#### Section 5: Management of obesity 2

15

#### Sibutramine (Reductil): marketing authorisation suspended

On 21 January 2010, the MHRA announced the suspension of the marketing authorisation for the obesity drug sibutramine (Reductil). This follows a review by the European Medicines Agency which found that the cardiovascular risks of sibutramine outweigh its benefits. Emerging evidence suggests that there is an increased risk of non-fatal heart attacks and strokes with this medicine.

The MHRA advises that:

- Prescribers should not issue any new prescriptions for sibutramine (Reductil) and should review the treatment of patients taking the drug.
- Pharmacists should stop dispensing Reductil and should advise patients to make an appointment to see their doctor at the next convenient time.
- People who are currently taking Reductil should make a routine appointment with their doctor to
  discuss alternative measures to lose weight, including use of diet and exercise regimens. Patients
  may stop treatment before their appointment if they wish.

NICE clinical guideline 43 recommended sibutramine for the treatment of obesity in certain circumstances. These recommendations have now been withdrawn and healthcare professionals should follow the MHRA advice.

#### Management of obesity in clinical settings

#### 15.1 General introduction to clinical management

This section presents the reviews used by the Guidance Development Group (GDG) to inform recommendations. The reviews were conducted to address the identified key clinical questions (see Appendix 2 for details).

We have presented the reviews for children and adults separately. Each review consists of a narrative summary (with a quantitative summary of appropriate information) with the associated evidence statements. Evidence tables and excluded studies can be found in Appendices 13 and 14 for children and Appendices 15 and 16 for adults, respectively.

#### 15.2 Children

See also the adult reviews (section 15.3) for details of evidence on clinical settings, brief interventions, barriers and attitudes to management.

# 15.2.1 Factors to be considered in the clinical assessment of children and adolescents who are overweight or obese

[The aim of an initial assessment is to identify individuals who are at increased risk and who would benefit from intervention. This initial assessment should follow the classification of the degree of overweight or obesity as recommended by the GDG based on the earlier evidence reviews.

Therefore, the factors to be assessed at the initial presentation should be based on two evidence bases: one on the common comorbidities, and one on the effectiveness of weight loss in people with comorbidities and their expected health gain.

Further assessment(s) should aim to determine any determinants of energy imbalance.]

#### 15.2.1.1 Evidence statements (Table 15.1)

#### Table 15.1 Evidence statements and grading

No.	Evidence statement	Grade
1	Initial assessment should aim to identify children and adolescents at highest risk who have the potential to gain health benefits with weight loss	4
2	In children who are overweight or obese, individuals at highest risk and with the greatest potential to gain health benefits include those with current significant weight-related co- morbidities, high risk of developing significant co-morbidities in the future, or children with a significant level of psychosocial distress	2++
3	In children, contributors for energy imbalance can be as follows:	1++, 2++, 3
	<ul> <li>Underlying causes of obesity (genetic, single-gene defects and obesity syndromes, artificial infant feeding, early adiposity rebound, medications, parental weight issues, in timing or rate of growth, endocrine disease, central nervous system pathology, acute lymphatic leukaemia therapy)</li> <li>Co-morbidities</li> <li>Lifestyle, environmental, social and family (television viewing, energy expenditure, dietary fat, dietary carbohydrate and eating patterns, social factors and other behavioural or psychological factors)</li> </ul>	

### 15.2.1.2 Evidence review on factors to be assessed in children and adolescents

In September 2005, the National Guideline Clearinghouse synthesised the recommendations on the assessment and treatment of obesity and overweight in children from six published guidelines.<sup>1</sup>

The different scopes, target populations, intended users, and practices covered can be seen in Appendices 13 and 14 (evidence tables and excluded studies, respectively).

The authors of the synthesis identified areas of agreement between the included guidelines surrounding assessment. They concluded that:

'In addition to BMI, AAP, RNAO, SIGN, and Singapore MOH advise health care providers to evaluate other risk factors for obesity. Parental obesity is identified by these 4 groups as being a strong predictor that an obese child will become an obese adult. The evidence for other risk factors, with the exception of certain childhood syndromes (e.g., Praeder-Willi syndrome) or diseases (e.g., hypothyroidism) is less clear. In addition, these 4 groups cite physical inactivity and increased television viewing as probable risk factors for overweight and obesity. AHA, while not identifying specific risk factors to look for, notes that the identification of risk for overweight before adolescence is encouraged so that health habits can be improved at a stage of increased parental influence and control. USPSTF does not provide recommendations regarding other risk factors.<sup>1</sup>

The individual guideline recommendations on assessment are given in Table 15.2.

AHA (2005) New	Primary care providers should assess diet and activity habits at annual well-child visits; this should be routinely integrated into the overall care plan		
RNAO (2005)	Nurses assess physical growth and development of children and adolescents, which includes:		
	<ul> <li>discussing and documenting basic dietary patterns (level IV)</li> <li>discussing and documenting physical activity patterns including sedentary activity (for example, television and computer time) (level IV)</li> <li>identifying individual and family risk factors for childhood obesity</li> <li>monitoring changes in BMI, dietary and physical activity patterns over time and noting important variations (level IV)</li> </ul>		
Assessment	Assessment of other risk factors		
AAP (2003)	<ul> <li>Genetic, environmental, or combinations of risk factors predisposing children to obesity can and should be identified</li> <li>Identify and track patients at risk by virtue of family history,</li> </ul>		

#### Table 15.2 Recommendations on assessment

Assessment and classification of overweight/obesity

<sup>\*</sup> Recommendations on classification deleted as not relevant to this review.

	birth weight, or socioeconomic, ethnic, cultural, or environmental factors It has long been recognised that obesity 'runs in families' – high birth weight, maternal diabetes and obesity in family members all are factors – but there are likely to be multiple genes and a strong interaction between genetics and environment that influence the degree of adiposity. For young children, if one parent is obese, the odds ratio is approximately 3 for obesity in adulthood, but if both parents are obese, the odds ratio increases to more than 10. Before 3 years of age, parental obesity is a stronger predictor of obesity in adulthood than the child's weight status
AHA (2005) New	Identification of risk for overweight before adolescence is encouraged so that health habits can be improved at a stage of increased parental influence and control
RNAO (2005)	<ul> <li>Identify individual and family risk factors for childhood obesity (level IV)</li> <li>The nurse's assessment should include questions and observations related to individual or familial obesity risk factors. Studies have shown that children who have a genetic propensity for weight gain are more likely to become obese if they grow up in an environment that promotes overeating and inactivity.</li> <li>Numerous studies confirm that when parents are obese, the risk of persistent obesity in their children increases threefold. Monogenic (single gene) causes of obesity are being described with increasing frequency; this familial link to obesity, however, continues to represent only a minority of children with obesity.</li> <li>From a prevention perspective, it is more important to note that lifestyle patterns relating to nutrition and physical activity develop within the context of the family. Dietary energy and fat intake and physical activity profiles in children closely reflect those of their parents. Physical activity in pre-school children can be related to parental BMI. Reduced physical activity and increased sedentary behaviours in childhood are associated with higher levels of overweight and obesity</li> <li>Rates of overweight and obesity also vary by family income. The importance of a number of additional risk factors including gestational diabetes and maternal smoking during pregnancy,</li> </ul>
	reduced fetal growth, and bottle-feeding during infancy on the development of overweight in childhood remains to be fully elucidated
SIGN (2003)	<ul> <li>Parental obesity should be recognised as a risk factor for childhood obesity to persist into adulthood (recommendation grade: C)</li> </ul>

	In the UK, the prevalence of obesity increases with age through childhood and adolescence, and there is no evidence of any marked difference in prevalence between boys and girls. Limited survey data suggest that the prevalence of obesity rises with increasing socioeconomic deprivation. No study has appropriately examined specific environmental factors, such as low habitual physical activity and inappropriately high habitual energy intake, which are believed to have causal roles in the current epidemic of childhood obesity
Singapore MOH (2004)	Overweight in a child under 3 years of age does not predict future obesity, unless at least one parent is also obese. After 3 years, the likelihood that obesity persists increases with advancing age of the child, and is higher in children with severe obesity in all age groups. The presence of obesity in at least one parent increases the risk of persistence in children at every age
	In clinical evaluation of patients, practitioners should consider and exclude predisposing factors for, and secondary causes of, obesity (good practice point)
USPSTF (2005) New	No recommendations offered

AAP, American Academy of Pediatrics; AHA, American Heart Association; BMI, body mass index; MOH, Ministry of Health; RNAO, Registered Nurses Association of Ontario; SIGN, Scottish Intercollegiate Guidelines Network; USPSTF, United States Preventive Services Task Force.

Based on evidence for the common comorbidities, the National Health and Medical Research Council (Australia) (NHMRC)<sup>2</sup> recommended that an initial assessment in a child should include measurement of the waist circumference (although no cut-offs are defined) and blood pressure. However, the guideline stressed that these tests need to be performed and results interpreted in the context of greater degree of obesity, increasing age, history of comorbidities and a family history of metabolic disease related to obesity. These and other assessments should be made as follows:

- Waist circumference: Waist circumference appears to be associated with cardiovascular risk profile. However, cut-points for children and adolescents have not yet been established.
- Blood pressure: Use an appropriate size cuff. The child may be hypertensive if systolic or diastolic blood pressure is greater than or equal to the 95th percentile for age, sex and height. The child is normotensive if blood pressure is below the 90th percentile.
- Psychosocial distress: Clinicians should determine whether the child is being teased and bullied about their weight. If distress and low self-esteem cannot be managed by simple interventions, consider referral for expert counselling.
- Fasting lipid profile: Should be considered in obese children and adolescents, particularly those who have a family history of cardiovascular risk factors.
- Fasting insulin and glucose: Should be considered in obese children or adolescents, particularly those with a family history of type 2 diabetes, those with acanthosis nigricans, and those from certain ethnic backgrounds.
- Liver function tests: May be necessary in greater degrees of obesity, followed by hepatic ultrasound if transaminases are elevated.
- Endocrinology tests: Are not required unless there is other evidence of endocrine disease or short stature. Many overweight children and adolescents have cutaneous striae – do not investigate for Cushing's disease unless the patient is hypertensive with growth delay, and obesity is of recent onset.

#### 15.2.2 Energy imbalance in children and adolescents

The NHMRC guidelines<sup>2</sup> identified a number of risk factors associated with the development of obesity in children. These were:

- Genes: There is a significant genetic predisposition to obesity. Parental obesity is a risk factor for future, if not present, obesity.
- Television viewing: The (mainly American) data on television viewing indicate a positive correlation between hours of viewing and overweight. The correlation is stronger in older children and adolescents and clearer at low or high (less than 2 or greater than 5) hours of viewing per day. Studies on other forms of small-screen entertainment are awaited.
- Energy expenditure: (i) Just as measurement of obesity in children is limited by the lack of immediate morbidity and mortality data, so is the ability to develop physical activity – management guidelines that are based on evidence related to positive health outcomes. (ii) Measuring physical activity in the clinical setting is difficult. Until cheap, small and robust motion monitors become available, it will depend largely on self-reporting. (iii) Reduced physical activity energy expenditure may play a role in weight gain over time.
- Artificial infant feeding: The majority of cohort studies support the finding that breastfeeding plays a small protective role against subsequent overweight.
- Dietary fat, dietary carbohydrate and eating patterns: (i) The evidence that dietary fat intake is a significant risk for obesity in children and adolescents is minimal. (ii) There is no clear evidence that any particular dietary composition influences overweight or obesity in children or adolescents. (iii) There is minimal evidence that carbohydrate intake influences body weight in children and adolescents. (iv) Parents influence food choices and other eating behaviours in their children. Disordered eating in a parent may be associated with excess body weight in the child.
- Single-gene defects and obesity syndromes: (i) There are a number of single-gene abnormalities in which obesity is the predominant feature. (iii)

There are a number of rare congenital syndromes that have obesity as a component and in which intellectual impairment is a common feature.

- Ethnicity: International and local data suggest that certain ethnic backgrounds entail a higher predisposition to obesity.
- Early adiposity rebound: (i) There is evidence from population studies that early adiposity rebound is associated with higher adolescent and adult body mass index (BMI). (ii) No matter how overweight is defined in the individual study, there is a significant association between higher birth weight and higher weights in childhood. (iii) Additional risk is conferred by an average, rather than tall, birth length and by parental overweight. (iv) Small-forgestational-age babies who exhibit catch-up growth are at risk of obesity in childhood.
- Single-child, single-parent, rural versus urban, and socio-economic status: Evidence statements related specifically to Australia only.
- Endocrine disease: Clinical observation confirms an association between obesity and a number of endocrine disorders. Height–growth failure is the feature that should alert the clinician.
- Central nervous system pathology: Hypothalamic damage can result in a severe form of obesity in children and adolescents.
- Acute lymphatic leukaemia therapy: There is general agreement that, at the end of therapy for acute lymphatic leukaemia, there is a higher prevalence of obesity among participants than at the commencement of therapy and that obesity persists.
- Medications: The role of pharmacological agents in causing weight gain in children and adolescents has not been extensively studied.

Recommendations about what to assess included:

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- weight history of the child and first-degree relatives
- medical history
- family, school, and social environments (Australia data only)
- ethnicity (Australia data only)
- eating and physical activity behaviour of child and parents.

