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## Surgery for the treatment of obesity in children and adolescents (Review)

Ells, Louisa J.; Mead, Emma; Atkinson, Greg; Corpeleijn, Eva; Roberts, Katharine; Viner, Russell; Baur, Louise; Metzendorf, Maria-Inti; Richter, Bernd

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[Intervention Review]

# Surgery for the treatment of obesity in children and adolescents

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## ABSTRACT

### Background

Child and adolescent overweight and obesity have increased globally, and are associated with significant short and long term health consequences.

### Objectives

To assess the effects of surgical interventions for treating obesity in childhood and adolescence.

### Search methods

We searched the Cochrane Library, MEDLINE, PubMed, EMBASE as well as LILACS, ICTRP Search Portal and ClinicalTrials.gov (all from database inception to March 2015). References of identified studies and systematic reviews were checked. No language restrictions were applied.

### Selection criteria

We selected randomised controlled trials (RCTs) of surgical interventions for treating obesity in children and adolescents (age < 18 years) with a minimum of six months follow-up. Interventions that specifically dealt with the treatment of eating disorders or type 2 diabetes, or included participants with a secondary or syndromic cause of obesity were excluded. Pregnant females were also excluded.

### Data collection and analysis

Two review authors independently assessed risk of bias and extracted data. Where necessary authors were contacted for additional information.

## Main results

We included one RCT (a total of 50 participants, 25 in both the intervention and comparator group). The intervention focused on laparoscopic adjustable gastric banding surgery, which was compared to a control group receiving a multi component lifestyle programme. The participating population consisted of Australian adolescents (a higher proportion of girls than boys) aged 14 to 18 years, with a mean age of 16.5 and 16.6 years in the gastric banding and lifestyle group, respectively which was conducted in a private hospital, receiving funding from the gastric banding manufacturer. The study authors were unable to blind participants, personnel and outcome assessors which may have resulted in a high risk of performance and detection bias. Attrition bias was noted as well. The study authors reported a mean reduction in weight of 34.6 kg (95% confidence interval (CI) 30.2 to 39.0) at two years, representing a change in body mass index (BMI) of 12.7 (95% CI 11.3 to 14.2) for the surgery intervention; and a mean reduction in weight of 3.0 kg (95% CI 2.1 to 3.9) representing a change in BMI of 1.3 (95% CI 0.4 to 2.2) for the lifestyle intervention. The differences between groups were statistically significant for all weight measures at 24 months ( $P < 0.001$ ). The overall quality of the evidence according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) was low. Adverse events were reported in 12/25 (48%) participants in the intervention group compared to 11/25 (44%) in the control group (low quality evidence). A total of 28% of the adolescents undergoing gastric banding required revisional surgery. No data were reported for all-cause mortality, behaviour change, participants views of the intervention and socioeconomic effects. At two years, the gastric banding group performed better than the lifestyle group in two of eight health-related quality of life concepts (very low quality evidence) as measured by the Child Health Questionnaire (physical functioning score (94 versus 78, community norm 95) and change in health score (4.4 versus 3.6, community norm 3.5)).

## Authors' conclusions

Laparoscopic gastric banding led to greater body weight loss compared to a multi component lifestyle program in one small study with 50 patients. These results do not provide enough data to assess efficacy across populations from different countries, socioeconomic and ethnic backgrounds, who may respond differently. This systematic review highlights the lack of RCTs in this field. Future studies should assess the impact of the surgical procedure and post operative care to minimise adverse events, including the need for post operative adjustments and revisional surgery. Long-term follow-up is also critical to comprehensively assess the impact of surgery as participants enter adulthood.

## PLAIN LANGUAGE SUMMARY

### Surgery for the treatment of obesity in children and adolescents

#### Review question

How effective is bariatric surgery in safely reducing weight in obese children and adolescents?

#### Background

Across the world more children and adolescents are becoming overweight and obese. As overweight and obese children are more likely to suffer from health problems, more information is needed about how best to treat this problem.

#### Study characteristics

We found one randomised controlled trial with a total of 50 participants (25 in both the intervention and comparator group) and a follow-up of two years. The surgery used was 'laparoscopic adjustable gastric banding' (gastric band placed around the entrance of the stomach by means of keyhole surgery). The control group received a program consisting of reduced energy intake (individualised diet plans ranging between 800 and 2000 kcal per day, depending on age and weight), increased activity (target of 10,000 steps per day) with a structured exercise schedule of at least 30 minutes a day and behavioural modification.

