# IN DEPTH TOPIC: THE TREATMENT OF OBESITY IN CHILDREN AND ADOLESCENTS

# Introduction

The main reason why the rising prevalence of childhood obesity is an important public health issue is that obese children are likely to become obese adults at high risk of developing diabetes and cardiovascular disease and it is feared that the future cost of healthcare for obesity-related illnesses will be beyond the nation's resources [1,2].

From the perspective of the individual obese child and his or her family, however, more immediate consequences of obesity, such as having low self-esteem, being bullied, teased or socially marginalised, being unable to participate in physical activities and sport or to wear fashionable clothes, tend to be of greater importance. There is evidence that many parents of overweight or obese children are unaware of their child's weight status although the reasons for this have not been thoroughly explored [3]. Raising awareness of the significance of childhood obesity, as the Lets Move! campaign started by Michelle Obama has done in the U.S. [4,5], is important as unless parents are motivated to change their families' habits to improve their children's weight there is little point in offering intervention.

There is a general consensus among obesity experts that tackling the obesity problem requires a whole of society approach to prevention, and that this involves tackling complex social and economic issues and changing public policy in many areas including food production, manufacturing and retailing, trade, urban planning, transport, healthcare, education and culture [6].

Nevertheless, those who work in healthcare want to be able to help individual obese children and their families in the here and now. This in-depth topic aims to provide information on evidence-based interventions for the treatment of established overweight and obesity in children and adolescents. It is organised into five sections as follows:

- Identifying and engaging children (and their parents) who are candidates for weight management interventions
- Insights from a 2009 Cochrane review of obesity interventions in children and adolescents
- Insights from other reviews of obesity interventions in children and adolescents
- New Zealand interventions
- Primary care interventions, including recent RCTs addressing obesity in primary care

In addition, there are a number of evidence-based guidelines for the management of overweight and obesity in children and young people, including those published by the N.Z. Ministry of Health (2009) [7], the U.K. National Institute for Health and Care Excellence (2013) [8], the Scottish Intercollegiate Guidelines Network (2010) [9], and the Australian National Health and Medical Research Council (2013) [10]. Readers wanting more detailed information than is provided here might like to refer to these guidelines.

# Identifying and engaging children (and their parents) who are candidates for weight management interventions

It cannot be assumed that the parents of overweight and obese children are greatly concerned about their child's weight status and its implications for future health and will therefore seek assistance from health professionals. If interventions are to reach the children and young people most in need then those working in the health system may need to actively seek out and attempt to engage families of overweight and obese children [11], while being mindful that dealing with a child's overweight may not be a high priority in families who are struggling with more urgent problems.

#### Identifying children who are candidates for weight management interventions

Body mass index (BMI) is defined as weight/height<sup>2</sup> with weight measured in kg and height in metres. Plotting a child's BMI on a BMI-for-age reference chart allows easy assessment of a child's weight status in relation to that of other children of the same age and sex. Commonly used BMI charts for children are those of the World Health Organization [12] and the U.S. Centers for Disease Control and Prevention [13]. Children who have a BMI greater than or equal to the 95<sup>th</sup> percentile for their age are commonly classified as being obese, and those whose BMI is at or above the 85<sup>th</sup> percentile but less than the 95<sup>th</sup> percentile as being overweight [14]. A particular advantage of using BMI-for-age charts is that they allow monitoring of a child's BMI over time and allow the identification of children at risk of obesity because their BMI is increasing more rapidly than would be expected for their age (sometimes referred to as "upward percentile crossing").

All of the guidelines mentioned above agree that BMI percentile is the best indicator for identifying overweight and obesity in children over the age of two years (although they do not agree precisely on the BMI percentile values that indicate a need for intervention). This consensus is supported by a 2010 systematic review [15], (which recommended the use of national BMI-for-age reference data if this was available).

Severely obese children can have BMI values that are off the chart so the standard charts produced by the CDC or the WHO cannot be used to characterise or monitor the weight status of these children. Since severely obese children are at the greatest risk of obesity related health problems it is important to be able to identify the most severely obese children so that they can be given priority for intervention efforts and also to be able to monitor the effectiveness of any interventions attempted with these children [16]. To address the limitations of the standard BMI charts for these purposes Flegal et al. proposed that the BMI of a very obese child be described as "the percentage of the 95<sup>th</sup> percentile" [17]. Gulati et al. have used this idea to develop growth charts that have additional lines above the 95<sup>th</sup> percentile line corresponding to 110%, 120%, 130% and so on, of the 95<sup>th</sup> percentile BMI values [18]. They have used these charts to track the weight status of their severely obese child patients over time and have suggested that their charts may also be useful in research.

# Screening for overweight and obesity in children

It is recommended that both routine and health concern related child health provider contacts should include measurement of BMI-for-age-and-sex, provided the child's parent or carer agrees [7,10,19]. This could be regarded as "opportunistic screening". There is no New Zealand data on the degree to which this is happening in primary care other than as part of Well Child/Tamariki Ora services. A recent study from the U.S. used data from the National Health and Nutrition Examination Survey for the years 1999 through 2008 to examine trends in parental report of health professional notification of childhood overweight [20]. Parents were asked: "Has a doctor or health professional ever told you that your child is overweight?" The percentage of parents of children with BMIs ≥ the 85<sup>th</sup> percentile who recalled ever having been told that their child was overweight increased only slightly (from 19.4% to 23.2%) over the 1999-2006 period but increased to 29.1% in the 2007–2008 period. Even among the parents of very obese children ( $\geq$  the 99<sup>th</sup> percentile), on average only 58% recalled ever having been told that their child was overweight. The authors stated that "further research is necessary to determine where and why communication of weight status breaks down and how effective appropriate communication of weight status is in motivating families toward healthier living".

Whether more systematic screening is desirable is doubtful. Westwood et al. were commissioned by the U.K. Health Technology Assessment Programme to conduct a systematic review on whether or not primary school children should be routinely screened for obesity [21]. They found that there had been (up till July 2005) no trials assessing the effectiveness of monitoring or screening for identifying obesity in children and there was "extremely sparse" information on the attitudes of children, parents and health professionals to monitoring. The authors stated that "there is currently little evidence that

weight reduction interventions are effective and without this evidence any move towards identifying individual children appears difficult to justify". Another systematic review on this topic for the U.S. Preventive Services Task Force (2005) reached similar conclusions [22].

In the U.K. the National Child Measurement Programme (NCMP) measures the height and weight of all children in reception (ages four and five) and year six (ages 10 and 11) classes, except those of parents who have chosen to their opt their children out [23,24]. The NMCP is not a screening programme in the accepted sense of the term (since its primary aims are not to identify individual children at risk of obesity early so that they can be treated more effectively than would be possible if they were identified later on). The aims of the NMCP are: to inform local planning and delivery of services, to gather population-level data for monitoring trends in growth patterns and obesity, and to increase public and professional understanding of weight issues in children and be a vehicle for engagement with children and families regarding weight issues and healthy lifestyles [23]. Some, but not all, Local Authorities inform parents of their child's results by letter [24].

# Parental perceptions of children's weight status

Since screening cannot yet be recommended as a method of identifying obese children, it is worth considering how good parents are at recognising that their child is overweight or obese, how likely they are to seek help if they recognise that their child has a weight problem, and how they perceive health professionals' attitudes to them and their children.

Parry et.al undertook a systematic review of 23 studies (3864 children aged 2–12 years) which had assessed parental perceptions of their child's weight status and compared these to their child's actual weight status according to a recognised standard for defining overweight such as BMI centiles or International Obesity Taskforce cut-offs [25]. The percentage of parents who recognised their child's overweight status ranged from 6.2% to 73%, but in 19 of the 23 studies it was less than 50%. A more recent systematic review, by Rietmeijer-Mentink et al., included 51 publications (35,103 children) which were of variable methodological quality [26]. The pooled results from these studies indicated that, according to objective criteria, 11,530 children were overweight and, of these, 62.4% (7191) were incorrectly perceived by their parents as being of normal weight.

As part of the Pacific Island Families Study, when their children were four and six years old, 569 parents were asked, "How concerned are you about your child becoming overweight?" and their responses were compared with their child's BMI [27]. At four and six years the majority of parents were not concerned about their child's weight (62% and 69.1%) yet at four years only 40.1% of children were considered to be of normal weight but 34.1% were overweight and 25.8% obese. At six years the proportions were: 41.3% normal weight, 31.1% overweight and 27.6% obese. Parents were more likely to be concerned about their child's future weight status if their child was overweight or obese. At six years the percentage of parents who were concerned was 20% for normal weight children and 51% for obese children. The study authors stated that their findings raised the concern that there is normalisation of overweight and obesity among Pacific parents and/or their children. They suggested that attention be paid to addressing the socio-economic environment of Pacific families and raising parents' awareness of the links between obesity and eating and activity patterns.

# Parents' perceptions of health professionals' attitudes

Even if parents do recognise that their child has a weight problem they may be reluctant to seek help because of fear they will be "blamed and shamed" and they fear adverse effects on their child's mental well-being [28]. A number of studies have explored parent's views and experiences of their children's obesity-related encounters with the health system, either in primary care [28,29,30] or in specialist clinics [31,32,33,34,35]. Parents have often attempted their own dietary and physical activity strategies before seeking help so they are unlikely to be satisfied with general advice about eating less and exercising more [30]. If they have a weight problem of their own and they believe their GP has not helped them with it then they may think he or she will not be able to help their child either [28]. One researcher who interviewed a self-selected group of parents who had concerns about their child's weight (parents of 40 children in south-west England), found that professional

responses to parental help seeking had ranged from positive, but not very helpful, to negative and dismissive [30]. According to the parents interviewed in a later English study, it is important for practitioners to be non-judgmental and empathetic, to have sufficient knowledge and skills to treat childhood obesity, and to pay attention to broader issues such as low self-esteem and behavioural problems [28].

The long term health consequences of obesity may not be a major concern for many parents. They may be more concerned about their child being teased or bullied, or being unable to participate in physical activities and sport or to buy clothes that fit [28,32,36,37]. Health professionals need to be aware of this so they can focus on weight loss goals that have meaning for parents and children.

#### Engaging the families of obese children

It can be difficult to engage families of obese children with services that facilitate long term weight management, even if they are free as they are in the U.K. Banks et al. reported on a project which aimed to identify obese children (BMI  $\geq$  98th percentile) from the databases of 12 general practices in Bristol, U.K. and invite them for a primary care consultation and possible referral to a specialist secondary care clinic [38]. Invitation letters were sent to 285 families, 134 patients consulted their GP within the follow up period (minimum 3 months) and the child's weight was discussed at 42 of these consultations. Nineteen patients received a secondary care referral and six received an alternative weight management referral. The authors noted that children's weight is a sensitive issue, about which parents may feel guilt and shame, and it is therefore a difficult area for parents and health professionals to discuss. They also cite research which has found that many parents do not recognise their child's overweight or obesity as a health problem that needs attention.