A recent cohort study<sup>3</sup> aimed to identify risk factors in early life (up to 3 years of age) for obesity in children in the UK. Participants were 8234 children in a cohort aged 7 years and a sub-sample of 909 children with data on additional early growth-related risk factors. Data from 5493 children were available for the multivariate analysis. Risk factors in entire cohort were as follows: intrauterine and perinatal factors, infant feeding and weaning practice, family characteristics and demographics, lifestyle in early childhood, sedentary behaviour, and dietary patterns. From these, birth weight, parental obesity, sleep duration, and television viewing remained independently connected with the risk of obesity in the final model. Also, a further four factors were significant in the children in focus subsample: size in early life, weight gain in infancy, catch-up growth, and early adiposity or BMI rebound.<sup>3</sup>

## 15.2.3 Lifestyle interventions in weight management and other outcomes in children and adolescents

#### 15.2.3.1 Evidence statements (Table 15.3)

#### Table 15.3 Evidence statements and grading

No.	Evidence statement	Grade	
Weight loss			
1	The main requirement of a dietary approach to weight control is a reduction in total energy intake, with caloric expenditure exceeding caloric intake	GPP	
	Energy balance is critical to weight loss. Energy expenditure must		

No.	Evidence statement	Grade	
	exceed energy intake		
2	In specialist weight management programmes, physical activity and diet combined are more effective in weight management in children aged 4–16 years, than diet alone	1++	
3	There is no evidence on the effectiveness of physical activity alone in the treatment of childhood obesity in a clinical setting		
4	There is no clear evidence on which dietary intervention is the most effective in weight reduction and management in children and adolescents		
5	Any recommended diet should be consistent with other healthy eating advice	GPP	
	Strict diets are not appropriate for children and adolescents except in rare occasions where combined with specialist supervision and intensive follow-up		
6	As part of a specialist weight management programme in the USA, targeting sedentary behaviour <sup><math>†</math></sup> was shown to be as effective as promoting physical activity in managing weight in obese children aged 8–12 years.	1+	
7	As part of a specialist weight management programme in the USA, lifestyle <sup>‡</sup> exercise was shown to be more effective than aerobic and calisthenics exercise in maintaining weight loss in obese children aged 8–12 years.	1+	
8	In specialist weight management programmes, behavioural treatment combined with physical activity and/or diet is effective in the treatment of obese children and adolescents aged 3–18 years	1++	
9	In specialist weight management programmes behavioural treatment can be more effective if parents, rather than children (aged 6 to 16 years), are given the main responsibility for behaviour change.	1++	
10	There is no evidence on which components of behavioural treatment are the most effective for childhood and adolescent obesity		
Out	Outcomes other than weight loss (from trials that reported weight loss)		

<sup>&</sup>lt;sup>†</sup> Watching television, playing computer games, imaginative play, talking on the phone, and playing board games.

<sup>&</sup>lt;sup>+</sup> Lifestyle exercise relates to integrating exercise into the person's lifestyle without the focus on exercise intensity. It can be walking or cycling to school, walking up and down stairs or walking at lunch.

No.	Evidence statement	Grade
11	As part of specialist weight management programmes, physical activity can improve levels of fitness in obese children aged 8–12 years	1+
12	There is conflicting evidence on whether weight management programmes improve HDL and LDL cholesterol, and triglyceride levels in obese children	1++
13	There is conflicting evidence on whether weight management programmes improve diastolic and systolic blood pressure in obese children	1–
14	Specialist weight management programmes including diet and physical activity can improve the eating behaviour of 8–12-year-old obese children	1++
15	In specialist weight management programmes, behavioural treatment can have a positive effect on dietary quality	1++
16	In a specialist weight management programme targeting black adolescent girls aged 12-16 years, behavioural treatment improved self-esteem and feelings of depression	1+
17	In specialist weight management programmes, behavioural treatment can improve self-control in regard to weight-related behaviours in children aged 5–13 years	1+
18	In specialist weight control programmes, decrease in weight loss was associated with a decrease in consumption of 'red foods' in obese children aged 6–12 years	1+
19	Inpatient weight management programmes, with cognitive behaviour therapy can improve quality of life over time in obese children and adolescents aged 9–19 years	1+
Harr	ns (from trials that reported weight loss)	
20	Both a protein-sparing modified diet and a hypocaloric balanced diet delivered in a school and outpatient programme setting can produce mild to moderate side effects such as: fatigue, weakness, muscle cramps, bad breath, headaches and abdominal pain in obese children aged 7–16 years	2+

GPP, good practice point ; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

#### 15.2.3.2 Evidence review on lifestyle interventions

There is scarce evidence on which are the required components or treatment phases for childhood obesity. However, throughout the literature it appears that a multidisciplinary approach is most commonly advocated. Programmes normally include one or several of the following components:

- nutritional and physical activity advice
- behavioural treatment components
- decreasing sedentary activities, and increasing lifestyle activities
- social and/or psychological support.

This review is partially based on the Cochrane review published in 2003.<sup>4</sup> The aim of the Cochrane review was to systematically review the effects of a range of lifestyle interventions designed to treat obesity in childhood. The Cochrane review included interventions such as: diet, physical activity, and/or behaviour therapy with or without the participation of family members.

This section reviews evidence on the assessment of the effectiveness of lifestyle interventions such as dietary change, physical activity, behaviour therapy, or some combination of these components.

The inclusion criteria for this evidence review initially followed the steps of the Cochrane review, although in light of the scarcity of randomised evidence in regard to the treatment of obesity in adolescents and children, a revised inclusion criteria was defined which encompasses the following designs of studies.

#### Types of study

- Randomized randomised controlled trials (RCTs)
- Controlled clinical trials
- Controlled before-and-after studies

Only studies with a minimum duration of 6 months or above (including follow-up) and published after 1985 were included, and also RCTs with a primary aim other

than the treatment of childhood obesity. Studies based in a setting other than clinical were not included in this review.

Update searches have been undertaken, however no studies were included as none added further details or contradicted any of the recommendations.

#### Types of participant

 Participants aged under 18 years at the start of the study, and exceptionally studies where the age cut-off was above 18 years and where the majority of the participants were below 18 years or presented age stratification.

#### Types of outcome

- Primary outcomes to be measured (not self-reported) estimates of overweight in per cent, BMI, weight in kilograms, per cent weight loss, percentage of ideal body weight, BMI z-score and others.
- Secondary outcomes to be behaviour change, participants' views, measures of self-esteem, health status, well-being and quality of life.

Finally several other studies were retrieved by cross-referencing with the review of systematic reviews,<sup>5</sup> the Australian Clinical Practice Guidelines for the Management of Overweight and Obesity in Children and Adolescents (NHMRC),<sup>2</sup> The Scottish Intercollegiate Guidelines Network (SIGN),<sup>6</sup> and other reviews.<sup>7–17</sup>

We considered the following as a working definition of what is behavioural treatment<sup>§</sup> when reviewing and assessing the interventions described in the published papers.

 Behavioural treatment draws on the principles of learning theory (stimulus– behaviour contingencies or behaviour–reward contingencies)

<sup>&</sup>lt;sup>§</sup> Conceptual input from Professor Jane Wardle.

- Assessment consists of identifying and specifying problem behaviours and the circumstances in which they are elicited (both antecedents and consequences).
- Treatment starts with setting specific, measurable and modest goals that are continually revised as progress is achieved.
- Target behaviours are monitored usually by the child and/or parent to obtain a record of behaviour change.
- Behaviour change processes include stimulus control, graded exposure, extinction and reward.
- The perspective is educational: teaching behaviour change skills to the client. The term problem-solving skills may be used, but this does not necessarily mean that the treatment contains the other elements of conventional behavioural treatment.
- The term cognitive (as in 'cognitive behaviour' or CBT) may imply the inclusion of strategies designed to modify cognitions (thoughts) which can be identified as important stimuli for behaviour.

A treatment is behavioural if the published paper:

- uses the terms behavioural treatment, cognitive behavioural treatment, behaviour therapy or CBT
- mentions learning theory
- refers to the use of the common components of behavioural treatment (selfmonitoring, goal-setting, stimulus control).

Terms that do not, in themselves, denote behavioural treatment are:

motivational interviewing

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- counselling
- learning
- psychological
- psychotherapy
- problem solving
- cognitive.

#### Settings

From 42 studies that were included in this review the majority consisted of specialist outpatient weight reduction programmes in university obesity research clinics in the USA.<sup>18–23,25,27–31,38,40,43–47,51,53,59–61</sup> The other studies were as following:

- outpatient research clinic in Hong Kong<sup>33</sup>
- inpatient child obesity treatment programme in a medical centre in France<sup>35</sup>
- outpatient paediatric clinic at the University of Leuven (Belgium) <sup>34</sup>
- outpatient child obesity treatment programme at Tel Aviv University<sup>24</sup>
- outpatient child obesity research clinic at the University of Graz (Austria) <sup>32</sup>
- outpatient service at a paediatric hospital in Cuba<sup>36</sup>
- family paediatrician office (Primary Care) in Italy<sup>37</sup>
- referral from school after screening in Sweden<sup>26</sup>
- university outpatient research clinic in Australia<sup>39</sup>
- US outpatient paediatric primary care clinic<sup>41</sup>

- university outpatient research clinic in Isreal<sup>49</sup>
- appears to be a research clinic in Australia<sup>54</sup>
- inpatient rehabilitation hospital in Germany<sup>55</sup>
- outpatient and inpatient research programmes in Belgium.<sup>56–58</sup>

#### **Dropout rates**

Overall, the retrieved studies are of poor methodological quality, and the high dropout rates have an even greater impact on the robustness of the evidence for the treatment of obesity in obese/overweight adolescents and children, as seen in Table 15.4.

•	•
Epstein et al. 1995 <sup>19</sup>	10%
Epstein et al. 1985 <sup>21</sup>	17%
Epstein et al. 2000 <sup>20</sup>	15%
Epstein et al. 1985 <sup>40</sup>	5.%
Schwingshandl et al. 1999 <sup>32</sup>	33%
Woo et al. 2004 <sup>33</sup>	Unclear
Rolland-Cachera et al. 2004 <sup>35</sup>	40%
Reybrouck et al. 1990 <sup>34</sup>	48%
Amador et al. 1990 <sup>36</sup>	17%
Nova et al. 2001 <sup>37</sup>	30%
Spieth et al. 2000 <sup>38</sup>	56%
Figueroa-Colon et al.1993 <sup>22</sup>	No dropouts
Epstein et al. 1984 and 1989 <sup>23</sup>	20%
Eliakim et al. 2002 <sup>24</sup>	13%
Sothern et al. 2000 <sup>25</sup>	21% for treatment group
	65% for controls
Epstein et al. 2004 <sup>59</sup>	17%
Epstein et al. 1994 <sup>60</sup>	11%

#### Table 15.4 Dropout rates in studies on treatment of obesity

Epstein et al. 1987 <sup>61</sup>	Unclear
Flodmark et al. 1993 <sup>26</sup>	21% conventional treatment group
	37% for the family therapy group
	No details for control group.
Israel et al. 1990 <sup>28</sup>	Helper group 14%
	Weight loss group 8%
Epstein et al. 1986 <sup>29</sup> and 1987 <sup>30</sup>	20 %
Mellin et al. 1987 <sup>27</sup>	16%
Graves et al. 1988 <sup>53</sup>	23%
Epstein et al. 2000 <sup>31</sup>	7.5%
Epstein et al.1985 <sup>18</sup>	15%
Senediak and Spence 1985 <sup>39</sup>	31%
Golan and Crow1998 <sup>48</sup> and Golan et al. 2004 <sup>49</sup>	17%
Israel et al.1985 <sup>45</sup>	39%
Wadden et al. 1990 <sup>43</sup>	22% in paper, although equals 34% through calculation
Israel et al.1994 <sup>44</sup>	41%
Epstein et al. 1981 <sup>47</sup> and 1987 <sup>46</sup>	Unclear
Wrotniak et al. 2004 <sup>51</sup>	Not applicable
Duffy and Spence 1993 <sup>54</sup>	37%
Warschburger et al. 2001 <sup>55</sup>	No details given
Braet et al.1997 <sup>56</sup> and Braet and Van Winckel 2000 <sup>57</sup>	20%
Braet et al. 2003 <sup>58</sup>	Seven children left the programme during the study. At 6 months, data for 3 children could not be collected, and at 14 months one additional child could not be traced

#### **Guidelines summary**

In September 2005, the National Guideline Clearinghouse synthesised the recommendations on the assessment and treatment of obesity and overweight in children from six published guidelines (Table 15.5).

