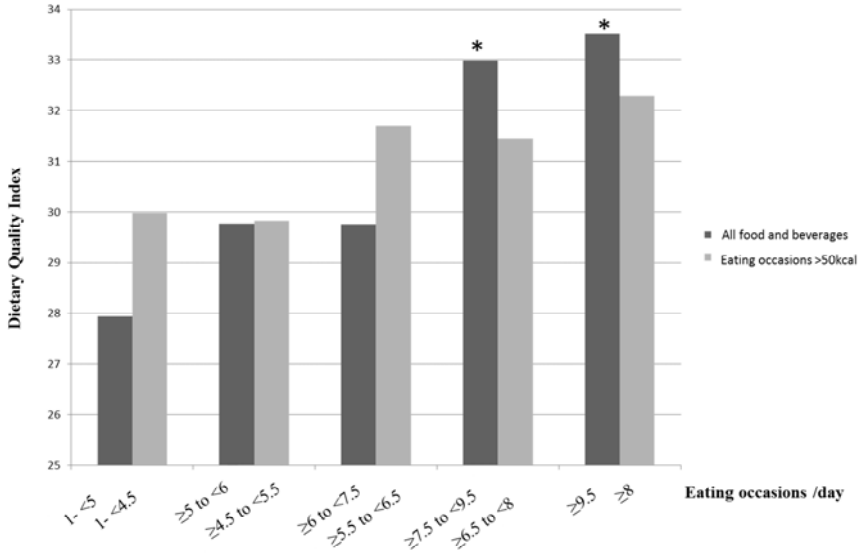
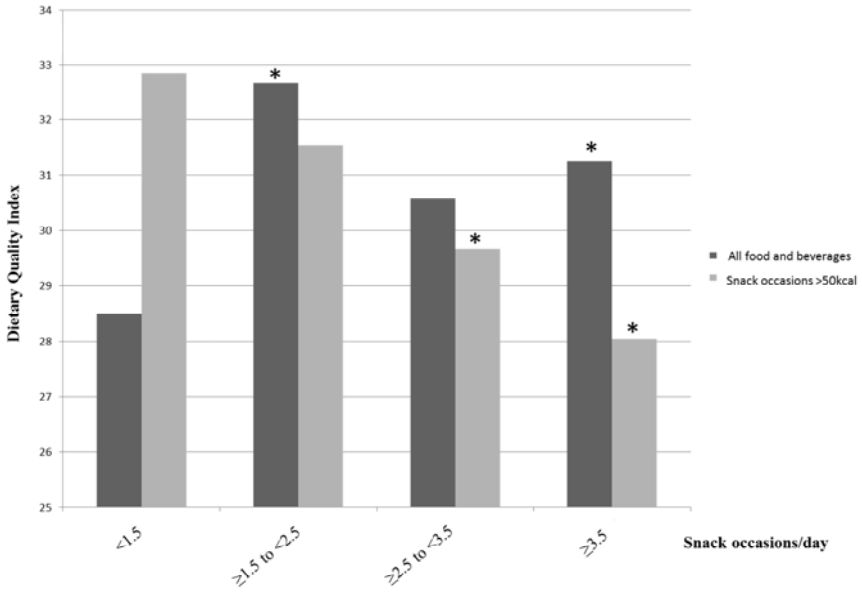


Fig 2 Relationship between Diet Quality Index for Adolescents (DQI-A) and snacks by categories using two definitions: a) including all foods and beverages, and b) deleting snacks with <50kcal compared with the reference group * P<0.05



TABLES

Table 1 Description of Diet Quality Index for Adolescents (DQI-A) scores in UK adolescents

	Total		**Males**		**Females**		**Between genders**
	n=884		n= 445		n= 439		
	Mean	95% CI	Mean	95% CI	Mean	95% CI	***p-value**
Age	14.5	14.4, 14.7	14.4	14.2, 14.6	14.6	14.4, 14.8	0.17
Energy (Kcal/d)	1785	1751, 1820	1984.1	1934, 2034	1584	1545, 1623	<0.01
Fat% energy	33.8	16.0, 48.0	33.6	18.9, 47.9	34	16.0, 48.0	0.24
Protein% energy	14.9	6.3, 32.3	15.2	6.3, 32.3	14.7	6.4, 31.5	0.02
CH% energy	50.6	50.2, 51.0	50.5	50.0, 51.0	50.7	50.1, 51.2	0.70
White% Ethnic Group	87.9		88.09		87.7		
DQI-A overall	31.1	30.2, 32.0	30.8	29.4, 32.2	31.4	30.2, 32.6	0.51
Diet Quality component (DQc)	2.1	0.1, 4.1	-1.3	- 4.2, 1.6	5.6	2.8, 8.4	0.01
Diet Diversity component (DDc)	54.9	54.1, 55.6	57.2	56.1, 58.3	52.5	51.5, 53.5	<0.01
Diet Equilibrium component(DEc)	36.3	35.6, 36.9	36.5	35.5, 37.4	36.1	35.2, 36.9	0.51
Diet Adequacy sub-component (DA)	51.0	50.3, 51.7	53.1	52.1, 54.1	48.8	47.9, 49.7	<0.01
Diet Excess sub-component (Dex)	14.7	14.3, 15.1	16.6	16.0, 17.2	12.8	12.2, 13.3	<0.01