A recently-published New Zealand study investigated what factors influence participation in a family-based weight management programme for overweight and obese four to eight year-old children identified through participation in by-invitation screening [39]. A key aim of this study was to determine whether motivational interviewing for feedback was an appropriate way to inform parents that their young child was overweight. All parents in the study received feedback consisting of a neutral presentation of their child's weight status. Parents of overweight (BMI 85th to <95th percentile) or obese children (BMI ≥95th percentile) were randomised to receive or not receive motivational interviewing before their child's weight status information was presented. Out of the 1093 children screened 24.8% were overweight or obese. Of these, 72.7% agreed to participation in the intervention. Overall there were few differences between participating and non-participating parents but non-participating parents more often came from homes in more deprived areas (p=0.039); participating mothers tended to be more highly educated (p=0.051); and fewer nonparticipating parents believed their child to be overweight (23% vs. 49%, p < 0.001) or were concerned about it (16% vs. 43%, p < 0.001), despite their children having an average body mass index close to the 95<sup>th</sup> percentile. The type of feedback received did not appear to influence participation rates (p=0.221). The authors of this study speculated that the reason why they achieved much higher uptake rates than the Bristol study could be because the parents in their study received face-to-face feedback about their child's weight status rather than being informed by letter.

# Interventions for treating obesity in children and adolescents

Interventions for treating obesity in individual children and adolescents fall into three broad categories: lifestyle (diet, physical activity and behavioural therapy, often in combination), drug treatment and surgery. There has been a considerable amount of research into various lifestyle interventions and a number of systematic reviews of lifestyle interventions have been published [40,41,42,43] but there is relatively little research on drug interventions or bariatric surgery both of which are considered appropriate only for obese adolescents.

# Insights from a 2009 Cochrane review of obesity interventions in children and adolescents

A 2009 Cochrane review aimed to determine the efficacy of lifestyle, drug and surgical interventions for the treatment of obesity in children from a review of all relevant randomised controlled trials which had a follow up duration of at least six months [43]. Lifestyle interventions were divided into three types, dietary, physical activity and behavioural, and discussed in two age categories, those for children under 12 years old and those for children 12 years old and older. The section which follows discusses some of the insights gained from this 2009 review.

#### Dietary interventions in children under 12 years old

There were four studies of dietary interventions in children under 12 years old. Two fulfilled all the criteria for meta-analysis but they made different comparisons so meta-analysis was not possible. One of these studies, involving children aged from three to 12 years, found a beneficial effect of a dietary intervention comprising a specific calorie-controlled diet, detailed guidelines regarding physical activity and parental commitment and the provision of a food diary with instructions for its use compared to provision of general obesity information leaflets on obesity risks, healthy eating and physical activity, both at six and 12 months follow up [44]. The intervention group (72 children, mean age 8.6 ± 1.9 years) had a significantly higher reduction in percentage overweight than the control group (n=114, mean age 8.6 ± 2.1 years): -8.8% at six months and -8.5% at 12 months vs. -2.9% at six months and -2.9% at 12 months. (Percentage overweight was defined in this study as ((actual weight – ideal weight) / ideal weight) \*100, where ideal weight was the 50<sup>th</sup> percentile weight for the age at which the child's height was at the 50<sup>th</sup> percentile.) BMI values at baseline, six and 12 months were 23.8 ± 2.7, 22.5 ± 2.5, 23.0 ± 2.4 in the intervention group and 22.4 ± 1.9, 22.2 ± 1.9, 22.7 ± 2.1 in the control group.

The other study compared a "making healthy food choices" intervention (n=21) to a "decrease high energy foods" intervention (n=20) [45]. The interventions lasted for five months and results were assessed at six, 12 and 24 months. Using a mixed effects regression model the study authors found that the children in the increase healthy foods group had greater reductions in BMI z scores than those in the reduce high energy foods group, both at 12 months (-0.30 vs. -0.15, p=0.01) and at 24 months (-0.36 vs. -0.13, p=0.04).

# Physical activity interventions in children under 12 years old

Nine studies in children under 12 years old focussed mainly on the physical activity component of the intervention. Four studies fulfilled the reviewers' quality criteria but had incomparable study designs and interventions and so were unsuitable for meta-analysis. One study randomised 90 families with obese 8–12 year old children to receive either emphasis on discouraging sedentary behaviours or on encouraging physically active behaviours as part of a comprehensive family-based behavioural weight control programme that included dietary and behaviour change information [46]. The study results indicated that targeting physical activity or sedentary behaviours was associated with similar decreases in per cent overweight and increases in physical fitness during the two-year observation period. Across all four groups in this study (high and low dose increasing physical activity and decreasing sedentary behaviour interventions) the change in per cent overweight was  $-25.5\% \pm 10.6\%$  at six months and  $-12.9\% \pm 17.0\%$  at 24 months. Changes in BMI z scores were not reported.

Another study randomised 192 families with at least one 7–14 year old child who was overweight or at risk of overweight to either an "America on the move" group or a self-monitoring only group [47]. Both groups were asked to use pedometers to record daily physical activity and, in addition, the "America on the move" group were asked to walk an extra 2000 steps per day above baseline and to eliminate 420 kJ per day from their diet by replacing dietary sugar with a non-caloric sweetener. At six months, the "America on the move" group had a significantly higher percentage of children who maintained or reduced their BMI-for-age (67% vs. 53%, p < 0.05) and a significantly lower percentage of children

who increased their BMI for age (33% vs. 47%, p< 0.05). Children in both groups had groups had small decreases in BMI-for-age z-scores which the study authors (rather optimistically) stated were "clinically meaningful and statistically significant". The "America on the move" group had a greater decrease in BMI-for age z score ( $-0.066 \pm 0.166$ ) than the self-monitoring group ( $-0.039 \pm 0.169$ ) but the difference between the two groups was not statistically significant (-0.027, 95% confidence interval -0.075 to 0.022, p= 0.282). There was no change in parent BMI in either group. The authors stated that their "small changes" approach could be useful for addressing childhood obesity by preventing excess weight gain in families.

### Behavioural interventions in children under 12 years

There were 24 studies of behavioural interventions in children under 12 years. Behavioural interventions included family therapy, problem-solving approaches, cognitive-behavioural treatment and multi-component behavioural programmes incorporating a variety of behavioural techniques. Meta-analysis of the results from four studies (301 participants) showed a small positive effect for parent-focused behavioural group intervention compared to standard care at six months: the BMI-SDS (z-score) difference was -0.06 (95% Cl -0.12 to -0.01), indicating that the average BMI in the intervention group was 0.06 of a standard deviation (based on BMI- for-age-and-sex reference values) below that of the control group. A second meta-analysis pooled the results of the three of these four studies that had also reported on 12 month follow up (264 participants) and found that at 12 months there was no benefit from the parent-focused behavioural group intervention compared to standard care: the change in BMI-SDS was -0.04 (95% Cl -0.12 to 0.04).

#### Dietary interventions in children 12 years and older

Two studies explored dietary interventions in children 12 years and older, but only one of them reported an intention-to-treat analysis. This small RCT (16 participants, 14 of whom completed) compared two dietary interventions, one with a reduced glycaemic index and one which was a standard dietary intervention with reduced fat load, both in combination with behavioural therapy [48]. At 12 months follow there was a significantly greater decrease in absolute BMI (mean  $\pm$  std. error:  $-1.3 \pm 0.7$  vs.  $0.7 \pm 0.5$ , p 0.02) and fat mass ( $-3.0 \pm 1.6$  vs.  $1.8 \pm 1.0$  kg, p=0.01) in the reduced glycaemic index group compared to the reduced fat load group. Compared to baseline values, there was a significant favourable effect on absolute BMI and fat mass at 12 months for the reduced glycaemic index group but not for the reduced fat load group.

# Physical activity-based interventions for children 12 years and older

Three studies compared an experimental activity programme to an "active placebo" or control intervention. Only one of these three fulfilled the review's quality criteria. This study compared an after school activity programme to an exercise placebo (light body conditioning/stretching exercises) or usual care. It found that, at six months follow up, there were no significant changes in BMI-SDS from baseline or between any of the groups, but there were significant changes (favouring the exercise group) in physical self-worth, associated measures of self-esteem and physical activity [49].

#### Behavioural interventions in children 12 years and older

There were 12 lifestyle interventions in adolescents with a behavioural component as the main focus of the intervention. Seven of these studies were of sufficient quality for their results to be pooled in a meta-analysis but only four reported similar outcomes at six months. A meta-analysis of pooled data from three studies at six months follow up indicated an overall effect of a behavioural intervention on BMI-SDS (291 participants' data) of -0.14 (95% CI -0.17 to -0.12) and an overall effect on absolute BMI (362 participants' data) of -3.04 (95% CI -3.14 to -2.94) kg/m<sup>2</sup>, in comparison to standard care or control condition.

One study found a non-significant decrease in BMI-SDS in adolescents who participated in a four month behavioural intervention initiated in primary care (phone and email contact), compared to a non-significant increase in BMI-SDS for adolescents receiving standard single physician care. This meant that at the end of the intervention (four months) there was a significant difference in change from baseline between the groups. At seven

months, however, there were no longer any differences between groups. The 20 intervention subjects' mean BMI (SD) values were 31.0 (3.5) at baseline, 30.9 (3.8) post-treatment and 31.1 (4.5) at follow up and the 19 people in the control group had BMI values of 30.7 (3.1) at baseline, 31.8 (3.4) post-treatment and 32.1 (3.8) at follow up [50].

Another RCT compared two additions to cognitive behavioural therapy: 'peer-enhanced adventure therapy' (similar to Outward Bound) and aerobic exercise [51]. Adolescents in both interventions lost significant amounts of weight at the end of treatment (16 weeks) but there was no significant difference in weight loss between groups. At 10 months from randomisation significantly more adolescents in the adventure therapy group had maintained a minimum 4.5 kg weight loss: 35% vs. 12% in the aerobic exercise group.

Three studies had 12 months follow up data. One study showed no effect of adding coping skills training to a four-month behavioural programme for 7–17 year old children. Neither change from baseline in absolute BMI nor differences between groups was significant. A meta-analysis of 12 month follow up data from two studies (321 participants) showed that changes in BMI-SDS and absolute BMI in favour of the behavioural management programme that were significant at six months were still significant at 12 months. The difference in BMI-SDS between the behavioural management groups and the control groups at 12 months was -0.14 (95 % CI -0.18 to -0.10), and the difference in absolute BMI was -3.17kg/m<sup>2</sup> (95% CI -3.38 to -3.17).

One study which had found that, in teenage girls, an internet-based behavioural programme was significantly superior to an internet-based control programme at six months, found that at 24 months follow up there were no longer any significant differences between groups since the girls in the intervention group had regained weight.

#### Drug interventions for obese adolescents

The Cochrane review identified ten studies reporting on drug trials for three medications: metformin (2 studies), sibutramine (5 studies), and orlistat (3 studies).

#### Metformin

Neither of the two Metformin studies reported an analysis based on intention to treat, therefore the reviewers did not consider the effectiveness or otherwise of this drug.

#### Orlistat

Orlistat works by inhibiting the enzymes (lipases) responsible for absorption of dietary fat leading to increased excretion of undigested fat in the stools and creating an energy deficit which promotes weight loss [52].

There were two RCTs of orlistat (trade name Xenical®) which fulfilled Cochrane criteria for meta-analysis. A pooled meta-analysis of data from 579 participants indicated that, in combination with a lifestyle intervention, orlistat (compared to placebo) had an effect on absolute BMI at six months follow up:  $-0.76 \text{ kg/m}^2$ , (95% CI -1.07 to -0.44, p< 0.00001).

In all three of the orlistat studies withdrawals due to adverse events were higher in the orlistat intervention groups compared to the placebo group, with withdrawal rates ranging from 3.4% to 31.8%. The most common types of adverse events reported in all three studies were associated with the gastrointestinal tract. They included oily spotting, fatty/oily stools or evacuation, increased defecation, cramps and abdominal pain.