### Table 15.5 Summary of recommendations on the assessment and treatment of obesity in children

Management of overweight and obesity		
AAP (2003)	No recommendations offered.	
AHA (2005)	The principal strategies for the treatment of overweight in children are similar to those for adults (dietary modification and increased physical activity), with treatment goals based on age, severity of obesity and the results of risk factor assessment	
	Five guiding principles are important for the treatment of overweight. These guiding principles can be summarised as follows:	
	<ol> <li>Establish individual treatment goals and approaches based on the child's age, degree of overweight, and presence of comorbidities.</li> </ol>	
	2. Involve the family or major caregivers in the treatment	
	3. Provide assessment and monitoring frequently	
	<ol><li>Consider behavioural, psychological and social correlates of weight gain in the treatment plan</li></ol>	
	<ol><li>Provide recommendations for dietary changes and increases in physical activity that can be implemented within the family environment and that foster optimal health, growth and development.</li></ol>	
	Treatment of overweight should rarely be instituted before 2 years of age because of the rapid growth and development that occurs during these early years and lower correlation with overweight in later years. Family involvement is critical in the treatment of childhood overweight. If treatment is initiated when a family is not ready to support the programme, then success is unlikely. The treatment planned should also take into consideration long-term management with the continued assessment of the child for adequate growth and development because overweight is a long-term problem	

Dietary management

Age-specific dietary modification is the cornerstone of treatment. The major goals in dietary management are to provide appropriate calorie intake, provide optimum nutrition for the maintenance of health and normal growth, and to help the child develop and sustain healthful eating habits

Estimated energy requirements vary throughout childhood and reflect large increments with a range of 570–3152 kcal/day for boys and 520– 2368 kcal for girls from age 3 months to 16 years. In addition, caloric needs may vary widely even for children of the same age because of normal differences in size. Thus, individualising the calorie intake recommendation and monitoring weight change are essential. Healthcare professionals must help parents or caregivers recognise and prevent overeating

Because it is difficult for parents to judge calorie intake and energy expenditure on a regular basis, it is necessary to help parents guide the diet and physical activity patterns of their children. Counselling and recommendations must be made and socioeconomic status. Involving children in meal planning, shopping, gardening, and preparation of food has been promoted, along with including all caregivers (including grandparents) in helping the child to adhere to recommended consumption patterns and healthier food choices

#### Physical activity

Regular physical activity is critical for the prevention of abnormal weight gain and weight maintenance. The current recommendation for the amount of physical activity is 30– 60 minutes of daily regular physical activity. 'Working up a sweat' during the activity suggests adequate effort expended. These recommendations apply to children of normal weight as well as to children who are overweight

Recommended activities must be enjoyable and congruent with the child's and family's lifestyle and be rewarding independent of the health benefit

A complementary approach is to restrict sedentary free-time activities to < 2 hours/day

RNAO (2005) No recommendations offered.

SIGN (2003)	Weight maintenance
	<ul> <li>In most obese children (BMI &gt; 98th centile) weight maintenance is an acceptable goal (recommendation grade: D)</li> <li>Weight maintenance and/or weight loss can only be achieved by sustained behavioural changes, for example:</li> </ul>

	Healthier eating, increasing habitual physical activity (for example, brisk walking) to a minimum of 30 minutes per day. In healthy children, 60 minutes of moderate vigorous physical activity/day has been recommended
	Reducing physical inactivity (for example, watching television and playing computer games) to < 2 hours/day on average or the equivalent of 14 hours/week (recommendation grade: D)
	In overweight children (BMI > 91st centile) weight maintenance is an acceptable goal. Annual monitoring of BMI percentile may be appropriate to help reinforce weight maintenance and reduce the risk of children becoming obese
Singapore	Dietary changes
MOH (2004)	In children, less restrictive diets should be used, rather than diets consisting of drastically altered portions of various nutrients, very-low- calorie diets, or protein-sparing modified fast regimens (grade B, level III)
	Physical activity
	Appropriately increased physical activity is recommended. Younger children generally need age-appropriate creative activities with generous periods of free play. Weight-bearing activities are recommended for overweight children, non-weight bearing activities for obese children, and preferably supervised activities for severely obese children. In the older obese pre-adolescent and adolescent, decreased time on sedentary pursuits and increased activity such as a moderate intensity, progressive physical activity programme with increasing levels of obesity are recommended (Grade B, level III)
	Behaviour modification
	Behaviour treatment programmes have shown consistent success in weight loss (Grade B, level IIa)
	Family involvement
	Interventions for obesity in children should be directed at both the parents and the child, rather than the child alone. (Grade B, level III)

#### USPSTF Insufficient evidence is available on the effectiveness of interventions for (2005) overweight children and adolescents that can be conducted in primary care settings or to which primary care clinicians can make referrals. No specific recommendations are given concerning management of overweight and obesity.

AAP, American Academy of Pediatrics; AHA, American Heart Association; BMI, body mass index; MOH, Ministry of Health; RNAO, Registered Nurses Association of Ontario; SIGN, Scottish Intercollegiate Guidelines Network; USPSTF, United States Preventive Services Task Force.

### Interventions emphasising a combination of diet and/or physical activity and behavioural modification component

Weight loss

According to the results from one study by Epstein and coworkers based on a specialist weight management programme, it appears that lifestyle exercise<sup>\*\*</sup> can be more effective than aerobic exercise and calisthenics in maintaining weight loss.<sup>18</sup> Children in the lifestyle group maintained their weight change, whereas children in the aerobic exercise group gained significant amounts of weight. After 24 months the lifestyle exercise group had significantly lower per cent overweight than the aerobic group. After 24 months the difference in per cent overweight between the lifestyle exercise group (large reduction in sedentary behaviours) and the calisthenics group was significant. At 24 months, the lifestyle group had maintained relative weight changes whereas the calisthenics group had returned to baseline levels.<sup>18</sup>

Two studies looked at the effect of decreasing sedentary behaviours on weight reduction. In one of these studies, Epstein and coworkers compared reinforcing decreased sedentary activity to reinforcing increased physical activity, and reinforcing decreased sedentary activity and increased physical activity.<sup>19</sup> The results suggest that the decreased sedentary behaviours group (reduced time spent on watching television, playing computer games, imaginative play, talking on the phone and playing board games) had a more significant reduction in

<sup>&</sup>lt;sup>\*\*</sup> Lifestyle exercise relates to integrating exercise into the person's/children's lifestyle without the focus on exercise intensity. It can be walking or cycling to school, walking up and down stairs or walking at lunch.

percentage overweight than the combined and exercise groups at year 1.<sup>19</sup> In another study, Epstein and coworkers compared decreased sedentary behaviours with increased physical activity; high against low doses of increased physical activity; and high against low doses of reducing sedentary behaviours.<sup>20</sup> Both the reduction of sedentary behaviours and increase of physical activity ranged from 10 to 20 hours per week. Results show a reduction in percentage overweight greater at 6 months than at 24 months for all groups, having a slightly higher reduction in both the high dose decreased sedentary behaviour and high dose increased physical activity groups. The results indeed suggest that targeting inactivity can be as useful as targeting increased physical activity. However, the results were only statistically significant for the first study.<sup>19</sup>

In one Epstein et al. study that included girls aged 8–12 years, percentage overweight in the diet plus exercise group showed greater decreases from baseline to 6 and 12 months, than in the diet-only group.<sup>21</sup> Nevertheless, results were only statistically significant for the 6 months follow-up. One clinical controlled trial<sup>22</sup> compared a protein-sparing modified fast diet (PSMF) (50% protein, 40% fat, 10% carbohydrate) with a hypocaloric balanced (HCB) (20% protein, 30% fat, and 50% carbohydrate) in children ranging from 7.5 to 16.9 years, associated with 20 minutes of daily aerobic activity and behavioural modification components. Results suggest that on a short-term basis (10 weeks), PSMF achieved a greater weight loss (statistically significant) than the HCB diet. At 6 and 14.5 months the results were not significant. However, percentage overweight significantly decreased in the PSMF compared with the HCB at 6 and 14.5 months.<sup>22</sup>

Epstein and coworkers<sup>23</sup> also assessed the effects of weight change on serum lipids in overweight children aged 8–12 years old. This study compared participants who were on diet only to participants with diet plus lifestyle change exercise programme and a control group, although the two treatment groups (which appear to have been given behavioural intervention as described in the evidence table) were then combined as no difference was found between them. Up to 6 months, significant improvements in weight and percentage overweight were reported, although such changes were not maintained at 5 years followup.<sup>23</sup>

Eliakim and coworkers compared the effects of a weight management programme on body weight in obese children and adolescents aged 6 –16 years against a control group that was referred every 3 months to an outpatient nutritional consultation. Participants were prescribed a hypocaloric diet, a twiceweekly training programme (1 hour) and encouraged to reduce inactivity. The treatment group had a statistically significant decrease in body weight and BMI at 3 and 6 months compared with the controls.<sup>24</sup>

Sothern and coworkers<sup>25</sup> evaluated the safety, feasibility and efficacy of a resistance-training programme in obese children aged 7–12 years, with a PSMF diet, a moderate-intensity progressive exercise programme and behaviour modification. Total body weight significantly decreased at 10 weeks (p < 0.0003) and 1 year (p < 0.0003), and BMI also significantly decreased at 10 weeks (p < 0.0003) the every structure of the 10 week and 1 year follow-up was not significant.<sup>25</sup>

Flodmark and coworkers<sup>26</sup> evaluated the effect of family therapy on 44 obese children aged 10–11, by studying two treatment groups: one whereby children were given family therapy, and a second group that was given conventional treatment (for further detail on each treatment see evidence table [Appendix 13]). The results suggest that the increase of BMI was higher in the control group and conventional treatment group (p = 0.04 and p = 0.02, respectively), than in the family therapy group.<sup>26</sup>

In the SHAPEDOWN programme study,<sup>27</sup> a range of cognitive, behavioural, affective, and interactional techniques was adapted to the needs of adolescents, encouraging adolescents to make continuous, sustainable, small modifications in diet, exercise, relationships, lifestyle, communications and attitudes. Relative weight decreased significantly during the first 3 months. For the subsequent 3

months, both groups decreased their relative weights in comparison with baseline values (p < 0.001), although by month 15 both groups' relative weight had diverged significantly (p < 0.01).<sup>27</sup>

Israel and coworkers<sup>28</sup> assessed two levels of parental involvement roles in the treatment of childhood obesity, and findings suggest that the group in which parents focused their efforts on the child (helper condition) was slightly superior than the group in which the parents also engaged in their own weight loss (weight loss condition), although there was no difference in the overall child's weight status at 1-year follow-up.

#### Parent weight as predictor of child weight

Epstein and co-workers also examined, in two studies belonging to the same trial,<sup>29,30</sup>, the effect of parent weight on the weight loss of obese pre-adolescent children – beyond the effect of parent control versus child self-control. At year 1, children of non-obese parents were significantly lighter (p < 0.01) than baseline (% = -16.3) and lighter (p < 0.01) than children of obese parents (% = -7.7). Nevertheless these changes were not significant at 5 years. Thus, parent weight can be related to weight loss, but not weight maintenance in obese children.

#### Other outcomes

In one study, physical work capacity improved significantly, with increases of 33% from baseline to 6 months, and 55% from 6 to 24 months. Per cent time of being active also increased from baseline to 2 years, and targeted sedentary behaviours showed significant decrease from baseline at 6 and 24 months.<sup>31</sup> Epstein and coworkers<sup>18</sup> reported that only children in the aerobic exercise group maintained significant improvements in fitness at 1 years, whereas in the lifestyle exercise group, significant improvements were observed up to 6 months, although they returned to baseline levels of fitness at 1 year. No changes in fitness were observed for the calisthenics group. In another Epstein et al. study, child fitness improved significantly over time, with no differential changes by

group.<sup>19</sup> Physical fitness was also improved in the family therapy group after 1 year follow-up (p = 0.047).<sup>26</sup>

Epstein and coworkers<sup>18</sup> also reported that eating behaviour in children improved significantly across all groups. The relative weight changes between parents and children increased across time, with p < 0.01 from 0 to 6 months, p < 0.01 from 6 to 12 months and p < 0.01 from 12 to 36 months.<sup>18</sup>

In one study, biochemical factors remained within normal values in every child throughout the duration of the study. Changes in both blood pressure and serum cholesterol and triglyceride levels were not significant. However, when the two groups were combined the initial mean serum cholesterol values decreased significantly at 10 weeks.<sup>22</sup>

Epstein and coworkers reported that high-density lipoprotein (HDL)-cholesterol levels significantly increased over the 6 months of the study. Serum cholesterol (p = 0.03) and serum triglycerides levels decreased (p = 0.01) significantly over 6 months. Moreover, fitness also improved significantly.<sup>23</sup>

In one clinical controlled trial, endurance time was significantly greater in the treatment group.<sup>24</sup>

Participants of the SHAPEDOWN trial showed significant improvements in weight-related behaviour, depression, self-esteem and knowledge of weight management concepts at post treatment and at 12 months follow-up compared with the control group.<sup>27</sup>

Children with non-obese parents were more compliant towards calorie limit (p = 0.01), exercise goal (p = 0.02), and self-monitoring (p = 0.01) components of treatment and showed better results in eating behaviour (p < 0.01), than those with obese parents.<sup>29,30</sup>

#### Reported harms

Almost half the children in two dietary groups reported decreased appetite. Hunger, fatigue, weakness, and muscle cramps were more common in the hypocaloric group. Of the children in the PSMF group, 11% reported bad breath, and 19% of the children in the HCB group reported headaches and abdominal pain.<sup>22</sup>

#### Other factors

No additional analysis was conducted on the effect of age, ethnicity, socioeconomic status, previous treatment for obesity, motivation, gender, degree of overweight/obesity, current medical conditions and setting and/or healthcare professional.

#### Methodological and context notes

It must be noted that in the study by Figueroa-Colon,<sup>22</sup> both dietary groups were placed on a hypocaloric diet after 3 months. However, this study was very small. The authors contend that both PSMF and HCB diets should not be used without close medical supervision.<sup>22</sup>

#### Interventions emphasising diet and physical activity

#### Weight loss

The results from three studies<sup>32–34</sup> suggest that combining physical activity with dietary interventions is more effective than diet alone. In one case, Schwingshandl and coworkers<sup>32</sup> reported that after 12 weeks the children given physical training and dietary advice (mean age 11.0) had significantly greater mean change in fat-free mass than the children given dietary advice alone (mean age 12.2).

An additional primary study, which was published after the Cochrane review, reported that at 1 year, there were significant changes in body fat content from baseline in the combined group but not in the diet-only group. No change in weight was reported, although BMI showed no significant changes in either group.<sup>33</sup>

Reybrouck and coworkers<sup>34</sup> compared a low-calorie diet (800–1000 kcal) combined with physical activity against diet only in children aged 3.9–16.4 years. The results also suggest that the mean decrease in overweight at 4 months was significantly greater for the children in the combined group than in those treated with diet only. At 8 months the mean decrease was much smaller and similar between the two groups.

