Clinical Practice Guideline for the Prevention and Treatment of Childhood and Juvenile Obesity

NOTE:

More than 5 years have passed since the publication of this Clinical Practice Guideline, and **its validity has not been reviewed**.

Therefore, **it is unclear whether its recommendations remain valid**; they should therefore be treated with caution and applied in accordance with **clinical judgement and the individual circumstances of each patient**.

CLINICAL PRACTICE GUIDELINES IN THE SPANISH NATIONAL HEALTHCARE SYSTEM
MINISTRY FOR HEALTH AND SOCIAL POLICY

MINISTERIO DE CIENCIA E INNOVACIÓN
MINISTERIO DE SANIDAD Y POLÍTICA SOCIAL
Plan de Calidad para el Sistema Nacional de Salud
Generalitat de Catalunya Departament de Salut

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This CPG (Clinical Practice Guideline) is an aid for healthcare decisions. It is not binding, and does not replace the clinical judgement of healthcare staff.

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Presentation

Appropriate, efficient, safe clinical decisions require professionals with up-to-date knowledge and skills.

Although scientific information is more accessible now than ever, the sheer volume of information, a lack of time and the need to weigh up the relevance of scientific evidence lead to a need for certain tools which aim to support the clinical decision process. Clinical Practice Guidelines (CPGs) answer the most important questions that may arise when a patient has a specific disorder, and present scientific evidence in the form of recommendations which are weighted according to the quality of the studies which support them.

Realising that CPGs make thousands of clinical decisions easier every day in healthcare, and that they are a tool to improve healthcare outcomes, the Quality Agency supports their development, dissemination and use, and also monitors the quality of CPGs developed in Spain.

In 2003, the Inter-Regional Council of the Spanish National Healthcare System (SNHS) created a project known as GuíaSalud. This aims to improve clinical decisions based on scientific evidence via training activities and by establishing a register of CPGs within the SNHS. Since then, the GuíaSalud project has evaluated dozens of CPGs according to explicit criteria established by its scientific committee, and it has registered them and disseminated them via the Internet.

In early 2006, the Management Body of the Quality Agency of the SNHS developed a Quality Plan for the SNHS, based on twelve strategies. The Quality Plan aims to increase cohesion within the SNHS, and to help ensure that the healthcare received by all members of the public is of the utmost quality, regardless of where they live.

Strategy 10 of the Plan is designed to improve clinical practice. Its aims include reducing variability in clinical practice and stimulating the development and use of CPGs. The aims stated in the Quality Plan are being responded to by GuíaSalud regarding creation of a register, training and consultancy, and by the CPG Development Programme regarding the creation of new guidelines.

In 2006, the task of developing eight CPGs was assigned to various agencies and groups of experts in prevalent disorders related to health strategies. The task of defining a common methodology for developing CPGs within the SNHS was also assigned. This job was stated in a Methodology Manual for Developing CPGs1, which has been available to all professionals since November 2007. This is the methodological point of reference for the guidelines developed within this programme.

Later on, in conjunction with the same institutions and with the participation of the scientific societies involved, another fourteen CPGs were begun. This CPG, which addresses the prevention and treatment of childhood and juvenile obesity, is part of this group of guidelines.

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The GuíaSalud project was updated in 2007, and the CPG Library was created. This project deals with the development of CPGs in depth, and includes other Evidence-Based Medicine services and products intended to support the clinical decision process.

It also places particular emphasis on the publicising, disseminating and implementing CPGs in order to promote their use, and on evaluating outcomes for public health.

Childhood and juvenile obesity is a major health problem in Spain. This is due to its increasing prevalence, its persistence into adulthood and its association with other diseases, as well as its huge financial impact. Changes in diet and lifestyle have led to an increase in this disorder. Treatment and, essentially, prevention require the adoption of healthy eating and physical exercise habits, but government and institutional support is needed to implement many of the changes required.

The development of this CPG has been aided by a team of professionals in different disciplines. They have made major efforts to draw up an evidence-based CPG and explicit recommendations for various fields from which childhood and juvenile obesity can be addressed. It is also endorsed by various scientific societies. The external review process was also multidisciplinary, with the participation of healthcare system users who supplied their points of view.

We hope that this project can make an effective contribution to the treatment, and especially the prevention, of childhood and juvenile obesity. This is the key to halting the advance of this health problem.

PABLO RIVERO CORTE
Director of the Quality Agency
of the Spanish National Healthcare System

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Spanish Nutrition Society (SEN)

Spanish Society of Dietetics and Food Science (SEDCA)

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The development of this document has not been affected by the views or interests of the parties providing funding.

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Questions to Answer

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DEFINITION AND INITIAL ASSESSMENT

1. How are overweight and obesity in childhood and adolescence defined?
2. What initial assessment should be made for an overweight or obese child or adolescent?
3. What are the criteria for referral to a specialist?

PREVENTION

4. Among children and adolescents of normal weight, how effective are school-based interventions in preventing obesity?
5. Among children and adolescents of normal weight, how effective are school-based interventions in improving diet, increasing physical activity levels or reducing sedentary lifestyles?
6. Among children and adolescents of normal weight, how effective are healthcare interventions in preventing obesity?
7. Among children and adolescents of normal weight, does measuring height and weight reduce the incidence of overweight and/or obesity?
8. Among children and adolescents of normal weight, do regular screening programmes prevent overweight and/or obesity?
9. Among children and adolescents of normal weight, does advice on diet and exercise and on reducing sedentary lifestyles prevent overweight and/or obesity? Does it improve knowledge of these three subjects? Does it lead to healthier habits?
10. In breastfed babies, does continuing breastfeeding prevent overweight and/or obesity when the children are older?
11. Among children and adolescents of normal weight, how effective are community interventions in preventing obesity?
12. Among children and adolescents of normal weight, how effective are community interventions in improving diet, increasing physical activity levels or reducing sedentary lifestyles?
13. Among children and adolescents of normal weight, how effective are family-based interventions in preventing obesity?
14. Among children and adolescents of normal weight, how effective are family-based interventions in improving diet, increasing physical activity levels or reducing sedentary lifestyles?

TREATMENT

15. Among overweight or obese children and adolescents, how effective is nutritional intervention in weight loss or maintenance and other specified outcomes?
16. Among overweight or obese children and adolescents, how effective is physical exercise or active play in weight loss or maintenance and other specified outcomes?
17. Among overweight or obese children and adolescents, how effective is reducing sedentary lifestyles in weight loss or maintenance and other specified outcomes?
18. Among overweight or obese children and adolescents, how effective is psychological treatment in weight loss or maintenance and other specified outcomes?
19. Among overweight or obese children and adolescents, how effective are combined interventions in weight loss or maintenance and other specified outcomes?
20. Among overweight or obese children and adolescents, how effective is sibutramine treatment in weight loss or maintenance and other specified outcomes?
21. Among overweight or obese children and adolescents, how effective is orlistat treatment in weight loss or maintenance and other specified outcomes?
22. Among overweight or obese children and adolescents, how effective is rimonabant treatment in weight loss or maintenance and other specified outcomes?
23. Among overweight or obese children and adolescents, how effective is metformin treatment in weight loss or maintenance and other specified outcomes?
24. Among overweight or obese children and adolescents, how effective is surgery in weight loss or maintenance and other specified outcomes?
25. Among overweight or obese children and adolescents, how effective are alternative treatments in weight loss or maintenance and other specified outcomes?

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Summary of recommendations

Evaluations of the quality of evidence and grading of recommendations were provided according to the system proposed by SIGN (*Scottish Intercollegiate Guidelines Network*) (**Appendix 1**), one of the systems recommended in the *Methodology Manual for Developing Clinical Practice Guidelines* of the Spanish National Healthcare System, the methodological reference framework of this CPG[1]. Below are the recommendations proposed in this CPG:

DEFINITION	
√	The growth curves and tables of the semi-longitudinal study by Hernández *et al*. (1988) are recommended for diagnosing overweight and obesity in childhood and adolescence.
√	For a diagnosis of overweight, BMI must be greater than or equal to P90 and below P97 for the patient's age and sex according to the growth curves and tables of the semi-longitudinal study by Hernández *et al*. (1988).
√	For a diagnosis of obesity, BMI must be greater than or equal to P97 for the patient's age and sex according to the growth curves and tables of the semi-longitudinal study by Hernández *et al*. (1988).
INITIAL ASSESSMENT	
D	BMI should be calculated and excessive body weight classed as overweight or obesity using the growth curves and tables of the semi-longitudinal study by Hernández *et al*. (1988), according to age and sex.
D	A full clinical history should be taken and a complete physical examination should be carried out, to detect obesity secondary to underlying disorders or malformation syndromes, and to exclude associated comorbidities.
D	The possibility of psychopathological conditions (anxiety, depression, bulimic behaviour) should be assessed. Such conditions may determine childhood or adolescent obesity.
D	Referral to a leading endocrinologist is recommended for obese children or adolescents with suspected underlying diseases causing their obesity, obesity in very young children, concurrence of associated disorders or extreme obesity. Referral to a leading mental health unit is recommended if there is an associated psychiatric disorder.
√	Pre-existing family dynamics should be assessed, as should the willingness of both the child and adolescent and his/her family to make changes, so that any intervention to tackle overweight or obesity can be targeted appropriately.

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PREVENTION	
School-based interventions	
B	Schools must promote physical education and sporting activities, both within and outside school.
C	Schools should include educational programmes which aim to improve diet, increase physical activity and reduce sedentary lifestyles. These should include families and teaching staff.
C	School-based interventions must be continued over time, both during school years and outside the school environment.
B	Food eaten in schools must be healthy, including a range of fruit and vegetables and meals low in fats and sugars.
B	Multidisciplinary interventions should be implemented in schools to encourage children and adolescents to eat fruit and vegetables.
√	A healthy dietary environment must be created in schools, reducing the availability of foods with high calorie contents (vending machines) and making healthy foods readily available.
B	Physical activity should be promoted among children and adolescents via interventions which target more than one environment (school, family, community). These should include environmental interventions.
√	Both families and professionals who work in schools must be included in school health education programmes. School activities aimed at reducing time spent watching television, playing video or computer games or using mobile phones should be encouraged.
Healthcare interventions	
B	Advice on nutrition and encouraging physical activity, suited to children's ages, should be included in child health monitoring visits.
√	At paediatricians' and general practitioner's appointments, children and the whole family should be encouraged to eat healthily and take exercise. All professionals within the primary healthcare team must be involved in receiving and disseminating messages about healthy eating and physical exercise.
√	Interventions to promote healthy eating and encourage physical activity must foster a positive body image and help build and reinforce young people's self-esteem. Particular care should be taken to avoid stigmatising or blaming overweight young people or their families.
√	Messages to young people must emphasise the light-hearted, enriching aspects of physical activity and a varied diet (fun, pleasure, new flavours, well-being, enjoying time with friends, etc.) and cater for their preferences. Health- and illness-related messages must play a secondary role.

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√	In order to support healthcare professionals' educational work, public healthcare services must provide written or audiovisual materials to support professionals and families. The contents of these must be non-discriminatory and culturally adapted to different social groups.
√	Activities and messages must be suited to the specific characteristics of each young person and his/her family, in line with their needs and preferences. Strategies or techniques such as motivational interviews may be appropriate in these processes.
A	It is recommended that babies be exclusively breastfed for six months, due to the many benefits of breastfeeding to children's health.
Community interventions	
B	For children and adolescents, sugary drinks should be limited. Community programmes that encourage drinking fewer sugary drinks and contribute to drinking water should be promoted.
√	The relevant authorities should take steps to restrict the range and promotion of foods containing high levels of unhealthy fats or sugars (sugary drinks, pastries, deli products, etc.).
√	Production and availability of fruit and vegetables should be encouraged using fiscal policies or subsidies.
√	Advertising aimed at children and adolescents for products that contain high levels of unhealthy fats or sugars should be restricted.
√	It should be made compulsory to label processed food with nutritional information and information on potential health-damaging effects.
B	Physical activity programmes outside school hours are recommended for children and adolescents. These must be suited to their ages and preferences.
B	Community programmes that aim to encourage a healthy lifestyle, healthy eating and physical exercise are recommended for children and adolescents.
√	Safe, pleasant spaces and suitable infrastructures for playing and sport for children and adolescents should be created in public areas.
√	Specific actions (free entry, benefits, etc.) should be launched to provide access to municipal sporting facilities for children, adolescents and relatives from socially disadvantaged groups.
Family-based interventions	
B	It is important to involve parents in programmes which aim to improve diet and increase physical activity levels in order to prevent obesity.
√	Educational programmes that target the family so as to encourage a healthy lifestyle are needed. These must cover healthy eating, education to understand nutritional information on food labels and the promotion of active leisure activities.

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√	Children should be involved in food shopping. Simple cooking techniques should be encouraged.
√	Children should eat regular meals, with their families and without distractions (television, etc.).
TREATMENT	
Dietary interventions	
√	A healthy, balanced diet according to the healthy eating pyramid is recommended for children and adolescents who are overweight or obese.
√	Dietary intervention for children and adolescents who are overweight or obese must not be a one-off event. Instead, it must be carried out as part of a change in lifestyle, including physical exercise, behavioural therapy and family-centred actions.
√	For children and adolescents who are overweight or obese, calorie intake must be lower than the energy they expend, and changes to their diet must be customised and consistent with healthy eating. The use of restrictive, unbalanced diets is not recommended, as these are not effective in the long term and may prove dangerous.
√	Advice on changes to diet must be given by healthcare professionals who deal with children and adolescents regularly.
D	Professionals in charge of looking after children and adolescents who are overweight or obese must pay particular attention to any risk factors or signs of eating disorders.
Exercise-based interventions	
√	For children and adolescents who are overweight or obese, spontaneous physical activity should be increased by more than one hour a day in order to encourage weight loss and cardiovascular health. Such physical activity may include outdoor play, helping with housework, walking to school, using stairs instead of lifts, etc.
√	Physical exercise suited to age and interests is recommended for children and adolescents who are overweight or obese. It should begin slowly and gradually increase in intensity and duration.
Interventions to reduce sedentary lifestyles	
D	In order to reduce their sedentary lifestyles, a maximum of 1½ hours a day watching television or playing video games is recommended for children and adolescents who are overweight or obese.
B	Reducing sedentary lifestyles is recommended for children and adolescents who are overweight or obese, in order to treat childhood and adolescent overweight and obesity.

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√	Televisions, video consoles and computers should be removed from the bedrooms of children and adolescents who are overweight or obese
Psychological interventions	
B	Psychological support (behavioural or cognitive behavioural therapy) is recommended for the treatment of overweight and obesity in children and adolescents.
√	Therapy aimed at reducing stress and other psychological techniques (goal-setting, self-monitoring, etc.) are recommended for the treatment of obesity in children and adolescents.
√	Individual or group psychological treatment should be included in combined interventions for children and adolescents suffering from obesity.
Combined interventions	
B	Combined interventions including diet, physical exercise and changes to behaviour, with family involvement, are recommended for weight loss in children and adolescents aged 6 16 who are overweight or obese.
√	The clinical and family environments are the most appropriate settings for combined interventions for weight loss in children and adolescents who are overweight or obese.
Drug-based interventions	
C	For adolescents (aged 12-18) suffering from obesity and severe comorbidities who have not responded to dietary and lifestyle treatment, sibutramine* treatment (10 mg/day) may be considered as part of a programme of changes to lifestyle. This must be supervised by specialists in endocrinology and nutrition, family medicine or paediatrics who have been trained to treat obesity. Currently, marketing authorisation for Sibutramine is suspended as risks of its use outweigh expected benefits.
C	For adolescents (aged 12-18) suffering from obesity and severe comorbidities who have not responded to dietary and lifestyle treatment, orlistat* treatment (120 mg with breakfast, lunch and dinner) may be considered as part of a programme of changes to lifestyle. This must be supervised by specialists in endocrinology and nutrition, family medicine or paediatrics who have been trained to treat obesity.
√	Orlistat treatment must be supplemented with a fat-soluble vitamin complex (vitamins A, D, E and K). This must be administered before bed or two hours after taking orlistat.
C	In adolescents (aged 12-18) who are obese and insulin-resistant or glucose-intolerant and who have not responded to dietary and lifestyle treatment, metformin treatment (500 850 mg/12 hours) may be considered as part of a programme of changes to lifestyle. This must be supervised by specialists in endocrinology and nutrition, family medicine or paediatrics who have been trained to treat obesity.

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√	As neither orlistat or sibutramine have been approved by the Spanish Agency for Medicines and Healthcare Products (AEMPS) or the European Medicines Agency (EMEA) for use in those under 18, and as metformin is not indicated for the treatment of obesity in adults or children, informed consent must be obtained from relatives, guardians and the adolescent in question if any of these drugs is prescribed. Currently, marketing authorisation for Sibutramine is suspended as risks outweigh benefits.
D	The decision to begin drug treatment must be taken individually for each patient. Such a decision may only be taken if there are severe comorbidities and other, associated treatments are also performed.
√	Treatments and their indication must be reassessed regularly, and must not be used indefinitely.
√	Relatives or guardians should always be informed of the risks and benefits of drug treatments, as should adolescents themselves.

* Sibutramine and orlistat are not funded by Spanish Social Security.

Surgery	
C	Bariatric surgery should only be performed in adolescents suffering from severe obesity (BMI≥40 kg/m^2) and severe comorbidity or who are extremely obese (BMI≥50 kg/m^2), and only when attempts to control weight via intensive actions to alter lifestyle, with or without drug treatment, for at least six months have failed.
√	Candidates for bariatric surgery must be selected after careful assessment by a multidisciplinary team with expertise in medicine, surgery, psychiatry and nutrition for surgical treatment of obesity in adolescents. Bariatric surgery should only be performed in adolescents who are physically and psychologically mature and aware of the risks and benefits of surgery, and with their family's support.
√	Bariatric surgery must only be performed by highly-specialised surgeons. Follow-up of patients who undergo bariatric surgery must be lifelong, in order to ensure optimum weight loss and good health.
√	Patients must be examined for possible vitamin (B12, B6, B1, B2, D, folates) and mineral (iron, calcium, zinc) deficiencies after bariatric surgery. Supplements must be administered if required.
Alternative treatments	
C	The use of alternative treatments for overweight and obesity in children and adolescents is not recommended.

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1. Introduction

The World Health Organisation (WHO) defines obesity and overweight as an abnormal, excessive accumulation of fat which may be harmful to the health, and which manifests itself as excess body weight and volume[2]. The WHO considers obesity the "epidemic of the twenty-first century", due to the scale it has acquired in recent decades and its impact on morbidity and mortality, quality of life and healthcare spending[2-4]. According to the WHO, in 2005 1.6 billion people aged over 15 and 20 million people aged under 5 were overweight, and 400 million people were obese. According to estimates, in 2015 approximately 2.3 billion adults will be overweight and more than 700 million will be obese.

The prevalence of overweight/obesity has been increasing in recent decades. Lindström et al.5 found that in the period 1986-1994, the prevalence of obesity increased from 4.6% to 11.4% in adult males, and from 6.1% to 9.8% in adult females. Overweight increased from 33.9% to 45.2% in adult males and from 19.6% to 29.1% in adult females. This is similar to the trend in Spain[6].

The prevalence of overweight/obesity in children and adolescents is following a similar trend in both developed[7,8] and developing countries[9]. In Spain, the 1984 study Paidos estimated the prevalence of childhood obesity at 4.9%10, while Serra *et al.* found that between 1998 and 2000 the overall prevalence of overweight and obesity were 12.4% and 13.9% respectively, both higher in males11. Other studies conducted in Spain have also shown increased prevalence of overweight/obesity in children and adolescents[12-14], and increased body fat percentages in the same population.

Obesity is considered a chronic disease in its own right, but also a major risk factor for other diseases which cause high morbidity and mortality rates in adults[17]. Thus obesity in this population has been associated with type II diabetes mellitus, high blood pressure, dyslipidaemia, ischaemic heart disease, bone and joint disorders, venous insufficiency, strokes, hyperuricaemia and gout, sleep apnoea, respiratory failure, psychological disorders, hepatic steatosis, hiatus hernia and malignant tumours in various locations (colon, rectum, prostate, ovaries, endometrium, breast, gall bladder). In women, it has also been associated with menstrual dysfunction, polycystic ovary syndrome, infertility, increased perinatal risk and urinary incontinence.

A link between childhood and juvenile obesity and the persistence of obesity in adulthood has been demonstrated[18-24]. It has been shown that in children and adolescents with obesity an increased body mass index (BMI) is associated with high concentrations of total cholesterol (TC), low-density lipoprotein cholesterol (LDL C), apolipoprotein B (apo B) and triglycerides (TG), and low concentrations of high-density lipoprotein cholesterol (HDL C) and apolipoprotein A (apo A)[25]. It seems that there is already a trend towards several different cardiovascular risk factors occurring early in life. A link has been found between a high BMI in childhood/adolescence and a higher incidence of ischaemic heart disease in adulthood[26,27].

To summarise, obesity in adolescence has been associated with a greater risk of overall mortality and specific mortality due to particular diseases in adult males[28]. Morbid-

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ity due to coronary disease and arteriosclerosis also increased in adults of both sexes[28]. Adolescent obesity was also associated with an increased risk of colorectal cancer and gout in adult males, and arthritis in women[28]. Adolescent-onset obesity was a more reliable predictor of these diseases than adult-onset obesity[28,29] A higher incidence of endocrinology disorders (hyperinsulinaemia, increased insulin resistance, glucose intolerance, type II diabetes mellitus and menstrual irregularity)[30-33] and psychological disorders (depression, low self-esteem) has been reported.

Alongside this, and as a result of all of the above, the increased prevalence of obesity is associated with an increase in financial costs arising from the treatment of the diseases associated with it. Most studies have been carried out in adults. In 1999, the direct costs of obesity in United States (USA) represented 7% of total healthcare spending. In Europe these costs are somewhat lower, between 1.5% and 4% according to a study which combined data from five countries (United Kingdom, France, Germany, Portugal and the Netherlands), probably because the prevalence of obesity in Europe is lower than in North America[36].

In Spain, the Ministry for Health estimates that obesity-related costs represented 7% of healthcare spending in 2007, i.e. a yearly expenditure of 2.500 million euros[37]. Cost studies involving children and adolescents are few and far between. In the USA, hospital healthcare spending attributable to diseases related to adolescent-onset obesity increased from 35 million dollars in the period 1979-1981 to 127 million dollars in 1997-199938. Greater use of healthcare services by obese children and adolescents than by children and adolescents of normal weight has been found[39].

Treatment of overweight/obesity yields varying results. A systematic review (SR) of 18 clinical studies of the treatment of childhood obesity concluded that the interventions evaluated did not provide conclusive results, as they were heterogeneous in nature (exercise, increased physical activity levels or reduced sedentary behaviour, treatment with behavioural therapy programmes) and individual studies had no statistical power to detect the efficacy of intervention[40]. More recently, a meta-analysis of 14 studies evaluated the efficacy of an intervention to alter lifestyles and concluded that it led to short-term weight loss, with some evidence that the loss could be sustained over time41. The efficacy of dietary interventions, if any, is short-lived. Drug and surgical treatment, meanwhile, must be used only in exceptional circumstances, in particular if there are severe comorbidities[43].

For all these reasons, as overweight/obesity which beings in childhood and adolescence shows a strong tendency to persist into adulthood, and as it has been amply demonstrated that overweight in adulthood reduces life expectancy because of the comorbidity associated with it, prevention in childhood is vital[37]. Some studies have yielded encouraging results of various interventions designed to promote healthy behaviour such as a balanced diet and physical exercise, behaviour which is necessary if overweight/obesity are to be prevented[44,45].

The results of studies of dietary habits conducted in Spain indicate that a high percentage of the population does not comply with recommendations for a diet which is considered healthy, and that the traditional Mediterranean diet is being abandoned in favour of others which have higher total fat and saturated fat contents because of the higher proportions of red meat, cold meat and eggs associated with lower consumption of fruit,

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vegetables, cereals and pulses[46]. Studies conducted in the Spanish population aged 4-14 show that only 34% eat two or more portions of vegetables every day, 60% eat two or more pieces of fruit a day, 32% eat sweets several times a day and 37% eat rice or pasta on almost every day[46].

Turning now to adolescents' physical fitness (aerobic capacity and muscle strength), studies conducted in Spanish children and adolescents show that they are less fit than adolescents from other European countries[47]. Spanish children take the least exercise outside school hours: more than 60% take no exercise or take exercise less than twice a week, a figure which rises to 75% for girls[48,49].

Whatever the figures, prevention of overweight/obesity in childhood and adolescence requires institutional involvement of the governments of countries affected by this disease, since the interventions required go far beyond the strictly medical sphere[36,50,51] To tackle the issue, since 2005 Spain has been driving the NAOS Strategy ('NAOS' is an acronym for 'Nutrition, Physical Exercise, Obesity Prevention and Health' in Spanish), which is promoted by the Spanish Ministry for Health and Consumption as part of the Quality Plan52. The aim of the NAOS Strategy is to promote actions which encourage healthy eating and physical exercise, in conjunction with health professionals, councils and regional governments, families, the education sector and business. Other actions within NAOS are protocols for primary care, designed in conjunction with scientific societies, in order to detect obesity early, and the development of follow-up programmes. Another aim is to drive obesity research, carry out an epidemiological assessment (via the Obesity Observatory) and establish a plan of action for prevention, with initiatives such as the PERSEO and THAO programmes.

This CPG, which addresses the prevention and treatment of childhood and adolescent overweight/obesity, is one of the actions of the NAOS Strategy. There are many CPGs throughout the world which deal rigorously with the prevention and treatment of childhood and adolescent obesity[43,53-58], but in Spain this initiative had not previously been put into practice. This is why this project aims to make an effective contribution to the prevention and treatment of overweight/obesity in this age group.

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2. Scope and Aims

2.1. Scope

This CPG covers the prevention and treatment of overweight and obesity in childhood and adolescence. To define overweight and obesity in this guideline the growth curves and tables of the semi-longitudinal study by Hernández *et al*. (1988)[59] were chosen. These were created in Spain, which means they are probably more directly applicable than those of other countries, and they were compiled before overweight/obesity began to rise. Regarding cut-off points, the 90% and 97% percentiles were agreed upon as the definitions of overweight and obesity respectively. However, the recommendations of this CPG can also be applied to patients with overweight and obesity diagnosed using alternative criteria.

The target population of this guideline are children and adolescents under 18, both those of normal weight and those who are overweight or obese. The treatment of secondary causes of childhood and juvenile obesity, eating disorders and comorbidities are explicitly excluded.

2.2. Aims

This CPG aims to establish a set of recommendations to prevent and treat overweight and obesity in childhood and adolescence. For prevention, the aim is to recommend strategies for schools, healthcare, community and health policy which make it possible to prevent overweight and obesity and maintain a suitable weight. Regarding treatment, the guideline covers clinical management of overweight and obesity in childhood and adolescence.

This guideline is intended for paediatricians, general practitioners/family doctors and nursing professionals who work mainly in primary care. Another target group are healthcare professionals working in specialist care, such as psychologists, nutritionists and dieticians. The recommendations of this CPG include some initiatives which will only be possible with the participation and involvement of public authorities and food and leisure companies which sell to children and adolescents. This means that these companies and institutions are a secondary target group of this CPG, as are those engaged in politics and managers. Finally, this guideline is also aimed at families, educators and the general public.

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3. Methods

The methods used are described in detail in the *Methodology Manual for Developing Clinical Practice Guidelines* of the Spanish National Healthcare System (SNHS)[1].