One study measured additional adverse effects: cardiovascular effects, gallbladder structure, bone mineral content/density, renal structure and other non-GIT effects. Ten patients in the orlistat group and one in the placebo group developed ECG abnormalities but an independent cardiologist did not consider that these were medication-related. At the end of the study six orlistat patients and one placebo patient were found to have asymptomatic gallstones that had not been seen at baseline and another orlistat patient had multiple gallstones at day 167, after a 15.8 kg weight loss, and later had a cholecystectomy. Ultrasound identified two new renal abnormalities in the orlistat group. The most common other adverse events that were more common in the orlistat group were headache, upper respiratory tract infection and nasopharyngitis.

Orlistat is listed in the New Zealand Formulary as a medication for adults [53] but the Ministry of Health's 2009 publication *Clinical Guidelines for Weight Management in New Zealand Children and Young People* suggests it may be considered in addition to lifestyle modification to assist weight control in obese young people (BMI  $\ge$  95<sup>th</sup> percentile) but only if a lifestyle change programme has failed and specialist services with experience in the use of anti-obesity drugs supervise its use [7]. Orlistat is not a funded medication and is relatively expensive, costing around \$180 for a 1-month supply [54].

### Sibutramine

The Cochrane review found a favourable effect of sibutramine (trade name Reductil®) plus lifestyle interventions compared to placebo plus lifestyle interventions at six months. Sibutramine has been withdrawn from sale in a number of countries, including New Zealand, because a major study found it increased the risks of heart attack and stroke [55].

#### **Bariatric surgery**

There were no studies of surgical interventions in adolescents that were eligible for inclusion in the Cochrane review. Another 2009 Cochrane review looked at surgery for obesity in adults [56]. This review included 26 studies: 20 RCTs comparing different bariatric procedures and three RCTs and three prospective cohort studies comparing surgery with non-surgical management. The authors concluded that surgery results in greater weight loss than conventional treatment, both in moderate (BMI > 30 kg/m<sup>2</sup>), and severe obesity (BMI > 40 kg/m<sup>2</sup>), that the weight loss from surgery persists for at least ten years, and that surgery also leads to reductions in comorbidities such as diabetes and hypertension. There were improvements in health-related quality of life at two years postsurgery but effects at ten years were mixed with improvements in some quality of life domains but not others. Surgery is associated with significant complications, including pulmonary embolism, and there have been deaths following surgery.

#### **Conclusions from the Cochrane Review**

The 2009 Cochrane review made a number of useful observations. They stated that:

- Family-based lifestyle interventions that include a behavioural component aimed at changing thinking patterns regarding diet and physical activity produce significant and clinically meaningful reductions in overweight in children and adolescents, compared to self-help or standard care in the short and long term.
- Parental involvement is important, particularly for pre-adolescent children,
- Consideration may be given to the adjunctive use of orlistat in adolescents but this therapy needs to be carefully weighed against possible adverse side effects.
- It was not possible to determine whether any one lifestyle intervention was better than another.

The authors also noted that most of the studies included in the review were small (44 out of 64 randomised <30 children to at least one group), most did not account for missing data, many had high dropout rates, and less than half performed an analysis based on intention to treat. Many studies were based in specialist clinics and some studies reported that transportation difficulties were a barrier to participation. Most of the lifestyle intervention studies (36 out of 54) did not report on measures of harm but 18 reported on adverse effects such as disordered eating, depression or anxiety and these studies reported no adverse effects on eating behaviours or psychological wellbeing. Lifestyle studies commonly reported on reasons for dropout and changes in linear height growth. No lifestyle studies reported an adverse effect of the intervention on linear height growth.

# Insights from other reviews of obesity interventions

This section presents information from a number of recent systematic reviews investigating the effectiveness of various obesity interventions in different age groups, plus the results of a few recent randomised controlled trials.

# Timing of solid food introduction for infants

There is much debate about the appropriate time to introduce solid foods into an infant's diet. The World Health Organization recommends exclusive breastfeeding for the first six months [57]. A 2010 systematic review by Moorcroft et al. considered whether there was an association between the timing of introducing solid foods in infancy and obesity in

childhood [58]. Studies were included only if they were undertaken in developed countries and measured obesity in infancy and/or childhood using an appropriate measure such as BMI or skinfold thickness or circumference measures, and if they were randomised, observational or case-control studies. The authors identified 24 studies that met their criteria (mostly cohort studies), with a total of over 34,000 participants. No clear association was found between the timing of introduction of solid food and the risk of overweight and obesity in infancy and childhood. The authors concluded that, when the whole complex situation regarding childhood obesity is considered, a whole family approach to the prevention of childhood obesity is necessary and that concentrating on a range of modifiable factors is likely to be more effective than concentrating on any single factor in isolation.

#### Physical activity interventions

Many interventions to treat childhood overweight and obesity incorporate physical activity components [59]. As part of their 2011 review on interventions for childhood obesity, Canoy and Bundred assessed the effect of physical activity interventions alone for helping children lose weight. They identified two systematic reviews on this topic [41,43] and two subsequent RCTS [60,61]. One of the reviews was the 2009 Cochrane review discussed earlier. The other, by McGovern et al. included 20 RCTs of physical activity interventions, five of which were also included in the Cochrane review [41]. The authors stated that the 17 trials with complete data yielded inconsistent results. When the trials were combined in two separate meta-analyses according to whether they had measured intervention effects as changes in BMI or changes in fat mass, physical activity interventions had an effect on fat mass (6 trials, 358 participants, standard mean difference = -0.52, 95% CI -0.73 to -0.30) but not on BMI (11 trials, 433 participants, SMD= -0.02, 95% CI -0.21 to 0.18) although the authors stated that reporting bias may explain this finding.

#### **Dietary interventions**

Since the publication of the 2009 Cochrane review there have been no new systematic reviews comparing the effectiveness of different dietary interventions for treating (as opposed to preventing) childhood obesity. Two earlier systematic reviews [62,63], were both published in 2006. Gibson et.al identified nine studies, seven of which were RCTs [63]. They reported that "low carbohydrate and low-glycaemic index diets appeared to be at least as effective as energy-restricted low fat diets for short-term weight loss, but most studies were too small to be informative, and none provided evidence on long-term weight control". They concluded that there was little evidence to support current dietary recommendations for weight reduction in children and adolescents and that there was an urgent need for well-designed RCTs to evaluate the long term effectiveness of alternative dietary interventions.

A review by Collins et al. [62,64] reported on RCTs that included a dietary component either alone or in combination with lifestyle changes and/or psychological therapies. The authors identified 37 RCTs (2262 participants in total). Only seven studies compared a dietary intervention alone with a non-intervention control group or a different treatment approach. Seventeen studies contained enough information to be included in a Forest plot of standardised effects but only a minority had an adequate control group and the treatments studied were highly diverse so the authors did not consider a meta-analysis appropriate. They did, however, perform meta-analyses of the results of the eight studies that included both a dietary component and an adequate control group and of the results of the four of these studies which had follow-up data (at  $\leq$  15 months). While the authors stated that their results should be viewed with caution because diet was only a component of the interventions they suggested that the results of the meta-analyses indicated that dietary components were effective in achieving weight loss but that the effects of interventions diminished over time. They stated that the two studies with the greatest standardised effect, neither of which reported follow-up data, reported reductions in the per cent body fat in adolescents of between three and six per cent. Overall, the authors concluded that "It is not possible to evaluate the effectiveness of dietary treatment for childhood obesity because of the lack of high-quality studies and the heterogeneity of



designs, treatment combinations, outcome measures, and follow-up". They stated that there was an urgent need to improve the quality of studies in this area.

In another review, Collins et al. highlighted some of the difficulties in measuring children's dietary intake for research studies and discuss how they contribute to the current limitations of the evidence base for dietary interventions [65]. Often studies rely on the child's or the parent's recall of what has been eaten and this information may be biased for a number of reasons: study participants may give inaccurate responses that they feel are socially desirable or likely to meet with approval, children tend to be less accurate at identifying portion sizes than adults, overweight children may be sensitive about their food intake and under report what they have eaten, and children of different ethnic or cultural backgrounds may differ in how accurately they recall their food intake. The use of doubly labelled water (DLW) provides a technique for accurately measuring total energy expenditure, which is close to dietary energy intake since only 1-2% of a child's energy intake is used for growth, but this method is expensive, technically demanding and of limited availability. Studies which have compared energy intake from reported food intake with the doubly labelled water method have shown that in younger children there can be large individual differences between parent reported energy intake and energy expenditure as measured by DLW and that in older children and adolescents under-reporting of energy intake using food records increases with age, females are more likely to under-report than males, and obese children are more likely to under-report than lean children.

#### **Family-based interventions**

The family is a key component of obesity interventions since the family is the major determinant of a child's eating and lifestyle habits and obese children frequently have obese parents [66].

Sung-Chan et al. conducted a systematic review of RCTs that had investigated familybased models for interventions to treat childhood obesity [66]. They included 15 RCTs of family-based lifestyle interventions for children and adolescents aged 2–19 years (published from 1975 to 2010), 3 of which were also included in the 2009 Cochrane review [43] discussed earlier.

They considered that overall these RCTs were of satisfactory methodological quality. Almost all studies (93%) had a sample size of less than 40 and only 66% reported follow-up results of the effects of treatment. Sixty per cent (9 of the 15) made follow-up measurements at 6–12 months after treatment and one study reported follow-up measurements at three months.

They classified the interventions into four categories based on the two underlying theoretical frameworks for the interventions: behavioural approach (8 studies), behavioural approach plus additional training in parenting and child management (5 studies), family approach (1 study) and a combination of behavioural and family therapy approaches (1 study). They assigned outcome scores ranging from 1 to 4 to each study according to whether the weight reductions in the treatment group (compared to the control group) were not significantly better (score=1), marginally better (score=2), significantly better, but not maintained at follow-up or there was no follow-up (score=3) or significantly better and largely maintained in the follow-up period (score =4).

Interventions based on behaviour theory aim to reduce the risk of child obesity by encouraging the adoption of a healthy lifestyle, particularly in regard to diet and exercise. Parents and children are taught behavioural knowledge about self-monitoring, goal setting for eating and physical activity, behavioural contracting and relapse prevention. Some behaviour theory-based interventions also include parent education aimed at improving authoritative parenting styles. Sun-Chen et al. found that, of the 15 studies that used a behavioural approach, the eight RCTs that focussed on healthy eating and exercising and involved one family member or the whole family were more effective (mean score =3.5) than the five RCTs that incorporated child management and parenting style components in addition to a family-based healthy lifestyle intervention (mean score = 2.6).

Interventions based on family therapy draw on the perspective of family systems theory which maintains that family dynamics are the key to understanding how the family, as a basic social system, influences children's behaviour via patterns of interaction between family members. According to family systems theory, child obesity is and expression of dysfunctional family dynamics, maintained via the development of an unhealthy lifestyle. Well-functioning families can adapt easily if lifestyle changes are needed whereas poorlyfunctioning families become more rigid in the face of change, making it difficult for them to adopt new patterns of diet and exercise. In one of the few examples of this approach to treating childhood obesity, Flodmark et al. [67] offered brief family therapy (six sessions spread over one year) in addition to dietary counselling and medical check-ups over a period of 14 to 18 months. During therapy sessions, family therapists tried to reinforce the families' resources and create an optimal emotional climate for helping the obese child. This three-arm RCT found that one year after the end of treatment, there was a significantly smaller increase in BMI in the family therapy group compared to the control (no intervention) group (mean +5.1% vs. +12.0%, p=0.022) but none of the differences between the family therapy and conventional treatment groups, or between the conventional treatment and the untreated control group, were significant.