[a]95% CI: 95% Confidence Interval

[b]DQI-A: Diet quality Index for Adolescence

* Ttest analysis between gender

OVERALL DISCUSSION

The present work provides the development, evaluation, and implementation of high quality school-based interventions to effectively tackle childhood and adolescent OB reducing this society need, by encouraging healthy lifestyles. Specifically, the EdAl program effectively reduces OB-related outcomes and improves PA at 4-y follow-up post-cessation intervention. Furthermore, the reproducibility study demonstrated the effectiveness of the program in increasing PA practice. From the EdAl experience, the "Som la Pera" intervention (European Youth Tackling Obesity "EYTO" project) was designed following the new evidence of SM as a tool to achieve objectives efficiently, and peer-led model as a closer individual approach than EdAl study was used to achieve significant results with respect to improvements in healthy lifestyles at the end-of-study. A new perspective to disseminate health messages through challenges by social media, social events and in high-schools will be tested in an adolescent population. Moreover, the sustainability was planned and assessed over the intervention to ensure the successful implementation of the program when completed.

In the mission to design new solutions to tackle chronic disease, including childhood OB, innovative approaches are a key strategy for Member States of the European Union in the areas of health promotion and prevention (Council of the European Union, 2010). The EdAl program is an innovative intervention program that focuses on the integration of different sectors, such as the education sector and health sector, to prevent childhood OB using the cooperation strategy proposed by "Health in all Policies" (Stahl et al., 2006). The integration of these sectors involves university students trained as HPAs to develop educational activities in schools, thereby promoting the practical training of university students. Moreover, the educational activities are undertaken by university students and supervised by health promotion university teachers to guarantee evidence-based interventions in 12 activities. Through this intervention, primary-school teachers can ensure the correct dissemination of health messages to the children. Thus, the intervention represents a win-win strategy because both university students and primary school children benefit from the program.

The “Som la Pera” intervention is an innovative intervention program that focuses on the SM and peer-led model. The SM strategy includes different domains to develop an effective intervention that involves different stakeholders; the peer-led model better motivates adolescents because the intervention is focused on their own interests. The 5 ACCs are trained to develop the intervention for their high-schools. The involvement of stakeholders facilitates the creation of a healthy environment and makes it easier for adolescents to select healthy choices. The social media use disseminates healthy messages and challenges among adolescents and represents an innovative approach that need to be evaluated.

The effectiveness of the EdAl program was evaluated with the reproduction of original EdAl study in another location (**Study 1**), and the long-term success of the original EdAl program was evaluated at 4-y follow-up after cessation intervention (**Study 2**).

The EdAl-2 program, a reproducibility study in Terres de l’Ebre, demonstrated that the intervention is useful for improving weekly after-school PA. However, the OB prevalence remained unchanged at 22 months, as has been reported in the data on the stability of OB prevalence observed in some European countries. The EdAl-2 program confirmed that after-school PA (in terms of hours/week) can be stimulated in primary school as part of a healthy lifestyle. As we had observed in the original EdAl program at 28 months of intervention, there was an increase of up to 19.7% of children dedicating >5 hours/week to after-school PA (Tarro, Llauradó, Albaladejo, et al., 2014). Furthermore, the after-school PA was promoted despite cessation of the intervention program at 2-y and 4-y follow-up (Tarro, Llauradó, Moriña, et al., 2014) (Llauradó et al., n.d.). The effect of the EdAl program during its implementation and post-intervention indicated an impact on after-school PA practice, whereas modification towards healthy food choices was not consistent. However, the study observed that food habits are improved over the intervention, as it observed in original EdAl program and EdAl-2 reproducibility program. Both programs demonstrated an increase in the number of children consuming a second fruit per day, one vegetable per day, and more than one vegetable per day.