The steps taken were as follows:

- The group which would develop the guideline was established, consisting of professionals in paediatrics, primary care (family and community medicine) and specialist care (endocrinology, gastroenterology and paediatric nutrition, physical education and sports medicine, psychiatry, nutrition). These professionals were contacted via the various scientific societies related to the subject of the CPG. Materials for patients were inspected by various members of the public.
- Clinical questions were formulated according to the PICO model: Patient, Intervention, Comparison, Outcome.
- A search of the literature, prioritising the identification of SRs and other documents which provided a critical synthesis of the scientific literature, such as health technology assessment reports. For this purpose, an initial phase comprised a search of other CPGs in order to ascertain which SRs they had considered as a basis for their recommendations. The main CPGs used as secondary sources are listed in Appendix 7. They were all evaluated using the AGREE Instrument. Additional SRs were identified subsequently, following the date on which the selected CPGs were searched. The following electronic databases were consulted in this initial stage:
- TRIP Database
- NHS National Library of Guidelines
- AHRQ National Guideline Clearinghouse
- Cochrane Database of Systematic Reviews (the Cochrane Library)
- Database of Abstracts of Reviews of Effects (DARE)
- Health Technology Assessment (HTA) Database
- NHS Economic Evaluation Database (NHS EED)
- MEDLINE (accessed via PubMed)
- EMBASE (accessed via Ovid)
- The publications of a number of technology assessment agencies were also consulted. These included the National Institute for Clinical Excellence (NICE) and agencies which issue CPGs, such as the Scottish Intercollegiate Guidelines Network (SIGN).
- In the second stage, an extended search of individual studies was carried out, in order to update the relevant SRs and answer the questions of the CPG. The main aim was to identify randomised clinical trials (RCTs) and observational

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studies, respecting the original search strategies of the relevant SRs. When these were not available, a specific strategy was designed for each question, adding validated filters in each case to identify RCTs and observational studies. The following electronic databases were consulted in this phase: the Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library), MEDLINE, EMBASE and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) (accessed via Ovid).

- No language restriction was established for the searches carried out, but most of the studies considered were written in Spanish, English or French. Searches were carried out up to August 2008, although relevant studies were identified in the highest-profile biomedical journals throughout the CPG development process.
- The search strategies used for each section of the guideline are available on request from the Iberoamerican Cochrane Centre (tsc@cochrane.es).
- Evaluation of the quality of evidence and grading of recommendations were provided according to SIGN's system (**Appendix 1**). Controversial recommendations or those with no evidence were resolved by simple consensus of the group that developed the guideline.
- The group of authors took part in all stages of the process except searching and evaluation of the quality of scientific literature. These were carried out by the authors who belong to the Iberoamerican Cochrane Centre.
- The text was reviewed by a multidisciplinary group of external reviewers. The final text of the guideline was reviewed and approved by the group of authors.
- It is intended that the CPG will be updated every three years. More frequent updating of the electronic version of the guideline is not ruled out, should this prove necessary.

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4. Definition and initial assessment

Questions to Answer

- How are overweight and obesity in childhood and adolescence defined?
- What initial assessment should be made for an overweight or obese child or adolescent?
- What are the criteria for referral to a specialist?

4.1. Definition of childhood and juvenile overweight and obesity

Obesity is defined as an excessive accumulation of adipose tissue which determines the appearance of associated comorbidities or represents a risk factor for these[2]. To define overweight and obesity, an indirect estimate of the body's fat content is usually carried out using the BMI, which is calculated by dividing weight in kilograms by the square of the height in metres (kg/m2). In adults, the WHO[2] defines overweight as a BMI greater than or equal to 25 kg/m^2, and obesity as a BMI greater than or equal to 30 kg/m^2.

It is difficult to measure overweight and obesity in children and adolescents because there is no standard definition of childhood obesity applied all over the world. This means that professionals have to use reference curves and tables which are valid and useful in their particular environment. A second problem is selecting cut-off points to define the categories of normal weight, overweight and obesity. At the time of going to press, there is no international consensus on these matters.

There are many organisations and initiatives, both in Spain[59,61-71] and internationally[72- 85], which work hard to provide reference curves and tables which give an accurate representation of the population in which they are developed. All of these have their advantages and disadvantages, arising mainly from the following factors: 1) the geographical location in which they are developed, which makes it difficult to generalise tables to other places; 2) when they are developed. It is known that the incidence of overweight and obesity in childhood and adolescence has increased over the last decade, which may make it difficult to apply recently-published tables, as they may classify as normal cases which older tables classed as overweight, or may classify as overweight cases which older tables classed as obese; 3) the variation in cut-off points used by different authors to define overweight and obesity, generally established using percentiles (P).

As the most recent growth references, while having the advantage of reflecting the long-standing trend towards increasing height, have the disadvantage of updating the long-standing undesirable trend towards a disproportionate increase in weight in relation to height, and therefore in BMI, some countries have proposed not updating BMI references[86,87]. As a result, when the reference graphs and tables for weight and BMI which are currently available in the USA were compiled, the most recent weight (and therefore BMI) data, corresponding to children under 6 or more in the NHANES III Study con-

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ducted between 1988 and 1994, were excluded. This was because of the greater prevalence of obesity in this sample than in those from earlier studies conducted in the USA. Similarly, it has been recommended that BMI references based on data collected between 1978 and 1990 in the United Kingdom not be updated[87].

In the USA and Canada, local BMI references from growth graphs developed by the Centres for Disease Control and Prevention (CDC) in the USA[78] are used in clinical practice, with percentiles P85 and P95 recommended as cut-off points for the diagnosis of overweight and obesity respectively[53,58,78,88] In contrast, European countries which have their own BMI references use percentiles P90 (P91 in the UK) and P97 (P98 in the UK) respectively for the same purposes in clinical practice[72-76,79,80]. This latter recommendation is included in both European CPGs which cover childhood and adolescent obesity[56,43].

Of the BMI references available in Spain, three have been most popular among the CPG working group members: 1) those included in the Growth Curves and Tables (Longitudinal and Cross-Sectional Studies) of the Institute for Growth and Development Research of the Faustino Orbegozo Foundation, published in 200467; 2) those based on the data of the 2008 Spanish Cross-Sectional Growth Study, published in 2008; 3) those established in the Growth Curves and Tables of the semi-longitudinal study of the Institute for Growth and Development Research of the Faustino Orbegozo Foundation, published in 198859. Below are the main characteristics of each of these (Table 1):

Table 1: BMI reference curves and tables compiled in Spain

REFERENCE	METHODS & DATE	STRENGTHS	WEAKNESSES
LONGITUDINALAND CROSS-SECTIONAL STUDIES (FAUSTINO ORBEGOZO FOUNDATION)[67]	• Based on data obtained during a longitudinal study over the 18 years of complete growth of 300 girls and 300 boys born in 1978-1980, ending in 1998, and 2) based on the data of a cross-sectional study conducted in 2000-2001 with 6443 subjects, ages ranging from 0 to 18 years. • Percentile cut-off points established for the diagnosis of overweight and obesity: P85 and P95 respectively	• Reflect an essential aspect of the long-standing acceleration of growth by bringing together the long-standing trend towards increasing height. • P85 and P95 are the BMI diagnosis cut-off points with which many healthcare professionals are most familiar and identify the most, as a result of the greater dissemination of US scientific publications, in which these BMI thresholds are generally used exclusively to diagnose overweight and obesity.	• The study population consisted of children from middle and lower socioeconomic groups in Bilbao and the region surrounding it. • The data on body weight and BMI for the second half of growth from the longitudinal study were collected when BMI was already increasing and obesity was becoming more prevalent in industrialised societies. This leads to undesirable aspects of the long-standing acceleration of growth, such as the disproportionate increase in weight in relation to height and increased BMI, being classified as normal.

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2008 SPANISH CROSS-SECTIONAL GROWTH STUDY[69]	• Based on data from 32,064 subjects, ages ranging from 0 to 24 years, who made up the total sample of four cross-sectional studies conducted between 2000 and 2004 in Andalusia, Barcelona, Bilbao and Zaragoza. • Percentile cut-off points established for the diagnosis of overweight and obesity: P85 and P95 respectively.	• The sample size and great geographical distribution of the population studied, which consisted of 32,064 subjects from Andalusia, Barcelona, Bilbao and Zaragoza. • Reflect an essential aspect of the long-standing acceleration of growth: the long-standing trend towards increasing height. • P85 and P95 are the BMI diagnosis cut-off points with which many healthcare professionals are most familiar and identify the most, as a result of the greater dissemination of US scientific publications, in which these BMI thresholds are generally used exclusively to diagnose overweight and obesity.	• The data on body weight and BMI were collected when the prevalence of obesity was already significantly increasing all over the world, and references established in these circumstances update undesirable aspects of the long-standing acceleration of growth, such as the disproportionate increase in weight in relation to height and increased BMI, classifying these as normal.
SEMI-LONGITUDINAL STUDY (FAUSTINO ORBEGOZO FOUNDATION)[59]	• Based on data from three groups of 600 children selected at random, whose ages at the beginning of the study in 1978 were 0, 5 and 9 years respectively, and in whom longitudinal monitoring was carried out over 9 years. Those who missed two successive control evaluations were systematically excluded. • Percentile cut-off points established for the diagnosis of overweight and obesity: P85 and P95 respectively.	• Until very recently, these were the most widely-used references in Spain. • The time at which the data used to establish the references were collected: data were obtained right up until BMI and the prevalence of obesity in children and adolescents began to increase in some of the world's most industrialised countries, from the second half of the 1980s onwards. • Their application in clinical practice is completely in line with practice in other European countries which also have their own BMI references, with percentile cut-off points which are identical or practically identical for the diagnosis of overweight and obesity (P90/91 and P97/98), such as Germany, France, Italy, the UK, Sweden and Switzerland.	• The study population consisted of children from middle and lower socioeconomic groups in Bilbao and the region surrounding it. • An essential aspect of growth, namely the long-standing trend towards increasing height, has not been updated. This means that these tables should not be used for isolated evaluation of height, with the notable exception of the BMI references, whose advantage over updated references has already been highlighted in the previous column

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At the time of going to press, it has not been possible to establish a unanimous agreement as to which references should be considered valid. In this situation, faced with the need to provide a frame of reference for all healthcare professionals in charge of health-

care for Spain's child and juvenile population, the authors propose the use of the tables of the semi-longitudinal study begun in 1978-80 by the Faustino Orbegozo Foundation, compiled by Hernández et al59. These tables were compiled in Spain, before the beginning of the increase in overweight/obesity, which means that they are more directly applicable than those of other countries. We therefore propose using BMI as the parameter to establish the cut-off points for overweight and obesity, as follows:

- Overweight: BMI≥P90 and <P97 for the corresponding age and sex
- Obesity: BMI≥P97 for the corresponding age and sex.

Recommendations

√	The growth curves and tables of the semi-longitudinal study by Hernández *et al*. (1988) are recommended for diagnosing overweight and obesity in childhood and adolescence.
√	For a diagnosis of overweight, BMI must be greater than or equal to P90 and below P97 for the patient's age and sex according to the growth curves and tables of the semi-longitudinal study by Hernández *et al*. (1988).
√	For a diagnosis of obesity, BMI must be greater than or equal to P97 for the patient's age and sex according to the growth curves and tables of the semi-longitudinal study by Hernández *et al*. (1988).

4.2. Initial Assessment

Detecting overweight and obesity in children or adolescents at primary-care paediatric and general practice/family medicine appointments must be based on a series of key points so that the decisions taken are the most suitable for developing an intervention strategy which will be effective in addressing this health problem[88-92].

Experts' opinion 4

These key points are as follows[88-92]:

1. Calculate BMI and classifying excessive body weight as overweight or obesity using the growth curves and tables of the semi-longitudinal study by Hernández *et al*. (1988), for the appropriate age and sex.
2. Take a full family history, including ethnic group, country of origin, family history of obesity and associated disorders (high blood pressure, type II diabetes mellitus, dyslipidaemia or early heart disease), socioeconomic setting, family dynamic regarding food and physical exercise. If possible, record the BMI of the members of the family unit.
3. Take an exhaustive personal history, including obstetric history and neonatal

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anthropometry; breastfeeding guidelines and the beginning of weaning, psychomotor development milestones, previous or current illnesses and/or treatments; when weight gain began and progressed; and any trigger factors.

4. Evaluate the child or adolescent's lifestyle, exploring in particular their dietary habits (meal structure, distribution of meals throughout the day, any compulsive eating, number of snacks or drinks between meals and their composition) using a prospective dietary survey (seven days) and a physical exercise survey (objective recording of time spent on sedentary behaviour and daily exercise).
5. Evaluate the willingness to make changes (to acquire healthy eating and physical exercise habits) of both the child or adolescent and his/her family.
6. Consider the possibility of concurrent disorders associated with obesity (high blood pressure, type II diabetes mellitus, dyslipidaemia) when overweight/obesity is diagnosed in a child or adolescent.
7. Perform a general physical examination, emphasising the following:

   – General appearance (distribution of adipose tissue, muscle tone, signs of psychomotor delay).

   – Record blood pressure, evaluating percentiles for the appropriate age, height and sex. Record girth, evaluating percentiles for the appropriate age, height and sex.

   – Attitude and behaviour (signs of anxiety or depression).

   – Examination of skin and mucous membranes (jaundice, dry skin, abnormal pigmentation, acanthosis nigricans, stretch marks, acne and/or hirsutism).

   – Dysmorphic facial and body features

   – Inspection and palpation of the thyroid.

   – Any hepatomegaly.

   – State of pubic development, gynaecomastia in boys. Any premature adrenarche.

   – In girls, the age of the menarche should be evaluated, as should any menstrual irregularities.

   – Consider a full blood chemistry test to determine levels of glucose, cholesterol, triglycerides and thyroid hormones, in order to detect any other associated disorders.

   – Compensatory orthopaedic alterations.
8. Consider referral to a leading endocrinology specialist in selected cases which require subsequent diagnostic evaluation or specific treatment. This may be due to suspected underlying diseases causing obesity, diagnosis in small children, associated disorders or extreme obesity.

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Recommendations

D	BMI should be calculated and excessive body weight classed as overweight or obesity using the growth curves and tables of the semi-longitudinal study by Hernández *et al*. (1988), according to age and sex.
D	A full clinical history should be taken and a complete physical examination should be carried out, to detect obesity secondary to underlying disorders or malformation syndromes, and to exclude associated comorbidities.
D	The possibility of psychopathological conditions (anxiety, depression, bulimic behaviour) should be assessed. Such conditions may determine childhood or adolescent obesity.
D	Referral to a leading endocrinologist is recommended for obese children or adolescents with suspected underlying diseases causing their obesity, obesity in very young children, concurrence of associated disorders or extreme obesity. Referral to a leading mental health unit is recommended if there is an associated psychiatric disorder.
√	Pre-existing family dynamics should be assessed, as should the willingness of both the child and adolescent and his/her family to make changes, so that any intervention to tackle overweight or obesity can be targeted appropriately.

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5. Prevention

5.1. School-based interventions

This guideline classifies preventive interventions according to where they were carried out: schools, the healthcare system, the community and the family, although this classification system may seem arbitrary as the interventions often include actions in two or more of these spheres. Most studies conducted to date have taken place in schools, which is why this is the longest section of the guideline.

Questions to Answer

Among children and adolescents of normal weight:

- How effective are school-based interventions in preventing obesity?
- How effective are school-based interventions in improving diet, increasing physical activity levels or reducing sedentary lifestyles?

Many randomised clinical trial (RCTs) have been published regarding the prevention of childhood and juvenile obesity in schools, often with major methodological shortcomings. There have also been many SRs[9,44,45,93-103] and some CPGs[43,53,88]. However, the trials evaluated show a great deal of variation in the strategies implemented (diet, physical exercise, less time spent watching television, etc.), location (school, workplaces, etc.), family involvement or even the outcomes considered. This section has classified the information identified into interventions designed to prevent obesity (with results outcomes to measure this) and interventions designed to improve diet, increase physical activity levels and reduce sedentary behaviour. The main outcome used to measure obesity in the studies evaluated is BMI.

5.1.1. Dietary interventions to prevent obesity

A RCT conducted in the UK (644 schoolchildren aged 7-11 years) evaluated the efficacy of reducing the consumption of carbonated drinks in decreasing BMI in the children over the course of a school year. Each class taking part in the intervention received three one-hour sessions which encouraged the children to drink water or diluted fruit juice[104]. In evaluation at 12 months, consumption of carbonated drinks (number of glasses) fell significantly in the group taking part in the intervention (-0.6, CI 95%, -0.1 to -1) but not in the control group (0.2, CI 95%, -0.2 to 0.5). However, there was no significant difference in the change in the BMI z-score (BMIz) between the intervention and control classes. The percentage of overweight or obesity increased by 7.5% in the control group, while a drop of 0.2% was recorded in the group taking part in the intervention (mean difference: 7.7%, CI 95%, 2.2% to 13.1%). The authors acknowledge a shortcoming due to potential contamination, as classes rather than schools were randomised. This may have minimised the beneficial effect of the intervention and therefore reinforces the results observed.

RCT
1+

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Subsequent evaluation[105] (434 schoolchildren) analysed the results of this trial two years after the intervention ended. This found no differences in the prevalence of overweight, which had increased in both groups. RCT 1+

5.1.2. Exercise-based interventions to prevent obesity

Trials lasting one year or more

Pre-school children

Three-hundred and ten Thai pre-school children with a mean age of 4.5 years, in ten classes within two different schools, were randomised in a RCT[106]. The groups taking part in the intervention received additional physical education lessons for 29 30 weeks. In the initial evaluation at 29.6 weeks, a drop in the prevalence of obesity was found in the group taking part in the intervention as compared to the control group, but the difference was not statistically significant. RCT 1+

At the end of the trial, the overall prevalence of obesity (using P95 of the thickness of the triceps skin fold test as the cut-off point) had fallen significantly in the group taking part in the intervention, from 12.2% (initially) to 8.8%, while in the control group it fell from 11.7% to 9.7%, which was not statistically significant.

Schoolchildren

A RCT conducted in the USA (549 schoolchildren, 9.25 years) evaluated the SPARK (Sports, Play and Active Recreation for Kids) intervention, which consisted of three 30 minute sessions of physical education per week, as compared to the usual school physical activity programme[107]. Four schools were randomised into the groups that took part in the intervention (two led by specialists and two by teachers), and another two were randomised into the control group. RCT 1–

Adiposity was evaluated using triceps and calf skin fold tests, and the BMI was measured at 6 month intervals over 18 months. No significant differences between the groups were found.

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In another recent RCT conducted in Australia (311 schoolchildren, 10 years), participants were divided into four groups: behavioural modification, movement skills, a combination of the two and a control group[108]. RCT 1–

At 12 months, after adjusting for calorie intake and physical activity levels, a significant decrease in BMI was observed in the combined intervention group: -1.53 (CI 95%, -2.82 to -0.24). In comparison to the control group, those in the combined intervention group had a 60% lower probability of suffering from overweight or obesity between the beginning of the study and the end of the intervention. The children in the movement group enjoyed physical activity more, and those in the behaviour group showed higher physical activity levels but also spent more time watching television.

Trials lasting less than a year

Schoolchildren

A RCT conducted in the USA (198 schoolchildren aged 8-10 years) analysed the efficacy of an intervention which aimed to reduce time spent watching television and playing video games. This consisted of adding eighteen 30 50 minute lessons to children's standard study programme109. Results were measured initially and after six months. The change in BMI between the beginning and six months later was from 18.38 to 18.67 in the group taking part in the intervention, and from 18.10 to 18.81 in the control group. The average difference adjusted for initial values, age and sex was -0.45 (CI 95%, -0.73 to -0.17). There were also significant differences in the change in thickness of the triceps skin fold test and in girth between the group taking part in the intervention and the control group. RCT 1+

The RCT trial Action Schools! BC[110-113], conducted in Canada (268 schoolchildren aged 9-11 years) evaluated an intervention designed to increase physical activity levels over nine months and found no differences in BMI between the intervention and control groups. The intervention consisted of 75 extra minutes of intense physical activity per week, combined with changes in the school, family and community environments to promote the concept of "active school". RCT 1+

The clinical RCT by Martínez *et al.*[114], conducted in Spain over 24 weeks (1,044 schoolchildren, 9.4 years), analysed the effect of non-competitive physical recreational activities carried out at school outside school hours, and showed no differences in BMI between the intervention and control groups. However, significant differences were observed in the thicknesses of the triceps skin fold test in both sexes, and in girls also in body fat percentages. RCT 1+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The four-week RCT by Jago *et al*.[115], conducted in the USA (30 girls, 11 years), analysed an intervention involving one hour's Pilates a day five days a week as an extracurricular activity at school. A significant decrease of 3.2 points was observed in the BMI percentile of the group taking part in the intervention, versus an increase of 0.8 points in the control group (with statistically significant differences between the groups). In another RCT (425 schoolchildren, 7 years), two extra hours of physical activity per week significantly improved body composition as compared to the control group after six months, although BMI did not change and the effect was greater in obese schoolchildren than in non-obese schoolchildren[116]. Neither were there any changes in BMI in a RCT that evaluated the PLAY intervention[117] and lasted for 12 weeks (606 schoolchildren aged 9-10 years).

RCT 1-

RCT 1-

RCT 1-

Adolescents

A RCT conducted in the USA (the *New Moves* trial)[118] involved 201 girls aged 14-18 years. They were offered physical exercise four times a week, and fortnightly dietary and social support sessions. In follow-up at eight months, there were no significant differences in BMI between the schools that took part in the intervention and the control schools. The participants in the schools where the intervention had been carried out reported positive changes in their behaviour and personal factors, but the majority were not statistically significant.

RCT 1-

A 12 week RCT conducted in the USA (110 adolescents aged 10-13 years) randomised participants to carry out dance activities (three 50minute sessions per week, plus a health education programme twice a week) or to the control group, which carried out normal physical activities[119]. At the end of the trial, significant reductions in BMI were observed in the girls in the group taking part in the intervention as compared to those in the control group (change in BMI: -0.8 and 0.3 respectively). In boys, a similar trend was observed but was not statistically significant, and there were no differences between groups.

RCT 1-

A controlled trial[120] in which 58 adolescent girls were randomised to a group taking part in an intervention (special physical education lessons and theoretical support) or a control group for four months showed no significant effects on BMI. Another RCT[121] involving 2,744 girls (average age 13.6 years), in which a school environment that encouraged physical exercise was promoted in the group taking part in the intervention, also failed to find any significant differences in BMI.

RCT 1-

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

5.1.3.Dietary and exercise-based interventions to prevent obesity

Trials lasting one year or more

Pre-school children

A RCT analysed the intervention '*Hip-Hop to Health*' in encouraging physical exercise in schools with high percentages of Afro-American pre-school children[122], and observed significantly smaller increases in BMI in the group taking part in the intervention than in the control group in follow-up both at one year (-0.53 [CI 95%, -0.91 to -0.14]) and at two years (-0.54 [CI 95%, -0.98 to -0.10]), adjusted for baseline age and BMI. Turning to positive changes in diet or physical activity levels, only the percentage of calories in the diet which came from saturated fat was significant in follow-up at one year (11.6% vs 12.8%, p=0 .002). RCT 1-

A RCT conducted in schools with high percentages of Latino pre-school children[123] showed no differences between the group taking part in the intervention and the control group in follow-up at either one year or two years in terms of BMI, or in changes to diet or physical activity levels, although the intervention was very well received. RCT 1-

Schoolchildren

The Pathways[124] RCT was conducted in the USA and involved 1,704 Caucasian US children (aged 8-11 years) in 41 schools. Pathways was a multicentre, multifactor, school-centred intervention lasting three years. It aimed to reduce the body fat percentage and was led by existing school staff. The intervention consisted of four components: 1) changes in food intake; 2) increased physical activity levels; 3) a study programme centred on healthy eating and lifestyle; 4) a family involvement programme. RCT 1+

At the end of the three-year intervention no significant differences were found in BMI, skin fold tests or body fat percentages. School lunches showed a reduction in the percentage of calories from fat. Knowledge improved in the schools where the intervention was implemented over the course of the three years.

The Planet Health RCT125, conducted in ten US schools, involved 1,295 schoolchildren (aged 11-12 years). The intervention lasted two academic years, was multidisciplinary and included encouragement of physical exercise, alterations to diet and a reduction in sedentary behaviour. RCT 1+

More than 5 years may passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The primary results were BMI and the triceps skin fold test, measured initially and at 18 months. In girls, the prevalence of obesity in the control group increased (from 21.5% to 23.7%), while in the group taking part in the intervention it fell (from 23.6% to 20.3%). Follow-up evaluation showed that with the intervention the percentage of obese girls in the schools fell in relation to the controls, adjusted for initial obesity (adjusted OR 0.47, CI 95%, 0.24 to 0.93). Among boys, obesity fell in both the control group and the group taking part in the intervention (from 29.3% to 27.8% in the group taking part in the intervention, and from 34.7% to 31.5% in the control group).

The RCT of the Kiel Obesity Prevention Study (KOPS)[126], conducted in Kiel (Germany), provides results on the effect of the KOPS programme in 1,640 schoolchildren aged 5-7 years (67.2% of the 2,446 who were randomised). The programme lasted eight years. The educational and behavioural interventions were aimed at both schoolchildren and their families (eating fruit and vegetables every day; reducing intake of high-fat foods; physical exercise for 1 hour/day or more; watching television for less than 1 hour/day). RCT 1-

At one year, there was no difference in the average change in BMI between the adolescents in the two groups. In contrast, the changes in the triceps skin fold test at one year were statistically significant in favour of the group taking part in the intervention (11.3 mm in the schools taking part in the intervention 11.3 mm, versus 13.0 mm in the control schools).

The results of the KOPS programme[127] at four years showed no differences in mean BMI between the two groups (1,764 schoolchildren aged 6-10 years). The cumulative incidence rates of overweight in the intervention and control groups were similar. The intervention did have a significant effect on the prevalence of obesity and overweight in children from families with high socioeconomic status (adjusted OR 0.35, CI 95%, 0.14 to 0.91), and a smaller difference in children whose mothers were of normal weight (OR 0.57, CI 95%, 0.33 to 100). RCT 1-

The RCT APPLES (Active Programme Promoting Lifestyle in Schools) conducted in England (634 schoolchildren aged 7-11 years), evaluated a one-year multidisciplinary programme designed to influence dietary and exercise-related behaviour. The whole school community was involved, including families, teachers and meal supervisors[128]. Controls received the usual study programme. RCT 1+

More than 5 years have passed since the publication of the Clinical Practice Guideline and its validity has not been reviewed

At one year, there were no differences in the change in BMI between the schoolchildren in the two groups, and no differences in dietary behaviour. However, participants in the group taking part in the intervention reported that they now ate more vegetables. Sedentary behaviour was greater in schoolchildren with overweight in the group taking part in the intervention than those of overweight in the control group, and the overall score for personal value was greater in obese schoolchildren in the group taking part in the intervention than obese children in the control group.

Be Smart[129], a RCT conducted in England, randomised 218 schoolchildren aged 5-7 years from three schools to four options: 1) a nutrition group; 2) a physical exercise group; 3) a combined nutrition and physical exercise group; 4) a control group. The intervention took place over 20 weeks, spread over four terms (approximately 14 months), and was held in the lunch areas. The research team provided an interactive nutrition or physical exercise programme suited to the children's ages. These programmes included the children's families. The control group received an education programme which covered non-nutritional aspects of food and human biology. RCT 1-

At the end of the study, no significant changes in overweight or obesity rates were observed as a result of the three different approaches, and the number of subjects was too small for statistical analyses. Significant changes were found in the level of knowledge reported personally and in diet. This trial may have been affected by ceiling effects, as the population studied had received a fairly good education and 39% of their parents held a degree and/or postgraduate qualification.

The Wise Mind Project[130] RCT, conducted in the USA in 670 children in the 2nd 6th grades of primary school in four schools, evaluated the efficacy of a multidisciplinary school-based intervention over two academic years. Results were collected from the 586 schoolchildren who remained in the study (87.5% of those who began it). RCT 1+

No significant differences in BMI percentile were found between the treatment and control groups. Neither were significant differences found regarding prevention of weight gain or body fat percentage.

Differences were observed, however, in diet, choice of food and leftovers. Those in the group taking part in the intervention consumed fewer calories, less protein and less total and saturated fat. A marginally significant improvement was also found in physical activity levels, as measured by the SAPAC (Self-Administered Physical Activity Checklist) questionnaire.

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The RCT on the School Nutrition Policy Intervention[131], conducted in the USA in 1,349 schoolchildren in the 4th 6th grades in schools where more than 50% of pupils were from low socioeconomic levels, analysed a two-year multidisciplinary intervention: self-assessment of the school, nutritional education, changes in meal policy, social marketing and workshops with families.