Rolland-Cachera and coworkers<sup>35</sup> compared two different diets in an inpatient setting in France: one composed of 15% protein and 54% carbohydrates (prot –), and the other composed of 19% protein and 50% carbohydrate (prot +) in children aged 11–16 years, with no statistically significant differences being reported between the two groups. Both groups showed a mean BMI decrease of 12.5 (statistically significant). Results suggest that the prot+ content did not induce any additional effectiveness in the treatment of childhood obesity, although weight loss was achieved with the combination of a moderately energy-restricted diet and normal fat content and physical activity (7 hours per week of vigorous sports and 7 hours per week of outdoor activities).

Amador and coworkers<sup>36</sup> compared a non-restricted diet with a restricted one (up to 30% of energy requirements) combined with a physical activity programme. Results suggest that a non-restricted diet delivered a greater weight decrease (statistically significant) than the restricted diet at 6 and 12 months, although greater at 6 months. Nova and coworkers<sup>37</sup> assessed the effect of having a greater level of involvement of the family paediatrician and family in the long-term management of obese children aged 3–12 years. The results suggest that a greater involvement from the family paediatrician and commitment from the family have a significantly greater reduction in percentage overweight at 6 and 12 months.

#### Other outcomes

In one trial, a significant decrease was seen in total cholesterol in both groups with low-density lipoprotein (LDL)-cholesterol decreasing only in the exercise group. Fasting glucose (p < 0.002) reduced slightly in the exercise group only. Between the first and second year, in both groups the energy intake increased by 171 kcal, physical activity decreased and time watching television increased.<sup>35</sup>

#### Other factors

No additional analysis was conducted on the effect of age, ethnicity, socioeconomic status, previous treatment for obesity, motivation, gender, degree of overweight/obesity, current medical conditions and setting and/or healthcare professional.

#### Methodological and context notes

Again, there is lack of robust evidence on this specific topic, thus, the validity and generalisability of the conclusions remain unconfident. Nevertheless, it is worth noting that due to the other health benefits, a healthy diet and physical activity are recommended for everyone regardless of their weight. In this sense, a healthy diet and the increase of the levels of physical activity in children should be promoted, regardless of their effect on weight reduction.

#### Interventions emphasising diet only

Weight loss

Few studies have examined the effects of dietary interventions alone on weight reduction in obese children, and to date we have not found any randomised clinical trial that assesses such interventions per se. Nevertheless, one retrospective cohort study<sup>38</sup> has suggested that a low glycaemic index (GI) diet can be effective in the management of childhood obesity with a mean age of 10.6 years. The results indicate that the low-GI diet (with no restriction of total energy or specific macronutrient consumption) had a statistically significant BMI

reduction of -1.47 kg/m<sup>2</sup> whereas the standard reduced-fat diet had a reduction of -0.20 kg/m<sup>2</sup> (statistically significant).<sup>38</sup>

#### Other outcomes

No other outcomes have been reported.

#### Other factors

The statistically significant difference (-1.15 kg/m<sup>2</sup> for the low-GI diet vs -0.03 kg/m<sup>2</sup> for the reduced-fat diet) remained the same after adjusting for age, sex, ethnicity, length of follow-up, baseline BMI and behaviour therapy referral.<sup>38</sup> No further analysis was conducted on socioeconomic status, previous treatment for obesity, motivation, degree of overweight/obesity, current medical conditions and setting and/or healthcare professional.

#### Methodological and context notes

It must pointed out that the data concerning dietary interventions were based on a retrospective cohort study, with a significant dropout rate and possible biases.<sup>38</sup>

# Interventions where the main focus was behavioural treatment in comparison with no treatment or usual care *Weight loss*

Part of the evidence suggests that behaviour therapy can be more effective than conventional care, as three studies reported better results for behaviour therapy compared to usual care<sup>††</sup> and/or controls.<sup>39–41</sup> Senediak and Spence<sup>39</sup> examined the effects of rapid (eight sessions in 4 weeks) or gradual (eight sessions over 15 weeks) behaviour therapy versus a non-specific control condition and a wait-list control group in obese children aged 6–13 years. Percentage overweight in the rapid behaviour group significantly decreased from baseline to 6 months, and in the gradual behaviour group, percentage overweight significantly decreased from

<sup>&</sup>lt;sup>††</sup> For further details, see evidence tables for each study.

baseline to 6 months. In the non-specific control group, mean percentage overweight significantly decreased from baseline to 6 months. No significant differences were found between the rapid and gradual groups over 6 months.<sup>39</sup> In one of Epstein and coworkers' trials, which assessed a family-based behaviour therapy on obese children aged 5–8 years, BMI significantly decreased from baseline to 12 months in the behaviour group compared with the control group (prescribed with the traffic light diet<sup>‡‡</sup> and physical activity six times per week, but no behavioural intervention).<sup>40</sup> Post-hoc analyses showed significant differences between groups for per cent overweight and BMI at 8 and 12 months. In Saelens and coworkers<sup>41</sup> evaluation of a behavioural weight control programme for obese children aged 12–16 years, the results suggest that the BMI for the experimental group (healthy habits [HH] – multi-component behavioural weight control intervention) decreased (not significant) from baseline to follow-up. For the usual care group (typical care [TC] – single session of physician weight counselling), BMI significantly increased after the 4-month treatment and 3-month follow-up.<sup>41</sup>

#### Other outcomes

In one study, results suggest that treated children had improved eating habits compared with the control group, and a main effect of improved self-control was observed over time in children, although no changes in parent self-control were reported.<sup>40</sup> According to Saelens and coworkers,<sup>41</sup> the HH adolescents reported higher rates of total and eating specific behavioural skills use than the TC adolescents (p < 0.03). Parents of the HH adolescents also reported that their

<sup>&</sup>lt;sup>‡‡</sup> The majority of the studies from Epstein and coworkers (which are extensively used as evidence throughout interventions to treat childhood obesity) are based on the traffic light diet. This is a calorie-based food-exchange system. Foods are divided into five groups (fruits and vegetables, grains, proteins, dairy and other foods) and the foods in each group are colour coded according to nutrient density: green for 'go', yellow for 'eat with care'; and red for 'stop'. Green foods are foods containing fewer than 20 calories per serving, yellow foods are the staple of the diet and provide most of the basic nutrition, and red foods are those foods high in fat and simple carbohydrates. All sweets and sugared beverages are classified as red foods. Families are then instructed to count calories and cannot have more than four red foods a week.

adolescents used more overall and specifically eating-related behavioural skills than did parents of TC adolescents (p < 0.04). HH adolescents continued to report higher overall and eating-related behaviour skills use at follow-up assessment compared with the TC adolescents (p < 0.01).

#### Other factors

No additional analysis was carried out on the effect of age, gender, ethnicity, socioeconomic status, previous treatment for obesity, degree of overweight/obesity, motivation, frequency or length of the intervention and current medical conditions.

### Interventions comparing behavioural treatment at varying degrees of family involvement

Weight loss

Several pieces of research on obesity treatment in children and adolescents have assessed the influence of including family members in the therapy process.

There seems to be substantial evidence that behavioural treatment is more effective in children and adolescents aged 6–16 years if the parent(s) are given the main responsibility for the behaviour change.<sup>42–47</sup> Golan and Crow<sup>48</sup> published a 7-year follow-up of previous studies,<sup>42,49</sup> and results demonstrated that the mean reduction in per cent overweight was superior in children of the parent-only group compared with those in the children-only group (p < 0.005). These results suggest that involving parents in the therapy process can be also more effective on a long-term weight loss and maintenance basis in obese children, as also seen in the next study. A 10-year follow-up study published by Epstein and coworkers<sup>50</sup> with children aged 6–12 years aimed to compare three groups: child and parent target (group 1), child target (group 2), and non-specific target (group 3). At both 5 and 10 years, significant per cent overweight differences (p < 0.05) were shown between children in groups 1 and 3 with children in group 2 midway between the other groups.

#### Parent weight as predictor of child weight

One study which consisted of a secondary data analysis based on three RCTs<sup>51</sup> (already included in this review), aimed to assess whether parent-standardised BMI (z-BMI) change influences child z-BMI (in children aged 8–12 years). Results suggested that parent z-BMI change can be a predictor of obese child z-BMI change in family-based treatment. Children of the parents in the greatest z-BMI change quartile had greater reductions in z-BMI changes over time (p = 0.01) than children of parents in the other three groups, who had smaller reductions or gains in z-BMI.<sup>51</sup> Nevertheless, it seems that the results are also connected with the participation of the parents in the treatment process, and not solely due to their weight loss.

#### Other outcomes

Wadden and coworkers<sup>43</sup> reported that total cholesterol concentration and HDLcholesterol decreased significantly during treatment (p< 0.01 and p < 0.06, respectively). Furthermore, scores on the Pier–Harris scale<sup>§§</sup> increased significantly (p < 0.05) during treatment, indicating possible improvement in selfesteem, and the child depression inventory decreased significantly (p < 0.01), which shows reductions in feelings of depression.<sup>43</sup> Even before treatment, participants scored well within normal limits on both measures.<sup>43</sup> Neither the participants mean initial risk of cardiovascular disease, nor mean triglyceride level or blood pressure registered any significant changes.<sup>43</sup>

Golan and coworkers<sup>42</sup> pointed out that significant increase in the children asking permission to take or buy sweets was noted only in the experimental group – (p < 0.001) for taking and (p < 0.01) for buying – at termination of the programme. An overall reduction in the prevalence of poor eating habits was significantly greater in the experimental group. Moreover, a significant positive

<sup>&</sup>lt;sup>§§</sup> Piers EV. *Piers–Harris children's self-concept scale revised manual*. Los Angeles, CA: Western Psychological Services, 1984.

correlation was reported between the children's reduction in overweight and the following: presence of food stimuli in the house, eating while standing, eating while doing another activity, eating following stress situations, eating between meals, place of eating and activity level.<sup>42</sup> At the 7-year follow-up, Golan and coworkers reported that 6.6% of the girls from the child-only group reported eating disorder symptoms (binging and purging).<sup>48</sup>

Israel and coworkers<sup>44</sup> reported that the analysis of the Eating and Activity Self-Control Scale (EASC) indicated an increase in children's self-control and parental control regarding weight-related behaviours (p < 0.001 and p < 0.05), respectively). Parental opinion from the self-control rating scale also indicated significantly more self-controlled behaviours at week 26 than at week 1. Moreover, higher EASC self-control scores were significantly correlated with decreases in percentage overweight during treatment (p < 0.05).

Epstein and coworkers<sup>47</sup> indicated that there was an overall decrease in food intake from pre to post treatment (8 months), and that there was a strong relation between changes in red food intake and weight loss (p < 0.02).

#### Other factors

No additional analysis was carried out on the effect of age, gender, ethnicity, socioeconomic status, previous treatment for obesity, degree of overweight/obesity, motivation, frequency or length of the intervention and current medical conditions.

#### Methodological and context notes

Another study examined the feasibility and generalisability of a family-based behavioural treatment for childhood obesity in a clinical setting in Britain, and assessed whether the results were comparable with the original studies in the USA. Although this study was excluded from our review, it is important to mention, considering the proportion of studies from the USA that are included in this study. The results support the applicability of the family-based behavioural treatment in a clinical setting in Britain.<sup>52</sup>

#### Interventions comparing problem solving, in addition to behaviour therapy with usual care or behaviour therapy *Weight loss*

Based on the analysis of the results from two studies, there seems to be some contradictory evidence regarding the comparison of problem solving with behaviour therapy. Graves and coworkers<sup>53</sup> aimed to examine the effects of incorporating parental problem solving training in a behavioural weight reduction programme in obese children aged 6–12 years. Results suggest that combining problem solving with behaviour therapy may be more effective than behaviour therapy alone, as percentage overweight in the problem solving group had a greater decrease (p < 0.01) from baseline to 6 months than in the behaviour treatment only group .<sup>53</sup> Epstein and coworkers<sup>31</sup> also compared including parent and child problem solving to a behavioural weight control programme, only child problem solving and standard treatment (behavioural intervention only) in obese children aged 8–12 years. Nevertheless, the results suggest that problem solving did not provide any additional benefits in terms of weight loss.<sup>31</sup>

#### Other outcomes

Improvements in problem solving for both parents and children was reported in one study for the problem solving group vs problem solving with family.<sup>31</sup> In another study, parents in the problem solving group increased their problem solving ability from pre to post treatment, whereas behavioural and instruction-only parents did not.<sup>53</sup>

Children in both the problem solving and behavioural groups increased their consumption of green food and decreased their consumption of red foods significantly more than instruction-only children.<sup>53</sup> Moreover, a positive correlation was found between pre-and post-treatment weight change, and change in the consumption of red foods (p < 0.05) and green foods (p < 0.01).

#### Other factors

No additional analysis was carried out on the effect of age, gender, ethnicity, socioeconomic status, previous treatment for obesity, degree of overweight/obesity, motivation, frequency or length of the intervention and current medical conditions.