Moreover, these habits were maintained at the 2-y follow-up post-cessation intervention. At the 4-y follow-up post-cessation intervention, the food habits followed a similar pattern between the groups, exhibiting a reduction in the consumption of healthy foods, such as dairy products, fruit and fish. Thus, it appears that at the 4-y follow-up, the improvements in food-related habits had begun to disappear. This finding may suggest that healthy dietary habits should be encouraged at the 2-y follow-up post-cessation intervention to maintain healthy food intake.

According the proposal to confirm the best childhood OB prevention practices, the reproducibility of successful studies must be assessed (Wang et al., 2013). Currently research focuses on the importance of transferring an intervention to other locations because the repetition of health promotion interventions is complex and requires some adaptation depending on the location. As was observed in the EdAl-2, even though the population exhibits similar characteristics, the “Terres de l’Ebre” towns were more rural, whereas Reus and surroundings towns were more developed. These differences contributed to differences in the study population; for example, “Terres de l’Ebre” towns had low levels of fast-food consumption, possibly because fast-foods restaurants were far away. However, the prevalence of OB was higher in the South of Catalonia than in Reus and surroundings towns. Moreover, EdAl study distributed workbooks about the eight EdAl lifestyles objectives by schoolchildren over 3 academic years (1/academic year). However, workbooks were not used in the same way in all schools of the EdAl-2 intervention.

Due to the context and environment, the implementation of each program is different, and public health research aim to demonstrate program successes rather than universal success (Wang, Moss, & Hiller, 2006). Therefore, the greater the transferability of an intervention, the greater its capacity to be reproduced (Cambon, Minary, Ridde, & Alla, 2013). A school-based intervention called the “Comprehensive School Health” program that aimed to assess the effectiveness of an applicable intervention in other settings demonstrated that the increase in fruit and vegetable consumption was implemented in two different locations in Canada (Fung et al., 2012).

On the other hand, a main goal of school-based intervention studies to prevent OB is the long-term maintenance of the health and well-being of population effects produced by the intervention. Thus, intervention studies need to conduct a follow-up beyond the cessation of the intervention as a measure of the long-term beneficial effects in reducing OB or promoting healthy lifestyles (Lai et al., 2014b). At 2-y follow-up after intervention cessation, a multiplier effect of benefits achieved at the end-of-study was observed. The intervention group exhibited a significant reduction of -0.29 units in the BMI z-score and -5.9% in the OB prevalence in adolescents compared with the control group. Moreover, at 4-y follow-up, a significant reduction of -0.33 units in the BMI z-score of the girls in the intervention group and -7.7% in the prevalence of OB in the boys in the intervention group compared with those in the control group was observed. These reductions were effective, according to the proposal that a reduction of -0.15 units in BMI z-scores between the pre- and post-intervention groups relative to the changes in the control group is effective (Waters et al., 2011). Thus, the intervention maintained long-term effectiveness in improving OB-related outcomes in adolescents who participated in the original EdAl intervention implemented in Reus.

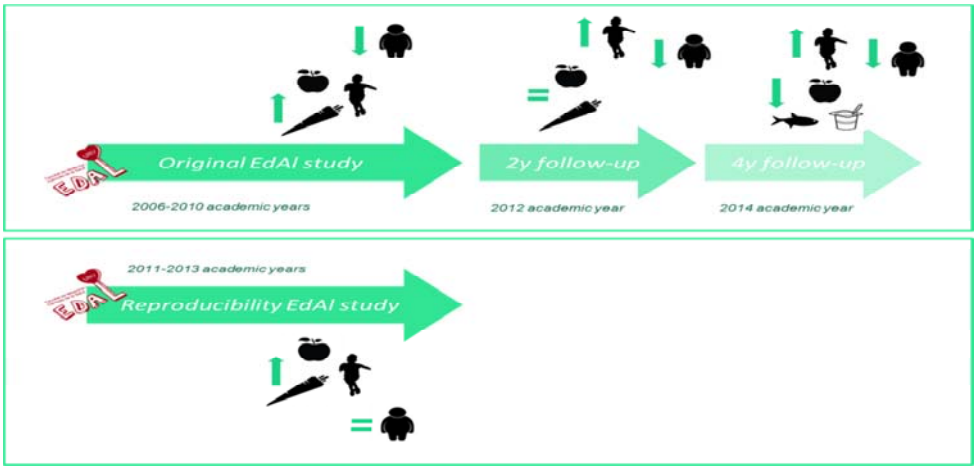
At 2-y follow-up, the practice of ≥4 hours/week of after-school PA increased significantly by 16.8% in adolescents in the intervention group relative to control group. At 4-y follow-up, a positive tendency of 19% greater percentage of boys in the intervention group performed ≥4 hours/week of after-school PA compared with the control. Following the same pattern, at the end-of-study, an increase of 5.1% of children engaging in >5 hours/week after-school PA practice was observed. Thus, OB-related variables and after-school PA practice are maintained in the long-term, whereas healthy food behaviour requires reinforcement after 2-y follow-up post-cessation intervention.