RCT
1+

The intervention resulted in a significant, 50% reduction in the incidence of overweight in the group taking part in the intervention versus the control group: 7.5% versus 14.9% at two years (adjusted OR: 0.67, CI 95%, 0.47 to 0.96). No significant differences were found in the incidence of obesity between the two groups. The prevalence of overweight fell at two years in the group taking part in the intervention (from 16.3% to 14.6%), whereas it increased in the control group (from 15.9% to 20%) (adjusted OR: 0.65, CI 95%, 0.54 to 0.79). No significant differences were found regarding the prevalence of obesity between the two groups. The intervention was not effective in reducing the prevalence of overweight/obesity in schoolchildren who had these disorders at the beginning of the study.

A controlled, non-randomised trial[132] conducted in the USA involving 338 schoolchildren (aged 8-11 years) analysed a two-year multidisciplinary intervention intended to reduce calories, fat and sodium in school meals and hold formal meetings with kitchen staff five times a year. Nutritional education modules and a 30-40 minute physical exercise programme three times a week were also carried out. The physical exercise programme emphasised aerobic lifestyle activities rather than competitive games.

Controlled, non-randomised trial
1-

Follow-up found that although there were some positive changes in objective behaviour, at the end of two years there had been no effect on obesity.

Adolescents

The Haerens RCT[133-135] was conducted in Belgium with 2,840 adolescents in classes 7 and 8 of technical and professional training schools (mean age 13.0±0.8 years). 2,287 adolescents (80.5%) completed the trial. The intervention lasted for two years and included a healthy-eating programme (consumption was measured using questionnaires) and an exercise programme (measured using questionnaires and accelerometers), combining various changes in the school environment with an interactive IT program. One group also included a family intervention.

RCT
1+

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

In girls, BMI and BMIz increased significantly less in the combined group taking part in the intervention with family support as compared to the control group and the group without family involvement. In contrast, no significant effects were found in boys.

Studies lasting less than a year

Pre-school children

A RCT[136] involving 54 children in the group taking part in the intervention and 47 in the control group, all aged 5-6 years, analysed a 14 week multidisciplinary intervention involving dietary education and an exercise plan for the children (45 minutes/day, six days a week), accompanied by an educational intervention for their families.

RCT

1+

Positive changes were observed in the group taking part in the intervention as compared to the control group in weight (0.35±0.08 kg versus 0.9±0.1 kg, p<0.0005), BMI percentile (-3.8±1.3 kg/m2 versus 2.9±1.5 kg/m2, p<0.001), fat percentage in skin fold test (-0.65±0.3% versus 1.64±0.3%, p<0.028) and physical condition, estimated using the time taken to run a 600 m race. Physical activity levels were significantly higher in the group taking part in the intervention than in the control group.

Schoolchildren

A controlled trial conducted in Chile[137] analysed the effects of a six-month intervention which consisted of improving nutritional information education and encouraging physical exercise in 2,375 primary-school children.

Controlled, non-randomised trial

1-

In the evaluation at the end of the intervention, there was no significant difference in BMI between the children taking part in the intervention and the controls: BMI 19.5 (SD 3.7) vs 18.9 (SD 3.3), or at six-month follow-up: 19.5 (SD 3.5) vs 19.2 (SD 3.1). The z scores for girth and BMI did improve in the children involved in the intervention, but none changed significantly and there were no similar findings for the triceps skin fold test. Girls showed no significant differences in anthropometric measurements, but like boys did improve in the same tests of physical condition with the intervention, and there were differences between the intervention and control groups.

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One RCT evaluated an educational intervention carried out by teachers. The intervention consisted of altering the school curriculum and increasing aerobic physical exercise (1,013 primary-school children)[138]. At the end of the study (which lasted one school year) a significant decrease of 2% was observed in overweight (BMI>85%) in the group taking part in the intervention, along with an increase in fruit and vegetable consumption (in both groups) and in physical activity (in the group taking part in the intervention).

RCT
1-

The Amaro RCT[139], conducted in Italy (307 children aged 11-14 years) analysed an educational intervention in the form of Kaledo, an educational board game played by the children, in 15-30 minute weekly sessions for 24 weeks. No differences were found between the Kaledo and control groups regarding the daily time spent on physical exercise or in changes in BMIz. The children who had played Kaledo did show a significant increase in nutritional knowledge and weekly vegetable consumption, 3.7 portions (CI 95%, 3.5 to 4.1) in the group taking part in the intervention versus 2.8 portions (CI 95%, 2.4 to 3.3, p<0.01) in the control group.

RCT
1-

A RCT that evaluated changes in the canteen and school environment and a programme which promoted healthy eating, physical exercise and changes to behaviour, with changes to the school curriculum (1,000 adolescents aged 12-13 years), showed no significant differences in BMI between the intervention and control groups after eight months[140].

RCT
1-

5.1.4. Interventions to improve diet

Several SRs have evaluated the efficacy of interventions designed to improve diet. The SR by Thomas[141] had the following aims: to evaluate the efficacy of interventions intended to promote healthy eating and increase the intake of fruit and vegetables, to explore what enabled and prevented children aged 4-10 years from eating healthily, and to collate information on the perceptions of the children themselves.

SR of RCTs
1++

Almost all studies concerned multidisciplinary interventions, including class activities and activities which involved the whole school. Around half of them also included family or community-based interventions. In most studies it was the teachers themselves who carried out the interventions. 19 studies were included, 11 of which were RCTs.

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– Fruit consumption: meta-analysis of ten studies involving various interventions showed a statistically significant increase in the number of portions of fruit consumed. The difference was equal to two thirds of a portion of fruit per day (standardised mean difference [SMD] 0.10, CI 95%, 0.03 to 0.17). Three of the studies showed no differences between intervention and control groups.

– Vegetable consumption: meta-analysis of twelve studies showed a statistically significant increase in vegetable consumption, slightly less than 1/5 of a portion extra per day (SMD 0.23, CI 95%, 0.11 to 0.34). One study did not reveal any differences and another showed lower consumption in the group taking part in the intervention.

– Combined fruit and vegetable consumption. Meta-analysis of thirteen studies found a statistically significant increase in combined fruit and/or vegetable consumption, slightly less than half a portion extra per day (SMD 0.23, CI 95%, 0.11 to 0.35).

– Knowledge, attitudes and self-efficacy. Meta-analysis of seven studies showed a significant improvement in knowledge (effect size 0.67, CI 95%, 0.54 to 0.79), equivalent to an increase of one grade in compulsory subjects. Meta-analysis of the three studies which analysed attitudes found a significant improvement (effect size 0.65, CI 95%, 0.38 to 0.91). Meta-analysis of seven studies which analysed self-efficacy showed a small improvement (effect size 0.69, CI 95%, 0.00 to 0.17).

The authors conclude that various different interventions have a positive, though small, effect on children's fruit and vegetable consumption. The interventions which have the greatest positive effects are those involving parents with cardiovascular risk factors and those which concentrate explicitly on fruit and vegetable consumption, excluding other aspects such as exercise or reduced salt or fat intake. Interventions which take only one approach, such as lessons or shops selling only fruit, are ineffective.

The most effective interventions were those which concentrated on enjoyment or pleasure in food rather than health-related aspects and authors considered it necessary to involve children in the design of interventions and messages. It is easier to increase fruit consumption than vegetable consumption. Making school-centred interventions effective requires skill, time and the support of a range of people.

Shepherd's SR[142] had the following aims: to draw a systematic picture of what helped and hindered young people aged 11-16 eating healthily, particularly young people in 'socially excluded' groups (those with few financial resources and ethnic minorities); to evaluate the efficacy of interventions designed to improve the diets of these groups in priority areas; and to collect information on the perceptions of young people themselves.

SR of RCTs
1++

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Four RCTs and two controlled, non-randomised studies met Shepherd's criteria. Nearly all of these were studies on multidisciplinary interventions, including class-based, school-based, home-based and sometimes community-based activities.

Two RCTs showed efficacy of increasing the availability of fruit and vegetables[143,144]. Another two RCTs[143,145] and one controlled, non-randomised study[146] showed that teachers, school staff and other pupils are effective ways for nutrition-related interventions in schools to increase fruit and vegetable consumption and knowledge and to improve attitudes.

This SR concluded that there is some evidence that multidisciplinary interventions can be effective, although the effect tends to vary according to age and sex. The authors think that interventions that design messages tailor-made for each group are promising and worthy of evaluation. One key factor is the value young people attach to being able to choose and their autonomy regarding food. The authors also believe that increasing the range and variety of healthy snacks and meals available in schools and recreational facilities allows them to choose healthy, tasty options.

Another SR includes information from 15 controlled studies: 11 randomised and 4 non-randomised[147]. Twelve of the studies were conducted in the USA, two in the UK and one in the Irish Republic. Because of the varied nature of the interventions and the ways in which the results were measured, no meta-analysis was carried out. There were no differences between the effects of the randomised and non-randomised studies.

SR of RCTs
1++

Of the 11 studies in primary-school children, nine showed a significant increase in fruit and vegetable consumption, with an interval of 0.3 to 1 piece or portion per day, while two studies showed no differences. Of the four interventions in secondary-school children, only one had a positive effect, and only in girls[125]. The other three revealed no differences between the treatment groups and the control groups[144,148,149].

The factors which appeared to be associated with greater impact were as follows (the order in which they appear here is not the order of importance): concentrating on fruit and vegetables rather than nutrition in general; direct exposure to fruit and vegetables (tasting and/or cooking); particular attention to teachers' training; pupils' participation as leaders or the use of comic-book characters; kitchen staff involvement; family involvement at school and at home; community involvement; and length of intervention (generally, the longer an intervention lasted the more effective it was).

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The authors conclude that there is evidence in favour of multidisciplinary interventions to promote fruit and vegetable consumption in children.

One SR (8,156 schoolchildren, seven studies, of which only three were RCTs) aimed to evaluate whether or not school-based interventions could be effective in increasing fruit and vegetable consumption, and if the effect of these interventions was altered by dose, duration and/or type of intervention[150]

SR of RCTs
1-

By combining the results of several individual studies, meta-analysis revealed a difference of 0.38 (CI 95%, 0.31 to 0.44) more portions of fruit or vegetables in children who received an intervention versus control groups. They had access to individual data, and combined analysis of them found a slightly greater effect (0.45 portions more), which was also statistically significant. Meta-analysis of the seven studies showed that the net relative change in fruit and vegetable intake was a 12% increase in pupils in groups taking part in interventions, whereas it had fallen by 6% in the control group. This result is statistically significant.

Analysis of covariables revealed that both being in a higher class at the beginning of the study (older children) and the time-intensiveness of interventions were inversely correlated to the net favourable relative change in fruit and vegetable consumption. In other words, the most effective interventions were those involving the youngest children and those lasting the least time. The authors recommend that this latter finding be treated with caution, as analysis is based only on school-based interventions and does not take into account the relative influence of the other aspects of interventions (family, canteen, community, media).

Another SR aimed to learn from five studies funded by the UK Food Standards Agency on various different interventions designed to alter eating habits in UK schools and reflect on the outcomes which might make an intervention viable and effective[151]. Only two of the studies were randomised. Although they had different approaches, all showed a moderate increase in fruit consumption and could potentially be put into practice in schools.

SR of RCTs
1-

An SR of observational studies[152] which aimed to analyse the environmental factors related to consumption of calories, fat, fruit, vegetables, snacks, fast food and sugary drinks in children and adolescents did not find any evidence in favour of making fruit and vegetables available in schools.

SR of observational studies
2+

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Some subsequent RCTs have evaluated various environment and curriculum-based interventions, with inconsistent results: three RCTs showed no significant differences in fruit and vegetable consumption[153- 155], while another one (1,730 schoolchildren aged 5-14 years) compared two interventions over a full school year and found them to be equally effective in increasing fruit and vegetable consumption[156]. Meanwhile, the Bere RCT157 (517 schoolchildren, mean age 11.3 years) followed children for 2.1 years and showed a statistically significant difference in fruit and vegetable consumption of 0.6 portions per day more in the group taking part in the intervention than in the control group.

RCT
1-

5.1.5. Interventions to increase physical activity levels

One SR, designed to review the efficacy of educational, environmental and multidisciplinary interventions to encourage physical exercise in children and adolescents, included 47 RCTs[158].

SR of RCTs
1+

It was impossible to combine the results of different trials, as they included many different types of intervention, target population and quality of design. Results were also reported in various different ways. Trials with significant results were variable. For example, in those which yielded significant results increases ranged from 2.6 minutes in physical education (PE) lessons, 42% in taking regular physical exercise, up to 83 min/week of moderate or intense physical exercise.

In children, results were found only in favour of interventions involving children of low socioeconomic status and environmental interventions. Even this evidence was limited. In adolescents, clear evidence was found in favour of multidisciplinary and school-based interventions, but with family or community involvement. No positive effect was observed for other types of intervention.

One RCT involving 2,840 adolescents from 15 schools[159,160] compared the results of an intervention that encouraged exercise and a healthy diet (including environment-based activities and computer support) with the same intervention with family support and a control group. At nine months, physical activity had increased significantly in the intervention group with family support (6.4 minutes more per day) and in the group with the intervention alone (4.5 minutes more per day) in comparison to the control group. However, low-intensity physical activity fell significantly, by 21 minutes per day in the intervention group with family support and by 57 minutes in the control group.

RCT
1-

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Other RCTs evaluated PE-based interventions in schools: one[161] showed increases of around 7% in children who walk to school and in the time spent on moderate/intense physical activity in PE lessons in the intervention group as compared to the control group. Another RCT162 showed a 7% increase in maximum oxygen consumption. Lastly, another RCT163 found no increase in the distance run in nine minutes in girls, but did find a slight increase in boys, of around 3%. RCT 1-

5.1.6. Interventions to reduce sedentary lifestyles

Pre-school children

A RCT conducted in the USA (176 pre-school children aged 2.6-5.5 years) analysed an intervention which consisted of seven 20 minute interactive educational sessions over six months, plus supplementary materials and activities suggested for lessons and families[164]. In the intervention group, there was a drop in the number of hours spent watching television of 3.1 hours/week, whereas there was an increase of 1.6 hours/week in the control group (p=0.02). The percentage of pre-school children who watched television for more than two hours per day fell from 33% to 18% in the intervention group, while it increased from 41% to 47% (p=0 .047) in the control group. RCT 1-

Another two RCTs[122,123] analysed the intervention 'Hip-Hop to Health' in schools with high percentages of Latino and African American pre-school children. Hip-Hop to Health included three educational sessions a week for 14 weeks, accompanied by 20 minutes of aerobic exercise. No differences were found between the intervention and control groups in terms of the number of hours per day spent watching television. RCT 1-

Schoolchildren

In one recent RCT, 70 schoolchildren aged 4-7 years (BMI≥P75) were randomised to an intervention group, in which the time spent watching television was gradually reduced and families suggested alternative activities, or a control group with free access to television[165]. After 24 months, significant reductions were observed in the mean number of hours spent watching television in the intervention group (-17.5, standard deviation [SD] 7.0 per week, vs -5.2 [11.1] in the control group) and in BMIz as compared to the control group (-0.24 [0.32] vs -0.13 [0.37]). There was a greater reduction in calorie intake in the intervention group than in the control group, with significant differences between baseline and 18 and 24 months. RCT 1+

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In another RCT conducted over six months in the USA, 221 girls in 9th grade were randomised to a standard PE lesson or an in-class educational intervention plus reinforced physical exercise166. The intervention emphasised social interdependency, environmental factors and problem-solving skills.

RCT
1-

The percentage of girls who spent three hours or more per day watching television fell from 22.3% to 17% in the intervention group, and remained constant at 26.7% in the control group.

Another three RCTs have shown inconsistent results: one of them (198 schoolchildren aged 8-10 years), with an intervention consisting of 18 lessons over seven months[109], showed a statistically significant decrease of 5.53 hours/week (CI 95%, -2.42 to -8.64 hours/week) of television, and 2.54 hours/week (CI 95%, -4.48 to -6.0 hours/week) spent playing video games as compared to the control group. The RCT APPLES (Active Programme Promoting Lifestyle in Schools) (634 schoolchildren aged 7-11 years) with a multidisciplinary programme lasting one year found no significant differences between the control and intervention groups in terms of sedentary behaviour, measured as the number of hours spent watching television in the previous 24 hours (0, CI 95%, -0.1 to 0.1), except that it was greater in overweight children in the intervention group than in overweight children in the control group (0.3, CI 95%, 0.0 to 0.7)[128]. However, the Planet Health RCT (1,295 schoolchildren aged 11-12 years) evaluated a multidisciplinary intervention which reduced the number of hours spent watching television in girls (-0.58 hours/day, CI 95%, -0.85 to -0.31 hours/day, p=0.001) and in boys (-0.4 hours/day, CI 95%, -0.56 to -0.24 hours/day, p<0.001)[125].

RCT
1+

1+

A 16 week controlled study in 312 schoolchildren with an average age of 10.2 years (+/- 0.7) in ten schools in socially-deprived areas[167] analysed the educational intervention 'Switch Off-Get Active', designed to increase physical activity levels and reduce the number of hours spent watching television. No significant differences were found between the control and intervention groups in terms of time spent watching television.

Controlled, non-randomised trial
1–

Evidence summary

Dietary interventions to prevent obesity	
1+	School-based interventions aimed at reducing the consumption of carbonated drinks do not significantly reduce overweight or obesity[104,105].
Exercise-based interventions to prevent obesity	

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1-	In trials lasting one year or more, school-based interventions aimed at encouraging organised physical exercise in pre-school children are moderately effective in preventing obesity while the interventions last[106]. Those conducted in primary schools have shown inconsistent results: one RCT did not show any difference in BMI[107], whereas another did[108]. In trials lasting less than a year, school-based interventions aimed at increasing physical exercise alone showed no significant change in BMI[109,110,114,121].
Dietary and exercise-based interventions to prevent obesity	
1+	Multidisciplinary interventions to prevent obesity which include encouraging physical exercise, diet improvement, reduction of sedentary behaviour and family involvement do not lead to significant decreases in BMI, although they do significantly increase fruit and vegetable consumption[122-133,136,140]. There have been no trials analysing the Spanish population.
1+	Multidisciplinary interventions aimed at preventing obesity in schools have a greater effect in girls[125,133], and may be more effective in groups of high socioeconomic status[127].
Interventions to improve diet	
1-	Multidisciplinary interventions improve fruit and vegetable consumption and diet[128-130,132,139].
CHILDREN	
1++	Information from various SRs[141,142] shows positive effects on diet as a result of multidisciplinary interventions which include in-class activities and activities based in the school as a whole, in combination with a family or community-based intervention. The interventions with the greatest positive effects are those in children whose parents have cardiovascular risk factors and those which concentrate explicitly on fruit or vegetable consumption, excluding other aspects such as exercise or reducing salt or fat consumption. Single-component interventions seem ineffective. The most effective interventions are those which emphasise taking pleasure in food rather than health-related issues. It has been shown to be easier to increase fruit consumption than vegetable consumption.
ADOLESCENTS	
1+	Multidisciplinary interventions that include in-class activities, activities in the school as a whole and in families and communities can be effective in improving diet, although efficacy tends to vary according to age and sex[142].
Interventions to increase physical activity levels	

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1++	One SR[158] shows that some educational, environmental and multidisciplinary interventions are effective in promoting physical exercise in children and adolescents. These interventions achieved increases in physical activity levels from 2.6 to 83 minutes of overall physical activity per week. In interventions involving schoolchildren, there is only limited evidence in favour of interventions in children of low socioeconomic status and environmental interventions. In adolescents there is firmer evidence in favour of school-based interventions, but with an added component of family involvement.
Interventions to reduce sedentary lifestyles	
1+	Interventions aimed at reducing sedentary lifestyles in preschool children and primary-school children yield inconsistent results[109,122,123,125,128,164-166].

Recommendations

B	Schools must promote physical education and sporting activities, both within and outside school.
C	Schools should include educational programmes which aim to improve diet, increase physical activity levels and reduce sedentary lifestyles. These should include families and teaching staff.
C	Interventions in schools must be continued over time, both during school years and outside the school environment.
B	Food eaten in schools must be healthy, including a range of fruit and vegetables and meals low in fats and sugars.
B	Multidisciplinary interventions should be implemented in schools to encourage children and adolescents to eat fruit and vegetables.
√	A healthy dietary environment must be created in schools, reducing the availability of foods with high calorie contents (vending machines) and making healthy foods readily available.
B	Physical activity should be promoted among children and adolescents via interventions which target more than one environment (school, family, community). These should include environmental interventions.
√	Both families and professionals who work in schools must be included in school health education programmes. School activities aimed at reducing time spent watching television, playing video or computer games or using mobile phones should be encouraged.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

5.2. Healthcare interventions

Questions to Answer

In children and adolescents of normal weight:

- How effective are healthcare interventions in preventing obesity?
- Does measuring height and weight reduce the incidence of overweight and/or obesity?
- Do regular screening programmes prevent overweight and/or obesity?
- Does advice on diet and exercise and on reducing sedentary lifestyles prevent overweight and/or obesity? Does it improve knowledge of these three subjects? Does it lead to healthier habits?
- In breastfed babies, does continuing breastfeeding prevent overweight and/or obesity when the children are older?

Identifying children and adolescents who are overweight or have a high risk of developing obesity is an activity usually performed by healthcare services. In our context, it is carried out essentially in primary care services, by both paediatricians and nursing staff. These consultations can also explore and detect unhealthy food-related behaviour and sedentary lifestyles, identify children at greater risk of becoming overweight and begin taking steps to prevent this, involving both children and their families. This section summarises the information available on the interventions carried out within the sphere of healthcare to prevent childhood and juvenile obesity.

5.2.1 Measuring height and weight

Children's height and weight can be measured at healthcare services using standardised techniques and well-calibrated tools, either routinely or opportunistically, in children who consult a doctor for reasons other than regular check-ups. The measurements recorded must be compared with the specific standard percentiles for the child's sex and age in a reference population (see the section *Defining Overweight and Obesity*).

SR of studies of diagnostic tests

2-

One SR which aimed to evaluate the efficacy of monitoring and screening for overweight and obesity in children[168] was unable to identify any controlled studies which compared height and weight measurement with not taking these measurements in the detection and treatment of childhood and juvenile obesity. Eleven studies of various diagnostic tests for overweight and obesity in children were identified, but they did not include any information on long-term usefulness. No other studies evaluating the efficacy of measuring height and weight in preventing and treating childhood and juvenile obesity have been identified.

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5.2.2 Screening programmes

Two SRs[168,169] were identified. They found no direct information to show that screening for overweight or obesity in children and adolescents (with the relevant intervention if necessary) improves food- or exercise-related behaviour, physiological measurements (BMI or body fat) or health outcomes.

SR of studies of diagnostic tests

2-

The first of these169, which served as the basis for the recommendations of the US Preventive Services Task Force on screening and interventions in childhood obesity, reviewed the information available to find out which diagnostic tests to screen for overweight in children are reliable and valid in predicting obesity in adulthood.

SR of studies of diagnostic tests

2-

Nineteen cohort studies of good methodological quality on BMI and other weight measurements in childhood and adulthood were identified. These confirmed that BMI measurements show a lifelong correlation as good as or better than other measurements of overweight (e.g. ponderal index or skin fold measurements). Isolated BMI measurements in childhood or adolescence (6-18 years) are similar to BMI measurements in early adulthood (20-37 years), with moderate correlations observed in follow-up studies between BMI measurements in childhood and adulthood.

The second SR[168] evaluated the reliability and validity of diagnostic tests to screen for overweight in children for predicting results in adulthood.

SR of studies of diagnostic tests

2-

It identified 11 observational studies conducted in the USA which examined the risks associated with childhood overweight and its repercussions in adulthood, including socioeconomic outcomes, mortality rates and several diseases and cardiovascular and other risk factors. These studies rarely controlled for BMI in adulthood, which is a major cause of confusion. In the one study that did do so, the apparent association between BMI at 10 years of age and various increased cardiovascular risk factors (total cholesterol, LDL, insulin levels, blood pressure) disappeared in the analysis.

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The opinion of the Childhood Obesity Working Group of the US Preventive Services Task Force[170] is that although BMI is a simple measurement which is convenient and widely recommended in identifying obesity, it is not clear which BMI values are correlated with good future health. BMI in children seems to correspond to BMI in adulthood, although prediction is weak at early ages and improves mainly from preadolescence onwards. Other risk factors, such as genetics, good fitness levels, ethnicity or sex, may significantly affect health outcomes, so that the long-term risk may be greater for children of "normal" weight than for those classified as overweight on the basis of their BMI alone.

Expert opinion
4

Regarding a potential negative effect of screening, no specific studies analysing possible harm caused by a programme to detect overweight or obesity in children and adolescents have been located.

Expert opinion
4

The potential negative effects that have been mentioned include the following[169,171]:

– Stigma, due to people being labelled as 'obese' or 'ill',
– Low self-esteem, unhappiness with one's own body, feelings of guilt,
– Unsuitable, unhealthy diets of those affected or members of their families with adverse consequences, such as yo-yo dieting,
– Exercise-related injuries,
– Family anxiety,
– Inefficient use of resources if this has no positive effect or resources could be used for another activity with a better cost/benefit ratio.

5.2.3. Dietary interventions

No specific RCTs in children or adolescents have been found regarding healthcare interventions aimed exclusively at diet in preventing obesity. This section reviews the effect of breastfeeding.

5.2.3.1. Breastfeeding

Four SRs have analysed the information available on the impact of breastfeeding on childhood obesity[172-175]. These include only observational studies.

SR of observational studies
2+

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The Arenz SR[172] concluded that breastfeeding has a small but consistent protective effect against childhood obesity (OR 0.78, CI 95%, 0.71 to 0.85). A dose-effect ratio was also observed: the longer breastfeeding lasts, the lower the risk of obesity.

The Harder SR[173], which explicitly analysed the relationship between duration of breastfeeding and obesity, also confirmed an inverse relationship between the length of breastfeeding and the risk of obesity, which was lower the longer breastfeeding lasted. For each month of breastfeeding, there was a 4% drop in the risk of obesity. This effect lasted up to nine months of breastfeeding, and was independent of the definition of overweight and the age of follow-up.

The Owen SR[174], which analysed the effect on subsequent obesity in both childhood and adulthood, showed that the mean BMI was slightly lower in those who had been breastfed (-0.04, CI 95%, -0.05 to -0.02). However, the authors felt that the difference was small and may be significantly influenced by a publication bias and other causes of confusion. Analysis adjusted for socioeconomic status, maternal tobacco consumption during pregnancy and maternal BMI showed that in many of the studies the effect disappeared.

One final SR[175] showed that it is more unlikely that people who have been breastfed can be classed according to obesity or overweight criteria (OR 0.78, CI 95%, 0.72 to 0.84) with no adjustments for age group, length of breastfeeding or control of outcomes that might cause confusion (socioeconomic status and parents anthropometry).

Regarding the promotion of breastfeeding to prevent overweight or obesity, several Cochrane SRs have been identified that analyse the effect of various interventions designed to encourage breastfeeding, but none of these evaluate the potential effect on preventing childhood obesity or on children's BMI[176-179]. Other systematic or narrative reviews analyse interventions designed to encourage breastfeeding in various environments, but these do not evaluate the effect on obesity prevention, either[180-182].

Only one cluster RCT analysed the effect of encouraging breastfeeding in the prevention of childhood obesity (Prevention Promotion of Breastfeeding Intervention Trial, PROBIT)[183]. This analysed the effects of an intervention designed to encourage exclusive breastfeeding over long periods on height, weight, adiposity and blood pressure at 6.5 years, in comparison to the breastfeeding directives used in the hospitals in the control group. No significant differences in any of these outcomes were observed between the children in the intervention group and those in the control group.

RCT
1+

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On the basis of several SRs, the World Health Organization[184] recommends that newborns be exclusively breastfed up to the age of six months wherever possible, as there is conclusive proof of the benefits of breastfeeding for the short- and long-term health of mothers and newborns. These benefits include the following[178]:

SR of RCT
1+

– Short-term: reduced mortality in premature babies, lower infant mortality due to digestive, respiratory, urinary and middle-ear infections, fewer atopic diseases.
– Medium-term: protection from childhood diseases such as juvenile-onset insulin-dependent diabetes mellitus and high blood pressure, and diseases later in life, such as atopic diseases and high blood pressure. Breast milk is also associated with significantly higher cognitive development scores.
– On the mother's health: lower incidence of breast and ovarian cancers and hip fractures.