One of the studies identified by Sun-Chen et al. could be classified as having used a hybrid approach, incorporating elements from both Family Systems and Social Cognitive Theories to enhance family variables (family competence, nurturance, conflict resolution and cohesion) and to help participants gain knowledge and self-esteem, understand the benefits of not being obese, and develop skills in self-monitoring, goal setting, substituting healthful alternatives, and enlisting social support [68]. This study randomised 42 adolescent girls (with BMI ≥ 95<sup>th</sup> percentile) and their families into three groups: a multifamily therapy plus psycho-education group (n=14), a psycho-education only group (n=13) and a control (wait list) group (n=8). At the conclusion of the 16 week trial, none of the participants had significant changes in BMI but those in the psycho-education only groups showed a greater decrease in energy intake (based on a dietician-administered structured interview to determine 24 hour diet recall) compared to the multifamily therapy plus psycho-education group (p<0.01). There was an association between positive changes in family nurturance and lower levels of adolescent energy intake (p < 0.05) and the authors stated that this indicated nurturance can be an important family variable to target in adolescent dietary and weight loss programmes.

# The use of Health Information Technology in the treatment of childhood obesity

The 2009 US Congressional Act, Health Information Technology for Economic and Clinical Health, includes incentives for using IT to facilitate delivery of BMI screening and counselling on diet and physical activity, e.g. by using computerised growth charts [69,70].

A recently published systematic review by Smith et al. examined the effect of health IT (electronic health records, telemedicine, text messaging or telephone support) on care processes and patient outcomes in paediatric obesity management [71]. This review identified five treatment studies (4 RCTs and one before-and-after study) that reported patient outcomes, with sample sizes ranging from 17 to 475 participants, at one to ten practice sites. Three of the treatment studies focussed on obese children aged 8–12 years, one on obese younger children aged 2–6.9 years, and one on overweight adolescents aged 13–16 years.

Of the two telemedicine studies, one was a RCT (17 participants) of group counselling and one a before-and after study (294 participants) of individual counselling. The group counselling study did not demonstrate any improvement in patient outcomes, including BMI z-score but the individual counselling study found that 64% of children counselled by telephone had decreased BMI percentile at one year (compared to 69% of children counselled in person).

Three studies looked at the effects of text messaging and telephone support on BMI and other clinical outcomes. One RCT (220 participants) involving group counselling offered some families an additional 10 maintenance sessions using automated telephone counselling. Those children whose families completed 6–10, but not those who completed



0–5, telephone sessions had greater decreases in BMI z-scores at one year than children whose families received group counselling alone. Another RCT (151 participants) compared adolescents who received group counselling followed by text message, telephone, or e-mail contact every other week to adolescents who received group counselling alone and found no difference in mean changes in BMI, waist circumference, or blood pressure at one year, but there was low adolescent engagement since <22% of messages marked "please reply" were replied to. In the largest RCT (475 participants) no difference in BMI or BMI z-score was found between children who received usual care at 1 year, but although all intervention participants were offered three clinic visits and three phone calls less than half of families completed two or more calls or visits.

The authors considered that health IT interventions increase access to obesity treatment and can decrease travel costs for families but their impact on weight loss and other outcomes has been insufficiently studied and inconsistent.

This review was reviewed by the NHS Centre for Reviews and Dissemination (CRD) [72]. The CRD reviewers commented that, "Given the potential for bias in the review, poor quality of the included studies and limited evidence synthesis, the authors' conclusions regarding treatment access and adherence to guidelines may be overstated".

#### Interventions for children under the age of two years

As previously discussed, there is evidence that a child's weight status and weight gain trajectory early in life may have implications for future obesity status. For this reason, Ciampa et al. conducted a systematic review to assess the evidence for interventions to prevent or reduce overweight and obesity in children under the age of two years [73]. They identified 10 studies of poor to fair quality, eight of which used educational interventions to promote healthy dietary behaviours and two of which used a combination of nutrition education and a guided programme of physical activity.

There were a variety of study settings: home (n=2), classroom (n=4), clinic (n=3) and a combination (n=1). The interventions generally lasted for less than six months and had only modest success in altering measures such as dietary intake and parent's attitudes and knowledge about nutrition. None of the studies improved child weight status.

The authors concluded that few published studies had attempted preventive or therapeutic obesity interventions in very young children but there was limited evidence that interventions may improve parent's knowledge and attitudes about nutrition for young children.

The Centre for Reviews and Dissemination commentary on this review stated: "The substandard quality of included studies and potential methodological limitations in the review process mean that the authors' conclusion might not be reliable" [74].

#### Interventions for pre-school children

Noting that two previous systematic reviews of weight management schemes for the under-fives had included studies of uncontrolled design and with potentially biased self-reported outcomes, Bond et al. restricted their 2009 systematic review to controlled trials with objective outcome measures [75]. They found four RCTs assessing the effectiveness of preventive interventions but no treatment or cost-effectiveness studies.

Only one of the prevention trials (in a Latino community) showed a statistically significant advantage from the intervention in terms of a slower rate of increase in BMI but in the other three studies trends in decrease in BMI and weight loss favoured the intervention groups. Bond et al. hypothesised that important components to include in future interventions might be effective training for staff involved in delivering the intervention, cultural sensitivity, sustained moderate to vigorous exercise, active engagement of parents as participants in the programme and as role models for healthy lifestyles, and nutritional education for children.

The Centre for Reviews and Dissemination considered that this was a well-conducted review and that the authors' cautious conclusions reflected the scarce and disparate evidence for obesity interventions in the under-fives [76].

Since the publication of the Bond et al. review in 2009, there have been a few RCTs of interventions for pre-school children. The "High Five for Kids" and the "Buffalo Healthy Tots" studies are discussed in a later section on primary care, while the "LAUNCH" study is reviewed in the text box below.

#### The LAUNCH study

Stark et al. conducted a pilot RCT to evaluate the efficacy of a 6-month clinic and home-based intervention, known as LAUNCH (Learning about Activity and Understanding Nutrition for Child Health), for obese (BMI ≥95<sup>th</sup> percentile) pre-schoolers [77].The Launch intervention consisted of two phases. Phase one consisted of 12 weekly sessions that alternated between group-based clinic sessions (concurrent groups for parents and children) and individual home visits. The parent group sessions were conducted by a licensed clinical psychologist following a written manual. Phase two (the maintenance phase) consisted of 12 weeks of every other week sessions alternating between group sessions and home visits. The 90-minute parent group sessions addressed dietary education, physical activity and parenting skills. Parents were taught techniques to manage child behaviour including: praise and attention to increase healthy eating and physical activity; ignoring and time-out to manage tantrums; contingency management; and modelling. The child group sessions included nutrition education via games and art activities, trying new foods during a structured meal and 15 minutes vigorous physical activity. The home visits were carried out by psychology postdoctoral fellows and were designed to support generalisation of clinic learning to the home and help parents eliminate unhealthy foods from the home and set up a safe place to play.

Fifty-six eligible families were identified from records of a large U.S paediatric practice, with 38 declining to participate. Eighteen families were randomised to either LAUNCH or a control intervention consisting of a single session of paediatrician counselling (PC) with recommendations for diet and physical activity. At six months, there were statistically significant differences in weight outcomes between the LAUNCH children and the PC children as follows: BMI z-score ( $-0.59 \pm 0.17$ ), BMI percentile ( $-2.4 \pm 1.0$ ), and weight gain ( $-2.7 \text{ kg} \pm 1.2$ ) and these differences were increased at 12-month follow-up. The difference in weight loss between the LAUNCH parents and the PC parents was also significant: ( $-5.5 \text{ kg} \pm 0.9$ ) at month 6 and ( $-8.0 \text{ kg} \pm 3.5$ ) at month 12.

The authors concluded that, based on the data from their small sample, an intensive intervention including child behaviour management strategies to improve healthy eating and activity appeared to be more promising for reducing preschool obesity than a low intensity intervention that was typical of treatment that could be delivered in primary care.

#### Weight loss camps and other residential interventions

In some countries, including the U.S. and U.K, children's weight loss camps are an option for some obese children. These camps typically combine dietary restriction, physical activity and behaviour modification [78]. They may be for-profit commercial enterprises or non-profits run in association with academic institutions or children's hospitals [79]. They are usually only accessible to children from relatively wealthy families since the fees are normally paid by parents, but in the U.K. the National Health Service has paid for some children to attend the Carnegie Weight Management residential camp [80], now known as More-life [81].

Kelly and Kirschenbaum have reviewed published studies on "immersion treatment" (weight loss camps and other residential programmes) [82]. These authors, who are both employees of Wellspring, a leading provider of weight loss camps in the U.S. [83], identified 22 published studies of interventions which targeted and assessed change in weight status and involved a minimum stay of 10 days and nights. The interventions typically included controlled diet, activities, therapy and/or education regarding behaviour change and nutrition education. The authors stated that: "compared with results highlighted in a recent meta-analysis of out-patient treatments, these immersion programmes produced an average of 191% greater reduction in per cent-overweight at post treatment and 130% greater reduction at follow-up". They also stated that their review showed that interventions which included cognitive behaviour therapy seemed to have better outcomes and "outperform the non-CBT interventions by a wide margin" despite the

CBT studies generally having longer follow-up periods which tend to be associated with poorer outcomes.

This review was reviewed by the NHS Centre for Reviews and Dissemination (CRD) at the University of York, [84]. The CRD reviewer(s) noted a number of limitations to the review: the studies appeared to be heterogeneous in terms of intervention, design and outcomes; the authors did not state that quality assessment of included studies was performed and it appeared that the study designs were at high risk of bias since although six studies used control or comparison groups, only one reported randomised assignment of participants and only one reported an intention-to treat analysis; a limited number of databases were searched for published studies in English and therefore publication bias and language bias could not be ruled out. The CRD reviewers considered that the methodological limitations of the review and the considerable risk of bias meant that the conclusions should be interpreted cautiously.

#### Lifestyle interventions: impact on weight change and cardio-metabolic risk factors

A recent systematic review by Ho et al. examined the impact of lifestyle interventions with a dietary component on both weight change and cardio-metabolic risk factors, such as blood pressure, serum lipids and fasting insulin, in overweight and obese children [85]. The review included 38 RCTs, published between 1975 and 2010 and of variable quality, comparing the effectiveness of a lifestyle intervention including a dietary or nutrition component with wait-list or no treatment control, usual care, written diet and physical activity education materials or minimal advice. The number of participants per study ranged from 16 to 258. Thirty three studies had adequate data for meta-analysis on weight change and 15 reported on lipids, fasting insulin or blood pressure.