The published school-based intervention follow-up studies focused on the prevention of OB and did not report long-term food habits outcomes; thus, further research is needed.

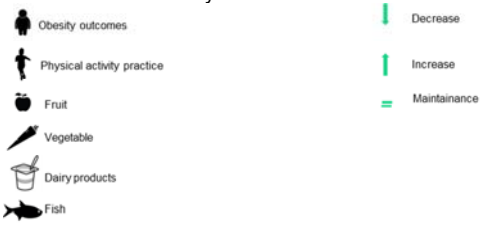
However, some school-based intervention studies have reported PA after a long-term follow-up. For example, the CATCH study reported that the PA levels of the intervention students declined after the intervention ended, although their self-

reported PA were higher compared with the controls (Nader et al., 1999). The Cretan Health and Nutrition Education Program (Manios et al., 2006) reported a pattern similar to the CATCH study at the 4-y follow-up post-cessation intervention, reporting higher levels of MVPA in the intervention students compared with the controls. However, these PA levels were lower at the follow-up than at the end-of-study (Nader et al., 1999). Interestingly, in the present study, the participants' after-school PA practice increased at the end-of-study and at the 2-y post-cessation intervention follow-up. Some studies have reported the maintenance of the results achieved at the end-of-study, such as the Cretan Health and Nutrition Education program, which observed a maintenance of the BMI and PA levels at the 4-y follow-up post-cessation intervention (Manios & Kafatos, 2006)(Manios et al., 2006). However, the KOPS reported sustained effects only in an intervention subgroup, which was characterized by high SES, at the 8-y follow-up (Plachta-Danielzik et al., 2011). However, the EdAl program improved the results obtained at the end-of-study, at the 2-y follow-up (Tarro, Llauradó, Moriña, et al., 2014) and the 4-y follow-up (Llauradó et al., n.d.). Figure 9 simplifies the results achieved in the EdAl program, including follow-up studies and reproducibility study.

Figure 9: Diagram of the EdAl program outcomes achieved at the end-of-study, 2-y follow-up, and 4-y follow-up, and the reproducibility of the EdAl program in other locations



Source: Elaborated by the author.



The EYTO project ("Som la Pera" intervention) was designed in consideration of factors to improve its effectiveness, including the implementation of SM and peer-led model (**Study 3**), and the sustainability success was evaluated in parallel in an ongoing program (**Study 4**).

As we can observe in the following table, the SMBC are considered in all aspects of the "Som la Pera" intervention.

Table 7. Social Marketing Benchmark Criteria used in "Som la Pera" intervention

Social Marketing Benchmark Criteria	*How it is considered in "Som la Pera" intervention?*
Customer Orientation	The peer-led model promotes the motivation of adolescents to participate and interact in the intervention because the 5 ACCs prepared activities directed at adolescents. Thus, the approach considers their motivations and behaviours.
Behaviour	Aims to improve the consumption of fruits and vegetables, PA practice, and breakfast consumption and to decrease the TV, computer and videogame behaviour.
Theory	Uses the conductual behavioural change framework, taking into account the "Behaviour Change Wheel" (Michie, van Stralen, & West, 2011).
Insight	The peer-led model attracts the motivation of adolescents to participate and interact in the intervention because the 5 ACCs prepared activities directed at adolescents. Thus, the approach considers their motivations and behaviours.
Exchange	The consideration of the cost-effectiveness of the intervention will be evaluated at the end-of-study analysis.
Competition	The 5 ACCs discussed enablers and barriers that adolescents face in achieving behavioural changes. From this debate, changes were proposed to improve success, including stakeholders.
Segmentation	The intervention is focused on adolescents from 13-16 y old who attend the participant high-schools and tend to exhibit low socioeconomic characteristics.
Methods Mix	The intervention involved the use of social media, education activities proposed as challenges and designed by the 5 ACCs and social media, and support using visual materials in high-schools and social media, and the design and control will be applied with the suggestions provided by the 5 ACCs.

Source: Elaborated by the author.