#### Key results

Australian adolescents (higher proportion of girls than boys) with an average age of 16.5 and 16.6 years in the gastric banding and 'lifestyle' group participated. The study authors reported an average reduction in weight of 34.6 kg at two years, representing a change in body mass index units ( $\text{kg}/\text{m}^2$ ) of 12.7 for the gastric banding group; and an average reduction in weight of 3.0 kg representing a change in body mass index units of 1.3 for the lifestyle intervention. Side effects were reported in 12 of 25 (48%) participants in the intervention group and in 11 of 25 (44%) in the control group. A total of 28% of the adolescents undergoing gastric banding

required a 'revisional procedure' (surgery because of complications from the gastric banding surgery). No data were reported for all-cause mortality, behaviour change, participants views of the intervention and socioeconomic effects. At two years, the gastric banding participants performed better than the lifestyle participants in two of eight health-related quality of life concepts as measured by the Child Health Questionnaire (physical functioning score (94 versus 78, community norm 95) and change in health score (4.4 versus 3.6, community norm 3.5).

#### **Quality of the evidence**

Our results are limited to two years of follow-up and are based on just one small Australian study with some risk of bias which was conducted in a private hospital, receiving funding from the gastric banding manufacturer. There is currently insufficient evidence to make an informed judgement about surgery for the treatment of obesity in children and adolescents.

#### **Currentness of evidence**

This evidence is up to date as of March 2015.

## SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Surgery compared with a multi component lifestyle programme for obese children and adolescents						
<b>Population:</b> children and adolescents with obesity <b>Settings:</b> community, clinic <b>Intervention:</b> laparoscopic adjustable gastric banding surgery <b>Comparison:</b> multi component lifestyle programme						
Outcomes	Laparoscopic adjustable gastric banding surgery	Multi component lifestyle programme	No of participants (studies)	Quality of the evidence (GRADE)	Comments	
<b>a) BMI</b> [kg/m <sup>2</sup> ] <b>b) Weight loss</b> [kg] Follow-up: two years	a) -12.7 (-11.3 to -14.2) b) -34.6 (-30.2 to -39.0)	a) -1.3 (-0.4 to -2.9) b) -3.0 (-2.1 to -8.1)	50 (1)	⊕⊕○○ <b>low<sup>a</sup></b>	-	
<b>Adverse events</b> [revisional procedure] Follow-up: two years	7/25 (28%) participants	0/25 (0%)	50 (1)	⊕⊕○○ <b>low<sup>b</sup></b>	-	
<b>Health-related quality of life</b> [CHQ (8 subscores); scale 0 to 100, where 0 indicates the worst possible health state and 100 the best possible health state] <sup>c</sup> a) physical functioning (community norm 95) b) change in health (community norm 3.5) Follow-up: two years	a) 94 b) 4.4	a) 78 b) 3.6	50 (1)	⊕○○○ <b>very low<sup>d</sup></b>	-	
<b>All-cause mortality</b>	See comments	See comments	See comments	See comments	Not reported	
<b>Morbidity</b> [metabolic syndrome] <sup>e</sup> Follow-up: two years	0/24 (0%) participants completing the study	4/18 (22%) participants completing the study	50 (1)	⊕○○○ <b>very low<sup>f</sup></b>	-	

<b>Socioeconomic effects</b>	See comments	See comments	See comments	See comments	Not reported
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\*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).  
**BMI**: body mass index; **CHQ**: child health questionnaire; **CI**: confidence interval; **RR**: risk ratio

GRADE Working Group grades of evidence

**High quality**: Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality**: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality**: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality**: We are very uncertain about the estimate.

<sup>a</sup>Downgraded by two levels because of one study only with small number of participants, and unclear risk of performance and detection bias

<sup>b</sup>Downgraded by two levels because of one study only with small number of participants

<sup>c</sup>Poor health-related quality of life is defined as two standard deviations below the mean of the normative sample or a physical functioning or psychosocial health summary score less than 30

<sup>d</sup>Downgraded by three levels because of one study only with small number of participants, and high risk of performance, detection and attrition bias

<sup>e</sup>The metabolic syndrome is a weak surrogate endpoint for illness or harm associated with the intervention or the condition

<sup>f</sup>Downgraded by three levels because of one study only with small number of participants, indirectness, and high risk of performance, detection and attrition bias