5.2.4. Exercise-based interventions

A narrative review of interventions designed to promote physical exercise in children and adolescents[185] located three primary-care studies: one in Spain[186], one in Ireland and one in the USA[188].

Schoolchildren

Two low-quality studies were found. The most recent is a pilot study[188] conducted in 28 African American families with low income levels and children aged between 7 and 12. Both the control group and the intervention group received a family session advice session lasting 5-10 minutes and a leaflet on the risks of spending excessive amounts of time watching television. The intervention group also received an extra 20 minute session to explain how much time was permissible, as well as an electronic device to manage time spent watching television. At four weeks, a significant increase was found in the intervention group in terms of participation in organised sports (2.5 hours more per week) and in time spent playing outdoor games (1 hour more per week).

Controlled, non-randomised trial
1-

The Irish Galway Health Project[187], which was not controlled, targeted schoolchildren (aged 8-15 years) in primary healthcare centres. The intervention, which lasted ten minutes, consisted of an interview with a doctor or nursing staff and an educational leaflet. At one year no significant changes were observed in exercise habits.

Before-&-after study
2-

Adolescents

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A RCT conducted in Spain involving 448 adolescents aged 12-21 years was identified. The adolescents were tracked for one year186. In the intervention group, doctors gave the adolescents three ten-minute advice sessions on physical exercise, while the control group received no exercise and no intervention. On the basis of the data from 392 adolescents who completed the study, there were increases in physical activity levels in the intervention group at 6 and 12 months of 36 and 48 min/week respectively, while in the control group there were decreases of 28 and 36 min/week. RCT 1-

The Childhood Obesity Working Group of the US Preventive Services Task Force[170] states that although intensive medical advice given in specialist obesity clinics to selected groups of children achieves sustained drops in overweight of between 7% and 25%, no proof has been found for interventions conducted in paediatric primary care services. Similarly, although community-based interventions that may contribute to healthy lifestyles have been identified, little is known as to whether primary care professionals can be effective in generating and serving as links between patients and their families and these community-based services.

Also, there is no information available on the efficacy of paediatrics or primary care interventions, or on their effect on families. Except in the case of older children, interventions should be aimed at the whole family.

5.2.5. Dietary and exercise-based interventions

Three RCTs in adolescents have been located in this field[189-191]. A RCT conducted in the UK[190] involving 1,516 adolescents aged 14-16 years, recruited from primary care registers, analysed a 20 minute nursing intervention. This consisted of giving advice on healthy behaviour, including diet and exercise. No significant changes were identified in physical activity levels at three months or at twelve months. Far more adolescents in the intervention group reported positive changes in relation to diet and exercise at three months, but the differences between them and the control group could not be demonstrated objectively twelve months after the intervention. RCT 1+

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The first PACE+ (Patient-Centred Assessment and Counseling for Exercise plus Nutrition)189 study was conducted in the USA in 117 adolescents aged 11 18 years, in primary healthcare. Each participant underwent a computer-assisted evaluation on their exercise and dietary habits, and chose which area or behaviour they wanted to change (moderate physical activity, vigorous physical activity, fat intake or fruit and vegetable intake). Next, a plan and targets for change were established and then approved by the medical professional, who gave specific advice. The participants were then randomised to either having no more contact with the professional or receiving more advice from him/her by email or telephone. At four months, improvements were found in all target areas except vigorous physical exercise. No significant differences were observed between the results of those who had been randomised to have more contact with professionals and those who had not.

RCT
1+

The second PACE+ study[191], conducted in 878 children and adolescents aged 11-15 years, included a control group that received advice on protection from sun exposure. The intervention group included the PACE elements of the previous study, plus 12 months of advice by email or telephone. No differences in BMI were found between the two groups, but those in the intervention group significantly reduced their sedentary behaviour levels, by around one hour per day, while in the control group sedentary behaviour remained the same or increased by 0.2 hours per day. In the intervention group there was also a significant increase in the average number of active days per week (+0.3) in boys, and in fruit and vegetable consumption in the girls, with 0.3 portions more per day than in the control group. In the intervention group the percentage of girls who put recommendations on saturated fat consumption into practice was significantly higher, as was the number of days per week with physical exercise for boys.

RCT
1+

One controlled, non-randomised trial evaluated the efficacy of motivational interviews in preventing childhood obesity[192]. Fifteen paediatricians and five dieticians were assigned to a control group, a minimum intervention group (one interview with the paediatrician) or an intensive intervention group (two interviews with the paediatrician and dietician). The professionals for the intervention groups were trained in giving motivational interviews. Ninety-one children were enrolled in the trial (aged 3-7 years, BMI P85-P95 or one family member with BMI>30), and saw the paediatrician for a follow-up visit. At six months' follow up, there were decreases in the BMI percentiles of all three groups, with no significant differences, although 94% of families reported that the intervention had made them think about their lifestyles.

Controlled, non-randomised trial
2+

More than 5 years have passed since the publication of this clinical practice guideline, and its validity has not been reviewed

NICE's guideline[43] provides indirect evidence on preventive studies in healthcare conducted in adults, with the following conclusions: CPG 4

- Long-lasting interventions carried out by primay care professionals and targeting diet and/or physical exercise are effective in maintaining a healthy weight.
- Interventions that combine dietary advice and support and physical exercise are more effective in achieving weight control aims than interventions that concentrate on physical exercise alone. There is no reliable information on interventions that target diet only.
- Although some interventions do not achieve favourable weight changes, they can achieve positive changes in diet and physical activity.
- Educational or behavioural interventions to increase physical activity levels are moderately effective, particularly in promoting moderate exercise outside facilities or sites, such as walking, although these improvements may not be maintained over time.
- There is some evidence, though limited, that free access to sports facilities, used as an incentive, increases physical activity levels, but only while the intervention lasts.
- Moderate or intensive dietary interventions tend to achieve significant reductions in fat intake and increases in fruit and vegetable consumption.
- Brief interventions consisting of dietary advice given by health professionals may be effective in improving diet, but they achieve smaller changes than more intensive interventions.
- The most effective interventions are usually those that combine the highest number of components.

The following conclusions can be drawn on the implementation of interventions, in relation to adults in each case:

- For the efficacy of interventions consisting of dietary advice, customising the advice to the specific barriers and circumstances of each individual case (tastes, costs, availability, points of view of family members, time) is more important than where the advice is given.
- For the efficacy of interventions which encourage physical exercise, it is essential that advice is suited to the specific barriers and circumstances of each individual case: lack of time, access to sports facilities, need for moral support or individual beliefs.

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– The specific type of professional that gives the advice is not a key factor, provided that they are sufficiently trained and experienced, enthusiastic about providing motivation and able to provide long-term support.

– It is not clear whether or not interventions conducted by multidisciplinary teams are more effective.

Evidence summary

Measuring height and weight	
2-	It is not known for certain whether measuring height and weight reduces the incidence of overweight and obesity[168].
Screening programmes	
2-	The effects of screening for overweight and obesity in children and adolescents (and the relevant intervention if necessary) on food- or exercise-related behaviour, physiological measurements (BMI or body fat) or health outcomes are not known[168,169].
Physical exercise	
1-	Advice on taking physical exercise may contribute to a moderate increase in exercise taken (36-48 min/week in adolescents, 2.5 hours/week in children)[186,188].
Combined interventions	
1+	Giving adolescents advice on healthy eating and taking physical exercise is moderately effective in improving diet and increasing physical activity levels, particularly if various different methods are used to provide advice, such as email, telephone and personal consultations[189-191].
Breastfeeding	
2+	Breastfeeding may have a moderate protective effect against childhood and juvenile obesity[172-175], although the efficacy of promoting breastfeeding in preventing overweight and obesity is not known.
1-	One RCT showed no significant differences in weight or adiposity between children involved in an intervention to promote breastfeeding and children who had not, at the age of 6½ years.
1+	Exclusive breastfeeding for six months is beneficial to babies' short- and long-term health[175].

Recommendations

B	Advice on nutrition and encouraging physical activity, suited to children's ages, should be included in child health monitoring visits.

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√	At paediatricians' and general practitioner's appointments, children and the whole family should be encouraged to eat healthily and take exercise. All professionals within the primary healthcare team must be involved in receiving and disseminating messages about healthy eating and physical exercise.
√	Interventions to promote healthy eating and encourage physical activity must foster a positive body image and help build and reinforce young people's self-esteem. Particular care should be taken to avoid stigmatising or blaming overweight young people or their families.
√	Messages to young people must emphasise the light-hearted, enriching aspects of physical activity and a varied diet (fun, pleasure, new flavours, well-being, enjoying time with friends, etc.) and cater for their preferences. Health- and illness-related messages must play a secondary role.
√	In order to support healthcare professionals' educational work, public healthcare services must provide written or audiovisual materials to support professionals and families. The contents of these must be non-discriminatory and culturally adapted to different social groups.
√	Activities and messages must be suited to the specific characteristics of each young person and his/her family, in line with their needs and preferences. Strategies or techniques such as motivational interviews may be appropriate in these processes.
A	It is recommended that babies be exclusively breastfed for six months, due to the many benefits of breastfeeding to children's health.

5.3. Community interventions

Questions to Answer

In children and adolescents of normal weight:

- How effective are community interventions in preventing obesity?
- How effective are community interventions in improving diet, increasing physical activity levels or reducing sedentary lifestyles?

Various published RCTs have analysed community interventions, i.e. those based outside schools or healthcare centres, in preventing childhood obesity. With some exceptions, many of these studies were conducted in the USA. They were generally small and lasted less than a year, and several of them were conducted in socially disadvantaged groups. Nearly all found modest improvements in diet- and exercise-related behaviour.

No studies have been identified which evaluated interventions based on a broader community, or interventions in health policy.

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5.3.1 Dietary interventions

One RCT analysed an intervention designed to reduce the consumption of sugary drinks in 103 adolescents (aged 13-18 years) who drank at least one portion of fizzy drinks per day[193]. Drinks with low calorie contents (water or soft drinks) were delivered to the homes of the adolescents in the intervention group every week for 25 weeks, free of charge, and they were also advised not to drink higher-calorie drinks. RCT 1-

Consumption of sugary drinks fell by 80% in the intervention group and remained unchanged in the control group. The change in BMI was not statistically significant. Subgroup analysis, according to BMI at the beginning of the study, did show significant differences in the subgroup with the top third of BMIs before the beginning of the study: the difference was -0.75±0.34 kg/m^2 compared to the control group.

5.3.2 Exercise-based interventions

A RCT conducted in 953 12 year-olds and lasting for four years aimed to alter their attitudes towards physical activity, promote moral support from families and teaching staff and provide environmental and institutional conditions so that the children would use their knowledge and skills to change their habits[194]. Children in the schools randomised to the intervention group were offered chances to take physical exercise in break times and lunch hours and after lessons. RCT 1+

After four years, results were obtained for 732 participants and small, significant decreases in BMI were observed in the intervention group (difference between groups: 0.25 [CI 95%, -0.51 to 0.01]). Participants of normal weight showed a smaller increase in body fat index, while in those who were overweight the results were not sustained over time. Increases in physical activity levels and decreases in time spent watching television were also observed, independently of initial weight.

One RCT[195] evaluated the efficacy of a team football programme at the end of the school day in preventing obesity in 21 Americans aged 9 10 years who were overweight (BMI≥P85) and of low socioeconomic status and belonged to ethnic minorities. The children were randomised to the football programme for six months, or to a health education intervention. In comparison to the control group, those who played football showed significant decreases in BMIz (difference 0.08, statistically significant in comparison to the control group) and significant increases in physical activity. This was an acceptable intervention for this group. RCT 1-

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Three controlled, non-randomised community trials involving physical exercise interventions have been identified. The first of these[196] involved 28 children aged 8-11 years, including physical exercise after school and exercises to develop strength and muscle resistance. These activities lasted up to one hour per day, depending on the task, three times a week for ten weeks. There were no changes in body fat measured using skin fold tests at the end of intervention.

Controlled, non-randomised trial
2+

Another study[197] involved 22 families (23 children) aged 6-16 years. It evaluated educational and physical activities for children and their families, including aerobic exercise, healthy snacks and nutritional education, with eight weekly sessions over three months. No differences were found in BMI and there were no changes in physical activity levels, but there was a drop in saturated fat consumption.

Controlled, non-randomised trial
2+

Lastly, another study[198] evaluated an intervention in 79 children aged 7 11 years. This was based on a physical training programme with financial rewards, lasting 40 minutes per day, five days a week, for four months. A 2.2% reduction in body fat and abdominal subcutaneous adipose tissue was observed.

Controlled, non-randomised trial
2+

5.3.3. Dietary and exercise-based interventions

The Girls' Health Enrichment Multi-Site (GEMS) study included four RCTs with a target population of African American pre-teen girls (aged 8-10 years) and their families[199-202]. These trials were conducted over 12 weeks in USA, and aimed to evaluate GEMS' acceptability and viability.

RCT
1-

The RCTs concentrated on changing dietary and exercise-related behaviour and improving self-esteem, with a different emphasis in each one. The control groups of each trial were offered a less wide-ranging intervention (reinforcement of self-esteem and awareness programme). All four had common data-collection methods initially and at 12 weeks. The authors acknowledged that the small number of participants gave insufficient statistical power to compare changes in BMI, and no significant differences were observed, although all showed positive trends in the anthropometry of the intervention groups. Positive trends were also found for behavioural changes in all four trials, some of them significant.

One RCT compared a community intervention with a control group in 730 children (aged 5-12 years), randomised by school[203]. Coordinators were provided in the intervention schools, and they promoted community activities to encourage the children to be more physically active, increasing extracurricular activities in break times and lunch breaks and participation in after-school activities (games, housework, gardening, etc.).

RCT
1+

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In the second year, simple messages on healthy eating (reduced consumption of sugary drinks, increased fruit and vegetable consumption), a triathlon game involving cards and an increase in PE equipment at school were added. Z scores for average BMI were (significantly) lower in the intervention group than in the control group, at the end of both the first year (adjusted difference -0.09, CI 95%, -0.18 to -0.01) and the second year (-0.26, CI 95%, -0.32 to -0.21), with some relationship to the difference in initial weight (boys in the intervention group were somewhat slimmer). Girth was also somewhat lower in the intervention group in both follow-up measurements.

A controlled, non-randomised trial conducted in Australia[204] evaluated a multidisciplinary intervention for community empowerment to promote healthy eating and physical exercise (Be Active Eat Well) in 1,001 children aged 4-12 years. At three years, the children in the intervention group showed lower increases than those in the comparison group, and statistically significant differences (comparing different groups) in weight (mean: 0.92 kg, CI 95%, -1.74 to -0.11), girth (-3.14 cm, -5.07 to -1.22), girth/height (-0.02, -0.03 to -0.004) and BMIz (-0.11, -0.21 to 0.01).

Controlled, non-randomised trial

2+

A controlled, non-randomised trial[205] analysed a community intervention in 631 children aged 6-8 years who attended state schools in Massachusetts, and used 1,065 children from another two cities in the same state, with similar socioeconomic profiles, as controls. The percentage of individuals with BMI>P85 was high in the children in all three groups: 44%, 36% and 43%. The intervention was multidisciplinary and included various components aimed at achieving a suitable energy balance, increasing physical activity options and the availability of healthy food during the day in all environments: before, during and after school, at home, at school and in the community. It required the participation and involvement of many different people: children, families, teachers, school canteen staff, local council departments, medical staff, extracurricular programmes, restaurants and the media.

Controlled, non-randomised trial

2+

The main result measured was BMIz, which at the end of the first year of the intervention showed a better result in the intervention group, with a difference of -0.1005 compared to the control groups (CI 95%, 0.1151 to -0.0859, p=0.001).

KidFIT[206], a before-and-after study with no control group, evaluated the efficacy of a six-week intervention consisting of various different components designed to encourage physical exercise and healthy eating in 120 children aged 6-12 years. They belonged to socially disadvantaged groups in Houston and had high percentages of overweight children (54%) or children at risk of overweight (71% with BMI≥P85).

Before-&-after study

3

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At the end of the study, there was a decrease in the weight of the overweight children (0.3±0.2 kg [standard error]) and in BMI (0.1±0.1 kg/m^2). In children of normal weight before the study, both weight (0.4±0.1 kg) and BMI (0.2±0.1 kg/m^2) increased. Statistically significant improvements were also observed in the suppleness, stamina and muscle strength of all the children.

Evidence summary

Dietary interventions	
1-	The reduction in the consumption of sugary drinks in adolescents aged 13-18 years who were enrolled in a community programme showed slight decreases in BMI, particularly in those with the highest BMIs[193].
Exercise-based interventions	
1+	A multidisciplinary programme involving families and teachers and including institutional and environmental strategies led to slight changes in BMI, increased physical activity levels and a decrease in time spent watching television[194].
1-	An extracurricular football programme led to a slight decrease in BMI and was effective in increasing physical activity levels[195].
Dietary and exercise-based interventions	
1-	Programmes to promote healthy eating and physical exercise in the community have yielded inconsistent results: four RCTs in African American girls, lasting 12 weeks, were not effective in reducing BMI[199- 202], whereas a two-year RCT in Australian children showed moderate decreases in BMI[203].

Recommendations

B	For children and adolescents, sugary drinks should be limited. Community programmes that encourage drinking fewer sugary drinks and contribute to drinking water should be promoted.
√	The relevant authorities should take steps to restrict the range and promotion of foods containing high levels of unhealthy fats or sugars (sugary drinks, pastries, deli products, etc.).
√	Production and availability of fruit and vegetables should be encouraged using fiscal policies or subsidies.
√	Advertising aimed at children and adolescents for products that contain high levels of unhealthy fats or sugars should be restricted.

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√	It should be made compulsory to label processed food with nutritional information and information on potential health-damaging effects.
B	Physical activity programmes outside school hours are recommended for children and adolescents. These must be suited to their ages and preferences.
B	Community programmes that aim to encourage a healthy lifestyle, healthy eating and physical exercise are recommended for children and adolescents.
√	Safe, pleasant spaces and suitable infrastructures for playing and sport for children and adolescents should be created in public areas.
√	Specific actions (free entry, benefits, etc.) should be launched to provide access to municipal sporting facilities for children, adolescents and relatives from socially disadvantaged groups.

5.4. Family-based interventions

Questions to Answer

In children and adolescents of normal weight:

- How effective are family-based interventions in preventing obesity?
- How effective are family-based interventions in improving diet, increasing physical activity levels or reducing sedentary lifestyles?

The dividing line between community and family-centred interventions is very complex, as families are generally involved in many of the interventions carried out both in the community and in schools and health-care centres. Even so, this section describes some RCTs, all conducted in the USA, which analyse various interventions aimed primarily at families. These studies are generally small, and several of them were conducted in groups with unfavourable socioeconomic conditions. They show that various interventions in these groups have positive effects in promoting healthy diet- and exercise-related behaviour in children.

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A family-centred intervention consisting of taking 2,000 extra steps per day and eating cereal in 105 families with children (aged 8-12 years) who were overweight or at risk of becoming overweight was evaluated in a 13 week RCT[207]. The intervention was effective both in reducing children's BMI and body fat and in reducing their relatives' weight, BMI and body fat percentage as compared to the control group. Subgroup analysis showed that the positive effects of the intervention occurred mainly in girls and mothers. RCT 1-

Another RCT (192 families)[208] evaluated the effects of taking 2,000 extra steps per day and reducing food intake by 100 Kcal per day, replacing sugar consumed with a calorie-free sweetener. The control group was asked to use pedometers, but was not given any exercise or dietary targets. At six months, the children in both groups showed significant decreases in BMI for their age, but a greater percentage of the children in the group that had been set targets maintained or reduced their BMIs. There were no significant increases in BMI during the trial period in the relatives of either group. RCT 1-

One RCT randomised 87 families into three groups: use of pedometer and educational advice, pedometer alone and a control group[209]. Those who received pedometers were encouraged to take 10,000 steps a day for 12 weeks. At the end of the trial, slight decreases were observed in the weight of children and their relatives, along with increased activity levels, which were similar in both groups given pedometers to use. However, most were unwilling to continue using the pedometers after the end of the trial. RCT 1-

In one RCT, 43 Indian American mothers with pre-school children (aged between 9 months and 3 years) were randomised to an educational intervention or a control group (the usual childrearing programme) for 16 weeks[210]. Fifty-four percent of the children were boys, and their mothers had BMI>25. The percentage of children classified as obese (obesity defined as z score of weight for height>P95) was 3% in the intervention group and 5% in the control group. RCT 1-

At the end of the intervention, maternal BMI and prevalence of obesity were not significantly different, but calorie intake had fallen in the intervention group and increased in the control group in mothers and their children.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Another RCT analysed an intervention aimed at obese parents whose children were not obese, in order to alter their behaviour by increasing fruit and vegetable consumption or reducing consumption of food with high levels of fats and sugars[211]. The results at one-year follow-up showed improvements in the consumption of healthier food and a decrease in consumption of less healthy food, both in family members and in the children themselves, and the percentage of overweight adults fell.

RCT
1-

A controlled, non-randomised pilot study[212] evaluated a one-year intervention to promote healthy habits in the families of pre-school children. The study consisted of attending group educational sessions and visits to a nutritionist. Statistically significant positive effects (in comparison to the control group) were observed in the frequency with which children were offered water instead of sugary drinks and the number of times family members played active games with the children.

Controlled, non-randomised trial
2+

Evidence summary

1-	Interventions aimed at parents and designed to improve dietary habits and increase physical activity levels show slight changes in children's BMI. and minor improvements in diet and physical activity levels in the whole family[207-211].

Recommendations

B	It is important to involve parents in programmes which aim to improve diet and increase physical activity levels in order to prevent obesity.
√	Educational programmes that target the family so as to encourage a healthy lifestyle are needed. These must cover healthy eating, education to understand nutritional information on food labels and the promotion of active leisure activities.
√	Children should be involved in food shopping. Simple cooking techniques should be encouraged.
√	Children should eat regular meals, with their families and without distractions (television, etc.).

More than 5 years have passed since the publication of the Clinical Practice Guideline, and its validity has not been reviewed

More than 5 years have passed since the publication of this Clinical Practice Guideline,and its validity has not been reviewed

6. Treatment

6.1. Lifestyle interventions

For overweight children and adolescents, and for most of those who are obese, maintaining a constant weight is considered an acceptable target until BMI is below P85 (of the CDC [Centres for Disease Control and Prevention] tables), unless the child presents comorbidities or is above P99. In this case, gradual weight loss is required, not exceeding 400 g per month in children aged 2-5 and not exceeding 800 g a week in children and adolescents aged 6 18. Tracking girth, an indirect estimator of visceral fat content, should also be considered when treating childhood and juvenile obesity, although not all studies provide data on this. There are national references published in Spain[214].

Various lifestyle interventions designed to control the weight of children and adolescents have been evaluated, including advice on nutrition and exercise, behavioural treatments, reducing sedentary activities and moral or psychological support. To date, combined interventions (diet, exercise and changes to behaviour) have proved the most effective, particularly if parents are involved in treatment[43,44,53,88]. Many studies have been conducted in specialist outpatient centres within university hospitals, and are generally of poor methodological quality.

6.1.1 Dietary interventions

Questions to Answer

In overweight or obese children and adolescents:

- How effective is nutritional intervention in weight loss or maintenance and other specified outcomes?

Various dietary proposals to promote weight loss in the paediatric population have been studied. These include low-calorie diets and other micronutrient-altering diets (protein-rich, fibre-rich, low-glycaemic index or low-fat diets). The most commonly-used diet within combined intervention programmes is the Traffic Light Diet (TLD)[215].

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The TLD groups foods into three categories corresponding to the colours of traffic lights: "green" foods contain 0-1.9 g fat per portion, "amber" foods contain 2.0-4.9 g, and "red" foods contain 5 g or more. The aim is to promote the consumption of "green" foods and reduce that of "red" foods, according to the food pyramid[216-218] (see Appendix 3). To date, no studies have compared this diet with any other, although combined interventions (including physical exercise and behavioural therapy) which have used this diet have shown moderate improvements in overweight five and ten years after the intervention[219-221].

Several SRs of studies that evaluate the efficacy of nutritional intervention for paediatric overweight and obesity have been identified, although most also include other interventions. This section therefore evaluates interventions in which the main component is nutrition-related.

SR of various types of study 1-

One SR (37 RCTs, 51 observational studies) evaluated interventions that included a dietary component in the treatment of overweight or obese children and adolescents[222]. Most studies included physical exercise, behavioural therapy, cognitive behavioural therapy or reduced sedentary behaviour. The diets evaluated were low-calorie diets, the TLD, low-fat diets and slight variations on these.

Participants' ages ranged from 3 to 18 years. Both the RCTs (2,200 patients) and the observational studies (6,000 patients) showed high levels of heterogeneity and poor methodological quality, although dietary interventions yielded a short-term relative weight loss in comparison to a control group or various treatment combinations. The authors concluded that there is insufficient information to determine the long-term efficacy of dietary interventions, or to recommend any specific diet. Although meta-analysis of eight RCTs showed a significant reduction in weight after the intervention as compared to no intervention (SMD 1.82, CI 95%, -2.4 to -1.23), these results may not be reliable, due to the poor quality of the studies examined.

SR of various types of study 1-

Another SR included trials (randomised and non-randomised) which evaluated dietary interventions in obese children or adolescents using a comparator group[42]. Dietary interventions combined with physical exercise or behavioural therapy were included, provided that the treatment groups differed only in the dietary interventions. These were divided into four groups: low-carbohydrate diet (≤20 g or ≤10% of total calories), medium-carbohydrate diet (45% 50% of calories), low-glycaemic index diet and low-calorie diet. Only nine trials were ultimately included, and these were poor-quality and short-term. Low-carbohydrate and low-glycaemic index diets were as effective as low-calorie diets in short-term weight loss, but none of the studies provided information on long-term weight control. This same conclusion was reached by another SR, which also included trials conducted in adults and only one RCT involving adolescents[223].

More than 5 years have passed since the publication of this clinical practice guideline and its validity has not been reviewed

Nutritional interventions were evaluated in a CPG[53], although the small number of studies, their poor quality and their methodological limitations make it difficult to draw valid conclusions on the various diets involved. This guideline therefore highlights the need to conduct long-term RCTs in obese paediatric patients, evaluating the various diets. NICE's CPG[43] concluded that the main requirement for a dietary approach to weight control is to reduce total calorie intake. Any recommended diet should be consistent with other healthy eating advice.

CPG 4

A link has been suggested between diets and eating disorders, although it has not proved possible to establish a direct causal relationship. This link seems common in groups with moderate or severe dietary restrictions[224] or those with unhealthy dietary habits[225], as reported by the guideline of the Canadian Medical Association[53]. Some studies indicate that weight-loss interventions administered by professionals pose an insignificant risk of triggering eating disorders[225-227].

Observational studies 2-/3

Evidence summary

1-	Studies identified which involve nutritional interventions in overweight or obese children and adolescents are short-term and poor-quality, and do not evaluate long-term weight loss. It is therefore not known which diet is the most effective in treating paediatric overweight and obesity[42,222,223].
1-	Low-carbohydrate and low-glycaemic index diets have been shown to be as effective as low-calorie diets in short-term weight loss[42].

Recommendations

√	A healthy, balanced diet according to the healthy eating pyramid is recommended for children and adolescents who are overweight or obese.
√	Dietary intervention for children and adolescents who are overweight or obese must not be a one-off event. Instead, it must be carried out as part of a change in lifestyle, including physical exercise, behavioural therapy and family-centred actions.
√	For children and adolescents who are overweight or obese, calorie intake must be lower than the energy they expend, and changes to their diet must be customised and consistent with healthy eating. The use of restrictive, unbalanced diets is not recommended, as these are not effective in the long term and may prove dangerous.
√	Advice on changes to diet must be given by healthcare professionals who deal with children and adolescents regularly.

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D	Professionals in charge of looking after children and adolescents who are overweight or obese must pay particular attention to any risk factors or signs of eating disorders.

6.1.2 Exercise-based interventions

Questions to Answer

- In overweight or obese children and adolescents, how effective is physical exercise or active play in weight loss or maintenance and other specified outcomes?