The peer-led instructors include the 5 ACCs who received 1.30 hours of training each week over 12 weeks in two subsequent academic years (1st and 2nd academic year) reflecting a total of 12 sessions/academic year and 24 sessions/overall intervention. These sessions were performed by university specialist with the aim of training adolescents with respect to health promotion, health education, communication and social media so that the adolescents could design the activities for their peers. The university specialists provided the 5 ACCs with the primary and secondary objectives of the program, and the 5 ACCs had to design activities, proposed as challenges, for their schoolmates to accomplish the marked objectives.

The activities proposed as challenges developed over 2 academic years are described in Table 8.

Table 8. Challenges of the "Som la Pera" intervention created by the 5 ACCs

Challenges designed on 1st academic year	Challenges designed on 2nd academic year
Challenge nº1 - Sport selfies: The 5 ACCs were challenged to post a photo to Facebook® of themselves engaging their preferred sport.	**Challenge nº6 - "Som la Pera" exhibition:** The campaign aims, photographs and healthy lifestyle recommendations were exhibited in a university hall and in a local theatre
Challenge nº2 - Healthy food photos: The 5 ACCs were challenged to post a photo of a plate composed of vegetables, fruits and cereals to Facebook®.	**Challenge nº7 - Sugared beverages:** The 5 ACCs designed a classroom activity focused on sugared beverages and healthy beverages alternatives.
Challenge nº3 - Gymkhana: The 5 ACCs designed 5 activities for their high-school mates on the playground of the high-schools. The activities involved tasting different fruits and vegetables, performing different PA and using the creativity to compose a song about healthy habits.	**Challenge nº8 - Balanced PA and food options**: The 5 ACCs designed a playground activity focused on energy balance in which adolescents had to choose some food options and identify the equivalent PA.
Challenge nº4 - Peraxef Contest: Related to Masterchef® TV contest, the 5 ACCs designed a contest in which adolescents in groups had to prepare 2 plates (healthy and creative salad and dessert).	**Challenge nº9 - Peraxef 2 Contest:** Related to Masterchef® TV contest, the 5 ACCs designed a contest in which the adolescents in groups had to prepare 2 plates (summer healthy and creative recipes) integrating parents, relatives and friends.
Challenge nº5 - Christmas Peraxef: Related to Masterchef® TV contest, the 5 ACCs designed a contest in which adolescents in groups had to prepare 1 plate (healthy Christmas starter or dessert).	**Challenge nº10 - Nutritional Myths Contest:** Related to the Buzz!™ Quiz World Play-Station® game contest, the 5 ACCs designed contests about nutritional myths and concepts related to the "Som la Pera" intervention concepts.

Source: Elaborated by the author.

Table 9 described which challenges are related to each of the objectives of "Som la Pera" intervention study.

Table 9. Challenges of the campaign related to the "Som la Pera" intervention objectives

Primary objectives	Challenges of "Som la Pera" intervention
Increase the consumption of fruit and vegetables	Challenge nº2 - Healthy food photos Challenge nº3 - Gymkhana Challenge nº4 - Peraxef Contest Challenge nº5 - Christmas Peraxef Challenge nº6 - "Som la Pera" exhibition Challenge nº7 - Sugared beverages Challenge nº8 - Balanced PA and food options Challenge nº9 - Peraxef 2 Contest Challenge nº10 - Nutritional Myths Contest
Increase PA practice	Challenge nº1 - Sport selfies Challenge nº2 - Healthy food photos, Challenge nº6 - "Som la Pera" exhibition Challenge nº8 - Balanced PA and food options Challenge nº10 - Nutritional Myths Contest
Decrease TV/PC/videogames usage	Challenge nº10 - Nutritional Myths Contest
Secondary objectives	**Challenges of "Som la Pera" intervention**
Increase breakfast consumption	Challenge nº10 - Nutritional Myths Contest
Increase the engagement with stakeholders	Challenge nº3 - Gymkhana Challenge nº4 - Peraxef Contest Challenge nº5 - Christmas Peraxef Challenge nº6 - "Som la Pera" exhibition Challenge nº9 - Peraxef 2 Contest

Source: Elaborated by the author.

The social media used to disseminate the intervention information and healthy messages included the Facebook® platform, Instagram® and YouTube®. This new perspective for the dissemination of health messages need to be evaluated in the adolescent population.

Sustainability is the ability to maintain the program implementation over time if there are positively health benefits (Schell et al., 2013). However, we suggest that the prediction of the sustainability capacity before starting the intervention would be beneficial with respect to solving possible problems while the intervention is ongoing. As mentioned, the "Som la Pera" intervention aimed to considerer, plan and assess the sustainability of the program, and a recent review suggested that understanding the sustainability process could improve the permanently

sustainability of intervention programs (Wiltsey Stirman et al., 2012). Despite this recommendation, many research studies in this field are underdeveloped according to funding limitations after the initial program implementation (Wiltsey Stirman et al., 2012). Thus, some domains of sustainability detected by the PSAT tool are not satisfied, although these domains can be adapted to achieve the permanently sustainability of the intervention. A community-based child OB intervention called "ACT! Actively Changing Together" demonstrated the feasibility of developing, enhancing and sustaining the program for 10 years after its implementation (Grow et al., 2014).