## BACKGROUND

The prevalence of overweight and obese children and adolescents has increased throughout the world, presenting a global public health crisis (Ng 2014; WHO 2015a). Although once considered to be a condition affecting only developed countries, rates of paediatric overweight and obesity have recently started to rise dramatically in some developing countries (Wang 2012). Using the International Obesity Task Force (IOTF) standard definition the age standardised prevalence of overweight and obesity in children and adolescents has increased in both developed and developing countries over the last thirty years (Cole 2000). In 2013 the prevalence of overweight and obese children and adolescents in developed countries was estimated at 23.8% (95% confidence interval (CI) 22.9 to 24.7) for boys and 22.6% (95% CI 21.7 to 23.6) for girls. In developing countries the prevalence was estimated as 12.9% (95% CI 12.3 to 13.5) of boys and 13.4% (95% CI 13 to 13.9) of girls (Ng 2014). Very young children are also affected. In 2010 De Onis 2010 used the WHO growth standards (WHO 2015b) to estimate that over 42 million children under five years were overweight or obese, with approximately 35 million of these children living in developing countries.

Inequalities in overweight and obesity prevalence have also been documented. Generally, socioeconomically disadvantaged children in developed countries (Knai 2012; Shrewsbury 2008), and children of higher socioeconomic status in developing countries (Lobstein 2004; Wang 2012), are at greater risk of becoming overweight. However, this relationship may vary by population demographics (e.g. age, gender, ethnicity), and environment (e.g. country, urbanisation) (Wang 2012). The prevalence of obesity has been shown to vary by ethnicity, with large data sets showing substantial ethnic variation in English (HSCIC 2015), American (Freedman 2006; Skinner 2014), and New Zealand (Rajput 2014) child populations.

Whilst there is some evidence that the rate of increase in paediatric obesity may be slowing in some developed countries, current levels remain too high, and continue to rise in many developing countries (Olds 2011; Rokholm 2010). However, an additional concern in some developed countries such as the USA (Kelly 2013; Skinner 2014), and England (CMO 2015; Ells 2015), is the rise in severe paediatric obesity. Whilst the IOTF published an international definition for severe paediatric (morbid) obesity in 2012 (Cole 2012), often severe obesity prevalence is reported using country specific cut points making international comparisons difficult. However, data from the USA (Skinner 2014) and England (Ells 2015) has shown that the prevalence of severe paediatric obesity varies by socioeconomic status and ethnicity, and may result in a greater risk of adverse cardio-metabolic events and severe obesity in adulthood (Kelly 2013).

## Description of the condition

Childhood overweight and obesity results from an accumulation of excess body fat, and can increase the risk of both short and longer term health consequences. Numerous obesity related comorbidities can develop during childhood, which include muscular skeletal complaints (Paulis 2014); cardiovascular risk factors such as hypertension, insulin resistance and hyperlipidaemia (Reilly 2003), even in very young children (Bocca 2013); and conditions such as sleep apnoea (Narang 2012), asthma (Egan 2013), liver disease, and type 2 diabetes (Daniels 2009; Lobstein 2004). The condition can also affect psychosocial well being, with obese young people susceptible to reduced self esteem and quality of life (Griffiths 2010), and stigmatisation (Puhl 2007; Tang-Peronard 2008). Evidence also shows that childhood obesity can track into adulthood (Parsons 1999; Singh 2008; Whitaker 1997), and is therefore associated with an increased risk of ill health in later in life (Reilly 2011).

## Description of the intervention

Given the serious implications associated with childhood and adolescent obesity, effective treatment is imperative. Whilst the fundamental principles of weight management in children and adolescents are the same as adults (i.e. reduced energy intake and increased energy expenditure), the primary aim of treatment (i.e. weight reduction or deceleration of weight gain) and the most suitable intervention approach varies, and is dependent on the child's age and degree of excess weight, among other considerations. Bariatric surgery is an established treatment for severely obese adults (Colquitt 2014), however the role of surgery in severely obese children and adolescents is less clear. In some severely obese adolescents both adolescents and clinicians may consider surgery to be a pragmatic last solution to reduce body mass index (BMI) and associated comorbidities, and improve health-related quality of life.

### Adverse effects of the intervention

Bariatric surgery is a major surgical intervention, with risk of serious operative and perioperative complications and mortality. Depending on the type of surgery, adverse effects can include nutrient deficiencies, hernia, cholelithiasis, wound infections, pouch dilation, ulcers, port leakage and slippage (Black 2013). The restrictive or malabsorptive nature of some forms of bariatric surgery is an additional consideration in growing children, with guidelines largely agreeing that eligible candidates must be severely obese adolescents that have reached or nearly reached physical maturity (Baur 2011; Brei 2013). Additional considerations in adolescents include developmental issues around ability to consent and the need for family support. This is particularly important given severe obesity can be a comorbidity in some children with learning disabilities, with potentially limited ability to both consent and adhere to dietary regimes required for safe surgery. Contraindica-

tions to surgery include capacity to consent, pregnancy or breast feeding, medically correctable causes of obesity, substance abuse and a disability that may prevent adherence to post operative management (Hsia 2012).