Compared to no treatment, lifestyle interventions produced significant weight loss (at latest point of follow-up) as indicated by both pooled BMI ( $-1.25 \text{ kg/m}^2$ , 95% CI -2.18 to -0.32) and BMI z-score (-0.10, 95% CI -0.18 to -0.02). Lifestyle interventions also led to significant weight loss compared to usual care as measured by pooled BMI, both immediately at the end of active treatment (-1.30kg/m<sup>2</sup>, 95% CI -1.58 to -1.03), and at subsequent follow up at 7–12 months ( $-0.92 \text{ kg/m}^2$ , 95% CI -1.31 to -0.54). Lifestyle interventions led to significant improvements in low-density lipoprotein cholesterol (-0.30 mmol/L, 95% CI 20.45 to 20.15), triglycerides (-0.15 mmol/L, 95% CI -0.24 to -0.07), fasting insulin (-55.1 pmol/L, 95% CI -71.2 to -39.1) and blood pressure up to one year from baseline but for high-density lipoprotein cholesterol no differences were found. The authors noted that, without having individual participants' data, it wasn't possible to determine the relationship between the extent of weight loss and changes in the various cardio-metabolic outcomes. They also noted that the heterogeneity of the studies included in the review made it difficult to provide definitive recommendations for practice but they stated that almost all of the effective interventions, especially those in children under 12 years old, reported including a family component that included separate education sessions for parents and children.

The authors concluded that lifestyle interventions which include a dietary component together with an exercise or behavioural component are effective for treating childhood obesity and improving cardio-metabolic outcomes. The Centre for Reviews and Dissemination regarded this review as being generally well-conducted but noted that variations in intervention settings, constituent components, and duration meant that the evidence did not provide a clear indication on which intervention format was likely to be most effective in practice and in the long term [86].

#### Metformin for the treatment of overweight and obesity in adolescents

Metformin is an oral hypoglycaemic agent and is the most widely used drug for the treatment of type 2 diabetes in adults. Its primary action seems to be the inhibition of hepatic glucose production. At high concentrations, it also increases peripheral insulin sensitivity and glucose uptake [87]. As a consequence of the increase in prevalence of obesity in children and adolescents, there has been an increase in the number of children and adolescents with type 2 diabetes. Since insulin resistance related to excessive weight gain is a first step on the pathway to type 2 diabetes, metformin has been used in obese

children and adolescents who are not diabetic to reduce overweight and prevent or delay the onset of type 2 diabetes.

Two recent reviews have examined the use of metformin in overweight or obese nondiabetic children or adolescents [87,88].

A 2012 review by Brufani et al. identified 11 trials with duration of six months or more. The number of participants ranged from 16 to 151. All except one focussed mostly on adolescents. Eight were double-blind placebo RCTs and three compared metformin plus lifestyle intervention to lifestyle intervention alone without placebo. The trials differed in inclusion criteria, the use (or not) and type of lifestyle interventions, the indicators of insulin resistance/sensitivity, metformin dosage and participant ethnicity so the authors did not consider meta-analysis to be justified. Most of the trials (nine out of eleven) found a small but significant benefit of metformin in decreasing BMI by from 1.1 to 2.7 kg/m<sup>2</sup> compared to placebo or lifestyle intervention alone. The authors concluded that metformin has a very modest effect as an anti-obesity drug and noted that the trials in children and adolescents with severe obesity (BMI  $\ge$  32) had mean BMI reduction of from 1.1 to 1.7 kg/m<sup>2</sup> which is clinically insignificant.

Bouza et al. included nine RCTs in their review of the use of metformin in overweight and obese adolescents (498 participants, mean age 14.2 years, and mean BMI 36.4 kg/m<sup>2</sup>). All but one compared metformin plus lifestyle intervention to placebo plus lifestyle intervention. Meta-analysis indicated that metformin reduced mean BMI by 1.42 kg/m<sup>2</sup> (95% CI -2.18 to 0.66) and also had favourable effects on fasting insulin and the HOMA index (the homeostasis model assessment – a method of assessing  $\beta$ -cell function). Bouza et al. concluded that the available evidence indicated that, in the short term, metformin in addition to lifestyle intervention is relatively effective at reducing BMI and hyperinsulinaemia in obese adolescents without "related morbidity" (presumably without diabetes), and has an acceptable safety profile, but its long term effects are unknown. The NHS Centre for Reviews and Dissemination (CRD) commented on this review and pointed out that the estimate of change in BMI was very small and it was unclear whether it would be clinically significant among obese people [89]. The CRD reviewer(s) stated that: "Overall, the authors' conclusions reflect the evidence presented but cannot be considered reliable due to limitations of the evidence base".

#### **Bariatric surgery**

While surgery for obesity is not generally recommended for obese children or young people it has increasingly been used for treatment of those with extreme obesity and obesity-related comorbidities when more conservative treatment methods have failed [90]. The 2006 guidelines from the U.K. National Institute for Clinical Excellence [90] noted that there were (at that time) only three published guidelines that contained recommendations relating to bariatric surgery in adolescents: NHMRC Australian guidelines for the management of overweight and obese children and adolescents, the Singapore Ministry of Health clinical guidelines and the Institute for Clinical Systems Improvement (ICSI) guidelines. The Singapore guidelines [91] are now out of date but updated guidelines from the NHMRC [10] and the ICSI [92] suggest that a post-pubertal adolescent with a BMI of > 40 kg/m<sup>2</sup>, or > 35 kg/m<sup>2</sup> plus significant severe comorbidities such as type 2 diabetes or obstructive sleep apnoea, may be considered for bariatric surgery if other interventions have been unsuccessful. A working party from the Royal Australasian College of Physicians made similar recommendations [93].

There are a number of different surgical procedures used in bariatric surgery and they are all usually done laparoscopically. They include the Roux-en-Y gastric bypass, the adjustable gastric band, biliopancreatic diversion and the sleeve gastrectomy [94]. The best-studied procedure in adolescents is probably the Roux-en-Y gastric bypass. In this procedure, the stomach is stapled to exclude almost all of the stomach volume and create a small pouch at the top of the stomach. This is separated from the main body of the stomach and attached to the small intestine bypassing the duodenum and the proximal 20–39 cm of jejunum. The bypassed intestine coming from the main body of the stomach is then joined to the intestine beyond the new stomach outlet to allow drainage of gastric

secretions. Weight loss ensues from restriction of food intake and malabsorption [95]. Adverse effects that may follow the procedure include anastomotic leak, small bowel obstruction, dumping syndrome (symptoms that may include nausea, vomiting, bloating, cramps, diarrhoea and/or other symptoms), protein-calorie malnutrition, and micronutrient deficiency related to malabsorption [92].

#### Research on bariatric surgery outcomes in adolescents

There has been limited research on the effectiveness of bariatric surgery for obese adolescents. Treadwell et al. reviewed studies (published in English up until December 2007) that had reported outcomes on three or more patients aged ≤21 years who represented at least 50% of the paediatric surgical patients enrolled at a centre, and had followed up patients for at least one year. There were eight studies (352 patients, mean BMI 45.8 kg/m<sup>2</sup>) on laparoscopic adjustable gastric banding (LAGB), six studies (131 patients, mean BMI 51.8 kg/m<sup>2</sup>) on Roux-en-Y gastric bypass (RYGB), and five studies (158 patients, mean BMI 48.8 kg.m<sup>2</sup>) of other surgical procedures. The patients had an average age of 16.8 years and the age range was nine to 21 years. Of the total of eighteen studies only one reported on a control group of patients not treated by bariatric surgery and the patients in the control group were significantly different to the surgery patients since they had a lower BMI and no reported comorbidities. Most studies were retrospective and therefore possibly biased towards favourable outcomes since centres with unfavourable outcomes are less likely to choose to publish their results. There was considerable heterogeneity between studies.

Treadwell et.al conducted meta-analyses of the results of data on BMI reduction from six studies of LAGB and four studies of RYGB [96]. They reported that, for LAGB, the 95% confidence interval for change in BMI post-surgery was from -10.6 to -13.7 BMI units, and for RYGB it was -17.8 to -22.3 BMI units. Eight per cent (28/352) of the LAGB patients required re-operation because of various complications, and, in addition, there were eight cases of iron deficiency and five cases of mild hair loss. The RYGB studies reported that, although there were no in-hospital deaths, one patient died nine months after surgery due to severe *Clostridium difficile* colitis, and three other patients died from causes considered to be unrelated to the bariatric surgeries. The most frequently reported complication of RYGB was protein-calorie malnutrition and micronutrient deficiency but there were some potentially life-threatening complications including shock, pulmonary embolism, post-operative bleeding, severe malnutrition and gastrointestinal obstruction. Treadwell et al. concluded that bariatric surgery in paediatric patients produces clinically significant weight loss, but can have serious complications.

In their commentary on Treadwell et al.'s review, the NHS Centre for Reviews and Dissemination stated that the quality of the studies included in the review was low (almost all were case series), and the reporting of the review process and results was poor so the reliability of the authors' conclusions was unclear [97].

There has been a prospective RCT of gastric banding in adolescents which was conducted in Melbourne during 2004–08 [98]. It involved 50 patients between the ages of 14 and 18 years, with mean BMI > 35 kg/m<sup>2</sup>, who were randomised to either gastric banding or a supervised lifestyle intervention and followed up for two years. Those in the gastric banding group at follow up (data from 24/25 patients) had a mean weight loss of 34.6 kg (95% CI 30.2 to 39.0kg), representing an excess weight loss of 78.8% (95% CI 66.6% to 91.0%), 12.7 BMI units (95% CI 11.3 to 14.2), and a BMI *z*-score change from 2.39 (95% CI, 2.05 to 2.73) to 1.32 (95% CI, 0.98 to 1.66) while the lifestyle group (18/25) had a mean weight loss of 3.0 kg (95% CI 2.1 to 8.1), representing excess weight loss of 13.2% (95% CI 2.6% to 21.0%), 1.3 BMI units (95% CI, 0.4 to 2.9), and a BMI *z*-score change from 2.41 (95% CI 2.21 to 2.66) to 2.26 (95% CI, 1.91 to 2.43). At baseline, nine in the gastric banding and ten in the lifestyle group had metabolic syndrome and at follow up none in the gastric banding but four (out of 18) in the lifestyle group did. Eight of those in the gastric banding group required subsequent operations for either proximal pouch dilation or tubing injury. The authors concluded that gastric banding, compared to lifestyle intervention, resulted in a greater percentage of subjects achieving a loss of 50% of excess weight and greater improvements to health and quality of life.

Padwall et al. identified 31 RCTs of bariatric surgery in adults (2,619 patients, mean age 30–48 years, mean BMI 42–58 kg/m<sup>2</sup>) [99]. Compared to standard care, data from 15 trials (1103 participants) showed the following mean differences (MD) in BMI from baseline at one year: jejunoileal bypass (MD: -11.4 kg/m<sup>2</sup>), mini-gastric bypass (-11.3 kg/m<sup>2</sup>), biliopancreatic diversion (-11.2 kg/m<sup>2</sup>), sleeve gastrectomy (-10.1 kg/m<sup>2</sup>), Roux-en-Y gastric bypass (-9.0 kg/m<sup>2</sup>), horizontal gastroplasty (-5.0 kg/m<sup>2</sup>), vertical banded gastroplasty (-6.4 kg/m<sup>2</sup>), and adjustable gastric banding (-2.4 kg/m<sup>2</sup>). Padwall et al. concluded that, although data from large, adequately powered long term RCTs was lacking, bariatric surgery appeared substantially more efficacious than standard care for reducing BMI and that, compared to Roux-en-Y gastric bypass, adjustable gastric banding produces less weight loss but has fewer serious adverse effects. The NHS Centre for Reviews and Dissemination reviewed this review and considered that, based on the limited evidence available, the authors' conclusions were likely to be reliable [100].