Physical exercise is beneficial for people who are overweight or obese because it helps them lose weight and control other cardiovascular risk factors, particularly if combined with interventions to alter their diet[228].

One SR (14 RCTs, 481 participants) showed that aerobic exercise (155 180 min/week) of moderate-high intensity is effective in reducing body fat in children and adolescents (average age 12 years) who are overweight or obese (SMD of body fat percentage -0.4, CI 95%, -0.7 to -0.1), and encourages physical exercise[229]. However, no significant changes in body weight (weighted mean difference [WMD] -2.7 kg, CI 95%, -6.1 to 0.8) or outcomes related to central obesity (SMD -0.2, CI 95%, -0.6 to 0.1) were observed. The studies included evaluated the efficacy of physical exercise alone or in combination with other interventions.

SR of RCTs
1-

A RCT randomised 53 children aged 12 years with BMI>P95 who attended the same school to gym lessons which aimed to improve lifestyle and physical fitness (14 students in each class), or to normal gym lessons (35-40 pupils per class)[230]. At nine months, significant reductions in fat percentage were observed in the treatment group as compared to the beginning of the study and the control group. Although there were also improvements in cardiovascular fitness (max. VO_2) and fasting insulin levels in the treatment group, no significant changes in BMI were observed. Seventeen of these 53 children were randomised to another year's treatment and evaluated after the summer holidays[231]. The results obtained, in comparison with those from June the previous year, showed that the benefits of the intervention during the school year were lost during the school holidays.

RCT
1-

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The BMIs of 28 obese adolescents (aged 11-16 years) also failed to fall after a physical exercise programme supported by cognitive behavioural techniques. The main aim of this RCT (81 participants) was to evaluate the effect of physical exercise on psychological outcomes. A secondary aim was to evaluate its effect on BMI and other outcomes, such as increased physical exercise levels[232]. The participants were randomised to a physical exercise treatment group (with moderate-intensity aerobic exercise), a placebo group with gentler physical exercise or normal treatment. At 28 weeks, there were significant differences in the mean adjusted scores on the physical self-worth scale between the exercise treatment group and the other two groups (mean difference 0.23, p=0.04), but there were no significant changes in BMI in any of the groups.

RCT
1+

Some studies show that physical exercise can improve health and obesity-associated comorbidities in young people suffering from obesity[233,234], e.g. by improving their insulin levels. This means that physical exercise reduces cardiovascular risk factors. To achieve satisfactory cardiovascular and aerobic fitness levels, training must be arranged in intervals of varying intensity[235].

Observational studies
2-

Evidence summary

1+	Physical exercise programmes used in children and adolescents to treat overweight or obesity have not proved more effective in reducing BMI than their usual activities[232]. However, the studies available do show that physical exercise can temporarily reduce body fat percentage[229,230] and cardiovascular risk factors[233,234].

Recommendations

√	For children and adolescents who are overweight or obese, spontaneous physical activity should be increased by more than one hour a day in order to encourage weight loss and cardiovascular health. Such physical activity may include outdoor play, helping with housework, walking to school, using stairs instead of lifts, etc.).
√	Physical exercise suited to age and interests is recommended for children and adolescents who are overweight or obese. It should begin slowly and gradually increase in intensity and duration.

6.1.3 Interventions to reduce sedentary lifestyles

Questions to Answer

- In overweight or obese children and adolescents, how effective is reducing sedentary lifestyles in weight loss or maintenance and other specified outcomes?

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Sedentary lifestyles, particularly the amount of time spent watching television, playing video games and using computers, has been associated with obesity in children and adolescents[236,237]. Time spent watching television encourages calorie intake for two reasons: the increase in food consumption while watching television, and exposure to advertisements which encourage this[238-243]. This section reviews the efficacy of reducing sedentary lifestyles in treating childhood and juvenile obesity, although little information has been identified for this type of intervention alone.

Observational studies
2-/2+

1+

One SR (12 studies) evaluated the efficacy of interventions which aimed to limit sedentary behaviour in children and adolescents (aged 8-12 years) in order to achieve changes in behaviour and control weight[244]. Six of the studies were conducted in a clinical environment, and six were population-based preventive studies. The duration of the interventions varied greatly, but most lasted between six weeks and two years, with follow-up ranging from four weeks to one year. The results show that these interventions reduced sedentary behaviour and improved weight slightly. As the messages aimed at reducing sedentary behaviour were combined with other interventions, it is impossible to estimate how much weight loss is due to these messages.

SR of various types of study
1+

Thirty children aged 8-12 years with BMI>P85 were randomised to an intervention consisting of monitoring their physical exercise levels and rewarding it with time spent watching television, or to a control group, which underwent monitoring of physical exercise alone[245]. At eight weeks, a significant increase in time spent on physical exercise and a reduction in sedentary behaviour were observed in the intervention group as compared to the control group. The decrease in sedentary behaviour was also associated with reductions in weight ($r=0.70$, $p<0.001$), BMI ($r=0.54$, $p<0.05$) and calories from a fatty diet ($r=0.68$, $p<0.001$).

RCT
1-

On the basis of studies conducted in the USA, NICE's guideline[43] concludes that dealing with sedentary behaviour is as effective as promoting physical exercise in controlling the weight of obese children aged 8-12 years, within a specialised weight control programme.

CPG
4

Evidence summary

2-	Time spent watching television and playing video games has been associated with obesity in children and adolescents[236,237].
1+	Interventions aimed at reducing sedentary behaviour in children (aged 8-12 years) are effective: they slightly reduce BMI and sedentary behaviour[244,245].
1-	Reducing sedentary behaviour is effective in reducing calorie intake[245].

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Recommendations

D	In order to reduce their sedentary lifestyles, a maximum of 1½ hours a day watching television or playing video games is recommended for children and adolescents who are overweight or obese.
B	Reducing sedentary lifestyles is recommended for children and adolescents who are overweight or obese, in order to treat childhood and adolescent overweight and obesity.
√	Televisions, video consoles and computers should be removed from the bedrooms of children and adolescents who are overweight or obese.

6.1.4 Psychological treatment

Questions to Answer

- In overweight or obese children and adolescents, how effective is psychological treatment in weight loss or maintenance and other specified outcomes?

This section describes some studies involving isolated psychological interventions. However, most studies identified that involve psychological interventions are part of combined interventions, and are therefore evaluated in the following section.

Normal dietary treatment was compared with an intervention consisting of eight appointments with a dietician trained in behavioural techniques so that the child and his/her family would make changes to their lifestyles[246]. One hundred and thirty-four children aged 5-11 years with BMI≥P98 were randomised in this RCT. BMIz, the main outcome, showed no significant differences between the two groups from the beginning to six or twelve months later, although significant benefits were observed in physical activity levels and reduced sedentary behaviour in the intervention group.

RCT
1+

The effectiveness of cognitive behavioural therapy was evaluated in a RCT in which 47 adolescents (mean age 14.5±1.6 years, BMI 30.9±4.2) were randomised to the intervention group (ten weekly sessions of cognitive behavioural therapy and five fortnightly telephone sessions) or the control group (no treatment)247. In comparison to the control group, in the intervention group significant changes were observed in BMI (intervention: 1.3±0.4, control 0.3±0.3), weight (1.9±1.0 kg and 3.8±0.9 respectively), body fat (-1.5±0.9 kg and 2.3±0.9) and reduced consumption of sugary drinks.

RCT
1-

More than 4 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

A group treatment programme promoting a healthy lifestyle and involving family members was compared to normal treatment (two individual consultations with nursing staff) in 70 obese children aged 7-9 years (weight-for-height ranging from 120% to 200%)[248]. The intervention consisted of fifteen 90 minute sessions for parents and children separately, in which a healthy diet and physical exercise were recommended and behavioural techniques were offered, with no specific weight control. At six months, a change in weight-for-height of -6.8 (CI 95%, -8.9 to -4.7) was observed in the group that received the group programme, as compared to the normal treatment group (-1.8, -3.9 to 0.4). RCT 1+

One RCT[249] evaluated the efficacy of adding "adventure therapy" to a cognitive behavioural programme for weight control in overweight adolescents. Adventure therapy aims to increase self-esteem by relying on peers to promote change to achieve greater levels of suppleness and physical coordination. 76 adolescents aged 13-16 years (with overweight 20% to 80%) were randomised. Both groups attended 16 weekly sessions and 4 monthly sessions of the same cognitive behavioural intervention, were prescribed a low-calorie diet and were encouraged to increase their physical activity levels. The control group also took part in weekly aerobic exercise sessions, and the intervention group had an "adventure therapy" session, with group activities consisting of mental and physical challenges that aimed to develop social skills and self-confidence. At ten months, 35% of the treatment group showed weight loss ≥4.5 kg, compared to 12% of the control group. RCT 1+

Regarding psychological treatment, NICE's CPG[43] concluded that behavioural therapy may be more effective than conventional treatment, and may yield better results in children and adolescents aged 6-16 years, if parents take responsibility for changing behaviour. NICE concluded that the information on comparisons of this type of therapy with problem-solving is contradictory. The studies of cognitive behavioural therapy evaluated by NICE also failed to show consistent results, as did other psychological techniques such as contingent reinforcement or stimulus control. CPG 4

Evidence summary

1-	Cognitive behavioural therapy has shown moderate short-term reductions in BMI in obese adolescents[247,249]. In children, a group treatment programme involving behavioural techniques also moderately reduced weight at six months[248] but consulting a dietician with behavioural training did not lead to any changes in BMI[246].

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Recommendations

B	Psychological support (behavioural or cognitive behavioural therapy) is recommended for the treatment of overweight and obesity in children and adolescents.
√	Therapy aimed at reducing stress and other psychological techniques (goal-setting, self-monitoring, etc.) are recommended for the treatment of obesity in children and adolescents.
√	Individual or group psychological treatment should be included in combined interventions for children and adolescents suffering from obesity.

6.1.5 Combined interventions

Questions to Answer

- In overweight or obese children and adolescents, how effective are combined interventions in weight loss or maintenance and other specified outcomes?

Recent studies involving multidisciplinary programmes (diet and physical exercise with or without changes to behaviour) have yielded better results in the treatment of childhood obesity than programmes consisting of only one type of intervention. Family involvement is also important, and is associated with sustained weight loss in obese children[53].

Three SRs evaluated the efficacy of interventions that targeted lifestyle, diet, physical exercise and/or behavioural treatment for weight loss in children and adolescents[41,250,251]. All three SRs showed that the evidence identified had major methodological limitations, and although the interventions had significant short-term effects in comparison with no treatment, waiting lists or standard advice on diet and exercise as a control group, the long-term effects of the interventions were not evaluated.

SR of RCTs
1-

The following section describes the studies identified in the literature search, classified according to the various environments in which they were conducted.

Healthcare setting

One RCT that compared a programme including exercise, changes to behaviour and nutrition (Bright Bodies) with a control group in 209 young people (aged 9-16 years) with BMI>P95 showed a significant reduction in weight-related outcomes at six months and at one year[252]. The intervention was conducted in a paediatric obesity clinic, and consisted of twice-weekly sessions for six months and weekly sessions for another six months. Fifty minutes of each session were spent on exercise, and the other 40 minutes on nutritional and behavioural education. Families also attended all sessions.

RCT
1-

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Participants in the control group attended one appointment every six months and received advice on diet and exercise. At one year, the BMI of the treatment group showed a decrease of -1.7 (CI 95%, -2.3 to 1.1), versus an increase of +1.6 (0,8 to 2,3) in the control group. Weight increased much less in the intervention group (+0.3 kg, CI 95%, -1.4 to 2.0) than in the control group (+7.7 kg, 5.3 to 10.0), and body fat percentage fell (4.0, -5.2 to -2.8 and +2.0, 0.5 to 3.5 respectively).

Reducing BMI was the aim of a RCT conducted in 29 primary care centres in Australia253. One hundred and sixty-three children aged 5 12 years with overweight or slight obesity (defined according to the criteria of the International Obesity Task Force [IOTF]) were randomised to the intervention or the control group. The intervention consisted of four consultations over 12 weeks, attended by the child and his/her family, which covered aspects of nutrition, physical exercise and sedentary behaviour, and support material was provided for families in order to aid changes to behaviour. At 15 months, there were no differences in adjusted BMI between the intervention group and the control group. However, the intervention group did show a significant improvement in diet as compared to the control group. This improvement remained at 15 months, and was due mainly to increased skimmed milk and water consumption in the families in the intervention group. RCT 1+

A three-month RCT evaluated a combined intervention consisting of several sessions of nutritional education, a low-calorie diet and two hours of physical exercise per week in 46 obese schoolchildren and adolescents (BMI>P95, aged 6-16 years), in comparison to a control group (one nutritional consultation and promotion of physical exercise)[254]. At three months, significant decreases in BMI were observed in the intervention group (1.7±1.1 kg/m2 vs -0.2±1.0 kg/m^2 in the control group), as well as significant decreases in fat percentage (3.3±2.6% vs 1.4±4.7%) in the treatment group, and a significant increase in their usual activity index. One year after the intervention, these changes remained. RCT 1-

Individual out-patient follow-up (with dietary advice and encouragement of physical exercise) was compared with a group educational programme involving families in a study with 38 obese pre-teens (aged 7-13 years). At six months, significant differences were observed in sporting activities in the educational programme group. Although these strategies led to changes in dietary and exercise habits, no changes in BMI were observed in either group[255]. RCT 1-

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

A before-and-after study conducted in Spain evaluated a programme that aimed to alter dietary habits, lifestyles and emotional disorders in 81 obese children (aged 6-12 years) using 11 group sessions (for parents and children separately) lasting 90 minutes each[256]. At the end of the treatment, in 72 children (88.9%), BMI had fallen by an average (SD) of 27.8 (3.8) to 26.5 (3.6) (p<0.001) and 3.3 (1.4) to 2.6 (1.2) (p<0.001). BMI had not changed or had worsened in 9 children. There was an increase in the percentage of children who ate fruit (from 63.3% to 82.7%, p<0.001) and vegetables (from 45.6% to 88.2%, p<0.001) every day, and a decrease in the percentage of children who ate pastries (from 17.7 to 1.3%, p<0.001) or skipped breakfast (from 36.7% to 11.7%, p<0.001). Scores on anxiety and depression scales fell from a mean of 53.46 (27.69) to 47.22 (26.3) (p=0,03), and from 29.68 to 16.88 (p<0.001) respectively, as did the number of children at risk of displaying anxiety and depression (from 38.8% to 22.5%, p<0.001, and from 15% to 8.2%, p=0.01 respectively).

Before-&-after study
2-

One before-and-after study evaluated an intervention involving diet, physical exercise and behavioural therapy conducted in 170 schoolchildren (mean age 10 years) who were obese as defined according to the criteria of the IOTF. The schoolchildren took part in an outpatient programme lasting one year[257]. At the end of the intervention there were significant reductions in BMI SD as compared to the beginning of the intervention. These reductions remained until the end of follow-up at three years.

Before-&-after study
2-

BMI and dietary habits remained unchanged after a six-month pilot study conducted in 27 children aged 7 16 years with BMI>P90258. The intervention, conducted by family doctors, consisted of giving two talks on a healthy diet and exercise to both groups. The intervention group had to record the food they ate and the exercise they took every day in a diary, and they were phoned every week to improve their compliance with the treatment plan.

Controlled non-randomised trial
2-

School setting

One RCT evaluated the quality of life of 80 children and adolescents (average age 12.1 years, BMI>P85) who underwent a school intervention consisting of lessons on nutrition, physical exercise and behavioural strategies, compared to a control group which was given a self-help book[259]. At six months, a significant reduction in the BMIz of the group that took part in the programme was observed (0.13±0.14), as was a slight increase in BMIz in the control group (+0.04±0.12). No data comparing the two groups are available. Quality of life (measured using a paediatric questionnaire) increased considerably in the group that took part in the programme, particularly regarding physical well-being.

RCT
1-

More than 5 years may have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Sixty young people with BMI≥P95 showed a drop in weight (-1.5 kg±3.2 in the intervention group vs 2.3 kg±4.7 in the control group), BMI (-1.1±1.3 vs 0.4±1.5) and body fat (-1.6%±1.8 vs 1.2%±2.6) in comparison to sixty other children in a control group, following an educational programme involving PE sessions which was conducted in a school in Taiwan. This RCT[260], which lasted three months, aimed to evaluate the efficacy of this educational intervention in terms of body weight and risk factors for type 2 diabetes and cardiovascular disease in children aged 10-13 years.

RCT
1-

An after-school programme involving families, which consisted of nutritional education, physical exercise and behavioural therapy, showed a smaller increase in BMI in the intervention group than in the control group[261]. This non-controlled clinical trial, which lasted eight months, aimed to reduce BMI and improve motor skills. Two-hundred and seventy-six overweight or obese children were invited to take part, although only 185 completed the programme.

Before-&-after study
2-

Family setting

One SR (16 studies, 44 treatment or control groups) compared the effects of family-based behavioural interventions with those of other treatments or controls in weight loss in children aged 5 12 years[262]. Family/behavioural treatments showed a significant mean effect size (-0.89 [SD 0.68], CI 95%, -1.06 to -0.73) in comparison to other treatments or controls, although there was a great deal of heterogeneity. Family involvement varied between studies: in some they were treated for obesity, and in others trained to promote exercise and healthy eating in their children.

SR of RCTs
1-

Another two SRs showed significant improvements in weight-related outcomes in most of the studies included, although no overall conclusions were drawn due to the poor quality of the studies[263,264]. The studies included evaluated interventions designed to treat childhood obesity using nutrition, exercise and behavioural methods, and in which at least one parent was involved to a greater or lesser extent. However, there is significant uncertainty as to the best way to involve families in the treatment of childhood obesity.

SR of RCTs
1-

One RCT evaluated the efficacy of training families as a key strategy in the treatment of overweight children[265]. This programme is based on social learning, and aims to provide families with skills to handle their children's behaviour. One hundred and eleven overweight children (as defined by the IOTF) aged 6-9 years were randomised to a group in which families were trained and lifestyle education was provided, a group with family training only or a control group. The children themselves did not attend any of the training or educational sessions. In all three groups, BMIz decreased significantly after the beginning of the study, but there were no significant differences between the three.

RCT
1+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

One RCT evaluated the efficacy of an educational programme for families with overweight children in comparison to a waiting-list group[266]. Forty-three children (average age 7 years) with BMI≥P85 were enrolled. The intervention consisted of an initial session attended by a parent and child and four weekly group sessions attended by the parent, at which the various components were provided by a paediatrician, a dietician, a physiotherapist and a psychologist. At three months there was a decrease in the BMI of the intervention group (BMI fell from 26.4 [SD 2.1] to 24.8 [3.2] in the treatment group, and from 26.4 [2.3] to 26.5 [4.0] in the control group), although there were no differences between the groups in terms of physical exercise, reduced sedentary behaviour or family behaviour.

RCT
1-

Another family-based intervention, which compared educational sessions with families alone and sessions with both families and children, was evaluated in a RCT involving 32 families[267]. The sessions promoted healthy eating, increased physical exercise levels and reduced sedentary behaviour, and provided families with tools to improve their authority. The children's average age was 8.7 years, BMI>P85. At six months BMIz in the group with family participation had fallen from 2.0 to 1.6 ($p<0.05$), whereas in the group in which sessions were attended by families and children BMIz fell from 2.1 to 2.0. There were also significant differences between groups regarding the percentage of overweight children and BMIz. Physical activity levels increased and sedentary behaviour fell in both groups, and there was a significant decrease of 22% in overall obesity-linked habits in the family group (as compared to the beginning of the trial) and 15% in the group involving families and children.

RCT
1-

A family-based behavioural treatment programme showed a significant reduction in BMI at two years (2.6 [SD 1.6] vs -0.1 [1,1]) in the control group, as shown by a study conducted in China[268]. Sixty-eight schoolchildren (average age 13 years, BMI>26) from a single class were randomised to the intervention, which consisted of changes to diet and promotion of physical exercise. The intervention was conducted within families with the support and supervision of paediatricians, or to a control group.

RCT
1-

A historical cohort study[269] examined the efficacy of an educational treatment programme for obese children and adolescents and their families, conducted by a paediatrician at three sessions offering behavioural techniques and promoting a healthy lifestyle. One session was then held every six months for the first year, followed by one a year. One hundred and ninety children were enrolled in the study. At three years' follow-up, 72.9% of the children who remained in the programme had significantly reduced their BMI, versus 42.8% of the control group, who followed normal dietary treatment.

Observational study
2-

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Other settings

One RCT enrolled 147 obese adolescent girls (aged 12-16 years, BMI>P90) and randomised them according to the church to which they belonged, either to a "high-intensity" group (with 20-26 behavioural treatment sessions, 30 minutes of physical exercise, and cooking and eating healthy food), or a "low-intensity" group (with only six sessions). At six months' follow-up, no significant differences in BMI were observed in either group[270]. RCT 1-

Another RCT evaluated an online behavioural/family intervention. Fifty-seven African American girls with BMI≥P85 were randomised to this interactive programme, which promoted a healthy diet and physical exercise, versus a much more limited health education programme with no feedback. In both cases, a member of the family had to have BMI>30 and be part of the intervention or the control group. At six months, significant differences were observed in the fat percentage of girls in the treatment group (-1.12± 0.47% vs 0.43%±0.47% in the control group) and the weight of their parents, but these results were not maintained over the two years the intervention lasted. Use of the website fell drastically from the sixth month of the study onwards[271]. RCT 1-

A pilot study involving 30 obese children (average age 13.5 years, minimum 40% overweight) who followed a 10 month residential programme showed a significant decrease in weight and BMI, and an increase in physical activity levels[272]. However, these outcomes returned to their initial levels three months after the children completed the programme, which consisted of diet, regular physical exercise and psychological support. Controlled non-randomised trial 2-

A pilot study with 12 obese adolescents, which compared treatment involving a cognitive behavioural programme and physical exercise with a control group[273], showed significant changes in weight and BMI after 16 sessions, although the small number of participants considerably limits the possibilities of drawing conclusions from these results. Controlled non-randomised trial 2-

A recent evaluation by a medical technology agency[274] showed that combined interventions in schools or specialist centres may achieve moderate short-term results in terms of weight. However, the evidence that these improvements may remain up to 12 months after the intervention, and that there are few adverse effects, is much more limited.

NICE's guideline[43] also concludes that behavioural treatment in combination with physical exercise and/or diet in specialist obesity treatment programmes is effective in treating children and adolescents (aged 3-18 years) suffering from obesity, and that it may be more effective if parents take greater responsibility for altering behaviour. CPG 4

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Evidence summary

	Identified combined interventions show great variation in both the type of intervention and the outcome evaluated. This makes it difficult to draw conclusions from them.
1-	Most studies conducted in clinics involving combined interventions (diet, physical exercise and changes to behaviour) show moderate short-term decreases in BMI, weight and body fat percentage in children and adolescents aged 6-16 years[252,254]. Various studies also show increased physical activity levels and healthier diets[253-255]
1-	Two RCTs and one poorer-quality study conducted in schools, involving combined interventions (diet, physical exercise and changes to behaviour), show moderate short-term decreases in BMI in children aged 10-13 years[259-261]
1-	Three SRs showed that family/behavioural interventions were more effective than controls in weight loss[262-264]. Some subsequent RCTs involving these interventions show a moderate short-term decrease in BMI in children aged 6-13 years[265-268].

Recommendations

B	Combined interventions including diet, physical exercise and changes to behaviour, with family involvement, are recommended for weight loss in children and adolescents aged 6-16 who are overweight or obese.
√	The clinical and family environments are the most appropriate settings for combined interventions for weight loss in children and adolescents who are overweight or obese.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity hasn't been reviewed

6.2. Drug-Based intervention

Questions to Answer

In overweight or obese children and adolescents,

- How effective is sibutramine treatment in weight loss or maintenance and other specified outcomes?
- How effective is orlistat treatment in weight loss or maintenance and other specified outcomes?
- How effective is rimonabant treatment in weight loss or maintenance and other specified outcomes?
- How effective is metformin treatment in weight loss or maintenance and other specified outcomes?

Most studies on drug treatment for obesity have been conducted in adults, which means that most of the available evidence is indirect. Even these studies in adults do not provide information on morbidity and mortality or long-term safety.

The information available on anti-obesity drug treatment in adolescents is very limited, and there are no data for children. In obese adolescents, drug treatment should be used as one of the last resorts. It should only be considered in exceptional circumstances such as severe comorbidities, after lifestyle interventions have failed.

SR of RCTs 1+

One recent SR in adolescents has been identified. This shows that drug treatment combined with lifestyle interventions has a modest short-term effect in reducing body weight[275]. No information is provided on long-term effects.

In this SR, meta-analysis of three RCTs of sibutramine showed a standardised mean difference of 1.01 (CI 95%, 1.28 to 0.73), consistent with a decrease in BMI of 2.4 kg/m2 (CI 95%, 1.8 to 3.1 kg/m2) after six months of treatment. Meta-analysis of three RCTs of orlistat showed a small, moderate effect (0.29, CI 95%, 0.46 to 0.12) consistent with a decrease in BMI of 0.7 kg/m2 (CI 95%, 0.3 to 1.2) six months into treatment. Meta-analysis of three RCTs of metformin revealed an insignificant effect on obesity-related outcomes.

The following sections evaluate the RCTs included in this SR.

6.2.1. Sibutramine

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Adults

The Spanish Agency for Medicines and Healthcare Products (AEMPS) suspended the marketing authorisation for Sibutramine on 21st January 2010 as risks of its use outweigh expected benefits.*

Sibutramine is a central monoamine reuptake inhibitor, and is sold as a coadjuvant in obesity treatment for adults (>18 years old). A recent SR that evaluated the efficacy of anti-obesity drug treatments in adults276 included ten RCTs of sibutramine (2,623 patients). These showed a weight loss of 4.2 kg (CI 95%, 3.6 to 4.7) in the treatment group as compared to the placebo group. Sibutramine also significantly reduced BMI, girth and triglyceride concentration, and increased HDL c. Compared to a placebo, sibutramine increased systolic blood pressure by 1.7 mmHg (0.1 to 3.3), and diastolic blood pressure by 2.4 mmHg (1.5 to 3.3). It also increased heart rate by 5.6 beats/min (3.5 to 5.6). Patients who took sibutramine reported insomnia, nausea, dry mouth and constipation at a rate of 7% to 20%.

SR of RCTs
1+

Adolescents

Five randomised trials were located that evaluated the efficacy of sibutramine in adolescents, all funded by the pharmaceutical industry and all of moderate quality.

A multicentre RCT involving 498 participants (aged 12-16 years) and lasting 12 months showed a reduction in weight of -6.7 kg±0.5 in the sibutramine 10 mg/day treatment group versus 1.8±0.9 in the placebo group (p<0.001)277,278. However, blood pressure and heart rate differed significantly between the two groups throughout the study. Mean differences were 1.0 mmHg (0.1 to 1.9) for systolic pressure, 1.7 mmHg (1.0 to 2.5) for diastolic pressure and 2.5 beats/min (1.6 to 3.3) for heart rate. Twenty-three participants (6.3%) of the sibutramine group left the trial because of side effects, compared to 5.4% of the placebo group (seven participants).

RCT
1-

The second RCT compared treatment with sibutramine 10 mg and placebo in a group of 46 obese adolescents (aged 14 18 years) who followed a low-calorie diet and took 30 minutes of aerobic exercise a day[279]. After six months of treatment there were no significant differences between the weights of the two groups. There were no losses due to side effects and no significant increase in blood pressure or heart rate.

RCT
1-

Two other RCTs with similar numbers of patients also showed significant decreases in weight and BMI. In a six-month RCT[280] involving adolescents (60 participants aged 14-17 years), from which those with major comorbidities such as type 2 diabetes mellitus were excluded, there was a mean decrease of -10.3 kg±6.6 in the group treated with sibutramine 10 mg/day, versus a loss of -2.4 kg±2.5 in the placebo group (p<0.001). Although the authors did not obtain a significant difference in favour of sibutramine in most biochemical parameters, its use was associated with a significant decrease in triglycerides and VLDL c. HDL c increased by 15% in the treatment group.