#### Interventions focusing on CBT

#### Weight loss

Duffy and Spence<sup>54</sup> did not find any additional effectiveness of cognitive therapy techniques such as targeting monitoring of negative thoughts, restructuring of maladaptive thoughts, problem solving, and self-reinforcement as adjuncts to behaviour therapy for 7–10-year-old and 10–13-year-old children. According to the results, percentage overweight significantly decreased (p < 0.001) in the relaxation control group from pre-treatment to the 6-month follow-up. In the CBT group percentage overweight also significantly decreased (p < 0.001) from pre-treatment to the 6-month follow-up. In the CBT group percentage overweight also significant differences were observed between groups.<sup>54</sup> Similar results were reported in another study by Warschburger and coworkers,<sup>55</sup> in which 6 months after intervention, 14.8% of the children and adolescents in the experimental group could be classified as non-obese, against 9.7% in the control group. However, these differences were not statistically significant.<sup>55</sup>

Braet and coworkers<sup>56,57\*\*\*</sup> examined adding a healthy eating lifestyle programme rather than a strict diet, combined with CBT, delivered through different therapeutic forms to children aged 7–16 years. Significant loss of weight was reported in all therapeutic groups, as early as 3 months up to 1-year follow-up, and the results suggest that group rather than individual approaches result in significantly better outcomes. No significant results were found when comparing the 1-year follow-up with the 4.6 year follow-up.

<sup>&</sup>lt;sup>\*\*\*</sup> Both Braet and coworkers<sup>57,58</sup> other outcomes are in section 15.2.8.

Braet and coworkers<sup>58+++</sup> also-assessed a 10-month inpatient cognitive behavioural weight loss programme, where the participants' median age and BMI was 14 years and 33 kg/m<sup>2</sup>, respectively. During treatment, the children in the study group showed a decrease in the median adjusted BMI of –48% (range –4% to –102%). At 14-month follow-up, 13/27 children showed an increase in their overweight of less than 10% or continued to lose weight, compared with their post-treatment weight and 14/27 children had an increase of more than 10% overweight (up to +41%).

### Other outcomes

Duffy and Spence<sup>54</sup> reported a significant reduction in the consumption per day of red foods from pre-treatment to post-treatment in both groups (p < 0.001), with no significant differences between groups.

Warschburger and coworkers<sup>55</sup> reported that both groups showed improvements in their quality of life over time (p < 0.01), and improvements in self-reported eating behaviours for the experimental group compared with the control group (p < 0.05).

#### Other factors

No additional analysis was carried out on the effect of age, gender, ethnicity, socioeconomic status, previous treatment for obesity, degree of overweight/obesity, motivation, frequency or length of the intervention and current medical conditions.

## Interventions focusing on reinforcement and/or stimulus control of sedentary behaviours

Weight loss

From the analysis of the results of one study, there appears to be no significant improvement in applying mastery criteria and contingent reinforcement, as the

<sup>&</sup>lt;sup>†††</sup> Both Braet and coworkers<sup>57,58</sup> other outcomes are in section 15.2.8.

experimental group decreased from 60.6 % (SD 25.3) at baseline to 30.5% at 6 months and 34.1% at 1 year, and in the control group mean per cent overweight decreased from 58.8% (SD 19.6) at baseline to 38.8% at 6 months and then increased to 42.1 % at 1 year.<sup>59</sup>

Based on one study, results suggest that stimulus control and reinforcing reduced sedentary behaviours are equally useful to reduce sedentary behaviours and consequently in reducing standardised BMI (z-BMI) figures. z-BMI values (kg/m<sup>2</sup>) for the stimulus control group were  $3.3 \pm 1.0$ ,  $2.3 \pm 1.0$  and  $2.4 \pm 1.0$ , at 0, 6 and 12 months, respectively, whereas the values for the reinforced reduction group at the same time were  $3.2 \pm 1.0$ ,  $2.2 \pm 1.1$  and  $2.6 \pm 1.0$ , respectively.<sup>60</sup>

Epstein and coworkers<sup>61</sup> assessed how preferences for food used to reinforce behaviour change in young children can be applied to modify food preferences of older, obese children. Two groups were assigned: one treatment group where novel low-calorie foods were given contingent upon the behaviour changes established for weight loss; and a control group where low-calorie foods were provided for a daily snack and not contingent upon behaviour change. There was also no difference in the rate of change in percentage overweight between the two groups, although both had a significant decrease (p < 0.01) from 2 to 6 months (25.1%). The findings of this study do not back-up the hypothesis that by using unfamiliar foods as reinforcers, one can change the preference of children for those unfamiliar foods.

#### Other outcomes

Significant changes regarding consumption of red foods per week (p < 0.05) and days within the caloric range (p < 0.025) were reported. Moreover, parents showed a significant improvement in knowledge of behavioural principles across time (p < 0.001). Epstein and coworkers<sup>60</sup> also reported significant reductions in the consumption of high-energy-density foods, and increases in physical activity and consumption fruits and vegetables were observed in both groups.

#### Other factors

There were differences between children who substituted physically active for sedentary behaviours and those who did not. There were a higher percentage of boys substituting physically active for sedentary behaviours than girls.<sup>60</sup>

No additional analysis was carried out on the effect of age, ethnicity, socioeconomic status, previous treatment for obesity, degree of overweight/obesity, motivation, frequency or length of the intervention and current medical conditions.

## 15.2.4 Pharmacological Interventions

# Orlistat in weight loss and other outcomes in children and adolescents

#### 15.2.4.1 Evidence statements (Table 15.6)

#### Table 15.6 Evidence statements and grading

No.	Evidence statement	Grade
Weig	ht loss	
1	In children (aged 7–12 years) orlistat (120 mg three times a day) in combination with advice on reducing fat is effective in producing weight loss at 12 weeks (decrease in BMI of approximately 2 kg/m <sup>2</sup> )	3
2	In adolescents (aged 12–16 years), orlistat (120 mg three times a day) in combination with a hypocaloric diet is equally effective for weight loss as diet and activity at three weeks (approximately 7 to 8% of initial body weight)	1–
3	In adolescents (aged 10–16 years), orlistat (120 mg three times a day) in combination with a hypocaloric diet and increased activity is more effective for weight loss than diet and activity at 10–11 months (decrease in BMI of approximately 4 kg/m <sup>2</sup> )	1–
4	In adolescents (aged 12–16 years) orlistat (120 mg three times a day) in combination with a hypocaloric diet, increased	1+

No.	Evidence statement	Grade
	activity, and behaviour modification is more effective for weight loss than placebo (with diet, activity and behaviour modification) at 12 months (decrease in BMI of approximately 0.5 kg/m <sup>2</sup> )	
Outco	omes other than weight loss (from trials that reported weight le	oss)
5	In children (aged 7–12 years) orlistat (120 mg three times a day) in combination with advice on reducing fat did not result in any significant changes in levels of plasma cholesterol or triglycerides. Some U-shaped variation was seen in levels of vitamins A and E, compared with a slight decrease in vitamin D	3
6	In the one study that reported outcomes related to psychological health, no negative effect of the use of orlistat and dietary advice was seen. Increased avoidance of fattening foods, and increased oral control were reported, as was a trend towards improved body image and increased motivation (although this was not significant)	3
7	In adolescents (aged 12–16 years) orlistat (120 mg three times a day) in combination with a hypocaloric diet, increased activity and behaviour modification is more effective in improving diastolic blood pressure (approximately –0.5 mm Hg) than placebo (with diet, activity and behaviour modification) at 12 months. No significant improvements were seen for systolic blood pressure, or levels of lipids, triglycerides, or fasting plasma glucose	1+
8	Rates of growth (height and stages of sexual maturation) were not significantly different for adolescents taking orlistat compared to placebo	1+
9	Levels of vitamins and minerals were not significantly different for adolescents taking orlistat compared with placebo	1+, 1–
Harm	s (from trials that reported weight loss)	
10	Orlistat treatment is associated with increased rates of gastrointestinal events. However, these are frequently mild and transient	3
11	Only one serious reported event (symptomatic cholelithiasis leading to cholecystectomy) was assessed as being possibly related to orlistat treatment	1+
Gene	ralisability (from trials that reported weight loss)	
12	None of the included studies were conducted in the UK	3
13	All included studies were conducted in specialist centres, with	3

No.	Evidence statement	Grade
	specialist healthcare professionals (dietitians, behavioural psychologist, paediatricians, paediatric endocrinologists and paediatric nurses)	
14	One study was conducted in an inpatient unit, but the aim of this study was not to assess weight loss, but mineral balance	1–
15	Where reported, studies recruited mainly through referrals to the specialist centres, with some advertising only in one study	3
16	From the included studies not conducted in an inpatient setting, the follow-up rate varied from weekly telephone contact to every 2 months. Two studies used an approach of decreased contact over time. However, most studies were of a very short duration.	3
	In the two studies lasting longer than 3 months, participants were contacted every 2 weeks for first 4 months then every 2 months in one study, and participants maintained contact with dietitian monthly with an appointment at the outpatient clinic every two months in the other study	

BMI, body mass index.

#### 15.2.4.2 Orlistat (120 mg three times daily) versus placebo

### Weight loss

Two placebo controlled randomised trials were identified.<sup>62,63</sup> One trial<sup>62</sup> compared the use of orlistat in combination with a nutritionally balanced hypocaloric diet (designed to produce an initial weight loss of 0.5–1.0 kg per week), an exercise plan and a programme of behaviour modification (see evidence table for details [Appendix 13]). The study participants (n = 533) were adolescents aged 12–16 years who were overweight and obese (BMI ≥ 2 units above the 95th centile, excluded if BMI ≥ 44 kg/m<sup>2</sup> or weighed over 130 kg). Both groups lost weight during the first 4 weeks of the intervention, with weight loss remaining stable in the placebo group from weeks 4 to 12 compared with continued weight loss in the orlistat group until week 12. Weight increased in both groups from week 12 onwards. At 12 months, the group assigned to orlistat gained less weight than the group assigned to placebo (+0.53 kg vs +3.14 kg,

p < 0.001) with decrease in BMI compared with an increase in the placebo group (-0.55 vs +0.31, p = 0.001). Significantly more participants lost 5% or more and 10% or more of initial BMI in the orlistat group at 12 months. Overall, the trial was assessed as being of good quality.<sup>62</sup> It is important to note that some of the children would have completed linear growth, although some would have been still growing during the study.<sup>62</sup>

Another RCT<sup>63</sup> compared the effect of orlistat with placebo alone, without any additional dietary or activity component. This trial was assessed as of poorer quality than Chanoine's 2005 study,<sup>62</sup> and was considerably smaller. Participants (n = 32) were aged between 12 and 16 years, and were overweight or obese (BMI  $\geq$  85th centile adjusted for age and gender). At three weeks, participants in both groups had lost weight (7.0% orlistat vs 7.8% placebo of initial body weight), but the difference did not appear to be significant (no p value was reported). This trial, however, was not designed to measure weight loss, but the effects of orlistat on mineral balance.<sup>63</sup>

A quasi-randomised controlled study<sup>64</sup> investigated the effect of orlistat in combination with diet (20% reduction in kcal per day) and activity (at least 30 minutes moderate daily physical activity). Participants (n = 42) were aged 10– 16 years, and were obese (> 140% weight for height index). A significant weight change was seen in the orlistat-treated group compared with placebo (–6.27 kg vs +4.16 kg, p < 0.001) at approximately 10–11 months (follow-up varied). Similarly, the orlistat group showed a decrease in BMI compared with an increase in the control group, and weight loss (percentage of initial weight) compared to a weight increase in the control group. However, the participants in the orlistat group had a higher mean initial BMI than the placebo group (32.5 vs 31.2, p = 0.018). Again, this study<sup>64</sup> was small and was assessed as of poorer quality than Chanoine's study above.<sup>62</sup>

Two before-and-after studies investigated the effect of orlistat in children<sup>65</sup> and adolescents.<sup>66</sup> Norgren and colleagues<sup>65</sup> conducted a pilot study of orlistat and

dietary advice (sources of fat and recommended daily fat intake) in children (n = 11) aged 7–12 years (pre-pubertal) and who were overweight or obese (BMI >4 SD above normal). In the 12 weeks preceding treatment (no intervention), children tended to gain weight. However, at 12 weeks after initiation of orlistat treatment, the median weight change was –4.0 kg (range –12.7 kg to +2.5 kg, p = 0.016), with an corresponding decrease in BMI.<sup>65</sup>

Another study<sup>66–68</sup> assessed the effect of orlistat as an adjunct to both a comprehensive behavioural programme and periods of inpatient evaluation (see details below). Participants (n = 20) were aged 12–17 years and were obese (BMI  $\geq$  95th centile for age, sex, race). Significant weight loss was seen at both 4 and 6 months (–4.4 kg and –5.4 kg, respectively), with a corresponding decrease in BMI. At 6 months, 30% of participants has lost 5% or more of initial weight and 15% had lost 10% or more.<sup>66–68</sup>

Both of these before-and-after studies were small, and due to the design used had increased potential for bias compared with studies using a controlled study design.

## Other outcomes

A large good-quality RCT showed significant decreases in diastolic blood pressure (DBP), but not in other outcomes such as lipids, glucose levels, triglycerides or systolic blood pressure (SBP) at 12 months.<sup>62</sup>

The remainder of the studies reported a variety of different outcomes at different times.

## Other factors

Age

Most studies included adolescents only (range 10–17 years), but one study<sup>65</sup> included pre-pubertal children aged 7–12 years.

Current medical conditions

McDuffie and coworkers<sup>66</sup> included adolescents with one of several obesity associated comorbidities (hypertension, type 2 diabetes or glucose intolerance, hyperinsulinaemia, hyperlipidaemia, hepatic steatosis, sleep apnoea). All other studies included otherwise healthy participants.

#### Degree of obesity

Most studies included children or adolescents who were overweight or obese, but Chanoine<sup>62</sup> included only adolescents who were overweight (and excluded those who were very obese) and Ozkan and coworkers<sup>64</sup> included only obese adolescents.

## Setting

All studies were based in specialised treatment or research centres. Two studies included either partial<sup>66</sup> or total<sup>63</sup> inpatient treatment.