One of the key reasons for encouraging weight loss in obese children and adolescents is the belief that weight loss will reduce the risk of developing metabolic syndrome, diabetes and cardiovascular disease later in life, but, according to a 2013 systematic review produced by the Australian National Health and Medical Research Council, "there are no longer term data available from high quality studies that assess the impact of bariatric surgery on cardio-metabolic outcomes in adolescent patients" so the effect of adolescent bariatric surgery on future disease risk is as yet unknown [101]. While most obese adults who have bariatric surgery lose substantial amounts of weight, many initially have such high BMIs that even after substantial weight loss following surgery they still have BMIs in the obese range. This observation has been used as an argument for intervening earlier in life [102,103].

#### Conclusions from other reviews of obesity interventions

The key findings from the other reviews of obesity interventions discussed above are:

- There is no clear association between the timing of introduction of solid food and the risk of overweight and obesity in infancy and childhood
- Physical activity interventions alone probably decrease fat mass but may not result in decreases in BMI
- There is a lack of evidence for the effectiveness of dietary treatment because of a lack of high quality studies
- Family-based interventions are more effective if they include a behavioural component dealing with self-monitoring, goal setting for eating and physical activity, problem solving, behavioural contracting and relapse prevention. Enhancing family competence, nurturance, conflict resolution and cohesion may also be helpful
- The use of IT could increase access to obesity interventions, especially for those in more remote areas, but it is unknown if child or adolescent obesity treatment via IT is effective
- There is little evidence regarding interventions for very young children
- Weight loss camps and other residential interventions may be effective but have not been evaluated via RCTs and their long-term effects are largely unknown
- Lifestyle interventions which include a dietary component together with an exercise or behavioural component are effective for treating childhood obesity and improving cardiometabolic outcomes for at least a year from the end of the intervention
- Metformin produces small and clinically insignificant reductions in BMI in obese adolescents who do not have obesity-related comorbidities (i.e. diabetes) in the short term
- Bariatric surgery produces significant reductions in BMI for obese adults and one RCT done in Melbourne found that it was also effective for obese post-pubertal adolescents. The long term effects of bariatric surgery in adolescents are unknown

# **New Zealand interventions**

Reports of a number of interventions for preventing or reducing the prevalence of childhood overweight and obesity in New Zealand children have been published in the international literature [104,105,106], but none of these interventions have been targeted at obese children alone. There are no published RCTs of New Zealand interventions that are specifically for obese or overweight children only, such as Bodywise and Green Prescription Active Families, although there are published reports of other types of evaluations of these interventions.

Waikato DHB funds Project Energise, a population-based intervention which aims to increase the quality and quantity of physical activity and improve nutrition for primary school children [107,108]. Trained "Energisers" work with schools to develop and support programmes for healthy eating and physical activity. The project included an evaluation of the intervention programme via a RCT which ran from 2004-2006 [107]. Schools were randomised with stratification by rurality and socio-economic status (SES) to receive the intervention (62 schools) or act as controls (62 schools). Children aged five and ten years had weight, height, body fat (by bioimpedance) and resting blood pressure (BP) measured at baseline and two years later. Over the two years, after adjustment for baseline measure, rurality and school decile there was no difference between the intervention and control groups in BMI standard deviation score (SDS, = z score) in either the younger or the older children but the 5-7 year olds in the intervention group had improved % body fat SDS (intervention – control = -0.14, 95% confidence interval -0.26 to -0.01) and the 10–12 year olds in the intervention group had an improvement in systolic blood pressure SDS (intervention – control = -0.23, 95% CI -0.43 to -0.02) and, to a lesser extent, diastolic BP SDS (intervention – control = -0.14, 95% CI -0.30 to 0.04).

Subsequently the intervention was extended to more schools and, by 2011, all but two of the 235 school in the Waikato region were engaged [108]. In 2011, to assess the effect of the programme, researchers compared indices of obesity and physical fitness in seven year old and ten year old children in schools that had been "energised" for at least 18 months with historical measurements. Obesity indices were compared with the 2004 measurements of control children in the earlier RCT and fitness measures (time taken to run 550m) with those of Canterbury children obtained between 2001 and 2007. The 2011 children were a little younger than the historical control children (on average 1.5 months for the younger and 3.6 months for the older children) but of the same average height. The 2011 children had lower prevalence of overweight and obesity combined, (younger children 19.5 vs. 23.8%, older children 26.6 vs. 27.8%). They also had lower BMI (younger children 16.83 vs. 17.36, older children 18.7 vs. 19.3 kg/m<sup>2</sup>), and had faster times for the 550m run (younger children 183.2 vs. 212.7, older children 164.2 vs. 179.8 seconds). After adjusting for age, sex, ethnicity (not for the run times), SES and school cluster effects, the odds ratios for combined obesity and overweight were: younger children: 0.69 (95% confidence interval 0.54–0.88) and older children: 0.85 (95% CI 0.72–1.00). The adjusted relative (%) differences in mean BMI were: younger children: -3.0 (95% CI -4.3 to -1.7), older children: -2.4 (BF 95% CI -3.7 to -1.1), and the adjusted relative (%) differences in mean time to run 550m were: younger children: -13.7 (BF 95% CI -15.8 to -12.3), older children: -11.3 (95% CI -14.1 to -9.0).

The project evaluation report indicates that children who participated in Project Energise became fitter, had decreased waist measurements compared to earlier cohorts of Waikato children of the same age, and had good knowledge about healthy eating and physical activity [109]. The programme is reported to be affordable, costing around \$45 per child per year in 2010, and cost effective [110].

Waikato DHB is currently running Bodywise, a family-focussed 12-month intervention for children aged 5–12 years who require weight management [111]. Bodywise involves an initial appointment at the hospital children's clinic, followed by a six week group programme at Sport Waikato (attending twice per week) and monthly follow-up home visits by a dietician and active families coordinator. A formal evaluation of this programme has yet to be published but preliminary results were presented at the CAMHS conference in

2007 [112] and these indicated modest decreases in BMI z-scores but marked improvements in the percentage of programme participants who met food and nutrition guidelines and increases in time spent in physical activity and time spent outdoors. The intervention was well-received by parents and children.

Green Prescription Active Families is an initiative (introduced in 2004 as an offshoot from the Green Prescription for adults) which aims to increase physical activity for children, young people and their families [113]. It is funded by the Ministry of Health. On July 1st 2012 funding and management was devolved to DHBs who currently contract eighteen providers to deliver the initiatives. Criteria for referral to the programme are inactive overweight or obese children who have a family motivated to make lifestyle changes. Priority is given to children aged 5–12 years. The programme includes group sessions with physical activity components, where participants work on individual goals, plus information and education about general well-being, healthy eating and physical activity. People participate for up to 12 months and the long term goal is for each child to have a minimum of 60 minutes of moderate-intensity physical activity on most days.

The latest survey of participants in the Green Prescription Active Families programme involved 133 families (61% of the total) who participated in the programme between July 2012 and May 2013 and it found that the contract holders exceeded all nine of the key performance indicators measured [114]. Eighty-four per cent of participating families reported that they had noticed positive changes in their child's health since joining the programme particularly that they had more energy, were more willing to try new activities, and were more confident. Seventy-seven per cent said their child was more active and almost all children understood the benefits of healthy eating (87%) and being physically active (83%). Eighty-five per cent said their family had dietary changes, most commonly generally eating more healthily including eating less takeaways or junk food (26%), having less sugar or sugary food and drinks (19%), eating smaller meals (14%) and eating more fruit and vegetables (13%). Forty-one per cent said that their child had either lost weight or noticed their clothes being looser. Overall most survey respondents said they were either satisfied (28%) or very satisfied (68%) with the programme.

# Key points about New Zealand Interventions

- Project Energise, a DHB-funded school-based intervention for primary school children in the Waikato, is a promising population-based preventive intervention
- Bodywise (funded by Waikato DHB) and Green Prescription Active Families (funded by all DHBs) are interventions for overweight and obese children that are well regarded by families. There is no clear evidence that they improve children's BMIs but participants in these interventions report improvements in behaviours related to diet and physical activity

# Primary care interventions

While much of the research into treatment programmes for obese children has been done in specialist hospital clinics, given the large number of children who are now overweight or obese there is a clear need for interventions that are based in primary care or other community settings [115]. Vine et al. recently reviewed the published literature from 2006 to 2012 to provide U.S. examples of the range of roles that primary care providers can play in the prevention and treatment of childhood obesity and to synthesise evidence concerning the important characteristics, strategies or features of successful communitybased models [115]. They noted that a U.S. nationwide survey of primary care providers (PCPs) found that fewer than half were assessing BMI percentiles regularly in children despite this being recommended by the White House Taskforce on Childhood Obesity [2], the American Academy of Pediatrics [19] and the American Heart Association [116], and only 18% reported referring children for further evaluation or management [117].

This review identified seven studies relating to primary care treatment of overweight and obesity in American children and adolescents, none of which were RCTs although one was related to a RCT (it examined the correlates of participation in a trial of an obesity intervention). Vine et al. reported that treatment interventions that involved individual case

management or patient-centred counselling over multiple sessions showed some evidence of success. Examples of these kinds of interventions included private, ageappropriate conversations with clinicians about achieving a healthy weight; goal setting; motivational interviewing; and discussions with registered dieticians about patient readiness for long term behavioural change, diet, and exercise.

Vine et al. stated that there is a need for primary care providers to move beyond measuring patients' height and weight and treating health problems and become involved in advocacy, modelling and promoting healthy behaviours in the community, participating in multi-sector community initiatives and counselling individuals and families about obesity prevention. This requires development of clinician skills in evidence-based assessment and counselling techniques and changes to clinical infrastructure and care models.

#### An example: Healthy weight clinics in Massachusetts

Anand et al. have reported on the development of "Healthy Weight Clinics" established within eight community health centres in Massachusetts serving predominantly poor minority patients among whom child rates of overweight or obesity range from 32% to 47% [118]. There are three key components to this care model: designated condition-specific visits that allow more time than standard primary care visits, multidisciplinary, team-based care, and specialised knowledge and training for members of the primary care team. Patients are seen in a series of one-hour visits by a three-person team consisting of a clinical champion, a dietician and a case manager. The clinical champion, or team leader, deals with the medical assessment of obesity, including reviewing laboratory results, family history and other health conditions such as sleep apnoea. The dietician reviews intake of sweetened beverages, fruit and vegetable consumption, and the ability of the patient (or patient's caregiver) to recall what the patient ate in the previous 24 hours. The case manager assesses sedentary activity, such as watching TV or playing video games, and physical activity. The team helps each family develop a self-management plan that is culturally appropriate and achievable with the available family and community resources, and behaviour modification techniques are used to set treatment goals that are agreed on by the patient, the family and the team. Children are typically seen every one to two months for a total of six visits.

The healthy weight clinic staff meet with staff at other healthy weight clinics via monthly teleconferences and two face-to-face meetings annually to solve common problems and share best practices. All clinics use a web-based quality monitoring system to report on key process and outcome measures including BMI, diet and physical activity. Preliminary results from 174 patients who had more than one clinic visit for the period June 2008–August 2009 were considered promising: 100% had a self-management plan, 79.8% had made any lifestyle change, 29.9% had reduced screen time, 45.5% had increased physical activity, 32.2% had decreased sweetened beverages, 33.3% had increased fruit and vegetables, and 50% had decreased BMI (but it was not reported by how much). Anand et al. consider that the Healthy Weight Clinics provide an example of an effective, efficient and family-centred model of secondary (referral-based) care within primary care, which is easier for patients to access and less costly than hospital-based programmes.