RCT
1-

More than 5 years have passed since the publication of this clinical practice guideline, and its validity has not been reviewed

*Source: Information note from the Spanish Agency of Medicines and Medical Devices – AEMPS, regarding Sibutramine (Reductil®) [21st January 2010]. Available at: http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/seguridad/2010/NI_2010-01_sibutramina_reductil.htm [NOTE: website in spanish]

In another RCT, which was also conducted in adolescents (aged 13-17 years) and lasted longer (12 months)[281], the mean weight loss was -7.8 kg±6.3 in the sibutramine group (15 mg/day) and -3.2 kg±6.1 in the placebo group (p=0.001). Mean blood pressure fell by 3.6 mmHg (SD 8.6 mmHg) in the third month in the placebo group, versus a significant increase in the sibutramine group: 1.8 mmHg (10.7 mmHg) (effect size 0.55, CI 95%, 0.1 to 1.0, p=0.02), but at six months the difference between the two groups was not significant. Medication was reduced or suspended in the treatment group in 19 of the 43 patients in response to increases in blood pressure, heart rate or both.

RCT 1-

Another RCT randomised 24 obese adolescents (11 boys aged 12 17 years) to a low-calorie diet, exercise and sibutramine (10 mg) or to the same diet and exercise with a placebo for 12 weeks[28]. Follow-up, which lasted 12 weeks, consisted of the same intervention but with no medication. There were no significant differences between the groups at the end of the trial.

RCT 1-

N.B.: Sibutramine is not funded by Spanish Social Security.

6.2.2 Orlistat

Adults

Orlistat is a pancreatic and gastric lipase inhibitor approved for the treatment of obesity in adults. Because of its mechanism of action, it may lead to deficiencies of fat-soluble vitamins.

One SR (16 RCTs, 10,631 adults)[276] showed a weight reduction of 2.9 kg (CI 95%, 2.5 kg to 3.2 kg) in the group treated with orlistat as compared to the placebo group. Orlistat was also associated with a reduced incidence of diabetes, from 9.0% to 6.2% (hazard ratio [HR] 0.63, CI 95%, 0.46 to 0.86), improved total cholesterol and LDL c, and a slight reduction in HDL concentration and improved blood pressure and glycaemic control in patients with diabetes. However, there was also an increase in gastrointestinal side effects. Steatorrhoea, tenesmus and incontinence occurred at rates of 15-30% in most trials. In addition, almost all the trials included in meta-analysis were funded by the pharmaceutical industry.

SR of RCTs 1+

Adolescents

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Only two RCTs (573 participants) evaluating the efficacy of orlistat have been identified. The first of these, which lasted six months, compared treatment with orlistat 120 mg three times a day with a placebo in 40 obese adolescents (aged 14-18 years) and showed a significant change in BMI between the beginning and the end of the trial, although there were no significant differences between the treatment and placebo groups (1.3±1.6 vs 0.8±3.0 respectively)[283]. Both groups followed a low-fat diet, took physical exercise three times a week and took a vitamin supplement. Weight loss (between the beginning and the end of the study) was not significant in either group, and there was no significant difference between the groups. Side effects, mainly gastrointestinal, appeared only in the group treated with orlistat.

RCT
1+

The second RCT showed a significantly greater decrease in BMI in the treatment group[284]. At 12 months, 26.5% of the treatment group had lost ≥5% of their initial BMI, versus 15.7% of the placebo group (p=0.005). In this study, orlistat 120 mg or placebo was administered three times a day, together with a diet, instructions on taking physical exercise and reducing sedentary lifestyles and advice on achieving changes in behaviour as well as a vitamin supplement. Although the trial population was large (533 obese adolescents aged 12-16 years), this trial was funded by a pharmaceutical company involved in the design, development and analysis and interpretation of its results. Also, the loss rate (35% overall, 12% in the placebo group and 23% in the orlistat group) compromises trial validity.

RCT
1-

The most common orlistat-related side effects were related to the gastrointestinal tract. They were mainly mild or moderate, and made it necessary to suspend the trial in 2% of those receiving treatment. Orlistat's data sheet adds that there was an unexplained increase in the incidence of bone fractures (6% versus 2.8% in the orlistat and placebo groups respectively) during this RCT.

A quasi-randomised trial involving 42 adolescents (aged 10-16 years) who also took exercise and followed a diet with a 20% reduction in calories[285] showed a significant decrease in all outcomes evaluated in the treatment group as compared to the control group. However, the groups were not similar at the beginning of treatment: BMI was significantly higher in the group treated with orlistat. A significant reduction was also observed in the outcomes analysed in two pilot studies, in children (aged 7-12 years) and adolescents (12-17 years) respectively[286] 288, although the studies' design and execution problems limit the validity and usefulness of these results.

Controlled quasi-randomised trial
2+

Before-&-after study
2-

A recent evaluation by the US Agency for Healthcare Research and Quality[274] concluded that both sibutramine and orlistat, in combination with behavioural interventions, can lead to weight loss (ranging from slight to moderate), with potential side effects of varying severity.

N.B.: Orlistat is not funded by Spanish Social Security.

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6.2.3 Rimonabant

Adults

The Spanish Agency for Medicines and Healthcare Products (AEMPS) suspended the sale of rimonabant in Spain on 23 October 2008, due to major psychiatric side effects[289].

Rimonabant is a CB1 cannabinoid receptor antagonist sold in several countries as an adjuvant treatment to diet and exercise in obese or overweight patients with a risk factor (e.g. diabetes or dyslipidaemia). In two recent meta-analyses[276,290], rimonabant demonstrated weight loss of 4.7 kg more (4.1 to 5.3) in the treatment group than in the placebo group at one year of treatment, with girth, blood pressure and triglyceride concentration falling and HDL c concentration rising. However, there was an increase in the incidence of psychiatric disorders (depression, anxiety, irritability, aggression). These occurred in 6% of participants receiving rimonabant (3% more likely in the treatment group than in the placebo group). Rimonabant caused significantly more severe side effects that the placebo (OR 1.4, CI 95%, 1.0 to 2.0, p=0.03); number needed to harm = 59 (27 to 830). Anxiety caused more losses in the treatment group than in the placebo group (OR 3.0, CI 95%, 1.1 to 8.4, p=0.03); number needed to harm = 166 (47 to 3,716).

SR of RCTs
1+

Adolescents

No trials of rimonabant in adolescents have been identified.

6.2.4 Metformin

Adults

Metformin is an oral biguanide used to treat type 2 diabetes. It has proven effective for weight loss, and in hyperinsulinaemia and hypoglycaemia in type 2 diabetes in adults[291]. In women with polycystic ovary syndrome, metformin reduces hyperandrogenism and total cholesterol, as well as lessening symptoms[292].

RCT
1+

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Adolescents

Four RCTs evaluating the efficacy of metformin in adolescents have been identified. Freemark *et al*.[293] compared metformin treatment at a dose of 500 mg/12 hours with a placebo in a group of 32 obese adolescents (aged 12-19 years) with hyperinsulinaemia and a family history of type 2 diabetes. After six months of treatment, there was a decrease of 0.12 standard deviations (SD) of BMI in the group treated with metformin, versus an increase of +0.23 SD in BMI in the placebo group. Two other RCTs (52 participants), which were of poor quality, also showed reductions in weight-related outcomes in adolescents (aged 9-18 years) following metformin treatment at a dose of 1 g/12 hours[294] or 850 mg/12 hours, as compared to a placebo.

RCT 1+

RCT 1-

One RCT[296] evaluated treatment with metformin 850 mg/12 hours in 39 adolescents (aged 10-17 years) with a weight increase secondary to treatment with atypical antipsychotic drugs (olanzapine, risperidone, quetiapine). After 16 weeks there was a -0.13 kg (2.88) decrease in the mean weight of the treatment group, versus a 4.01 kg (6.23) increase in the placebo group.

RCT 1-

Finally, two pilot studies in adolescents (aged 10-18 years) showed significant decreases in BMI after three months of metformin treatment. One of these was conducted in a subgroup of patients with metabolic syndrome[297], and the other in patients being treated with psychotropic drugs (olanzapine, risperidone, quetapine, valproate)[298].

Before-&-after study 2-

The most commonly-reported side effects in all these studies were nausea and diarrhoea, which were resolved by reducing the dose

A new drug, tesofensine, a noradrenaline, dopamine and serotonin reuptake inhibitor, has been evaluated in a Phase II RCT involving 203 obese adults, and has shown a moderate decrease in weight after 24 weeks of treatment, in combination with diet[299]. To date there are no Phase III RCTs, and tesofensine has not been evaluated in children or adolescents.

Recent CPGs on the treatment of obesity in children at adolescents also touch on the potential use of drugs in this group of patients. For example, the Canadian guideline[53] suggests that orlistat be considered as an aid to reducing and maintaining weight in adolescents, as part of an overall lifestyle intervention. For prepubescent children, the use of drugs should be considered only in the context of clinical trials.

CPG 4

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NICE's guideline[43] maintains that in adolescents, orlistat (120 mg three times a day) in combination with a low-calorie diet and physical exercise is more effective in weight loss than the combination of diet and exercise alone after 10-11 months. Regarding sibutramine (at a dose of 10 mg/day), NICE maintains that in specialist healthcare and in combination with diet and physical exercise sibutramine may cause greater weight loss than in control groups after six months of treatment. However, NICE's guideline recommends drug treatment for obese adolescents only in exceptional circumstances (where there are severe comorbidities).

Evidence summary

Sibutramine	
1-	In obese adolescents, sibutramine has shown significant decreases in weight-related outcomes at a dose of 10 mg/day as compared to a placebo (approximate decrease 7 kg)[277,278,280,281]. However, sibutramine is associated with side effects such as increased blood pressure, heart rate or both. No long-term data are available. Currently, marketing authorisation for Sibutramine is suspended as risks of its use outweigh expected benefits.
1+	In adults, sibutramine results in significant decreases in weight (-4.2 kg), BMI, girth and triglyceride contrition. It is also associated with increased blood pressure, tachycardia and other side effects such as nausea and dry mouth[276]. Currently, marketing authorisation for Sibutramine is suspended as risks of its use outweigh expected benefits
Orlistat	
1-	Orlistat has not shown consistent results in adolescents. Two RCTs have evaluated its efficacy (at a dose of 120 mg/8 hours) in adolescents[283,284]. Side effects, all of which were gastrointestinal, occurred in orlistat treatment groups and led to 2% of participants leaving the trials[284].
Rimonabant	
1+	There are no trials of rimonabant in adolescents. Two meta-analyses in adults[276,290] showed significant weight loss after one year of treatment, but also an increased incidence of psychiatric disorders (depression, anxiety, irritability, aggression), which occurred in 6% of participants treated with rimonabant (3% more likely in the treatment group than in the placebo group). Sale has currently been suspended due to severe psychiatric side effects.
Metformin	

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1-	Decreases in weight-related outcomes have been observed in obese adolescents treated with metformin (at various doses) as compared to a placebo[293-296]. Side effects (nausea, diarrhoea) have also been observed, and have been resolved by reducing the dose.

Recommendations

C	For adolescents (aged 12-18) suffering from obesity and severe comorbidities who have not responded to dietary and lifestyle treatment, sibutramine* treatment (10 mg/day) may be considered as part of a programme of changes to lifestyle. This must be supervised by specialists in endocrinology and nutrition, family medicine or paediatrics who have been trained to treat obesity. Currently, marketing authorisation for Sibutramine is suspended as risks of its use outweigh expected benefits.
C	For adolescents (aged 12-18) suffering from obesity and severe comorbidities who have not responded to dietary and lifestyle treatment, orlistat* treatment (120 mg with breakfast, lunch and dinner) may be considered as part of a programme of changes to lifestyle. This must be supervised by specialists in endocrinology and nutrition, family medicine or paediatrics who have been trained to treat obesity.
√	Orlistat treatment must be supplemented with a fat-soluble vitamin complex (vitamins A, D, E and K). This must be administered before bed or two hours after taking orlistat.
C	In adolescents (aged 12-18) who are obese and insulin-resistant or glucose-intolerant and who have not responded to dietary and lifestyle treatment, metformin treatment (500-850 mg/12 hours) may be considered as part of a programme of changes to lifestyle. This must be supervised by specialists in endocrinology and nutrition, family medicine or paediatrics who have been trained to treat obesity.
√	As neither orlistat or sibutramine have been approved by the Spanish Agency for Medicines and Healthcare Products (AEMPS) or the European Medicines Agency (EMEA) for use in those under 18, and as metformin is not indicated for the treatment of obesity in adults or children, informed consent must be obtained from relatives, guardians and the adolescent in question if any of these drugs is prescribed. Currently, marketing authorisation for Sibutramine is suspended as risks of its use outweigh expected benefits.
D	The decision to begin drug treatment must be taken individually for each patient. Such a decision may only be taken if there are severe comorbidities and other, associated treatments are also performed.

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√	Treatments and their indication must be reassessed regularly, and must not be used indefinitely.
√	Relatives or guardians should always be informed of the risks and benefits of drug treatments, as should adolescents themselves.
* Sibutramine and orlistat are not funded by Spanish Social Security.	

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6.3. Surgery

Questions to Answer

- In overweight or obese children and adolescents, how effective is surgery in weight loss or maintenance and other specified outcomes?

Obesity surgery for adolescents should only be considered in exceptional circumstances, such as severe obesity with severe comorbidities and failure of all the types of treatment evaluated above[300]. In addition, the only information available comes from case series and expert consensus, and its long-term effects are unknown. It must therefore be considered very carefully before use.

6.3.1 Intragastric balloon

An intragastric balloon is a silicon ball placed in the stomach endoscopically and then filled with 600 ml of saline solution. As it partly fills the stomach, it reduces the feeling of hunger and leads to a greater feeling of fullness on eating. Fitting of the balloon must be accompanied by a specific weight-loss diet. The balloon is removed after six months[301].

Adults

A Cochrane SR (9 RCTs, 395 patients)[301] analysed the efficacy and safety of intragastric balloons.

SR of RCTs

1-

The authors would like to highlight that the patients covered by their review included individuals with ages ranging from 14 to 64 years, but they do not provide separate information for patients aged 14-18, and the tables summarising the trials do not make it clear which trial involved adolescents or how many of them there were.

In trials comparing intragastric balloons with diets, it was observed that intragastric balloons have few benefits in terms of weight loss or BMI, and higher rates of minor and serious complications (mainly spontaneous emptying of Garren-Edwards balloons)[302-305]. A tendency towards weight gain after the balloon was removed was also observed, whereas the group on a diet tended to continue losing weight.

Adolescents

No clinical trials or cohort studies have been found specifically evaluating the efficacy and safety of intragastric balloons in obese children or adolescents. A case series of five adolescents (aged 11-17 years) suffering from extreme obesity who were fitted with intragastric balloons showed a significant increase in BMI in all the adolescents at six months[306]. Adolescent patients were also included in another case series (age range 12-71 years), but the results were not broken down by age group[307].

Case series

3

6.3.2 Bariatric surgery

Surgical procedures for obesity include biliopancreatic diversion, gastric bypass, gastroplasty and gastric bands. Most of these procedures can be performed laparoscopically. They must be accompanied by lifestyle changes to achieve the necessary weight loss.

Adults

A Cochrane SR[308] identified two RCTs and three prospective cohort studies comparing surgery with non-surgical treatment. It also included 21 RCTs that compared various different surgical procedures.

SR of various types of study

1-

This SR concluded that surgery led to greater weight loss than conventional treatment (21 kg weight loss at eight years, versus weight increase), with improvements in quality of life and comorbidities. There were some complications to surgery, such as wound infection.

Gastric bypasses were associated with greater weight loss, better quality of life and fewer check-ups, repeat operations or conversions than gastroplasty, but also resulted in more side effects.

Greater weight loss and fewer side effects and repeat operations were observed with adjustable gastric bands than with vertical banded gastroplasty, but laparoscopic vertical banded gastroplasty yielded more patients with excellent or good results and fewer subsequent complications than a laparoscopic adjustable silicon gastric band. Vertical banded gastroplasty was associated with greater weight loss but more vomiting than horizontal gastroplasty. There were some post-operative deaths in the studies.

Weight loss was similar in open and laparoscopic procedures. There were fewer serious complications with laparoscopic surgery, although it was sometimes necessary to switch to open surgery. Most studies showed that laparoscopic surgery took longer but resulted in less blood loss and faster recovery.

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A subsequent RCT that analysed the effect of a laparoscopic gastric band in 80 adults with moderate obesity (BMI 30-35) versus non-surgical treatment showed that the surgery group lost more weight (mean 21.6% of initial weight, CI 95%, 19.3 to 23.9%) than the non-surgery group (5.5%, CI 95%, 3.2% to 7.9%)[309]. RCT 1-

Adolescents

The direct evidence available on the efficacy and safety of bariatric surgery in children and adolescents is based mainly on case series and analyses of hospital records. There are very few cases of bariatric surgery in children under 12. The only case published is that of a child is diagnosed with Prader-Willi syndrome at the age of two, who was operated on when she was eight[310].

The information available, which comes from case series with small numbers of patients[311-325], shows consistently that bariatric surgery is effective in achieving major weight loss (between 33% and 87% of overweight) in adolescents suffering from extreme obesity (BMI≥40 kg/m^2). In most patients, this weight loss is maintained in the medium and long term. Case series 3

One trial, which aimed to analyse trends in the use of bariatric surgery in adolescents in the USA[326], analysed 771 cases (something under 0.7% of the total number of weight loss operations) and observed that 69.9% of patients were female; the youngest was 12 years old (96.4% were aged 15 19 years); 89.4% had no comorbidities; and 87.1% had undergone a gastric bypass. No deaths were recorded during hospitalisation among the adolescents who underwent surgery, whereas the overall death rate is 2 per 1,000 surgery patients. The surgery complication rates were similar to those of adults; the mean length of hospitalisation for adolescents was significantly shorter. Only 4.2% of patients suffered major complications, mostly respiratory (approx. 80%). Case series 3

An SR that evaluated mortality following bariatric surgery[327] carried out subgroup analysis of five studies in adolescents (132 surgery patients) and found no deaths in the first 30 days after surgery. The studies did not provide information on mortality after this period. SR of RCTs 2+

One study showed a considerable increase in quality of life after bariatric surgery, as assessed using questionnaire SF 36 (Short Form 36) in nine young people with an average age of 19325. The scores for the physical section of the questionnaire rose from 34.7±10 to 55.5±5, while those for the mental section rose from 40.6±13.5 to 55.2±8.6, ($p<0.0001$). The scores for the Adolescent Impact of Weight on Quality of Life-Lite questionnaire after surgery were similar to the averages for adults of normal weight (93%±7% vs 96%±7%, $p=0.15$). Case series 3

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Specific recommendations have been developed by the American Academy of Pediatrics and the US Endocrine Society on the requirements for adolescent bariatric surgery candidates[58,88,328]: 1) Surgery should only be considered after more than six months of failed treatment in adolescents suffering from severe obesity (BMI≥40 kg/m2) and serious associated comorbidity, or extreme obesity (BMI≥50 kg/m2). 2) When skeletal maturity is mostly complete (generally over 13 years of age in girls and over 15 years of age in boys). 3) Potential candidates should be referred to centres with multidisciplinary teams and extensive experience. 4) Surgery should be performed in tertiary institutions with teams who can cover these patients' needs and which allow long-term data on their clinical outcomes to be gathered.

Expert opinion 4

A recent evaluation by a medical technology agency[274] concluded that substantial weight loss had been observed following bariatric surgery in adolescents with extreme obesity. However, as the long-term risks of surgery and the short-term risks of specific types of surgery remain unknown, candidates must be assessed carefully.

Evidence summary

	No information has been identified on the efficacy of intragastric balloons in the treatment of obese adolescents.
3	Information on bariatric surgery for obesity in adolescents from case series310 325 shows that it may be effective in achieving major weight loss (between 33% and 87% of overweight), with complication rates similar to those of adults, and improvements in quality of life. However, there is no information available on the risks of surgical treatment to development, metabolism or psychological issues in childhood and adolescence.

Recommendations

C	Bariatric surgery should only be performed in adolescents suffering from severe obesity (BMI≥40 kg/m2) and severe comorbidity or who are extremely obese (BMI≥50 kg/m2), and only when attempts to control weight via intensive actions to alter lifestyle, with or without drug treatment, for at least six months have failed.

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√	Candidates for bariatric surgery must be selected after careful assessment by a multidisciplinary team with expertise in medicine, surgery, psychiatry and nutrition for surgical treatment of obesity in adolescents. Bariatric surgery should only be performed in adolescents who are physically and psychologically mature and aware of the risks and benefits of surgery, and with their family's support.
√	Bariatric surgery must only be performed by highly-specialised surgeons. Follow-up of patients who undergo bariatric surgery must be lifelong, in order to ensure optimum weight loss and good health.
√	Patients must be examined for possible vitamin (B12, B6, B1, B2, D, folates) and mineral (iron, calcium, zinc) deficiencies after bariatric surgery. Supplements must be administered if required.

6.4. Alternative treatments

Questions to Answer

- In children and adolescents, how effective are alternative treatments in weight loss or maintenance and other specified outcomes?

Adults

One SR evaluated the efficacy of complementary therapies in reducing the weight of obese adults[329]. Six systematic reviews and 25 RCTs were evaluated. These revealed that there is insufficient information on the efficacy of any of the complementary therapies evaluated (acupuncture, acupressure, dietary supplements, homeopathy). SR of RCTs 1-

One SR (15 RCTs, 1,219 patients) evaluated the efficacy of chitosan, a dietary supplement, in reducing the weight of overweight or obese adults[330]. The authors found that chitosan leads to significantly greater weight loss than a placebo (WMD -1.7 kg, CI 95%, -2.1 to -1.3 kg). SR of RCTs 1-

However, most of the studies were of poor methodological quality, and analysis of only better-quality studies showed a smaller, statistically insignificant decrease in weight (WMD -0.58 kg, CI 95%, -1.26 to 0.10).

Another dietary supplement, conjugated linoleic acid, was evaluated in a SR (18 RCTs) and was shown to be effective. It led to a modest reduction in fat[331]. No trials of this supplement in children or adolescents have been identified. SR of RCTs 1-

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Adolescents

RCT
1-

Only two trials evaluating alternative therapies in adolescents have been identified. There is very little information available, and it is of poor quality.

The first of these is a RCT which evaluated the efficacy and safety of a product containing ephedrine and caffeine[332], involving 32 obese adolescents with a mean age of 16 years and mean weight 104 kg. They all followed a diet of 500 kcal less than the calculated daily calorie requirement for 20 weeks, and were randomised to take a mixture of caffeine (100 mg) and ephedrine (10 mg) or a placebo.

The mean weight loss was greater in the caffeine/ephedrine group and the difference was statistically significant (14.4 vs 2.2 kg). This was also true for BMI (2.9 vs 0.5 kg/m2) and body fat (6.6 vs 0.5 kg). Side effects were minor and similar in both groups. Withdrawal symptoms when the treatment was ended were mild, transient and of similar frequency and severity in both groups.

Before-&-after study
3

One clinical trial was identified which had no control group and evaluated the efficacy and safety of a traditional Korean herbal remedy (based on a herb called *Taeumjowi-tang*). The trial involved hospitalised obese children with an average age of 11 years[332]. The herbal remedy was administered to them for 30 days, and no changes were made to their diet or physical exercise routines. Of the 31 original participants, nine left the trial.

Results revealed a decrease in BMI of 24.34±3.10 to 23.26±3.00 kg/ m^2, and a reduction in body fat percentage of 34.16±3.75 to 32.08±3.15%. Regarding the safety of the remedy, no changes in heart rate, blood pressure or liver or kidney function were observed.

Evidence summary

1-	There is very little information available on the efficacy of alternative treatments for obesity in children or adolescents. Ephedrine and caffeine treatment led to moderate decreases in weight and body fat in a short RCT involving a small number of participants[332].
2-	A pilot study with involving a herbal remedy showed slight changes in BMI and body fat[333].

Recommendations

C	The use of alternative treatments for overweight and obesity in children and adolescents is not recommended.

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7. Dissemination and implementation

7.1. Guideline formats, dissemination and implementation

There are various different versions of the CPG: full, summary, information for patients and a quick-consultation tool. All these versions are available in HTML and PDF format from the GuíaSalud website (www.guiasalud.es). A hard copy of the summary version containing a CD ROM of the full version is also published.

Dissemination and implementation strategies include the following:

- Official presentation of the guideline by healthcare authorities.
- Copies sent individually to professionals and potential users.
- Distribution of material for patients.
- Dissemination of the guideline in electronic format on the websites of healthcare services and scientific societies involved in the project.
- Presentation of the guideline at scientific events (conferences, meetings).
- Publication of the guideline in medical journals.

7.2. Proposed assessment indicators

With the help of colleagues and external reviewers, the authors of the CPG have designed a set of indicators, in order to provide tools to evaluate the degree of compliance with the CPG's main recommendations. These indicators are based on the recommendations backed up by the greatest amount of evidence and/or the most consensus among the guideline's authors.

7.2.1. Unit of analysis: school

Percentage of schools that implement educational programmes to improve diet

- Numerator: number of schools that implement educational programmes to improve diet.
- Denominator: total number of schools in a Spanish Autonomous Region.
- Approach: prevention.
- Type of indicator: process.
- Basis: schools should include educational programmes which aim to improve diet, increase physical activity and reduce sedentary lifestyles. These should include families and teaching staff (recommendation level C).

Percentage of schools that implement educational programmes to encourage physical exercise and reduce sedentary lifestyles

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- Numerator: number of schools that implement educational programmes to encourage physical exercise and reduce sedentary lifestyles.
- Denominator: total number of schools in a Spanish Autonomous Region.
- Approach: prevention.
- Type of indicator: process.
- Basis: schools should include educational programmes which aim to improve diet, increase physical activity and reduce sedentary lifestyles. These should include families and teaching staff (recommendation level C).

Percentage of schools that implement multidisciplinary interventions to encourage children and adolescents to eat fruit and vegetables.

- Numerator: number of schools that implement multidisciplinary interventions to encourage children and adolescents to eat fruit and vegetables.
- Denominator: total number of schools in a Spanish Autonomous Region.
- Approach: prevention.
- Type of indicator: process.
- Basis: multidisciplinary interventions should be implemented in schools to encourage children and adolescents to eat fruit and vegetables (recommendation level B).

Percentage of schools that provide written information on balanced school meals

- Numerator: number of schools that provide written information on balanced school meals.
- Denominator: total number of schools in a Spanish Autonomous Region.
- Approach: prevention.
- Type of indicator: process.
- Basis: food eaten in schools must be healthy, including a range of fruit and vegetables and meals low in fats and sugars (recommendation level B).

7.2.2. Unit of analysis: healthcare centre

Percentage of healthcare professionals who give advice on diet and physical exercise and record activities at child health monitoring visits

- Numerator: number of healthcare professionals who give advice on diet and physical exercise and record activities at child health monitoring visits.
- Denominator: total number of healthcare professionals who hold child health monitoring visits at a healthcare centre.
- Approach: prevention.
- Type of indicator: process.
- Basis: Advice on nutrition and encouraging physical activity, suited to children's ages, should be included in child health monitoring visits (recommendation level B).

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Percentage of babies less than one year old who are exclusively breast-fed for six months

- Numerator: babies less than one year old who are exclusively breastfed for six months.
- Denominator: babies less than one year old served by a healthcare centre.
- Approach: prevention.
- Type of indicator: result.
- Basis: It is recommended that babies be exclusively breastfed for six months, due to the many benefits of breastfeeding to children's health (recommendation level A).

Percentage of overweight or obese young people aged 6-16 who have been treated with diet, exercise and behavioural changes to behaviour

- Numerator: overweight or obese young people aged 6 16 who have been treated with diet, exercise and changes to behaviour.
- Denominator: children aged 6-16 years served by a healthcare centre.
- Approach: treatment.
- Type of indicator: process.
- Basis: Combined interventions including diet, physical exercise and changes to behaviour, with family involvement, are recommended for weight loss in children and adolescents aged 6-16 who are overweight or obese (recommendation level B).

Percentage of healthcare centres that implement combined interventions involving diet, exercise and changes to behaviour for weight loss in children and adolescents aged 6-16

- Numerator: number of healthcare centres that implement combined interventions involving diet, exercise and changes to behaviour for weight loss in children and adolescents aged 6-16.
- Denominator: number of healthcare centres in a province.
- Approach: treatment.
- Type of indicator: process.
- Basis: Combined interventions including diet, physical exercise and changes to behaviour, with family involvement, are recommended for weight loss in children and adolescents aged 6 16 who are overweight or obese (recommendation level B).