## Country

No studies were based in the UK.

## Methodological and context notes

Due to the inclusive searches and criteria, studies of varied design are included.

# Sibutramine in weight loss and other outcomes in adolescents and children

#### 15.2.4.3 Evidence statements (Table 15.7)

#### Table 15.7 Evidence statements and grading

No.	Evidence statement	Grade
Weigh	nt loss	
1	In specialist settings, a combination of sibutramine (ranging from 5 mg to 15 mg/day) with behaviour therapy, 1200–1500 kcal/day diet, and 120 minute/week aerobic exercise can result in a weight change of –7.8 kg at 6 months in obese adolescents aged 13–17 years compared with controls (–3.2 kg change)	1+
2	In specialist settings, a combination of 10 mg/day sibutramine, diet, 30 minute/day physical activity can achieve a weight and BMI change of –10.3 kg and – 3.6 kg/m <sup>2</sup> , respectively at 24 weeks in obese adolescents (with completed linear growth) aged 14–17 years compared with controls (–2.4 kg and –0.9 kg/m <sup>2</sup> , respectively)	1+
Outco	omes other than weight loss (from trials that reported weight	ght loss
3	In specialist settings, a combination of sibutramine, behaviour therapy, 1200–1500 kcal/day diet, and 120 minute/week aerobic exercise can increase HDL- cholesterol levels and reduce serum insulin levels in obese adolescents	1+
4	In specialist settings, a combination of diet, 30 minute/day physical activity and 10 mg/day sibutramine can decrease triglycerides and LDL-cholesterol levels in obese adolescents	1+
Harm	s (from trials that reported weight loss)	
5	In specialist settings, a combination of behavioural therapy and sibutramine can elevate blood pressure in obese adolescents aged 13–17 years	1+
6	In specialist settings, a combination of sibutramine diet and physical activity can cause constipation in obese adolescents aged 14–17 years	1+

The marketing authorisation for sibutramine has been suspended. See front cover for details.

No.	Evidence statement	Grade
Generalisability (from trials that reported weight loss)		
7	There is no evidence on the efficacy and safety of sibutramine in non-specialist setting and in non-volunteer populations	N/A
8	The two studies were conducted in Brazil and the USA and were based in university research centres. Recruitment was either not clear or not reported. Follow-up rate varied from every month ( $n = 1$ ), to a combined approach that went from every week to biweekly sessions (phase 1) and biweekly and monthly (phase 2) ( $n = 1$ )	N/A

BMI, body mass index; HDL, high-density lipoprotein; LDL, low-density lipoprotein; N/A, not applicable.

#### 15.2.4.4 Evidence review

This section reviews the evidence on the effectiveness of pharmacological interventions (sibutramine) combined with behaviour therapy and/or dietary interventions and physical activity in obese adolescents.

## Types of study

- RCTS
- Controlled clinical trials
- Controlled before-and-after studies
- Cohort studies with a control group

Only studies with a minimum duration of 6 months or above (including follow-up) and published after 1985 were included, and also RCTs with a primary aim other than the treatment of childhood obesity. Studies based in a setting other than clinical and delivered by non-health-care professionals (for example, school teacher) were not included in this review.

We did not retrieve any studies in the update searches that would potentially add further details or contradict any of the recommendations.

## Types of participant

 Participants aged under 18 years at the start of the study, and exceptionally studies where the age cut-off was above 18 years and where the majority of the participants were below 18 years or presented age stratification.

## Types of outcome

- Primary outcomes to be measured (not self-reported) estimates of overweight in per cent and BMI.
- Secondary outcomes to be behaviour change, participants' views, measures of self-esteem, health status, well-being and quality of life.

Again, there is limited evidence in this field. The American Heart Association (AHA) pointed out that sibutramine has been studied in an RCT. It stated that sibutramine had been shown to be efficacious compared with behaviour therapy alone, but it may be associated with side effects including increases in heart rate and blood pressure.<sup>1</sup> The NHMRC guidelines<sup>2</sup> stated that there is no evidence that sibutramine has a role in the management of adolescent obesity. Similarly, the Singapore Ministry of Health guidelines referred to the non-existence of data on the long-term efficacy and safety of medication in childhood and adolescent obesity (grade C, level).<sup>1</sup>

Only two RCTs<sup>70,71</sup> were retrieved from searches. One study consisted of 82 participants<sup>71</sup> whilst the other trial included 60<sup>70</sup>. One of the studies was a 6-month placebo controlled trial,<sup>70</sup> in which participants were given 10 mg/day. This 6-month period was preceded by a 4-week single-blind period where all participants were given a placebo capsule. Participants were also advised to achieve an energy deficit of 500 kcal/day and to undertake at least 30 minutes of moderate aerobic exercises per day, and to reproduce a 'regular' clinical setting, no behavioural counselling was given. Routine clinical advice to increase

physical activity was given by the medical practitioners in the form of a leaflet and only one appointment was made with the dietitian. At 6 months the sibutramine group had a statistically greater reduction in weight and BMI (p < 0.001) compared to the placebo group.

The other study consisted of a 12-month trial,<sup>71</sup> which comprised two phases: one placebo controlled period for 6 months and an open label extension for another 6 months. Participants were given a family-based behavioural weight loss programme including a 1200–1500 kcal diet and 120 minute/week of physical activity. At 6 months the placebo group had a significantly smaller reduction of weight and BMI than the sibutramine group (p = 0.001). The group that was randomised to sibutramine for the first 6 months and then continued on the medication for another 6 months gained weight during the second 6 months and ended up not significantly different from the placebo group. There was no statistically significant difference at month 12 between the two groups as the placebo group were able to switch to sibutramine in the open-label phase at 6 months to 12 months.

In one of the studies,<sup>70</sup> there was a significant decrease (p < 0.05) in triglycerides and very-low-density lipoprotein at week 24 in the sibutramine group. In the other hand, in the other study,<sup>71</sup> a significant increase in HDL-cholesterol (p = 0.001) and significant reductions in serum insulin (p < 0.001) were reported.

One of the studies<sup>70</sup> reported statistically significant adverse events – constipation (p = 0.039) in the sibutramine group. The other study<sup>71</sup> reported that during the 12-month study period, sibutramine was reduced to 10 mg in 16 participants and to 5 mg in 7 participants (42 participants in the sibutramine group). Ten participants discontinued treatment due to increases in blood pressure.

# 15.2.5 Surgery for weight loss and other outcomes in adolescents and children

#### 15.2.5.1 Evidence statements (Table 15.8)

#### Table 15.8 Evidence statements and grading

No.	Evidence statement	Grade
Inter	vention	
1	Evidence suggests that bariatric surgery should only be undertaken by highly specialised surgeons	4
2	Evidence suggests that bariatric surgery should only be performed in adolescents who are aware of the risks and benefits of surgery and who have a supportive family environment	3
3	Vitamin supplements should be given postoperatively and patients should be closely followed up to avoid deficiencies	3
4	There is no sufficient evidence on the use of surgery in obese adolescents due to obesity causes, e.g. Prader–Willi syndrome	
Weig	ght loss	
5	There is no evidence on which surgical procedure is the most effective in achieving weight loss in adolescents	
6	Evidence suggests that bariatric surgery should only be performed in obese adolescents who have systematically failed to manage weight for 6 months or more as determined by primary care provider	3
7	Evidence appears to suggest that an approximate change in BMI of –20 kg/m <sup>2</sup> (after approximately 2 years) can occur in obese adolescents who underwent bariatric surgery	3
8	Evidence appears to suggest a varying median excess weight loss ranging from 15.9% at 6 months to 69% at 24 months for laparoscopic adjustable gastric banding, and from 62% at 12 months to 87% at 2 years in adolescents who underwent gastric bypass	3
Outo	comes other than weight loss (from trials that reported weight lo	oss)
9	Evidence suggests that bariatric surgery can have an impact on psychosocial adjustment of severely obese adolescents	3
10	Some evidence suggests that bariatric surgery can reduce significant comorbidities in severely obese adolescents	3

No.	Evidence statement	Grade
Inte	rvention	
1	Evidence suggests that bariatric surgery should only be undertaken by highly specialised surgeons	4
2	Evidence suggests that bariatric surgery should only be performed in adolescents who are aware of the risks and benefits of surgery and who have a supportive family environment	3
3	Vitamin supplements should be given postoperatively and patients should be closely followed up to avoid deficiencies	3
4	There is no sufficient evidence on the use of surgery in obese adolescents due to obesity causes, e.g. Prader–Willi syndrome	
Harı	ms (from trials that reported weight loss)	
11	Evidence suggests that severely obese children and adolescents who undergo bariatric surgery may develop micronutrient deficiencies and other postoperative complications	3
12	Adolescents and children who undergo bariatric surgery (more common in gastric bypass) may require revisional surgery, or may develop other late postoperative complications such as cholecystitis or hernias	3
13	Some older studies have reported deaths due to perioperative and postoperative complications. There are no reports of deaths in recent studies	3
14	One recent study reported band slippage, port infection and replacement of a leaking port in adolescents who underwent laparoscopic adjustable gastric banding	3
Gen	eralisability (from trials that reported weight loss)	
15	Generalisability of the findings remains unclear, as no study was conducted in the UK, and all of the studies were based in university surgery departments	
16	Generalisability of the findings is all hindered by the limited quality of the retrieved studies	

#### 15.2.5.2 Evidence review on surgery

This section reviews evidence on the assessment of the effectiveness of bariatric surgery in obese adolescents. Due to the absence of methodologically strong studies among the existing literature, more expanded inclusion criteria were adopted for this particular review. Thus, the following were included:

## Types of study

- RCTs
- Controlled clinical trials
- Controlled before-and-after studies
- Cohort studies with a control group
- Non-comparative studies (case series and case studies)

Only studies with a minimum duration of 6 months or above (including follow-up) were included.

Update searches have been undertaken, however no further studies were identified.

## **Types of participant**

 Participants aged under 18 years at the start of the study, and exceptionally studies where the age cut-off was above 18 years but where the majority of the participants were below 18 years and results were stratified by age.

## Types of outcome

- Primary outcome of measured (not self-reported) estimates of weight change in per cent and BMI.
- Secondary outcomes of behaviour change, participants' views, measures of self-esteem, health status, well-being and quality of life.

The National Institutes of Health (NIH) Bariatric Consensus Development Conference in 1991<sup>72</sup> set out the basis for the increase in adult bariatric surgery undertaken in the previous 6 years. This conference concluded that insufficient data existed to make recommendations for patients younger than 18 years of age. Fourteen years later, outcome data remain limited for adolescents, with no controlled assessment of bariatric surgery in this group.

### Guidelines for surgical intervention

Only three guidelines have issued recommendations with regard to bariatric surgery in adolescents: NHMRC Australian guidelines for the management of overweight and obese children and adolescents,<sup>2</sup> the Singapore Ministry of Health clinical guidelines,<sup>73</sup> and the Institute for Clinical Systems Improvement (ICSI).<sup>74</sup> The Scottish Intercollegiate Guidelines Network (SIGN)<sup>6</sup> did not propose any recommendations.

The NHMRC Australian guidelines<sup>2</sup> recommended (grade C) that bariatric surgery might be considered as a last resource in severely obese adolescents with obesity-related comorbidity. The surgery should be carried out only in an experienced surgical centre after meticulous consultation, education of the patient and family, and a full psychological assessment. Furthermore, postoperative care should be ensured in an experienced weight-management centre. The Singapore Ministry of Health guidelines<sup>73</sup> stated that bariatric surgery cannot be recommended (grade B) for most adolescents, although with exceptions for those at the highest risk of mortality from obesity, and with both patient and parental understanding of the consequences of surgery. Finally, the ICSI<sup>74</sup> recommended that bariatric surgery should be undertaken in carefully selected patients, those with a BMI greater than or equal to 40 kg/m<sup>2</sup>, or with a BMI of 35–39.9 kg/m<sup>2</sup>, and those who are at a very high absolute risk for increased morbidity or premature mortality. Patients should be motivated, wellinformed in disease management, psychologically stable and accepting of operative risks.

Finally, the AHA guidelines stated that:

 'surgical approaches to treat severe adolescent obesity are being undertaken by several centres. Indications used include a BMI > 40 kg/m<sup>2</sup> and severe associated co-morbidities, such as obstructive sleep apnoea, type 2 diabetes mellitus, and pseudotumor cerebri

- 'more severe elevation of BMI (> 50 kg/m<sup>2</sup>) may be an indication for survival treatment in the presence of less severe co-morbidities such as hypertension and dyslipidemia, particularly if the degree of overweight hinders performing the activities of daily living
- 'an experienced team approach including comprehensive medical and psychological evaluation is critical both for selection of appropriate candidates and for postoperative care that is sophisticated and often intense
- 'weight loss goals and reduction of morbidity are often achieved with gastric bypass surgery. The rates of short-term mortality appear to be low but significant complications can occur. Intermediate and long-term outcomes, including information on malabsorption of critical nutrients, are unknown.
- 'overall, surgical therapy should be reserved for full-grown adolescents with the severest obesity-related morbidity, offered only by experienced multidisciplinary teams, and presented to families with appropriate informed consent procedures.'