# The 2010 USPSTF review of primary care interventions

Whitlock et al. conducted a systematic review for the U.S. Preventive Services Taskforce on the effectiveness of primary care weight management interventions for children and adolescents [119]. The review included controlled trials in primary care-relevant settings of interventions designed to promote weight loss or weight maintenance in overweight (BMI  $84^{th}-94^{th}$  percentile) or obese (BMI  $\ge 95^{th}$  percentile) two to 18 year olds (published in English from 1985 to June 2008). Trials had to report outcomes at least six months from the beginning of treatment and have at least 10 participants in each trial arm. The USPSTF review used different terminology from the 2009 Cochrane review and used the term "behavioural interventions" in a way that corresponds to what the Cochrane review calls "lifestyle interventions" to mean multi-faceted interventions that involve encouraging patients and families to adopt healthier patterns of eating and physical activity and, optimally, also include cognitive and behavioural management techniques to help change thinking patterns about food and the body.

This review included 11 behavioural intervention trials (1099 participants in total, six trials rated good quality, and five fair quality) which measured short term outcomes (6–12 months) in overweight or obese children and adolescents (4–18 years). All except three of these were also included in the 2009 Cochrane review. The three that were not included in

the Cochrane review were one study of an internet intervention for adolescents which was not included because it was not published until August 2008, one study excluded because it was not a RCT, and one excluded because it did not have sufficiently long follow-up.

The results of all eleven trials were consistent with a beneficial effect on BMI, BMI SDS (zscore) or percentage overweight although not all effects were statistically significant. In these 11 studies differences between intervention and control groups ranged from 0.3 to 3.3. kg/m<sup>2</sup>, reflecting weight loss as well as weight gain prevention for those in the intervention groups. The largest effects BMI differences of 1.9 to 3.3 kg/m<sup>2</sup> were seen in three comprehensive weight management programmes (these included diet or weight loss counselling, physical activity counselling or programme, and behavioural management techniques to aid behavioural change), with at least medium (26 to 75 contact hours) or high (≥ 76 contact hours) intensity. Meta-analyses of the results of all eleven weight management programmes in four categories (medium-to-high, low and very low intensity comprehensive interventions and focussed interventions), confirmed the superior effects of medium to high intensity interventions compared to all the other interventions for short term weight change and compared to the other comprehensive interventions for maintenance of weight change. The authors pointed out that the largest reported difference in BMI, 3.3 kg/m<sup>2</sup> over 6–12 months, would equate to a weight difference (assuming a height on the 50<sup>th</sup> percentile for age) of about 13 pounds (5.9 kg) for an eight year old boy, 17–18 pounds (7.9 kg) for a 12-year old boy or girl, 19 pounds (8.6 kg) for a 16 year old girl and 22–23 pounds (10.2 kg) for a 16 year old boy.

Owing to the small number of trials, the diversity of intervention components and the fact that most interventions included multiple components Whitlock et.al were not able to judge what the most beneficial elements of weight management programmes were, other than to say that it seemed that interventions with more hours of participant contact were better. While programmes that included organised physical activity appeared to be better than those that encouraged participants to exercise at home, this effect was confounded with treatment intensity and so it was impossible to determine whether it was the exercise programme or the overall treatment intensity that was responsible for the greater likelihood of successful treatment. Whitlock et al. noted that all the medium-to-high intensity interventions reviewed had been conducted in specialty healthcare settings and that the lower intensity (or focussed) interventions that might be feasible in primary care had more modest and less consistent effects on reducing BMI.

The best of the interventions conducted in a primary care setting, involving 44 adolescents aged 12-16 years, assessed a "Healthy Habits" intervention [50]. Participants used a computer programme which assessed participants' responses questions on eating, physical activity and sedentary behaviour and used this information to produce a personalised plan for improving habits in these areas. They were also given a nonpersonalised manual on behavioural skills for weight control. A paediatrician discussed the computer-generated plan with each participant and then telephone counsellors contacted the participants weekly for eight weeks and then biweekly for three more calls to help them implement their plan. The telephone counsellors used detailed scripts to ensure their calls covered all the key elements of the plan. At the beginning of the intervention, participants had an average BMI of 31.0 kg/m<sup>2</sup>, well above the 95<sup>th</sup> percentile. At the end of the fourmonth treatment phase, the average BMI had fallen to 30.7 kg/m<sup>2</sup> and three months after that it was 31.1 kg/m<sup>2</sup>. In comparison, the control group's average BMIs were 30.7 kg/m<sup>2</sup> at baseline, 31.8 kg/m<sup>2</sup> at four months and 32.1 kg/m<sup>2</sup> at follow-up. The difference between the two groups' baseline to follow up changes in BMI was not statistically significant (but the sample size was quite small, 44 participants in total). Whitlock et al. stated that for a 14 year old girl of height 5'4" (163 cm) who grew 1" (2.54 cm) over the study period and who had a BMI equal to the average for the study participants, these BMI differences would mean that over the seven months she would have gained seven pounds (3.2 kg, from 81.6 to 84.8 kg) if she had been in the intervention group and 14 pounds (6.4 kg, from 81.2 to 87.5 kg) if she had been in the control group. Whitlock et al. stated that further research on less intensive interventions suitable for use in primary care was greatly needed.

# Recent RCTs addressing childhood obesity in primary care

There have been a number of RCTs of obesity interventions for children or adolescents in primary care. The text box below reviews a number of recent RCTs of primary care interventions in pre-adolescent children, which were published after the 2008 cut-off for inclusion in the USPSTF review.

Examples of primary care interventions to treat obesity in pre-adolescent children:

#### The "High Five For Kids" study

The "High Five For Kids" study, is a cluster RCT involving 10 paediatric primary care offices of a multi-site group practice in Massachusetts [120]. In the trial, 475 children aged 2–6.9 years with either a BMI  $\geq$  the 95<sup>th</sup> percentile, or a BMI  $\geq$  85<sup>th</sup> and < 95<sup>th</sup> percentile and at least one overweight (BMI  $\geq$  25) parent, were randomised to ether usual care or an intervention carried out by paediatric nurse practitioners trained in motivational interviewing. This consisted of four 25-minute in person chronic-disease visits and three 15-minute telephone calls in the first year. The behavioural goals were less than one hour per day television/video viewing, no television in rooms where children sleep, one serving or less per week of fast food, and one serving or less per day of sugar-sweetened beverages.

After one year, the difference in mean BMI between the usual care group and the intervention group was not significant (-0.21; 95% confidence interval -0.50 to 0.07; p=0.15). Differences in consumption of fast-food and sweetened beverages were also non-significant but there was a significant difference in television viewing (-0.36 hours/day; 95% CI, -0.64 to -0.09; p=0.01). The authors noted that their observed BMI differences were of similar magnitude to those seen in the LEAP trial (see below) and they offered four possible reasons for the lack of a significant effect on BMI: it involved only the primary care setting and not the children's environments; adherence to the intervention was relatively low with only a little over half of participants completing at least two of the six visits/telephone calls; the motivational interviewing technique used allowed parents to choose to work on behaviours that could have had a lesser effect on BMI, such as increasing fruit and vegetable intake; and it is possible that BMI changes might lag behind behavioural changes.

Taveras et.al reported on the correlates of participating (475 parents) and refusing to participate (329 parents) in the above trial [121]. Parents were less likely to participate if they had a college degree and if their child was overweight rather than obese. Among the refusers with an obese child, 21% said they wouldn't participate as their child did not have a weight problem as did 30% of the refusers with an overweight child. Other reasons for not participating included: "study will take up too much time" (60%), "things (being) too difficult in the family right now—illness, divorce, new baby etc." (9%), and "clinical site too far away" (5%). Taveras et al. suggested that to prevent and manage obesity in pre-school children it is necessary to raise parental awareness of their child's weight status and the potential health risks associated with obesity, and also to address parental concerns about the time commitment required to participate in an obesity intervention.

#### **Buffalo Healthy Tots**

Quattrin et al. reported on a RCT designed to test the efficacy of a family-based primary care behavioural intervention for weight control, known as Buffalo Healthy Tots [122]. In this study, 105 children aged 2–5 years with a BMI  $\ge 85^{\text{th}}$  percentile and an overweight parent were recruited at a well- or sick-child visit to one of four suburban practices and randomised to receive either the intervention or an information-only control.

Both the intervention and control groups were offered ten 60-minute group meetings over six months and eight phone calls between meetings from an assigned "coach". The meetings for both groups involved a group leader delivering education on diet and physical and sedentary activities to the parents and trained staff engaging the children in active ball games. In addition, at the intervention group meetings, the group leader stressed behavioural and parenting strategies to promote parent and child behaviour change, such as selective ignoring, time out, praising, rewarding and contracting, and strategies aimed at changing parent behaviour in areas that would facilitate child and parent change, such as pre-planning, stimulus control, shaping, modelling, self-monitoring, changing the home environment, social support and changing black and white thinking. Either before or after the group meeting, each parent in the intervention group also had a one-to-

one meeting with an assigned coach, who helped the parent with shaping behavioural goals after reviewing the parent's and child's (parent-kept) food, activity and weight diaries.

Ninety six of the 105 randomised families started the programme and there were no baseline differences between the intervention (46 children) and control groups (50 children). The authors

expressed the changes in children's weights in units of %0BMI, defined as ((actual BMI –  $50^{\text{th}}$  percentile BMI)/  $50^{\text{th}}$  percentile BMI)\*100. Adjusted mean (±SD) estimates for child %0BMI at baseline, three and six months were  $30.6 \pm 9.7$ ,  $26.0 \pm 9.9$ , and  $24.2 \pm 10.1$  for the intervention group and  $30.5 \pm 9.3$ ,  $28.7 \pm 9.4$ , and  $28.3 \pm 9.5$  for the control group. The difference in %0BMI between the groups was statistically significant at three and six months. In both intervention and control groups, the children with a higher baseline %0BMI were more likely to have greater weight loss over time. There was a significant correlation between child %0BMI and parent BMI changes at six months.

This study demonstrates the benefits of concurrently targeting toddlers and parents for weight control and provides a model of an intervention that can be implemented in primary care setting. The authors stated it is not always easy to convince parents that their child needs weight management, but if the focus is shifted to the whole family then parents can model health lifestyle behaviours for their children.

# Healthy Living Today!

Arauz Boudreau et al. reported on a pilot RCT of a family-centred primary care-based intervention for overweight or obese Latino children in a predominantly low-income community in the U.S. [123]. The trial involved 41 children aged 9–12 years with a BMI > the 85<sup>th</sup> percentile who were randomised to an intervention group (23 children) or a wait-list control group (18 children). The intervention consisted of six interactive group classes focussed on nutrition, physical activity and stress management, followed by monthly culturally-sensitive health coaching in-person or by telephone for six months. The coaching was aimed at empowering families to incorporate learned lifestyle changes and address the family and social barriers to making changes. The 1.5 hour classes were conducted in five consecutive weekly sessions at the health centre, with a sixth session three months later. Fourteen of the intervention group (61%), and 12 of the control group (67%) attended the first the second visit and so provided (some) pre- and post-intervention data.

Health-related quality of life, as measured by both child self-report and parent proxy using PedsQL<sup>TM</sup>, improved in both groups but there was greater, though not significantly greater, improvement in the intervention children. Post-intervention, there were no differences between the intervention and control children for BMI, physical activity (as measured by accelerometers worn around the hip) or metabolic markers of obesity.