## How the intervention might work

Bariatric surgery aims to work by restricting intake, and by reducing the absorption of food. A number of different surgical procedures exist. The most common procedures include: Roux-en-Y gastric bypass which is a procedure combining restriction and malabsorption, adjustable banding and sleeve gastrectomy which are restrictive procedures, and biliopancreatic diversion which is a mostly malabsorptive procedure (Colquitt 2014; Hsia 2012). The most commonly performed procedures in adolescents are: the laparoscopic Roux-en-Y gastric bypass, which involves the surgical alteration of the gastrointestinal anatomy to create a small stomach pouch, which is joined directly to the middle section of small intestine, thus restricting food intake and reducing food absorption by passing the upper section of the small intestine, and the laparoscopic adjustable gastric band, which is the least invasive restrictive procedure involving the placement of an adjustable band around the upper section of stomach, to create a small gastric pouch that restricts food intake (Aikenhead 2011). There is also an increasing number of laparoscopic sleeve gastrectomies (the surgical reduction of stomach size) being performed. However, bypass is recognised the 'gold standard' procedure with relatively low quality observational data suggesting it is associated with greater weight loss than the gastric sleeve or band (Black 2013).

## Why it is important to do this review

The first version of this systematic review was published in 2003 (Summerbell 2003), and included analysis of childhood obesity treatment studies published up until July 2001. The second version was published in 2009 providing an update to the 2003 review (Oude Luttikhuis 2009).

To reflect the rapid growth in this field, the third update to this review has been split across six reviews focusing on the following treatment approaches: surgery; drugs; parent only interventions; diet, physical activity and behavioural interventions for young children aged 0 to 4 years; school children aged 5 to 11 years; and adolescents aged 12 to 17 years. This is the first review in this series which focuses on the efficacy of surgical interventions for obese children and adolescents. The review complements the Cochrane review on surgery for obesity (Colquitt 2014), and a Health Technology Assessment review (Picot 2009), which do not provide randomised controlled trial (RCT) data on bariatric surgery for children and adolescents. It is also important to note that future updates of the Colquitt 2014 review will exclude studies involving children and adolescents. The results of this current review and

other systematic reviews in this series will provide information to inform clinical guidelines and health policy for the treatment of childhood obesity.

## OBJECTIVES

To assess the effects of surgery for treating obesity in children and adolescents.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

We included randomised controlled trials (RCTs).

#### Types of participants

We included study groups consisting of obese participants, with a mean age of less than 18 years at the commencement of the intervention. Pregnant females and the critically ill were excluded, as were children with obesity due to a secondary or syndromic cause (e.g. Prader-Willi syndrome).

#### Types of interventions

We investigated the following comparisons of intervention versus control or comparator where the same letters indicate direct comparisons.

##### Intervention

- (a) Surgery.
- (b) Surgery + other therapy.

##### Comparator

- Placebo compared with (a).
- Usual care (non surgical treatment) compared with (a).
- Placebo + other therapy compared with (b).
- Usual care (non surgical treatment) + other therapy compared with (b).

Concomitant therapies were the same in the intervention and comparator groups.

#### Types of outcome measures

##### Primary outcomes

- BMI and weight loss.
- Adverse events.

## Secondary outcomes

- Health-related quality of life and self esteem.
- All-cause mortality.
- Morbidity (changes in disease status).
- Measures of body fat distribution.
- Behaviour change.
- Participants views of the intervention.
- Socioeconomic effects.

## Method and timing of outcome measurement

- BMI: defined as weight (kg) divided by height (m) squared and weight loss defined as loss in weight in kg from baseline, measured at baseline, 6, 12 and 24 months.
- Adverse events: defined as an adverse outcome that occurs during or after the intervention but is not necessarily caused by it, and measured at baseline, 6, 12 and 24 months.
- Health-related quality of life and self esteem: evaluated by a validated instrument such as Paediatric Quality of Life Inventory and measured at baseline, 6, 12 and 24 months.
- All-cause mortality: defined as any death that occurred during or after the intervention and measured at baseline, 6, 12 and 24 months.
- Morbidity: defined as illness or harm associated with the intervention or the condition and measured at baseline, 6, 12 and 24 months.
- Measures of body fat distribution: defined by the use of validated tools such as DXA, waist circumference, skin fold thickness, waist to hip ratio, dual x-ray absorptiometry or bioelectrical impedance analysis and measured at baseline, 6, 12 and 24 months.
- Behaviour change: defined as validated measures of diet or physical activity (Bryant 2014), and measured at baseline, 6, 12 and 24 months.
- Participants views of the intervention: defined as documented accounts from participant feedback and measured at baseline, 6, 12 and 24 months.
- Socioeconomic effects: defined as a validated measure of socioeconomic status such as parental income or educational status and measured at baseline, 6, 12 and 24 months.