## Views and insights from surgical societies and associations and expert opinion

Inge and coworkers<sup>75–77</sup> have thoroughly reviewed the role of surgery in the treatment of severe childhood and adolescent obesity. These authors contended that adolescents being considered for bariatric surgery should:

- have been unsuccessful at managing weight for ≥ 6 months, as determined by the primary care provider
- have achieved or nearly achieved physiological maturity
- have a BMI ≥ 40 kg/m<sup>2</sup> with serious obesity-related comorbidities or have a BMI of ≥ 50 kg/m<sup>2</sup> with less severe comorbidities
- be able to show adherence to comprehensive medical and psychological evaluations both before and after surgery

- agree to avoid pregnancy for at least 1 year postoperatively
- demonstrate responsibility in committing to nutritional guidelines postoperatively
- provide informed assent to surgical treatment
- possess decisional ability
- be surrounded by a supportive family environment (ensure that both patients and families understand that bariatric surgery is not a cure for obesity but an effective weight loss tool if used in compliance with specific dietary and physical activity regimens; and to understand the known risks and possible side effects of bariatric surgery).

The authors asserted that the above suggested criteria could not be applied strictly to each patient but should be tailored to the individual's needs, taking into account the level of maturity and severity of comorbid conditions. Strong emphasis was also placed on the requirement of having highly trained and skilled bariatric surgeons to perform safe and effective procedures, undertaken at appropriately equipped facilities capable of adolescent bariatric surgery. Furthermore, a multidisciplinary team with expertise in adolescent weight management and bariatric surgery is required to carefully manage all the aspects of the procedure for each individual.

Overall, the American Society for Bariatric Surgery<sup>78</sup> agreed with the criteria proposed by Inge and co-workers, although they added:

- A qualifier of a BMI of  $\geq$  35 kg/m<sup>2</sup> in the presence of significant comorbidities.
- A bariatric surgeon should have successfully performed at least 100 bariatric procedures or have completed a year-long bariatric surgery fellowship.

- The preoperative presence of comorbidities as an indicator for surgery is not appropriate, as bariatric surgery can play an important role in preventing such comorbidities.
- There is no real evidence that supports the argument that given any age and with a balanced nutrition, bariatric surgery will lead to impaired growth or early osteoporosis.
- Recommendations for procedures should not be limited to the Roux gastric bypass and laparoscopic adjustable gastric banding (LAGB).
- There is a need to discuss possible complications of gastric distension and possible rupture in the presence of a bowel obstruction when recommending the Roux gastric bypass; and an LAGB needs to encompass discussion of oesophageal dilation and the possible advent of functional and histological oesophageal problems in the future, alongside long-term risks of band erosion into stomach or balloon malfunction.

## Primary studies synthesis<sup>‡‡‡</sup>

No RCTs or clinical controlled trials were retrieved from the searches. The bulk of the evidence consisted of case studies, case series and retrospective reviews that addressed bariatric surgery procedures as follows: LAGB, vertical banded gastroplasty (VBG),<sup>§§§</sup> Roux-en-Y gastric bypass, jejunoileal bypass, biliopancreatic diversion and duodenal switch. All these come under the broader categories of restrictive, restrictive/malabsorptive, malabsorptive/restrictive surgical procedures.

 Restrictive: the gold standard is LAGB. VBG was a forerunner to laparoscopic gastric banding, but had high rates of complications/failure. Both operations

<sup>&</sup>lt;sup>+++</sup> We have excluded studies based solely on VGB, although included those which combine VGB with other surgery techniques, or have one group that was given VGB.

<sup>&</sup>lt;sup>§§§</sup> We have excluded studies based solely on VGB, although included those which combine VGB with other surgery techniques, or have one group that was given VGB.

have similar, expected clinical outcomes. Laparoscopic gastric banding restricts intake (volume) of solid food. Older operations are VBG, horizontal gastroplasty, open adjustable banding.

- Restrictive/malabsorptive: gold standard is gastric bypass (Roux-en-Y).
   Gastric bypass mainly restricts intake but also reduces absorption of nutrients.
- Malabsorptive/restrictive: these are more similar to the older operations. The gold standard is duodenal switch (DS) and biliopancreatic diversion (BPD).
   Jejunoileal switch was the forerunner to the DS, but was abandoned in 1982.
   These reduce calorie absorption, with limited restriction.

## Restrictive surgical techniques

## LAGB

Three of the studies consisted of prospective case series  $^{79-82}$  Abu-Abeid and coworkers<sup>79</sup> looked at adolescents aged 12–19 years (who had been under the care of a dietitian for at least 1 year, and had failed to reduce weight with a 800 kcal/day diet) who underwent LAGB. Widhalm and coworkers<sup>82</sup> followed eight patients with a mean age of 16.0 ± 1.3 years who underwent adjustable laparoscopic banding surgery. Dolan and coworkers<sup>80,81</sup> also studied adolescents aged 12–19 years who underwent LAGB.

In one case study, an inpatient physical activity programme and dietary restriction to 800 kcal per day was given to a 12-year-old girl for 6 weeks. Since severe obesity persisted, she underwent LAGB. After the surgery, a daily caloric intake was still restricted to 1200 kcal per day and physical activity at least twice a week.<sup>83</sup> Horgan and co-workers<sup>84</sup> addressed patients aged 19 or younger who underwent LAGB between 2001 and 2003. Angrisani and coworkers<sup>85</sup> also conducted a retrospective multicentre study in patients who underwent LAGB, aged 19 and younger.

#### Weight loss

In one study, BMI fell from 46.6 kg/m<sup>2</sup> preoperatively to 32.1 kg/m<sup>2</sup> at 23 months follow-up.<sup>79</sup> In two studies belonging to the same trial that compared weight and BMI reduction in adolescents and adults, the median BMI of the adolescents decreased from 42.2 kg/m<sup>2</sup> (preoperatively) to 32.4 kg/m<sup>2</sup> at 12 months and further to 30.2 kg/m<sup>2</sup> at 24 months.<sup>80,81</sup> No differences were observed in weight reduction between adults and adolescents.<sup>80,81</sup> Widhalm and coworkers<sup>82</sup> reported that in all their eight patients there were no major problems after surgery, and the mean weight change after a mean follow-up period of 10.5 ± 6 months was – 25.0 ± 3.8 kg. In one case study, weight loss in a 13-year-old girl was 14 kg at 3 months post-operation.<sup>83</sup>

Angrisani and coworkers<sup>85</sup> reported a mean percentage excess weight loss (%EWL) at 1, 3, 5 and 7 years follow-up of 45.6  $\pm$  29.6; 39.7  $\pm$  29.8; 43.7  $\pm$  38.1; and 55.6  $\pm$  29.2, respectively. Five of 25 (20%) patients had  $\leq$  25% EWL at 5 years' follow-up, whereas none of the 10 patients subject to follow-up at 7 years had  $\leq$  25% EWL.

#### Other outcomes

Abu-Abeid and coworkers<sup>79</sup> stated that all adolescents reported improved wellbeing; they were more physically active, more socially involved with their peers and reported feeling happier than before surgery.

#### Reported harms

Dolan and coworkers<sup>80,81</sup> reported that two patients had complications: one had slippage of the band, and another patient required port replacement. Horgan and coworkers<sup>84</sup> reported one patient who developed cholecystitis.

Angrisani and coworkers<sup>85</sup> reported the following cases:

'Laparoscopic conversion was necessary in 1 patient with gastric perforation on the anterior wall during perigastric band positioning. The overall postoperative complication rate was 6/58 (10.3%): Band slippage was observed in 1 patient and was treated by laparoscopic

repositioning after 4 days, gastric pouch dilatation was observed in 2 patients and was treated by band repositioning, and intragastric migration was observed in 3 patients and was treated with band removal. The band also was removed in 2 patients for psychologic intolerance, and 1 patient was converted 2 years after surgery to laparotomic gastric bypass. The overall band removal rate was 6/58 (10.3%). Biliopancreatic diversion with gastric preservation and band left in situ was performed in 2 patients (3.4%).'

Regardless of the type of procedure, the authors stated that the postoperative course in the eight adolescents who underwent reoperation was uneventful.<sup>85</sup>

## Older surgical techniques such as VBG, horizontal gastroplasty, open adjustable banding<sup>\*\*\*\*</sup>

Capella and coworkers<sup>86</sup> studied a form of gastric bypass which combined the VBG with a Roux-en-Y gastric bypass in adolescents aged 13–17 years of age. These adolescents had attempted several weight reducing regimens, such as medically supervised diets, physical activity, behaviour modification, commercial diets, psychological interventions and pharmacological agents. Postoperatively, patients were given advice from a dietitian on the benefits of a balanced diet and regular physical activity, and no attempts were made to refer them for another diet or behavioural modification programme.

Mason and coworkers<sup>87</sup> retrospectively studied 47 severely obese individuals who were under 21 when they underwent VBG.

### Weight loss

The mean BMI decreased from 49 kg/m<sup>2</sup> preoperatively to 28 kg/m<sup>2</sup> at 5.5 years post-operation.<sup>86</sup>

Mean BMI decreased from a mean 48.1  $\pm$  7.01 kg/m<sup>2</sup> at operation to 36.2  $\pm$  5.99 kg/m<sup>2</sup> at 5 years, and decreased from a mean 49.6  $\pm$  7.73 kg/m<sup>2</sup> at

These studies do not include evidence tables, as they are older procedures, and are not used in the NHS.

operation to  $39.2 \pm 7.15$  kg/m<sup>2</sup> at 10 years assessment. Average weight decreased from 138 kg at operation to 103.6 kg at 5 years, and from 135.8 kg at operation to 107.6 kg at 10 years.<sup>87</sup>

#### Other outcomes

In one study all serious comorbidities disappeared early in the weight loss process.<sup>86</sup>

#### Reported harms

No operation-related deaths among the 47 patients who underwent VBG were reported. No leaks, instances of peritonitis, wound infections or cases of pneumonia were reported. Three revisions were performed in female patients, two at 5 years, and the third at 12 years post-operation.<sup>87</sup>

## **Restrictive/malabsortive**

### **Gastric bypass**

The first studies on bariatric surgery date from the mid-1970s. In 1975, Soper and coworkers<sup>88</sup> reported 18 severely obese adolescents younger than 20 years of age who underwent either gastric bypass or gastroplasty. Anderson and coworkers<sup>89</sup> published a follow-up report on both procedures with 30 adolescents. In this study, careful dietetic counselling was provided to each patient and family. Both studies were case series.

Strauss<sup>90</sup> reviewed records of adolescents aged 17 years or younger who underwent gastric bypass surgery, and who had made serious attempts at weight loss in diet and behaviour modification programmes; Stanford and coworkers<sup>91</sup> also reviewed medical records of patients less than 20 years of age who underwent laparoscopic Roux-en-Y gastric bypass (RYGB). Breaux<sup>92</sup> reviewed 22 patients (11 with sleep apnoea and 11 without sleep apnoea), whose ages ranged from 8 to 18 years, and who had undergone VBG, RYGB or BPD. BPD was only performed in super-obese patients with sleep apnoea. One study consisted of interviews with patients who had undergone bariatric surgery;<sup>93</sup> 34 patients were interviewed an average of 6 years after the surgery and ranged from 11 to 19 years of age at the time of the surgery. Patients underwent RYGB or VGB.

#### Weight loss

The mean weight loss from two studies dating from 1975 and 1980 was approximately 40 kg at 3 years and 26 kg at 5 years post-operation.<sup>88,89</sup>

Strauss<sup>90</sup> stated that maximum weight loss occurred by 12–15 months after the operation; 9 of 10 adolescents had weight loss in excess of 30 kg. The mean weight loss was 53.6  $\pm$  25.6 kg for the nine adolescents who had persistent weight loss. Stanford and co-workers<sup>91</sup> reported a BMI decrease from 55 kg/m<sup>2</sup> (preoperatively) to 35 kg/m<sup>2</sup> at 20 months' follow-up. Rand and Macgregor<sup>93</sup> reported that preoperatively, patients had an average BMI of 47 kg/m<sup>2</sup>, and at 6 years follow-up the average BMI had dropped to 32 kg/m<sup>2</sup>. The patients' average excess body weight loss was 66%. Breaux<sup>92</sup> pointed out that in the group without sleep apnoea BMI improved from a mean 56.4 kg/m<sup>2</sup> to a mean 35.5 kg/m<sup>2</sup> post-operation. In the group with sleep apnoea, mean BMI dropped from 70.3 kg/m<sup>2</sup> to a mean BMI of 46.5 kg/m<sup>2</sup> post-operation.

#### Other outcomes

Rand and Macgregor<sup>93</sup> found that at follow-up, 82% of the patients considered themselves attractive, compared with a figure of 94% of those who felt unattractive before surgery.

#### Reported harms

Both Soper and coworkers<sup>88</sup> and Andersen and coworkers<sup>89</sup> reported postoperative complications. Soper reported: 3 wound infections; 3 patients with respiratory difficulty; 1 patient with thrombophlebitis; 1 patient with upper gastrointestinal bleeding; 1 patients with urinary tract infection; and 1 patient with protracted vomiting. Andersen reported: 3 patients with wound infections; 2 patients 'slow to open' due to stomal obstruction; 3 patients developed atelectasis; 2 developed pneumonia; and 1 developed a subphrenic abscess. Strauss <sup>90</sup> reported a serious complication in one patient with a distal gastric bypass who had protein-calorie malnutrition and micronutrient deficiency approximately 1 year after gastric bypass. Two other adolescents had symptomatic cholelithiasis requiring laparoscopic cholecystectomy. Small bowel obstructions occurred approximately 10 years after gastric bypass surgery in one patient.

Towbin and coworkers<sup>††††</sup> found three cases of beriberi (thiamine or vitamin B-1 deficiency) in adolescents who underwent gastric bypass. Breaux<sup>92</sup> reported nine complications including vitamin A and D deficiencies, folic acid deficiency, protein deficiency, gallstone development, kidney stone, postoperative laryngeal oedema and incisional hernia.