The authors noted that many caregivers cited factors outside their control as barriers to adopting healthy lifestyles such as the inability to find physical activities suitable for the whole family, inability to control what their child ate, children's emerging independence, and social stressors such as family conflict, time pressures and financial stress. They also noted that all participants had low quality of life scores suggesting that obesity has a substantial effect on children's quality of life although, given that the study was conducted in a low-income community, the effects of financial stress, racism and bias could not be discounted. They cited two possible reasons for the lack of statistically significant results: the small sample size and the possibility that families may require a more intensive intervention that includes scheduled coaching and/or changes to the environment.

# Helping HAND

O'Connor et al. reported on a pilot RCT of Helping HAND (Healthy Activity and Nutrition Directions), an obesity intervention targeting five to eight year old ethnic minority children in primary care clinics in Houston, Texas [124]. The six-month intervention was delivered by trained allied health staff in the child's community paediatric clinic. The 25 hours training for the five Health Advisors (HAs), three of whom were fluent in Spanish, covered the obesity intervention strategies recommended in the report of an Expert Committee of representatives from 15 national health care organisations [125], national recommendations for age-appropriate diet, physical activity and television viewing, authoritative parenting and effective behaviour-specific parenting strategies, patient-centred communication, and how to implement the helping HAND programme and worksheets. Each family was assigned an HA who met with the family once a month and encouraged them to self-select one behaviour to target from a menu of healthy behaviours which included: 'Watch less TV', 'Be more active', 'Eat more fruit', 'Eat more vegetables', 'Eat healthy snacks', 'Drink less sweet drinks', and 'Drink more water'. Worksheets for children and parents were used to help with goal setting, making plans to reach the goal by the end of the month and making goal-specific behaviour changes. Parents and children signed the worksheets so they functioned as a behaviour change contract. Two weeks after the meeting the HA phone the family to assess progress and help solve any

problems. At the next meeting families could chose to either continue working on the same goal for one more month or select a new behaviour to target.

The study randomised 40 families (parent-child dyads) to either the intervention or a waitlist control group. Eighty-two per cent of the families were Hispanic, 80% had girl, and 65% reported an income

of US\$30,000 or less. Eighty per cent of families attended four of more of the six sessions (a 20% attrition rate). During the six month study period, families selected an average of 4.75 (SD 1.75) behaviours to target and each of the seven target behaviours was chosen by between 45% and 80% of families. At the end of the intervention there were no differences between the intervention and the control group for child's BMI z-score, dietary intake or physical activity but the intervention group watched less television (14.9 (SE 2.3) vs. 23.3 (SE 2.4) hours/week, p< 0.05).

The authors concluded that Helping HAND was a feasible intervention for evaluation with a fullypowered RCT since it had a low attrition rate, appropriate content, overall participant satisfaction and was associated with improvements in some clinically relevant child and parenting behaviours.

#### A lifestyle intervention for Mexican youth

Diaz et.al conducted a 12-month RCT of lifestyle intervention in a primary care setting for obese Mexican youth [126]. The trial randomised 76 young people, aged 9–17 years with either a BMI >95<sup>th</sup> percentile or both BMI and waist circumference > 90<sup>th</sup> percentile, to either an intervention or a control group. Participants in the control group (n=22, mean age 11.7 years) attended 10–15 minute monthly consultations with a primary care physician who had received brief training on obesity.

Participants in the intervention group (n=21, mean age 11.6 years) attended a family-centred programme consisting of 12 consecutive weekly two-hour group sessions at the clinic, led by a registered dietician (RD). They also had weekly consultations with the RD for the first 12 weeks and then monthly thereafter and monthly 10–15 minute consultations with a primary care physician. The curriculum for the group sessions had a behaviour modification focus. Initially the programme focussed mainly on children's perceptions of susceptibility, severity, benefits, and barriers. The second part of the programme covered dealing with emotions, self-esteem, communication skills, information about body weight regulation, energy intake, nutrition, and physical activity, and the use of behaviour modification techniques. During the group sessions participants were encouraged to set their own goals for diet, physical activity and sedentary activity and these goals were revised and renewed at every session. There were six education sessions for parents, who were encouraged to lose weight if they were overweight.

Forty-three participants (57%) completed 12 months in the study. At 12 months, for those completing the study, mean changes in body weight were -0.8 kg (95% CI -3.2 to 1.5) in the intervention group and +5.6 kg (95% CI 3 to 8.2; p<0.001) in the control group. An intention-to -treat analysis confirmed significant differences in weight and BMI in favour of the intervention group: weight -3.5 kg, p<0.02; BMI  $-1.2 \text{ kg/m}^2$ , p< 0.03.

The authors stated that theirs was the first long term study to show significant effects on obesity parameters in a primary care setting, although compared to other studies, it had a relatively high attrition rate (43%). They also stated that it is possible that only high-intensity interventions, such as their study, can produce changes in obesity parameters in our obesogenic environment and that cost-effectiveness analyses are needed to assess the utility of such interventions in primary care.

# Live, Eat and Play (LEAP)

Two RCTs of a primary care intervention for overweight or mildly obese children have been conducted in Melbourne. The intervention was nested within a baseline cross-sectional BMI survey and known as Live, Eat and Play (LEAP). In the first trial, 163 overweight or mildly obese children (BMI z-score <3) aged 5–9 years were randomised to either an intervention or control group [127]. Families in the control group were notified of their child's weight status by letter. The intervention group received four standard GP consultations over 12 weeks, targeting changes in nutrition, physical activity and sedentary behaviour, plus a personalised "Family Folder" which include seven topic sheets, each relating to a single area of behavioural change necessary for weight control, and containing a brief summary of supporting evidence, modelled solutions to challenges, and additional suggestions for ways to attain the topic goal.

The GPs delivering the intervention attended three evening group educational sessions. The core component of these sessions was training in brief solution-focussed therapy techniques and the sessions also included didactic and reflective teaching on childhood obesity. Prior to the child's first GP appointment, the LEAP team provided the GP with the child's personalised folder, BMI, and a two-page summary of parent responses to the baseline questionnaire relating to current nutrition, physical activity patterns and concern about their child's weight status. During the four intervention consultations, GPs did not weigh or measure the child since the intervention was focussed on

behavioural change rather than weight change. GPs recorded discussion content, contracts made and visit dates on a LEAP form in the child's medical record.

Outcomes were measured at nine and 15 months. Attrition was 10%. The adjusted mean difference

(intervention–control) in BMI was not significant at either follow-up time:  $-0.2 \text{ kg/m}^2$  (95% CI -0.6 to 0.1; p=0.25) at 9 months and  $-0.0 \text{ kg/m}^2$  (95% CI -0.5 to 0.5; p=1.00) at 15 months. There was a significant improvement in nutrition scores at both nine and 15 months, due to a reduction in consumption of high-fat milk and an increase in low-fat milk and water consumption. There was weak evidence of an improvement in physical activity. The authors concluded that this intervention did not result in sustained reductions in BMI, despite the parent-reported improved nutrition. They suggested two possible reasons: that brief individual solution-focussed approaches may not be an effective method of dealing with child overweight or that the intervention might not have been

intensive enough and the GP's training insufficient. They stated that, based on this trial, they could not recommend that GPs adopt brief solution-focused behavioural strategies to deal with their overweight child patients.

The second LEAP trial, had the same enrolment criteria and intervention design as the first and randomised 258 children, 139 to either the intervention (139 children) or a control (119 children) group [128]. Outcomes were measured at six months and 12 months and attrition was 3.1% at six months and 6.2% at 12 months. The primary outcome was BMI and secondary outcomes were mean activity count/min by 7-day accelerometry, nutrition score from 4-day abbreviated food frequency diary, and child health related quality of life. Differences were adjusted for socioeconomic status, age, sex, and baseline BMI. Adjusted mean differences (intervention – control) at 6 and 12 months were, for BMI, -0.12 (95% CI -0.40 to 0.15, p=0.4) and -0.11 (-0.45 to 0.22, p=0.5); for physical activity in counts/min, 24 (-4 to 52, p=0.09) and 11 (-26 to 49, p=0.6); and, for nutrition score, 0.2 (-0.03 to 0.4, p=0.1) and 0.1 (-0.1 to 0.4, p=0.2). None of these differences were statistically significant. There was no evidence of harm to the children.

The authors concluded that, "primary care screening followed by brief counselling did not improve BMI, physical activity, or nutrition in overweight or mildly obese 5–10 year olds, and it would be very costly if universally implemented". They noted that only a third of families with an eligible child chose to take up the intervention. This suggests that the majority of families are not concerned about their child's weight status or have other priorities. The authors stated that health system resources for obesity interventions might be better spent divided between primary prevention at the population and community levels and improvement of treatment options for children with established obesity.

There were significant costs associated with the LEAP intervention for both the families and the health system [129]. A cost-consequence analysis indicated that the costs to the health system were AU\$ 873 per intervention family and AU\$ 64 per control family, a difference of AU\$ 809 (p< 0.001). These costs excluded the initial development cost of the LEAP intervention.

# Key points from the reviews and recent RCTs of primary care interventions:

Overall, the reviews and individual RCTS of primary care obesity interventions suggested that:

- There is no evidence that brief interventions in primary care are effective
- The few effective interventions that have been carried out in primary care settings have largely replicated the care model of a specialist obesity clinic and offered both a series of group sessions for parents and children (usually separately) and multiple individual consultations over an extended period, either in person or by phone

# Conclusions

There is considerable evidence indicating that childhood obesity has its origins very early in life, even before birth. It therefore seems that childhood obesity is best tackled early but there are a number of difficulties. Parents need to recognise that their overweight or obese pre-schooler has a problem about which something needs to be done. Evidence suggests that parents are not very good at recognising that their young child has a weight problem. Even if they recognise the problem, or it is pointed out to them by a health professional, they may feel that their child will grow out of it, that denying their child treats that everyone else gets is just too hard, or that there are other more pressing problems in their life. There is very little evidence regarding effective obesity interventions for pre-schoolers although two recently published trials of relatively high intensity interventions have shown promising results [77,122].

Given the high proportion of children who are currently overweight or obese there is no way that all of them can be treated by specialist paediatric services. There is a clear need for effective low-cost interventions that can be delivered in primary care. Unfortunately,

there is little current evidence that such interventions exist. Most of the research has been conducted in specialist clinics. The interventions that are effective tend to be resource intensive, involving at least 25 contact hours, and, although they may result in significant reductions in excess weight (i.e. significant reductions in BMI percentile or z-score), they do not usually make an obese child into a child of normal weight. Effective interventions include attention to diet and physical activity and also behavioural components aimed at changing thinking patterns regarding diet and physical activity, goal setting, and improving self-esteem. There is currently insufficient evidence to indicate which particular dietary, physical activity or behavioural interventions are the best. Effective interventions also usually involve addressing parents' overweight or obesity, since the likelihood of a child successfully losing excess weight is improved if the whole family adopts a healthier lifestyle.

The few small studies that have demonstrated good results in primary care settings have used a similar treatment model to those used in specialist clinics and offered both a series of group sessions for parents and children (usually separately) and multiple individual consultations over an extended period, either in person or by phone.

It seems likely that the health system cannot afford high intensity interventions for any but the most severely obese children. Most obesity experts believe that dealing with the obesity epidemic requires a whole of society approach to prevention. Cultural change is required to make healthy lifestyles the norm, but there are powerful commercial interests behind the provision of cheap but unhealthy food. It is unrealistic to expect that the health system can solve the problem of childhood obesity on its own.

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