Prevalence of overweight in children

- Numerator: population aged 2-10 years with BMI>P90 and <P97 (according to the semi-longitudinal study by Hernández *et al.*, 1988)[59].
- Denominator: population aged 2 10 years served by a healthcare centre.
- Type of indicator: result.

Prevalence of overweight in adolescents

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- Numerator: population aged 11 21 years with BMI>25.
- Denominator: population aged 11 21 years served by a healthcare centre.
- Type of indicator: result

Prevalence of obesity in children

- Numerator: population aged 2-10 years with BMI>P97 (according to the semi-longitudinal study by Hernández *et al.*, 1988)[59].
- Denominator: population aged 2 10 years served by a healthcare centre.
- Type of indicator: result.

Prevalence of obesity in adolescents

- Numerator: population aged 11 21 years with BMI>30.
- Denominator: population aged 11 21 years served by a healthcare centre.
- Type of indicator: result.

7.2.3. Unit of analysis: community

Percentage of towns/cities with community programmes that encourage healthy eating and physical exercise

- Numerator: number of towns/cities with community programmes that encourage healthy eating and physical exercise.
- Denominator: total number of towns/cities in a province.
- Approach: prevention.
- Type of indicator: process.
- Basis: Community programmes that aim to encourage a healthy lifestyle, healthy eating and physical exercise are recommended for children and adolescents (recommendation level B).

Percentage of towns/cities with suitable, accessible, safe infrastructures (1 sports centre per 15,000 inhabitants) for playing and sport for children and adolescents

- Numerator: number of towns/cities with suitable, accessible, safe infrastructures (1 sports centre per 15,000 inhabitants) for playing and sport for children and adolescents.
- Denominator: total number of towns/cities in a province.
- Approach: prevention.
- Type of indicator: structure.
- Basis: safe, pleasant spaces and suitable infrastructures for playing and sport for children and adolescents should be created in public areas (good clinical practice recommendation).

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8. Recommendations for future research

Screening

Qualitative research studies to find out the attitudes of children, parents or relatives, as well as those of healthcare professionals, towards monitoring height, weight and BMI or screening for childhood and juvenile obesity.

Studies that establish the risks and benefits associated with screening the population for childhood and juvenile obesity.

Prevention

Studies that determine the effect of physical exercise and diet on the risk of childhood and juvenile overweight and obesity and its persistence into adulthood. Longitudinal studies that carefully measure adiposity, diet and physical exercise levels are required.

Studies that analyse the possible relationship between BMI, lifestyle and cardiovascular risk factor-related parameters in children and adolescents.

Studies that determine beyond doubt the childhood and juvenile overweight and obesity risk factors that can be altered.

Studies that evaluate the long-term effects of childhood and juvenile obesity and the effects of weight change in overweight or obese children and adolescents.

Studies that determine the most effective interventions for different age groups: what type of preventive intervention, intensity, duration and environment (individual, family, community or school) is effective in preventing childhood and juvenile overweight and obesity.

Treatment

Clinical trials that determine the most effective type of dietary intervention for paediatric overweight and obesity.

Clinical trials that evaluate the efficacy of physical exercise for overweight and obesity in children and adolescents.

Clinical trials that evaluate the efficacy of short-term interventions in primary care in promoting a healthy diet, increasing physical exercise levels and reducing sedentary lifestyles.

Clinical trials that evaluate the efficacy of various types of psychological treatment.

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Clinical trials that evaluate the efficacy of various types of combined treatment (diet, exercise, behavioural) in the long term for the treatment of childhood and juvenile obesity.

Clinical trials that determine the most effective community-based interventions to treat childhood and juvenile obesity.

Clinical trials that evaluate the long-term efficacy of drug treatment in children and adolescents of various ages.

Trials that evaluate the side effects and compliance with drug treatment in children and adolescents of various ages.

Prospective longitudinal studies to estimate the risks and benefits of bariatric surgery in adolescents.

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Appendices

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Appendix 1: SIGN evidence statements and grades of recommendations

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Levels of evidence

1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias.
1+	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias.
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias.
2++	High quality systematic reviews of case control or cohort or studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

Grades of recommendations

A	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+

Studies classified as 1 and 2 should not be used in the process of developing recommendations due to their high possibility of bias.

Good practice points

√ *	Recommended best practice based on the clinical experience of the guideline development group
Source: Scottish Intercollegiate Guidelines Network. SIGN 50: A guideline developers' handbook (Section 6: Forming guideline recommendations), SIGN publication nº 50, 2001.	

* Sometimes the guideline development group becomes aware that there are some significant practical aspects they wish to emphasise and for which there is probably no supporting scientific evidence available.
Generally, these cases are related to some aspect of the treatment, considered to be a good clinical practice and that nobody would normally question.
These aspects are considered good clinical practice points.
These messages are not an alternative to evidence based recommendations, but must be only considered when there is not another way to highlight the aspect mentioned above.

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Appendix 2: Body Mass Index Reference Curves and Tables



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GROWTH CURVES AND TABLES

M. Hernández, J. Castellet, J.L. Narcaíza, J.M. Rincón, I. Ruiz, E. Sánchez, B. Sobradillo y A. Zurimendi

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Presentation

The curves given here are based on data obtained in the longitudinal growth study by the technical team at the Growth Research Institute of the F. Orbegozo Foundation.

In this second edition, we have added to those we published in 1985 by incorporating anthropometric data for ages up to 18 years. This has allowed us to cover the whole period of growth, and provides distance and growth rate curves for the various ages of childhood and adolescence. We have also added a new indicator, one which is becoming more and more widely used in nutritional anthropometry: body mass index (BMI), also called Quetelet's index or the Quetelet index.

A mixed longitudinal design was used. Three groups of 600 children were selected at random and monitored for nine years. Their ages at the beginning of the study were 0, 5 and 9 years respectively, and the intervals between measurements were 6 months, except during the first year when they were taken every 3 months. Children who missed two consecutive monitoring sessions were systematically excluded.

Most children in the sample belonged to a medium-low socioeconomic group. By comparing the groups for one year we were able to confirm that there were no significant differences between them, and that the graphs can be used as pure longitudinal curves representing a single population.

To construct distance graphs, variables with a normal distribution (height, sitting height, vertex-coccyx distance and head circumference) were represented directly by calculating the mean, standard deviation, range and percentiles. For weight, arm circumference and skin folds, whose distribution is asymmetrical, logarithmic transformations were used. The theoretical percentile values were obtained using the formula $\alpha = \bar{X} \pm t\alpha \times DS$ *where* α *is the percentile to be obtained,* $\bar{X}$ *the mean and* $t\alpha$ *the normal distribution for the percentile.*

For rate curves, to avoid distortion of the pubertal growth spurt caused by differing maturation rates, the graph was drawn by superimposing maximum growth peaks. The shape of the curve therefore represents the normal growth rate during this period.

Graphs were drawn according to the model used by the US National Center for Health Statistics to draw up the NCHS Growth Charts.

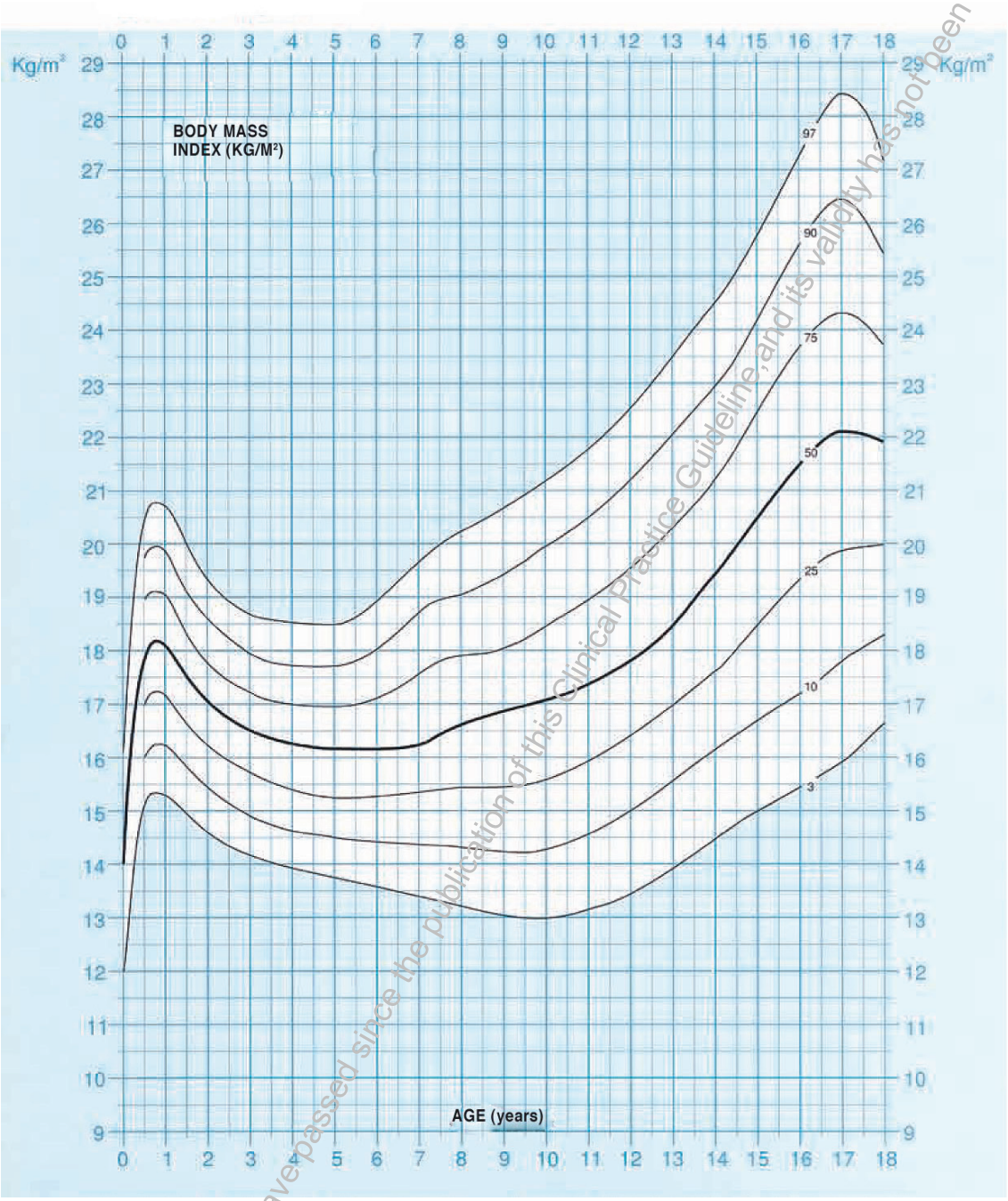
These curves represent the child population of Vizcaya, particularly the Greater Bilbao area. However, we believe that the size and nature of the sample and the methods used to draw the curves make them suitable for the rest of Spain and a clear improvement on those from other countries.

M. HERNÁNDEZ RODRÍGUEZ
Director, Growth Institute

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CHILDREN (BOYS): 0-18 years

BODY MASS INDEX (kg/m2)

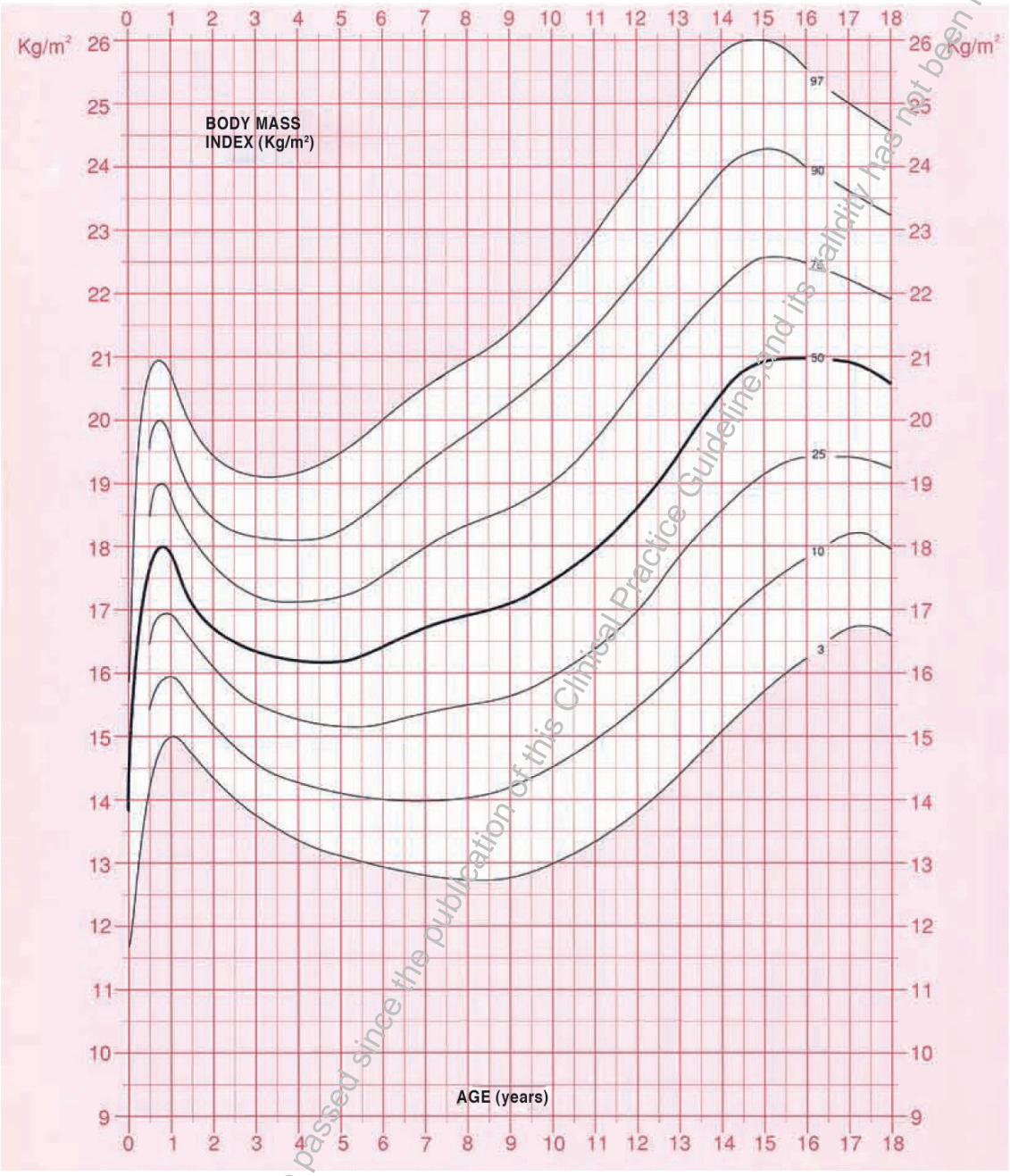


LONGITUDINAL GROWTH STUDY: CURVES FOR 0-18 YEARS

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CHILDREN (GIRLS): 0-18 years

BODY MASS INDEX (kg/m2)



LONGITUDINAL GROWTH STUDY: CURVES FOR 0-18 YEARS

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BOYS

AGE	Length * Height ** (cm)				Weight (kg)				Body mass index Weight/height² (kg/m²)				Head circumference (cm)			
	P3	P50	P97	DS	P3	P50	P97	DS	P3	P50	P97	DS	P3	P50	P97	DS
Birth	46,54	50,15	53,78	1.92	2.75	3.51	4,46	0,45	11,92	14,02	16.11	1,11	32.72	34,89	37.06	1,15
3 months	56,43	60,43	64,42	2.12	5.08	6.25	7,68	0,87	14,64	17,17	19.51	1,24	38.97	41,17	43.37	1,17
6 months	62,75	66,74	70,74	2.12	6.55	7.99	9,74	0,82	15,30	18,02	20.73	1,44	42.17	44,14	46.10	1,04
9 months	66,70	71,11	75,53	2.34	7.52	9.24	11,36	1,02	15,63	18,32	21.00	1,43	43.95	46,02	48.08	1,09
1 year	70,09	75,01	79,93	2.45	8.26	10.15	12,47	1,13	15,37	18,09	20.81	1,43	45.21	47,28	49,35	1,10
1 5 years	76,27	81,37	86,38	2.66	9.48	11.50	13,94	1,13	15,11	17,43	19.76	1,24	46.40	48,70	51,00	1,22
2 years	81,24	86,68	92,12	2.89	10,37	12.70	15,55	1,30	14,60	16,95	19.21	1,20	47.29	49,59	51,88	1,22
2 5 years	85,41	91,10	96,80	3,03	11.23	13.80	16,95	1,49	14,47	16,69	18.90	1,18	47.98	50,29	52,59	1,22
3 years	89,65	95,18	101,50	3,36	12,04	14.86	18,33	1,66	14,26	16,46	18.66	1,17	48.56	50,75	52,94	1,16
3.5 years	91,59	98,72	105,85	3,79	12,66	15.84	19,96	1,97	14,04	16,33	18.62	1,22	49.64	50,99	53,32	1,24
4 years	95,25	102,51	109,77	3,86	13,73	17.01	21,06	1,95	13,95	16,21	18.53	1,22	48.86	51,21	53,66	1,28
4.5 years	98,09	106,00	113,90	4,21	14,44	17.90	22,16	2,04	13,86	16,16	18.45	1,22	49.11	51,28	53,74	1,23
5 years	101,25	109,23	117,20	4,24	14,60	18.76	24,11	2,87	13,68	16,06	18.48	1,28	49.21	51,51	53,80	1,22
5 5 years	103 56	111,92	120,07	4,39	15,28	19.91	25,95	3,13	13,63	16,15	18.68	1,34	49.27	51,49	53,92	1,23
6 years	105 84	115,11	124,40	4,90	15,86	20.87	27,42	3,13	13,54	16,34	19.14	1,49	49.32	51,71	54,09	1,27
6 5 years	108 39	117,84	127,29	5,02	16,30	22.41	30,04	4,17	13,40	16,37	19.34	1,57	49.35	51,00	54,20	1,21
7 years	110,63	120,21	129,78	5,09	17,34	23.59	32,09	4,20	13,32	16,54	19.76	1,71	49.51	52,10	54,59	1,27
7 5 years	113,36	123,21	133,07	5,24	18,14	24.73	33,72	4,35	13,24	16,71	20.18	1,85	49.76	52,27	54,78	1,34
8 years	116,25	126,10	135,95	5,24	19,52	26.08	34,84	4,15	13,19	16,70	20.20	1,87	49.83	52,47	55,16	1,40
8 5 years	118,72	129,01	139,30	5,47	20,42	27.50	36,71	4,22	13,14	16,68	20.23	1,89	50.05	52,68	55,20	1,34
9 years	121 60	131,85	142,10	5,45	21,59	28.81	38,45	4,31	13,03	16,81	20.58	2,01	50.27	52,75	55,23	1,32
9 5 years	123 98	134,07	144,16	5,36	22,15	30.14	40,99	5,09	12,92	16,93	20.94	2,13	50.33	52,68	55,32	1,33
10 years	126 85	136,58	147,20	5,67	23,32	31.83	43,43	5,53	13,07	17,14	21.20	2,16	50.52	53,07	55,61	1,35
10.5 years	128 5	138,99	149,48	5,57	24,37	33.29	45,40	5,67	13,22	17,34	21.47	2,19	50.78	53,30	55,82	1,34
11 years	130 97	141,51	152,06	5,60	25,44	35.18	48,66	6,30	13,18	17,71	22,24	2,41	51.03	53,60	56,17	1,38
11.5 years	132 32	143,67	155,02	6,03	26,50	36.93	51,40	6,73	13,33	18,07	22,81	2,52	51.18	53,74	56,19	1,31
12 years	135 07	146,70	158,33	6,18	27,73	38.79	54,27	7,21	13,45	18,23	23,02	2,55	51.27	53,91	56,55	1,40
12.5 years	136 69	149,04	161,40	6,57	28,96	41.12	58,34	8,12	13,59	18,50	23,41	2,61	51.31	54,04	56,87	1,53
13 years	139 01	152,61	166,61	7,34	30,32	43.34	61,94	8,55	13,73	18,76	23,79	2,68	51.53	54,28	57,03	1,46
13.5 years	141 31	156,16	171,00	7,89	32,35	46.09	65,06	8,49	14,03	19,08	24,13	2,69	51.86	54,60	57,34	1,45
14 years	144 47	160,15	175,84	8,34	34,02	49.22	71,23	9,86	14,34	19,41	24,47	2,69	51,89	54,89	57,89	1,60
14.5 years	147 88	163,38	178,69	8,19	36,14	52.33	75,76	10,54	14,80	19,87	25,14	2,80	52,15	55,27	58,40	1,66
15 years	150 31	165,46	180,61	8,09	38,32	56.25	79,56	10,27	15,09	20,37	25,00	2,82	52,02	55,61	58,61	1,60
15.5 years	154 82	169,67	182,52	7,42	42,50	58.84	81,46	10,33	15,35	20,91	26,46	2,96	52,86	55,86	58,85	1,60
16 years	158 12	170 88	183 64	6,78	46,50	61.52	83,36	9,88	15,56	21,42	27,27	3,11	52,98	55,99	59,00	1,66
16.5 years	161 42	172 32	183 23	5,80	49,17	64.42	84,82	9,61	15,80	21,94	28,07	3,26	53,32	56,25	59,19	1,56
17 years	163 03	173 68	184 33	5,67	49,98	65.96	86,11	10,42	15,87	22,11	28,35	3,32	53,37	56,31	59,26	1,56
17.5 years	163 96	174 64	185 31	5,60	50,61	66.40	87,12	9,97	16,25	21,99	27,73	3,05	53,42	56,38	59,33	1,57
18 years	164 24	175 60	186 95	6,04	51,24	66.84	87,19	9,51	16,63	21,87	27,11	2,79	53,46	56,47	59,47	1,61

*: Up to 2 years
**: 2 years onwards

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GIRLS

AGE	Length * Height ** (cm)				Weight (kg)				Body mass index Weight/height² (kg/m²)				Head circumference (cm)			
	P3	P50	P97	DS	P3	P50	P97	DS	P3	P50	P97	DS	P3	P50	P97	DS
Birth	45,93	49,18	52,44	1,73	2,63	3,32	4,19	0,41	11,69	13,78	15,88	1,12	31,94	34,11	36,28	1,15
3 months	55,77	59,00	62,22	1,71	4,78	5,75	6,93	0,56	14,30	16,59	18,88	1,22	38,26	40,05	41,85	0,95
6 months	61,63	65,24	68,84	1,91	6,04	7,43	9,13	0,81	14,81	17,52	20,23	1,44	40,78	42,81	44,84	1,08
9 months	65,37	69,37	73,36	2,12	6,84	8,59	10,80	1,05	14,96	17,95	20,94	1,59	42,46	44,66	46,86	1,16
1 year	68,93	73,39	77,85	2,37	7,69	9,56	11,88	1,11	15,02	17,82	20,61	1,49	43,74	45,98	48,21	1,19
1.5 years	75,02	79,87	84,73	2,58	8,75	10,90	13,59	1,26	14,49	17,16	19,83	1,42	45,06	47,32	49,58	1,20
2 years	80,11	85,39	90,68	2,81	9,74	12,12	15,10	1,39	14,15	16,69	19,24	1,36	45,97	48,25	50,53	1,21
2.5 years	84,14	89,77	95,39	2,99	10,56	13,29	16,71	1,64	13,92	16,54	19,16	1,39	46,65	48,95	51,25	1,22
3 years	87,97	94,11	100,25	3,26	11,35	14,48	18,46	1,91	13,69	16,42	19,15	1,45	47,14	49,44	51,74	1,22
3.5 years	91,17	97,84	104,51	3,54	11,93	15,53	20,22	2,24	13,42	16,29	19,16	1,53	47,32	49,63	51,93	1,22
4 years	94,33	101,54	108,75	3,83	12,82	16,71	21,78	2,46	13,44	16,29	19,14	1,52	47,41	50,01	52,27	1,29
4.5 years	97,72	105,02	112,32	3,88	13,64	17,72	23,03	2,51	13,31	16,23	19,14	1,55	47,50	50,10	52,45	1,28
5 years	99,34	107,59	115,83	4,39	14,04	18,42	24,18	2,87	13,19	16,23	19,28	1,62	47,68	50,16	52,65	1,32
5.5 years	102,81	111,01	119,21	4,35	14,94	19,66	25,88	3,00	13,10	16,37	19,63	1,74	47,91	50,35	52,80	1,29
6 years	105,60	114,00	122,41	4,47	15,27	20,69	28,02	3,58	13,01	16,50	19,99	1,86	47,95	50,52	53,08	1,36
6.5 years	107,97	117,13	126,30	4,87	16,3	21,99	29,66	3,65	12,63	16,61	20,58	2,11	48,22	50,84	53,16	1,23
7 years	110,80	120,04	129,27	4,91	16,91	23,26	32,00	4,17	12,64	16,61	20,58	2,11	48,49	51,01	53,53	1,34
7.5 years	113,55	123,08	132,61	5,07	18,27	25,00	34,22	4,32	12,79	16,75	20,71	2,11	48,93	51,35	53,76	1,28
8 years	116,12	125,96	135,80	5,23	18,89	26,33	36,70	4,83	12,77	16,89	21,01	2,10	48,98	51,65	54,12	1,42
8.5 years	119,22	128,55	137,88	4,96	20,12	27,84	38,53	4,93	12,74	17,02	21,30	2,28	49,15	51,70	54,25	1,36
9 years	121,30	131,59	141,87	5,47	21,08	29,32	40,79	5,40	12,79	17,11	21,44	2,30	49,25	51,89	54,53	1,40
9.5 years	122,82	133,96	145,10	5,92	21,66	30,71	43,55	5,99	12,83	17,20	21,57	2,33	49,53	52,20	54,87	1,42
10 years	125,49	136,65	147,80	5,93	23,06	32,47	45,72	6,23	12,89	17,56	22,23	2,48	49,70	52,27	54,94	1,36
10.5 years	127,98	139,93	151,89	6,36	24,81	34,94	49,20	6,70	13,15	17,96	22,78	2,56	50,19	52,68	55,17	1,32
11 years	130,50	142,48	154,45	6,37	25,60	36,37	51,65	7,20	13,27	18,21	23,15	2,63	50,21	52,75	55,29	1,40
11.5 years	132,40	145,70	159,00	7,07	26,87	38,72	55,79	7,88	13,38	18,45	23,52	2,70	50,36	52,95	55,54	1,37
12 years	136,55	148,43	160,30	6,31	28,96	40,68	57,15	7,50	13,64	18,67	23,70	2,67	50,45	53,13	55,80	1,42
12.5 years	138,05	151,17	164,30	6,98	30,37	42,83	60,44	7,93	13,81	19,02	24,22	2,65	50,83	53,48	56,12	1,40
13 years	141,91	153,72	165,53	6,28	32,61	45,38	63,16	8,10	13,97	19,36	24,75	2,87	51,06	53,67	56,29	1,39
13.5 years	143,77	155,88	167,98	6,43	34,50	47,67	65,87	8,30	14,60	19,91	25,22	2,82	51,13	53,86	56,57	1,45
14 years	145,44	156,80	168,17	6,05	36,64	49,64	67,25	8,28	15,02	20,41	25,79	2,83	51,24	53,94	56,65	1,44
14.5 years	145,68	157,41	169,15	6,24	38,35	50,39	67,65	7,40	15,32	20,60	25,89	2,81	51,45	54,04	56,63	1,38
15 years	147,04	158,29	169,54	5,98	39,59	51,90	68,05	7,66	15,61	20,80	25,99	2,76	51,66	54,13	56,60	1,32
15.5 years	148,40	159,16	169,92	5,72	40,32	52,52	68,41	7,58	15,88	20,81	25,74	2,62	51,70	54,24	56,77	1,35
16 years	149,23	159,91	170,57	5,68	41,06	53,14	68,77	7,53	16,15	20,82	25,49	2,48	51,70	54,24	56,77	1,35
16.5 years	150,40	160,60	170,80	5,43	42,00	53,31	68,39	6,95	16,50	20,88	25,26	2,33	51,74	54,26	56,80	1,34
17 years	150,41	160,75	171,09	5,50	42,95	53,49	68,01	6,37	16,84	20,93	25,03	2,18	51,79	54,35	56,90	1,36
17.5 years	150,42	160,90	171,37	5,51	43,20	54,00	67,00	6,44	16,73	20,66	24,58	2,09	52,05	54,48	56,90	1,27
18 years	150,50	161,26	172,01	5,72	43,60	54,48	66,80	6,29	16,65	20,60	24,55	2,10	52,32	54,61	56,90	1,22

*. Up to 2 years
** 2 years onwards

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HOW TO USE THE GROWTH CURVES AND TABLES

TECHNICAL SPECIFICATIONS

All measurements were taken at the same time of day, and the children were naked.