From the "Som la Pera" intervention sustainability assessment, we plan to improve two domains that exhibited lower scores, namely funding stability and strategic planning, over the course of the intervention implementation and before the final assessment to guarantee the permanent implementation of the intervention if the results are positively beneficial for the health of adolescents.

The EdAl program and the "Som la Pera" intervention exhibited a common denominator: both programs aimed to prevent OB and encourage healthy lifestyles and based on school-based interventions (Figure 10). The components involved in these projects are similar. Moreover, both used closer individual to disseminate the health messages to target audience. In the EdAl program, the closer individuals were university students trained as HPAs to disseminate the messages to school children, whereas in the "Som la Pera" intervention, the closer individuals were adolescents trained as HPAs to disseminate the message to their peers, called ACCs. In the "Som la Pera" intervention, a close relationship was observed between the ACCs and people who received the program. With respect to the "health educators" definition of the WHO (World Health Organization, 2012), the HPAs of the EdAl program and the ACCs of the "Som la Pera" intervention accomplished the major responsibilities of "health educators".

- *Assessment of community needs*: Lifestyles objectives are based on evidence in both programs, but HPAs could propose improving some needs. The "Som la Pera" intervention allowed greater adaptation to this

responsibility because the ACCs knew first-hand the needs of their age group.

- *Planning of effective health education programs*: The HPAs of the EdAl program and the ACCs of the "Som la Pera" intervention designed the activities of the interventions. Moreover, the ACCs of the "Som la Pera" intervention decided the type, number and location of the activities.

- *Implementation of health education programs*: The HPAs of the EdAl program implemented the activities in school classrooms, coordinate by university teachers, whereas the ACCs of the "Som la Pera" intervention implement the activities those themselves coordinated with the support of university teachers.

- *Evaluate effectivity of health education program*: The HPAs of the EdAl program evaluated each activity using a observational or evaluation sheet, whereas the ACCs of the "Som la Pera" intervention measured the acceptability of the program using social media and encouraged their mates to answer the evaluation questionnaires assessed by university researchers.

- *Coordinate provision of health education service*: The ACCs of the "Som la Pera" intervention searched interactions with stakeholders, such as central market of Reus, but the coordination part was performed by university researchers. In EdAl program, the coordination was undertaken by university researchers.

- *Act as a resource person in health education*: The HPAs of the EdAl program used health education efficiently and were prepared to answer the questions of school-children in classrooms, but the selection of effective educational resources for communication were made with the help of active primary-school teachers. In the "Som la Pera" intervention, the ACCs were prepared to search for effective information and to answer the questions of their peers, and they select the effective educational resources to disseminate the messages.

- *Communication of health and health education needs, concerns and resources*: The HPAs of the EdAl program learned about the best methods

to communicate with children, and the ACCs of the "Som la Pera" intervention learned about the best methods to communicate with their peers and to assess which were the most effective.

Moreover, the HPA of the EdAl school-based intervention program and the ACCs of the "Som la Pera" intervention were trained to improve their capabilities in the following areas:

a) Knowledge:

- EdAl program: The basis of healthy eating; nutrition education methodology; the effects of physical activity; health education program planning and development; and preventive medicine.
- "Som la Pera" intervention: The basis of healthy eating and the effects of physical activity; and social media

b) Skills: Abilities and capacities were acquired through formation, standardization and training using simulation and repetition. These skills were achieved via sustained efforts in each activity.