### Malabsortive/restrictive

## Duodenal switch and biliopancreatic diversion

Breaux<sup>92</sup> reviewed 22 patients (11 with sleep apnoea and 11 without sleep apnoea), whose ages ranged from 8 to 18 years, and who had undergone VBG, RYGB or biliopancreatic diversion (BPD). BPD was only performed in super-obese patients with sleep apnoea.

### Weight loss

Breaux<sup>92</sup> found that in the group without sleep apnoea, BMI improved from a mean 56.4 kg/m<sup>2</sup> to a mean 35.5 kg/m<sup>2</sup> post-operation. In the group with sleep apnoea, mean BMI dropped from 70.3 kg/m<sup>2</sup> to a mean BMI of 46.5 kg/m<sup>2</sup> post-operation. Nevertheless, no figures were provided for the children who underwent BPD, as results for the three surgical procedures were all grouped together.

<sup>&</sup>lt;sup>++++</sup> Towbin A, Inge TH, Garcia VF et al. Beriberi after gastric bypass surgery in adolescence. *Journal of Pediatrics* 2004;145:263–7.

#### Other outcomes

All patients had resolution of sleep apnoea on the long-term follow-up.

### Older surgical procedures such as jejunoileal bypass

Two retrospective reviews were retrieved that examined the long-term effects of jejunoileal bypass in obese adolescents. Organ and coworkers<sup>95</sup> did a retrospective review on 16 patients aged 15–20 years at the time of the surgery (1970–1975). Silber and coworkers<sup>96</sup> reviewed 11 patients (who had made repeated failures of medical-dietary treatments) aged between 11 and 22 years at the time of the surgery (between 1972 and 1974). Another study which consisted of a case series of four patients aged 11–16 years who had failed dietary treatment of at least 1 year was also retrieved.<sup>97</sup>

#### Weight loss

With regard to the two studies that addressed jejunoileal bypass, in one study the mean weight dropped from 121.99 kg (pre-operative) to 77.07 kg (p< 0.001) after a mean follow-up of 8.2 years.<sup>96</sup> Mean BMI dropped from 43.21 kg/m<sup>2</sup> to 27.26 kg/m<sup>2</sup> (p< 0.001).<sup>95</sup> Randolph and coworkers<sup>97</sup> reported a mean percentage weight loss of 32.75% at 12 months.

#### Other outcomes

Organ and coworkers<sup>95</sup> discovered a significant change in attitude which reflected a greater sense of pride in the patient's own body. This also led to changes in their eating habits with greater psychosocial adjustment. Patients' involvement in social activities increased and many found themselves more employable. Randolph and coworkers<sup>97</sup> reported a gradual decrease in appetite, and that patients appeared brighter, more alert and more outgoing.

#### Reported harms

Randolph and coworkers<sup>97</sup> reported significant effects on levels of absorption, evidenced by flattening of the glucose and xylose tolerance tests, an increase in

faecal losses of fat and nitrogen, and lower levels of serum triglycerides and cholesterol.

#### Other factors

#### **Current medical conditions**

One or several comorbidities were present including dyslipidaemia, sleep apnoea, pulmonary hypertension, low back pain and severe arthalgias, hypertension, liver steatosis, hypertriglyceridaemia, hypercholesterolaemia, peptic oesophagitis, cholelithiasis, degenerative joint disease (DJD), bronchial asthma, type 2 diabetes mellitus, urinary urgency and stress incontinence, dependent oedema, and gastro-oesophageal reflux disease.<sup>84,86,90,91</sup> Rand and coworkers also reported anaemia and thyroid problems in seven patients. Breaux also reported sleep apnoea and brain-stem tumour.

In one case study,<sup>83</sup> a 12-year-old girl had arterial hypertension, uremic odour, end-stage renal failure, renal anaemia, hypercalcaemia, metabolic acidosis, preserved diuresis with isosthenuria and renal osteopathy.

Organ and coworkers<sup>95</sup> reported that no patients with the Prader–Willi or Laurence–Moon–Biedl syndromes or other endocrinopathies were included. Any existing metabolic defect was stabilised prior to surgical intervention. Silber and coworkers<sup>96</sup> reported three patients who died within a year of procedure (one with known incipient heart failure, one with established diabetes mellitus, who died of perinephric abscess and sepsis, and the third with hepatic disease). Two of these had Prader–Willi syndrome. Patients with Prader–Willi syndrome were also present in Randolph et al.'s case series,<sup>97</sup> and Widhalm et al.'s study.<sup>82</sup>

## Setting

All the retrieved studies were undertaken in university surgery departments.

## Country

The vast majority of the studies were from the USA, with the exception of: Australia,<sup>80,81</sup> Israel,<sup>79</sup> Germany<sup>83</sup> and Austria.<sup>82</sup>

## Methodological and context notes

All the retrieved studies were of poor quality, with no RCTs or other types of controlled study. Moreover, levels of statistical significance were either not applicable or not provided. Therefore the reliability and validity of the results remain uncertain, and robustness of the evidence statements and recommendations on the use of bariatric surgery in adolescents is extremely weak.

# 15.2.6 Referral to specialist care for children and adolescents

In September 2005, the National Guideline Clearinghouse synthesised the recommendations on the assessment and treatment of obesity and overweight in children from six published guidelines.<sup>1</sup>

Only the guidelines from SIGN<sup>6</sup> made detailed recommendations on the process of referral. These can be seen in Table 15.9. However, the authors noted that formal trials of the impact of different referral criteria are not easily carried out', and the subsequent recommendations were based on an expert committee statement.

The NHMRC guidelines recommended that:

- if a child presents with obesity in association with intellectual disability and multiple physical abnormalities, the child should be assessed by a paediatrician, an endocrinologist and/or a geneticist (level C)
- an obese child or adolescent with height–growth failure should be referred to a paediatrician or an endocrinologist or both (level B)

 conditions that cause hypothalamic obesity are rare and should be managed in a tertiary institution (level B).

Other recommendations were made around the use of very-low-energy diets, drugs and surgery **only** in specialist settings.

## Table 15.9 Referral recommendations from the Scottish Intercollegiate Guidelines Network<sup>6</sup>

The following groups should be referred to hospital or community paediatric consultants before treatment is considered [in primary care]:

- Children who may have serious obesity-related morbidity that requires weight loss (for example, benign intracranial hypertension, sleep apnoea, obesity hypoventilation syndrome, orthopaedic problems and psychological morbidity)
- Children with a suspected underlying medical (for example, endocrine) cause of obesity including all children under 24 months of age who are severely obese (BMI > 99.6th centile)
- All children with BMI > 99.6th centile (who are at higher risk of obesity-related morbidity)

The primary purposes of referral are to exclude underlying medical causes of obesity and to treat comorbidity. Most patients will not have an underlying medical cause and should be discharged back to management in the community

In patients with no underlying medical causes but with serious obesity-related comorbidity, treatment of the comorbidity may be indicated. In many cases (for example, type 2 diabetes), such treatment will be enhanced by weight management. In secondary care, treatment should follow the principles outlined above, but weight loss, rather than weight maintenance may be the appropriate aim

Where medical causes of obesity (or related) comorbidities exist, weight loss is indicated, and specialist referral may be appropriate

Where there is no underlying medical cause of obesity, patients should be referred back to primary care with the maintenance/prevention message reinforced

Obese children showing signs of distress and their families should be considered for referral for psychological assessment and treatment

# 15.2.7 Harms arising in children and adolescents who undergo weight management/maintenance programmes

## 15.2.7.1 Evidence statements (Table 15.10)

#### Table 15.10 Evidence statements and grading

No.	Evidence statement	Grade
Harm	ns (from trials that reported weight loss)	
1	There is no evidence to suggest that professionally administered weight management programmes for children and adolescents increase the likelihood of developing eating disorders or cause psychological harm	2+
2	There is no evidence to suggest that professionally administered weight management programmes for children and adolescents have a negative impact on growth or lean mass loss	2–
3	There is no evidence to suggest that professionally administered weight management programmes for children and adolescents have a negative impact on psychosocial well-being	2+
Gene	eralisability (from trials that reported weight loss)	
4	Generalisability of the findings remains unclear, as no study was conducted in the UK and majority of the studies were based in highly specialised research settings	N/A
5	Generalisability of the findings is hindered by the methodological limitations of the retrieved studies	N/A

N/A, not applicable.

#### 15.2.7.2 Evidence review on harms

## Types of study

We only included studies that specifically assessed the effects on eating behaviours and child/adolescent growth of professionally prescribed weight loss programmes, with the following designs:

- RCTs
- controlled clinical trials

- before-and-after studies
- cohort studies
- non-comparative studies (case series and case studies).

Again, we decided to adopt more expanded inclusion criteria due to the nature of the existing evidence. Studies that examined the effects of unsupervised dieting were not included in this review.

Update searches have been undertaken, however no studies were identified.

## Types of participant

Obese and/or overweight children and adolescents.

## Types of outcome

 Primary outcomes to be (not self-reported) reports of eating disorders and growth variations.

### Reports of harm in other guidelines

According to the National Guideline Clearinghouse Guideline synthesis,<sup>1</sup> none of the included guidelines reported any harm that may arise if children or adolescents undergo professionally delivered weight management/maintenance programmes. Only the United Stated Preventive Services Task Force (USPSTF)<sup>98</sup> tackled the topic of eating disorders, reporting one good-quality RCT in a primary care setting, where no problematic eating was detected in adolescents participating in a behavioural intervention treatment. The NHMRC<sup>2</sup> recommended that 'abnormal eating behaviours in childhood and adolescent obesity should be addressed both before and during weight-management programs'.

## Effects of professionally prescribed weight loss programmes on eating behaviour

We found one recent systematic review<sup>99</sup> that examined the effect of dieting on eating behaviour and psychosocial status. The findings of the five studies that

looked at the effects of dieting on eating behaviours, suggested that professionally delivered weight loss interventions did not contribute to the development of eating disorders in overweight children and adolescents.

Braet and coworkers<sup>58</sup> assessed a 10-month inpatient cognitive behaviour weight loss programme, where the participants' median age and BMI was 14 years and 33 kg/m<sup>2</sup>, respectively. At post-treatment, scores on the Drive for Thinness subscale of the Eating Disorder Inventory (EDI) decreased significantly, and the number of participants scoring at least one standard deviation above the norm on the subscale (showing an increased risk for developing an eating disorder) decreased from 7 to 2 during the treatment. On the Dutch Eating Behaviour Questionnaire (DEBQ), scores on the external eating subscale decreased, and no significant changes were found on the Emotional Eating or Restrained Eating scales.<sup>58</sup>

Levine and coworkers<sup>100</sup> assessed a family-based behaviour change programme in children with a mean age of 10.2 years and weight of 79.7 kg. Symptoms of eating disorders were measured at pre-treatment and follow-up by the Children's Eating Attitudes Test (ChEAT), which showed a statistically significant decreasing trend at follow-up, suggesting that concerns with dieting, unhealthy dieting behaviours and concerns regarding being overweight tended to decrease.<sup>100</sup>

Epstein and coworkers<sup>101</sup> examined an intervention in which all participants were given the traffic light diet, and some also received training in problem solving techniques. Participants had a mean age of 10.3 years and a weight of 59.5 kg. The Kids' Eating Disorder Survey (KEDS) which assesses weight dissatisfaction, purging/restricting and total symptoms of disordered eating did not show any significant changes.<sup>101</sup>

Braet and Van Winckel<sup>57</sup> evaluated a cognitive behaviour change programme that delivered self-regulation, problem solving techniques and promotion of lifestyle change to children with a mean age of 11 years and weight of 62 kg. This

programme was delivered either in a group or to individuals or as summer camp component. The DEBQ assessment showed that external eating decreased and restrained eating increased during the 4.6 years. On the other hand, emotional eating did not change. At follow-up, 9% of the participants scored more than one standard deviation above the norm on the bulimia subscale of the EDI.<sup>57</sup>

Another study of Epstein and coworkers<sup>102</sup> consisted of a 10-year follow-up of an earlier trial where all interventions were family based and included the traffic light diet. Participants had a mean age of 10.4 years and a weight of 55.3 kg. On a medical history form, 4% of the participants reported that they had been treated for bulimia nervosa during the 10 year follow-up, and none reported treatment for anorexia nervosa.<sup>102</sup> However, the authors pointed out that this prevalence of bulimia was not high, as self-reported studies have shown an average prevalence for eating disorders of 9% in girls.

## Effects of professionally prescribed weight loss programmes on child/adolescent growth

No recommendations were found in the National Guideline Clearinghouse Guideline synthesis or the NHMRC guidelines regarding the effects of professionally prescribed weight loss programmes on child or adolescent growth.

One study<sup>103</sup> examined whether a multidisciplinary weight loss programme in adolescents with severe obesity allowed adequate growth and avoided lean mass loss. Participants were aged 9 to 17 years and had a mean BMI of 38.4  $\pm$  8.0 kg/m<sup>2</sup> for girls and 34.5  $\pm$  3.2 kg/m<sup>2</sup> in boys. Total lean mass (LM) did not vary and was positively correlated to pubertal development in both sexes before and after weight loss.<sup>103</sup>

Another study<sup>104</sup> examined height velocities prior to and during weight reduction in 14 girls and 5 boys with a mean  $\pm$  SD age of 8.5  $\pm$  2.7, achieved by restricting caloric intake in all cases to two-thirds of the usual daily intake. Protein intake was maintained at 1.5–2.0 g/kg of initial body weight per day. A significant correlation between the change in z-scores of height velocity prior to and during weight reduction and the change in weight was observed. However, it should be noted that this was a poor-quality study, and biases may have occurred, leading to some misinterpretation of results.<sup>104</sup>

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