Length was measured in the supine position, using the *Holtain Harpenden Supine Measuring Table*, up to the age of 2 years. From this age onwards, the children were measured standing upright, using the *Holtain Stadiometer*.

Weight was measured using electronic scales with sensitivity 10 grams.

Skin folds were measured using the *Harpenden Skinfold Caliper*.

Sitting height was mentioned using the *Holtain Sitting Height Table*.

Data processing: This was carried out using the FOCREC program prepared for this study.

Una descripción detallada de las técnicas de medida puede encontrarse en ZURIMENDI, A., Planificación de un estudio semilongitudinal de crecimiento en la población infantil de Vizcaya. En M. Hernández, ed. **Nutrición, Crecimiento y Desarrollo**, Publicaciones del Instituto de Crecimiento y Desarrollo de la Fundación Orbegozo. Bilbao,1981, pág.: 23 33; SOBRADILLO, B.: Estudio longitudinal del crecimiento en los dos primeros años de vida en la población infantil de Vizcaya. **Tesis Doctoral**. Universidad del País Vasco. Bilbao, 1984; y Hernández, M., *et al*.: Valoración del crecimiento somático. En J. Peña, ed. **Crecimiento y Desarrollo**, vol. I. Monografías de Pediatría. Jarpyo Editores. Madrid, 1985, pág.: 16-23.

USE OF CURVES

Length/height, head circumference and sitting height curves: Note the child's measurement directly on the graph and check whether it is within or outside the normal variation limits, between the 3rd and 97th percentiles.

Arm circumference and skin fold curves: These are used as above. As the values do not have a normal distribution and are highly asymmetrical, these graphs have been drawn on logarithmic paper.

Weight/length curves: On the graph, note the point where the child's length and weight meet. This gives a direct estimate of whether or not the child's weight is suitable for his/her height. These graphs are only reliable during the period when the distribution of weight for height is independent of age, i.e. until puberty. After the onset of puberty this is no longer the case, and these curves should no longer be used.

Body mass index curves: On the graph, note the quotient obtained by dividing the weight in kilograms by the square of the height in metres in the place corresponding to the child's age.

Rate curves: The graphs for children under 2 have two scales. One of these indicates whether the increase over the previous three months is normal. The other is to calculate the rate of growth expressed in centimetres or kilograms per year.

The graphs for 2-18 years of age are suitable for evaluating the rate of growth, in cm/year for height and kg/year for weight. The annual increase should be noted at the midpoint of the year in which the observation was made. For example, if a child grows by 6 cm between the ages of 5 and 6 years, this figure must be noted on the graph in the place corresponding to 5.5 years.

The curve for growth rate during puberty was obtained by superimposing the subjects' maximum growth peaks, regardless of the age at which this occurs.

The percentile lines on the graphs represent the growth pattern of children whose growth peak occurs at an average age. The areas where the background has not been shaded are reserved for children who mature early or late.

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USING THE TABLES

The tables contain the mean values, represented by the 50th percentile, and the limits of the range of "normal" variation most commonly used in clinical practice (P3 and P97).

Standard deviation is also included, as this is essential for evaluating which children fall outside the range between the 3rd and 97th percentiles and to compare subjects of different ages. The value used for this is the score standard deviation, z, which yields the multiple or fraction of standard deviations separating a particular individual from the mean.

The formula used for this calculation is $Z=\frac{X-\bar{X}}{DS}$ where Z is the score standard deviation, X is the value of the variable to be calculated, $\bar{X}$ is the mean of the variable and SD is the standard deviation.

DECIMAL AGE

The decimal age panel is included to make growth rate easier to calculate. It must be used as follows: if a child is seen on 10th May 1983, the corresponding figure in the calendar for this date is 83.353. If the child's date of birth is 8th February 1982, the corresponding figure according to the table, found in the same way, will be 82.104. The difference between these two figures (83.353-82.104 = 1.249) is rounded off to 1 decimal place, giving a decimal age of 1.2 years.

The same technique can be used to obtain the fraction of a year between two measurements.

TABLE FOR CONVERTING TO TENTHS OF A YEAR

	1 JAN	2 FEB	3 MAR	4 APR	5 MAY	6 JUN	7 JUL	8 AUG	9 SEP	10 OCT	11 NOV	12 DEC
1	000	085	162	247	329	414	496	581	666	748	833	915
2	003	088	164	249	332	416	499	584	668	751	836	918
3	005	090	167	252	334	419	501	586	671	753	838	921
4	008	093	170	255	337	422	504	589	674	756	841	923
5	011	096	173	258	340	425	507	592	677	759	844	926
6	014	099	175	260	342	427	510	595	679	762	847	929
7	016	101	178	263	345	430	512	597	682	764	849	932
8	019	104	181	266	348	433	515	600	685	767	852	934
9	022	107	184	268	351	436	518	603	688	770	855	937
10	025	110	186	271	353	438	521	605	690	773	858	940
11	027	112	189	274	356	441	523	608	693	775	860	942
12	030	115	192	277	359	444	526	611	696	778	863	945
13	033	118	195	279	362	447	529	614	699	781	866	948
14	036	121	197	282	364	449	532	616	701	784	868	951
15	038	123	200	285	367	452	534	619	704	786	871	953
16	041	126	203	288	370	455	537	622	707	789	874	956
17	044	129	205	290	373	458	540	625	710	792	877	959
18	047	132	208	293	375	460	542	627	712	795	879	962
19	049	134	211	296	378	463	545	630	715	797	882	964
20	052	137	214	299	381	466	548	633	718	800	885	967
21	055	140	216	301	384	468	551	636	721	803	888	970
22	058	142	219	304	386	471	553	638	723	805	890	973
23	060	145	222	307	389	474	556	641	726	808	893	975
24	063	148	225	310	392	477	559	644	729	811	896	978
25	066	151	227	312	395	479	562	647	731	814	899	981
26	068	153	230	315	397	482	564	649	734	816	901	984
27	071	156	233	318	400	485	567	652	737	819	904	986
28	074	159	236	321	403	488	570	655	740	822	907	989
29	077		238	323	405	490	573	658	742	825	910	992
30	079		241	326	408	493	575	660	745	827	912	995
31	082		244		411		578	663		830		997
	JAN 1	FEB 2	MAR 3	APR 4	MAY 5	JUN 6	JUL 7	AUG 8	SEP 9	OCT 10	NOV 11	DEC 12

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FUNDACION
FAUSTINO ORBEGOZO EIZAGUIRRE
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48013 BILBAO

Appendix 3: Information for patients (*in Spanish unless stated otherwise*)

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Associations for obesity sufferers:

Spanish Association for the Acceptance of Obesity: http://www.gordos.org/index.html

Obesity, Family and Environment Association: http://asofe.org/

Worldwide Obesity Association: http://www.obesos.org

Information on healthy eating and exercise:

Website of the NAOS (Nutrition, Physical Exercise, Obesity Prevention and Health) Strategy, including information on healthy eating and exercise: http://www.naos.aesan. msc.es/

Feeding Your Children: Handbook of the Spanish Agency for Food Safety and Nutrition, available at: http://www.naos.aesan.msc.es/naos/investigacion/publicaciones/

Website of the PERSEO (Reference School Pilot Study for Health and Exercise Against Obesity) programme, with plenty of information on healthy eating, example meals, eating and exercise guidelines for the whole family and more: http://www.perseo.aesan.msc.es/ es/familia/Familia.shtml

Traditional games to stay active, healthy birthday celebrations and much more: http://www.perseo.aesan.msc.es/es/programa/secciones/material_divulgativo.shtml

Website of the Eroski Foundation, with plenty of information on food, meals, news and more: http://www.consumer.es/alimentacion/

Website for childhood obesity prevention of the Eroski Foundation: http:// obesidad-infantil.consumer.es/

Website of the Spanish Association for Primary Paediatric Care on food for children and adolescents: http://www.aepap.org/familia/alimentacion.htm

Interactive website on healthy eating of the Dept. of Education of the Government of Catalonia (in Catalan): http://www.xtec.cat/escola/tastam/logos.htm

Holistic treatment programme for childhood overweight and obesity, Children in Motion: www.nensenmoviment.net

Information on breastfeeding:

Breastfeeding Committee of the Spanish Paediatrics Association: http://www.aeped.es/ lactanciamaterna/index.htm

Website of the Spanish Association for Primary Paediatric Care on breastfeeding: http:// www.aepap.org/familia/lactancia.htm

Fisterra's health website on breastfeeding: http://www.fisterra.com/Salud/ 1infoConse/lactanciaMaterna.asp

World Health Organization information on breastfeeding (in English): http://www.who. int/topics/breastfeeding/en/

Information and support for mothers wanting to breastfeed: http://www.laligadelaleche. es/

Breastfeeding support groups throughout Spain: http://www.ihan.es/index3.asp

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La actividad física tiene efectos beneficiosos sobre:

- ✓ El crecimiento
- ✓ El corazón y los pulmones
- ✓ La función intestinal
- ✓ Las defensas
- ✓ La coordinación
- ✓ El desarrollo psicológico y la autoestima
- ✓ La salud presente y futura



¡Cualquier movimiento ES actividad física!

Consejos a los padres



- o Compartir con los hijos la actividad física
- o Lo importante es participar
- o Dar a conocer diferentes actividades y fomentar las actividades en grupo
- o Aumentar esfuerzo poco a poco
- o Respetar las normas de seguridad:
  - Protección adecuada (casco, gafas, protección solar...)
  - Respetar el tiempo de digestión, beber agua durante el ejercicio, ...





Actividad física en la infancia y adolescencia:



moviéndose ... se crece saludablemente



MINISTERIO DE SANIDAD Y CONSUMO

Plan de Calidad del Sistema Nacional de Salud

Centro Cochrane Iberoamericano
Iberoamerican Cochrane Centre

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Moviéndose ... se crece saludablemente

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed



Todos queremos ... lo mejor para nuestras familias



¿Qué más puedo hacer para alimentar bien a mis hijos?

- Darles un buen desayuno con:
  - Lácteo (leche, yogur, queso)
  - Cereales (pan, galletas, otros cereales)
  - Fruta (entera o en zumo)
- La cena debería ser más ligera que la comida, evitando la repetición de alimentos
- Conviene hacer 4-5 comidas al día y no picar entre comidas



Todos queremos ...



¿Cómo educar a mis hijos para que coman bien?

- Anímeles a participar en la compra y la preparación de los alimentos
- No utilice la comida como premio o castigo
- Aproveche el tiempo de las comidas para promocionar los hábitos saludables y las relaciones afectivas
- Coma en familia, sin televisor

¿Qué más puedo hacer para promover un estilo de vida saludable?:

- Vaya andando al colegio, juegue con sus hijos en el parque, practique deporte con ellos, suba las escaleras a pie,...
- Anímeles a reducir la actividad sedentaria: tiempo delante del televisor, ordenador...

lo mejor para nuestras familias

LA ALIMENTACIÓN SALUDABLE de niños y niñas y adolescentes



Consejos para padres y madres y cuidadores

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MINISTERIO DE SANIDAD Y CONSUMO

Plan de Calidad Sistema Nacional de Salud

Centro Cochrane Iberoamericano
Iberoamerican Cochrane Centre

GRUPOS DE ALIMENTOS:
Raciones recomendadas



Dulces, golosinas, embutidos, bebidas azucaradas
Consumo ocasional

Aceite de oliva
3-4 raciones diarias

Frutos secos
Ninguno: niños hasta 6 años
3-7 raciones semanales

Leche y derivados
2-4 raciones diarias

Carne, pescado, huevos y legumbres
2-3 raciones diarias

Verduras y hortalizas
2-3 raciones diarias

Fruta
2-3 raciones diarias

Agua
4 a 8 vasos/día

Feculentos: cereales, pan, pasta, arroz, patata
3-4 raciones diarias niños/4-6 adolescentes

La alimentación saludable en niños y niñas y adolescentes

- Conviene que coman de todo según la pirámide y con la mayor variedad:
  - Los feculentos son básicos
  - Potencie el consumo de frutas y verduras
  - Más pescado y legumbres y menos carnes
- Respete las raciones diarias recomendadas de los diferentes grupos
- Adapte las raciones a la edad

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Imagen pirámide: Enric Muñoz. Fuentes: *Departament d'Educació i Departament de Salut. Generalitat de Catalunya. Guia: l'alimentació saludable a l'edat escolar*, 2005 y *Departament de Salut. Generalitat de Catalunya. Pla Integral per a la promoció de la salut mitjançant l'activitat física i l'alimentació saludable* (PAAS), 2006.

Appendix 4: Acronyms and abbreviations

%: percentage

Apo-A: apolipoprotein A

Apo-B: apolipoprotein B

BMI: body mass index

BMIz: **BMI score z**

CI: **confidence interval**

CPG: **clinical practice guideline**

g: **gram**

HDL-c: **high-density lipoprotein cholesterol**

hr: **hour**

HR: **hazard ratio**

IOTF: **International Obesity Task Force**

kg: **kilogram**

LDL-c: low-density lipoprotein cholesterol

mg: milligram

min: minute

mmol/l: millimole per litre

NAOS (strategy): Nutrition, Physical Exercise, Obesity Prevention and Health

NHS: Spanish National Healthcare System

NICE: National Institute for Clinical Excellence

NNT: number needed to treat

OR: odds ratio

P: probability

P85: 85th percentile

P90: 90th percentile

P95: 95th percentile

P97: 97th percentile

PE_ physical education

RCT: randomised clinical trial

RR: relative risk

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RRR:	relative risk reduction
SD:	standard deviation
SIGN:	Scottish Intercollegiate Guidelines Network
SMD:	standardised mean difference
SR:	systematic review
TC:	total cholesterol
TG:	triglycerides
TV:	television
UK:	United Kingdom
USA:	United States of America
VLDL-c:	very low-density lipoprotein cholesterol
WHO:	World Health Organization
WMD:	weighted mean difference

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Appendix 5: Glossary

Bariatric surgery: Surgery to reduce weight.

Before-and-after study: A study in which the same group of people is evaluated both before and after an action or treatment.

Behavioural therapy: Behavioural therapy is based on the principles of learning theory (promotion of stimuli that lead to particular behaviour). It consists of assessment (identifying problematic behaviour and the circumstances that cause it), treatment (including small, easily-measured aims that are continually reviewed) and monitoring. The processes in behavioural change include stimulus control, gradual exposure and the disappearance of the behaviour and reward.

Bias: Error appearing in the results of a study due to factors that depend on data collection, analysis, interpretation, publication or review. These factors may lead to conclusions that are systematically different from the truth or which are incorrect with regard to research aims.

Blind study: A study in which one of the parties involved does not know who is receiving a particular treatment option or placebo. Blinding is used to prevent research results being influenced by the placebo effect or by observer bias. In order to evaluate blinding effectively, we need to know who has been blinded for the study (patients, investigators, healthcare professionals, results allocators and/or statisticians).

BMI z-score: Mean BMI of the reference population for the corresponding age and sex, minus the BMI of each participant, divided by the standard deviation of the reference population for the corresponding age and sex.

Body mass index: A measurement that associates an individual's weight and height, also called Quetelet's index or the Quetelet index. It is calculated by dividing the weight in kilograms by the square of the height in metres.

Case and control study: This is an observational epidemiology study in which study subjects are selected according to whether they have (cases) or do not have (controls) a particular illness or a particular effect in general. Once the individuals in each group have been selected, it is investigated whether or not they were exposed to a certain feature, and the proportion of people exposed in the case group is compared with the proportion in the control group.

Clinical practice guideline: A set of instructions, directives, statements or recommendations developed systematically in order to help professionals and patients take decisions on the appropriate healthcare for specific clinical circumstances.

Clinical series: Also called a case series, this is a type of study that describes experience with a group of patients with similar diagnoses, with no comparator group.

Clinical trial: An experimental study to evaluate the efficacy and safety of a treatment or action.

Cochrane Library: A database on effectiveness produced by the Cochrane Collaboration. It consists of the organisation's original systematic reviews and other items.

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Cochrane review: A systematic review carried out according to the methods of the Cochrane Collaboration and published in the Cochrane Library.

Cohort study: This consists of monitoring one or more cohorts of individuals with varying levels of exposure to a risk factor, in whom the onset of the illness or condition being studied is measured.

Comorbidity: The presence of several additional or associated illnesses.

Confidence interval: The interval at which the actual effect size (never known exactly) is found with a pre-established level of security, or confidence. We often speak of a "95% confidence interval" (or "95% confidence limits"). This means that the actual value would be within this interval in 95% of cases.

Confusing factor: This is a outcome that distorts measurement of the association between another two outcomes being studied. A confusing factor may lead to a non-existent effect apparently being observed or a real association being exaggerated (positive confusion); or, in contrast, it may lead to a real association being weakened or even the direction of a real association being reversed (negative confusion).

Effectiveness: The result of a diagnostic, preventive or therapeutic action when applied in normal practice, under non-experimental conditions.

Efficacy: The result of a diagnostic, preventive or therapeutic action when applied under experimental and/or controlled conditions, e.g. in a clinical trial.

Evidence: Proof. Evidence-based medicine: medicine based on scientific proof.

Gastroplasty: A surgical operation on the stomach to restrict and reduce food intake.

Incidence: The number of new cases of a disease arising in a population over a particular period of time. This tells us the probability of an individual without the disease developing it within a particular period.

Meta-analysis: A statistical technique that allows the results of several different studies (studies of diagnostic tests, clinical trials, cohort studies, etc.) to be combined in a single estimate which lends more weight to the results of larger studies.

Morbidity: Disease caused.

Motivational interview: A motivational interview is a type of patient-centred clinical interview which essentially helps the patient explore and resolve ambivalences on specific unhealthy behaviour or habits, in order to promote changes towards healthier lifestyles. It allows the patient to orient him-/herself towards a wish to change, aiming to help him/her to recognise and address his/her present and future problems and boosting his/her perception of efficacy[335].

NICE: An institution within the UK's NHS. Its role is to provide doctors, patients and the general public with the best available evidence, mainly in the form of clinical guidelines.

NNT/NNH: This is a measure of the efficacy of a particular treatment. The number needed to treat (NNT) is the number of people that need to be given a specific treatment to cause or prevent an additional event. Similarly, the number needed to harm (NNH) is defined to evaluate adverse effects.

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Obesity: Obesity is a condition in which the body's natural energy reserves, stored in the adipose tissue, increase to a point associated with a higher risk of suffering from various diseases and mortality. This guideline defines obesity in children and adolescents as a BMI above P97 for the child or adolescent's age and sex, according to the tables of Hernández et al. (1988)59. In adults, the WHO defines obesity as a BMI equal to or greater than 30.

Odds ratio (OR): A measure of the efficacy of a particular treatment. An odds ratio of 1 means that the effect of the treatment is no different from the effect of the control. An OR greater (or less) than 1 means that the effect of the treatment is greater (or less) than that of the control. Note that the effect measured may be either negative (e.g. death or incapacity) or positive (e.g. giving up smoking).

Overweight: Excessive weight in relation to height. This guideline classifies children and adolescents as suffering from overweight when their BMI is between the 90th and 97th percentiles for their age and sex according to the tables of Hernández *et al*. (1988)[59]. In adults, the WHO defines overweight as a BMI between 25 and 30.

Percentile: A value that divides an ordered set of statistical data so that a certain percentage of the data fall below this value. One of the 99 points that divides a distribution into 100 parts with the same frequency.

Placebo: An inactive substance or action used as a control in clinical research. It serves to rule out cures for unknown reasons which would not be attributable to be treatment being researched.

Prevalence: The proportion of individuals in a population who have a particular disease or characteristic at a particular point in time or during a particular period of time. This tells us the probability of an individual from a certain population having a disease at a particular point in time or during a particular period of time.

Randomisation: A procedure by which sample selection or allocation to a treatment option or placebo is carried out at random.

Randomised clinical trial: A type of clinical trial in which patients are allocated at random to the various treatments being compared.

Relative risk (RR): The quotient between the rate of events in a treatment group and a control group. This value is interpreted in the same way as the OR.

Risk factor: Any circumstance that increases the probability of someone contracting a particular disease.

SIGN: A multidisciplinary Scottish agency that publishes evidence-based clinical practice guidelines and methodological documents on guideline design.

Statistical power: The ability of a test to detect differences of a particular size between groups being compared as statistically significant.

Statistically significant: In a study, if the probability that the differences in effect found when two groups are compared is lower than a previously-defined significance level, the differences are said to be statistically significant. This means that the differences observed between the treatments or groups compared are highly unlikely to have occurred by chance. A significance level of 5%, generally written as $p<0.05$, is usually used. However, it should

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be borne in mind that even if the difference between treatments is statistically significant, this does not always indicate that the difference is "clinically significant" or relevant.

Systematic review (SR): A review in which the evidence on a particular subject has been systematically identified, evaluated and summarised according to a pre-established set of criteria. It may or may not include meta-analysis.

Weight for height: A method of evaluating the effect of height on a child's total weight. This is different from BMI. It consists of extrapolating the patient's weight to the percentiles corresponding to the age at which his/her height would be the 50th percentile, rather than directly to his/her chronological age. In other words, if a 5 year-old child is tall and his/her height corresponds to P50 for a child aged 7, his/her weight will be compared to the reference values for weight for his/her "height age" (7 years). The patient's weight is then divided by the 50th percentile of weight for this height, and multiplied by 100 to give the percentage that represents his/her weight in relation to his/her "height age".

Terms relating to methodological issues are based on the glossary of CASPe (Critical Appraisal Skills Programme Español), http://www.redcaspe.org/homecasp.asp

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Appendix 6: Disclosure of Interests

The authors', reviewers' and expert collaborators' disclosure of interests was compiled using the pre-established form included in the *Methodology Manual for Developing Clinical Practice Guidelines of the National Health Service*[1].

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Julia Colomer Revuelta obtained funding from Milupa and Nestlé for registration for the national conference of the Spanish Association for Primary Paediatric Care (2005-2006).

César García Vera obtained funding from Nestlé for accommodation at the Fourth Annual Conference of the Spanish Association for Primary Paediatric Care (May 2008), and from Lab. Ordesa for registration for the 33rd Annual Meeting of the Spanish Paediatric Neurology Society (September 2008). To date he has been Director of the Aragonese Association for Primary Paediatric Care for one year. He received sponsorship from the following private bodies (always in line with the commitment undertaken in the Association's Code of Ethics not to interfere in the selection of content or speakers) for the organisation of the Aragonese Annual Conference on Paediatric Primary Care and a workshop: Merck Sharp & Dohme, Lab. Ordesa, Nestlé, GlaxoSmithKline, Farma-Lepori, Phadia and Ferring. He did not receive any personal payment for any of these activities.

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Gabriel Ángel Martos received funding from Lilly, Serono, Novo-Nordisk, Pfizer and Ferring for registration for the conferences of the Spanish and European Societies for Paediatric Endocrinology (2004-2007), and received fees from Serono, Novo-Nordisky and Pfizer as a speaker at the paediatric endocrinology refresher courses (2004-2007).

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Javier Aranceta Bartrina received funding from Coca-Cola and Puleva to attend the meeting of the Governing Board of the Spanish Society for the Study of Obesity in January 2008, and from Puleva to hold a pre-conference course of the Spanish Community Nutrition Society (SENC) in Valencia in October 2008. He also received financial aid from Laboratorios Lácer for the DORICA study and the publication *Obesidad y riesgo cardiovascular en España* ('Obesity and Cardiovascular Risk in Spain').

Juan Ruiz-Canela Cáceres collaborated in the dissemination of the NAOS Strategy and was a content consultant for the compilation of *Cuentos para niños y niñas* ('Stories for Children'), funded by Puleva (April 2006, March 2007).

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Appendix 7: Main Clinical Practice Guidelines and other useful resources

During compilation of the CPG on the prevention and treatment of childhood and juvenile obesity, some published guidelines on the subject were consulted as secondary literature sources. All these were evaluated using the AGREE method60. Thanks to the rigour and clarity, some of these documents provided inspiration and served as examples for some sections. Below is a list and links to the full text of the main documents. Due to their high quality or recent publication date, these may constitute a major source of information for those using this guideline.

Clinical Practice Guidelines on childhood and juvenile obesity

Clinical Practice Guidelines on Tuberculosis

Title: August GP, Caprio S, Fennoy I, Freemark M, Kaufman FR, Lustig RH, et al. Prevention and Treatment of Pediatric Obesity: An Endocrine Society Clinical Practice Guideline Based on Expert Opinion. J Clin Endocrinol Metab 2008 Sep 9 [Epub ahead of print]. PMID: 18782869
Website: http://www.ncbi.nlm.nih.gov/pubmed/18782869

Title: Lau DC, Douketis JD, Morrison KM, Hramiak IM, Sharma AM, Ur E. 2006 Canadian clinical practice guidelines on the management and prevention of obesity in adults and children. CMAJ. 2007; 176 (8 suppl): S1-13.
Website: http://www.cmaj.ca/cgi/content/full/176/8/S1/DC1

Title: US Expert Committee. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. 2007.
Website: http://www.phac-aspc.gc.ca

Title: National Institute for Health and Clinical Excellence. Obesity. Guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children. NICE clinical guideline 43. December 2006.
Website: http://www.nice.org.uk/Guidance/CG43

Title: Registered Nurses Association of Ontario (RNAO). Primary prevention of childhood obesity. Toronto (ON): Registered Nurses Association of Ontario (RNAO); 2005.
Website: http://www.rnao.org/Page.asp?PageID=924&ContentID=811

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Title: U.S. Preventive Services Task Force (USPSTF). Screening and interventions for overweight in children and adolescents: recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2005.
Website: http://www.ahrq.gov/clinic/uspstf/uspsobch.htm

Title: National Guideline Clearinghouse. Guideline synthesis. Overweight and obesity in children and adolescents: assessment, prevention, and management. NGC, 2005.
Website: http://www.guideline.gov/Compare/comparison.aspx?file=OBESITY3_Child.inc

Title: National Health and Medical Research Council. Clinical Practice Guidelines for the Management of Overweight and Obesity in Children and Adolescents. Commonwealth of Australia, 2003.
Website: http://www.health.gov.au/internet/main/publishing.nsf/Content/obesityguidelines-guidelines-children.htm

Title: Scottish Intercollegiate Guidelines Network (SIGN). Management of obesity in children and young people. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003.
Website: http://www.sign.ac.uk/guidelines/fulltext/69/index.html

Related resources (*in Spanish unless stated otherwise*)

Title: Spanish Agency for Food Safety and Nutrition, NAOS Strategy: Strategy for Nutrition, Physical Exercise and Obesity Prevention, Spanish Ministry for Health and Consumption. Madrid; 2005.
Website: http://www.naos.aesan.msc.es/

Title: Reference School Pilot Study for Health and Exercise Against Obesity (PERSEO). Spanish Ministries for Health and Consumption, Education, Social Policy and Sport, in conjunction with the Regional Ministries for Health and Education of six Autonomous Regions.
Website: http://www.perseo.aesan.msc.es/es/programa/programa_perseo.shtml

Title: World Health Organization information on obesity (in English)
Website: http://www.who.int/topics/obesity/en/
Regional office for Europe: http://www.euro.who.int/obesity

Title: International Obesity Taskforce. An organisation that supports strategies to improve diet and exercise and prevent obesity and obesity-related diseases, with particular emphasis on childhood obesity.
Website: www.iotf.org

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More than 5 years have passed since the publication of this Clinical Practice Guideline, so its validity has not been reviewed



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