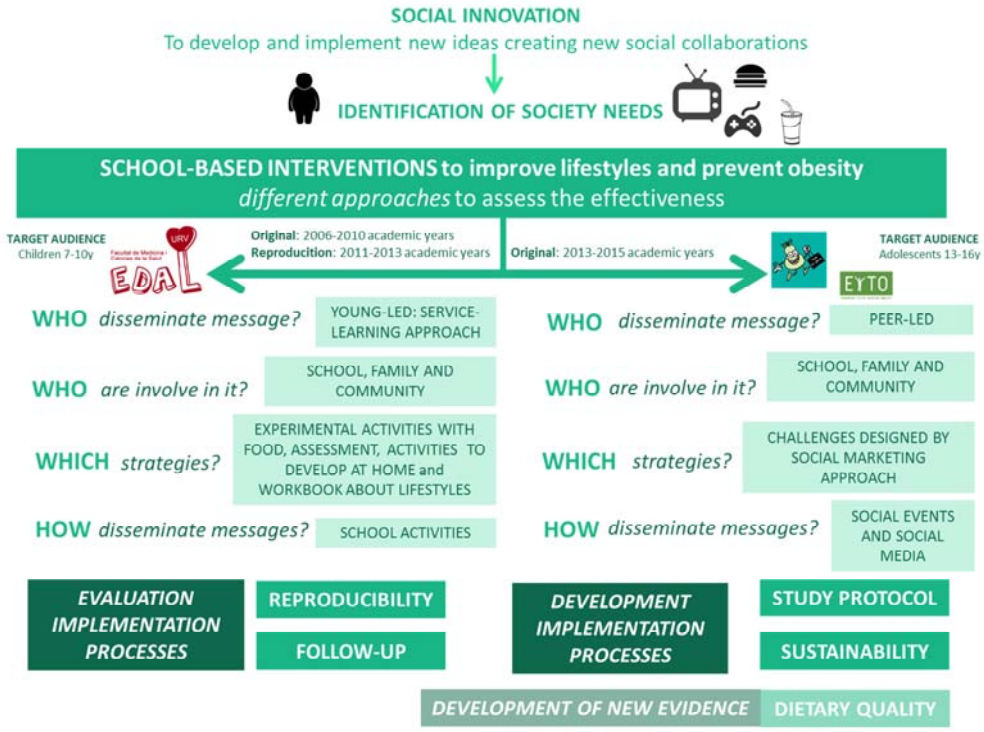
c) Abilities:

- EdAl program: The aptitude to develop health education to deliver a specific healthy lifestyle message using the following skills: knowledge of different health sciences education methods; communication techniques applicable to food and human nutrition; verbal and non-verbal communication; interpersonal relationship skills to promote the active participation of those enrolled in the program; different teaching techniques, including strategies for promoting health; human behaviour and the influence of personality and group dynamics; and theories of motivation and behavioural change.
- "Som la Pera" intervention: The aptitude to develop health education to deliver a specific healthy lifestyle message using the following skills, communication techniques applicable to food and human nutrition; verbal and non-verbal communication; interpersonal relationship skills to promote the active participation of those enrolled in the program; and strategies for promoting health.

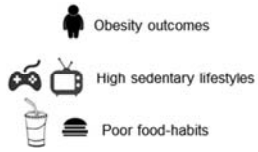
Despite those similarities, there were some differences (Figure 10):

- *Target audience*: The target population differed between the programs; the EdAl program focused on children 7-9 years old, whereas the "Som la Pera" intervention focused on adolescents 13-16 years old.
- *Disseminators of information*: In the EdAl program the people who disseminate the message were university students acting as HPAs, to be nearer to the target audience than the adult population. HPA were trained according to educational scholarship designed. The ACCs of the "Som la Pera" intervention were adolescents who disseminated the health messages to their schoolmates (other adolescents), achieving better motivation of the target audience. These ACCs were not formed with planned educational scholarship and used common tools to prepare the formative sessions.
- *Strategies*: In the EdAl program 4 activities were undertaken per year for a total of 12 activities (1 hour/activity) over the 3-y intervention. These activities were related to 8 evidence-based lifestyles topics, and all of these activities had the same structure (experimental activity with food, assessment and activities performed at home). In the "Som la Pera" intervention, the 10 challenges were designed by adolescent campaign creators and involved healthy messages considering 8 SM criteria.
- *Methods to spread the message:* In EdAl program the healthy messages were disseminated in the classroom by school activities and in performed at home. In the "Som la Pera" intervention, the healthy messages were disseminated using social media (Facebook®, Instagram® and YouTube®) and social events (activities englobing environment of adolescents outside of high-schools).

Figure 10: Diagram of the design and approaches used to improve and assess the effectiveness of two school-based interventions aimed at preventing childhood or adolescent OB and improving lifestyles



Source: Elaborated by the author.



From the results of the presented studies, we can confirm that the design and implementation of school-based intervention, including family and community environment components, are important to improve intervention effectiveness. The introduction of the SM strategy and peer-led model in school-based interventions will require further confirmation of their effectiveness.

European adolescents exhibit unfavourable changes in diet and lifestyles (Ortega et al., 2014), and research on how to revert these changes to minimize OB risk factors in children and adolescents, is an important matter. Dietary quality measures the diet adherence to national or international dietary recommendations

(Vyncke et al., 2013). In **Study 5**, the analysis of data on the frequency of eating occasions and snacks revealed interesting associations with DQ. However, our findings suggest that eating more than three times per day improves DQ, provided that nutrient-rich foods are consumed both at and between meals and that some low energy snacks are consumed (e.g., fruit, vegetables or water). According to Bellisle increases in the daily frequency of snacks and eating occasions that involve high-fat and high-sugar items have negative effects on DQ and body adiposity in adolescents (Bellisle, 2014). These findings suggest that these types of snacks should be avoided. To improve DQ, adolescents need encouragement to choose, purchase and consume healthier snacks and beverages. This goal will require changes in the environment through local and national policies to improve the availability, access and pricing of healthier foods. The constant update of dietary recommendations requires the use of evidence-based in the design and development of high-quality interventions.

CONCLUSIONS

CONCLUSIONS

1. The original EdAl school-based intervention program is feasible and reproducible by increasing after-school physical activity (to ≥4 h/week) in boys. Despite this improvement, the EdAl-2 program has no effect on BMI or the prevalence of obesity.

2. The EdAl-2 school-based intervention program induces healthy lifestyle effects (such as more physical activity and less sedentary behaviour), which can produce anti-obesity benefits in children in the near future beyond the limited length of our current study.

3. The EdAl-2 program exhibits the same pattern with respect to the improvement in healthy food-habits by increasing consumption to two fruits per day, one or more vegetables per day relative to the original EdAl school-based intervention program.

4. Four-year post-cessation intervention of the original EdAl program was associated with a lower BMI z-score and OB prevalence than the control group. The improvement in after-school PA practice was more likely to be maintained for the long-term after the cessation of the intervention, whereas encouraging healthy food habits in adolescents is a challenge.

5. In the original EdAl program, the reduction in obesity-related measurements in boys began during the intervention and continued after its cessation. Meanwhile, in girls, the decrease in obesity-related measurements requires 4-y follow-up post-cessation intervention.

6. The effect of the EdAl school-based intervention program on girls needs to be more closely studied.

7. The design of the “Som la Pera” randomized controlled social-marketing peer-led intervention to encourage healthy lifestyles in high-schools provides 10 challenges (5 challenges/year) designed by 5 adolescent coordinators and delivered to their schoolmates to encourage healthy lifestyles, including diet and physical activity practice.

8. The “Som la pera” intervention challenges use new approaches to disseminate healthy messages, such as social media, in addition to high-schools activities and activities delivered in different places identified as stakeholders of the intervention.

9. After sustainability assessment of the ongoing program, we will invest efforts to recover funding stability and strategic planning domains for the effective and long-term implementation of the “Som la Pera” intervention.

10. After sustainability assessment of the ongoing program, we propose that every 2 years, 5 ACCs be trained by health sciences university students’ acting as HPAs to disseminate healthy lifestyles information and propose challenges to their peers according to a social marketing and peer-led model.

11. The dietary quality could result superior in adolescents with the replacement of high-energy snacks with low-energy alternatives.

12. The identification of adolescents’ dietary quality contributes to improve the design interventions to encourage healthy lifestyles.

GLOBAL CONCLUSION

The development of the EdAl (Educació en Alimentació) school-based intervention program, which focused on the prevention of childhood obesity and encouraging healthy lifestyles in children, is effective at 4-y follow-up post-cessation intervention. The EdAl decreased the prevalence of obesity and BMI z-scores and increased the practice of physical activity. Moreover, this intervention confirmed the effectiveness on the reproducibility of the program in other location; the EdAl-2 program also improved lifestyles, including improved physical activity practices and food habits, similar to the original EdAl intervention program.

The “Som la Pera” intervention is designed according to evidence-based focused on social marketing and a peer-led model to improve healthy lifestyles and prevent obesity in adolescents. The planning and early assessment of the sustainability of this intervention promises effective permanently implementation beyond the intervention completion.

Furthermore, our study identified diet quality characteristics as a basis to integrate eating frequency recommendations with new effective strategies to tackle obesity in adolescents.

PERSPECTIVES

Long-term follow-up of the EdAl-2 program participants is needed to determine the post-cessation intervention effectiveness of the EdAl school-based intervention program.

End-of-study and long-term assessment of the “Som la Pera” intervention is needed to confirm its effectiveness and implementation sustainability. Additionally, assessments of the EYTO project must be conducted on a European level.

The assessment of relationship between dietary quality, eating frequency and obesity-related outcomes could be identified in a Spanish cohort to validate this recommendation in the Spanish population.

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