## 'Summary of findings' table

We present a 'Summary of findings table' reporting the following outcomes listed according to priority.

1. BMI and weight loss.
2. Adverse events.
3. Health-related quality of life.
4. All-cause mortality.
5. Morbidity.
6. Socioeconomic effects.

## Search methods for identification of studies

### Electronic searches

We searched the following sources on the 30th of March 2015 from inception to the specified database date and placed no restrictions on the language of publication.

- Cochrane Library:
  - Cochrane Database of Systematic Reviews (until issue 3, 2015).
  - Database of Reviews of Effects (until issue 1, 2015).
  - Cochrane Central Register of Controlled Trials (until issue 2, 2015).
  - Health Technology Assessment Database (until issue 1, 2015).
- MEDLINE (until 30th March 2015).
- EMBASE (until week 13, 2015).
- PubMed (only subsets not available on Ovid) (until 30th March 2015).
- LILACS (until 25th February 2015).
- [ClinicalTrials.gov](http://ClinicalTrials.gov) (until 30th March 2015).
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) - <http://apps.who.int/trialsearch/>, a meta-register of studies with links to several trial registers, including:
  - Australian New Zealand Clinical Trials Registry (23th March 2015).
  - Chinese Clinical Trial Registry (23th March 2015).
  - ClinicalTrials.gov (23th March 2015).
  - EU Clinical Trials Register (EU-CTR) (23th March 2015).
  - ISRCTN (23th March 2015).
  - The Netherlands National Trial Register (23th March 2015).
  - Brazilian Clinical Trials Registry (ReBec) (16th March 2015).
  - Clinical Trials Registry - India (2nd March 2015).
  - Clinical Research Information Service - Republic of Korea (3rd March 2015).
  - Cuban Public Registry of Clinical Trials (3rd March 2015).
  - German Clinical Trials Register (3rd March 2015).
  - Iranian Registry of Clinical Trials (3rd March 2015).
  - Japan Primary Registries Network (3rd March 2015).
  - Pan African Clinical Trial Registry (9th March 2015).
  - Sri Lanka Clinical Trials Registry (2nd March 2015).
  - Thai Clinical Trials Register (TCTR) (3rd March 2015).

For detailed search strategies see [Appendix 1](#). This strategy was based on the search undertaken by [Oude Luttikhuis 2009](#), but was

revised and adapted to expand the surgery search terms to capture the numerous different surgical interventions and associated nomenclature. We continuously applied a MEDLINE (via Ovid) email alert service to identify newly published studies using the search strategy detailed in [Appendix 1](#). After supplying the final review draft for editorial approval, the Cochrane Metabolic and Endocrine Disorders (CMED) Group performed a complete update search on all databases available at the editorial office and sent the results to the review authors. In case we identified new studies for inclusion we would have evaluated these, incorporated findings in our review and resubmitted another review draft ([Beller 2013](#)).

### Searching other resources

We tried to identify other potentially eligible trials or ancillary publications by searching the reference lists of retrieved included trials, (systematic) reviews, meta-analyses and health technology assessment reports.

## Data collection and analysis

### Selection of studies

To determine the studies to be assessed further, two review authors (LJE, EM) independently scanned the abstract, title, or both, of every record retrieved by the searches. We investigated all potentially relevant articles as full text. Where differences in opinion existed, they were resolved by discussion and consensus with a third review author (GA). If resolving disagreement was not possible, the article was added to those 'Studies awaiting classification' and we contacted study authors for clarification. We present an adapted Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram reporting the process of study selection ([Liberati 2009](#)).

### Data extraction and management

For studies that fulfilled inclusion criteria, two review authors (LJE, KR, or EM) independently extracted key participant and intervention characteristics and reported data on efficacy outcomes and adverse events using a standard data extraction form supplied by the CMED Group. Disagreements were to be resolved by discussion, or if required by a third review author (GA) (for details see [Characteristics of included studies](#); [Table 1](#); [Appendix 2](#); [Appendix 3](#); [Appendix 4](#); [Appendix 5](#); [Appendix 6](#); [Appendix 7](#); [Appendix 8](#); [Appendix 9](#); [Appendix 10](#)).

We provide information about potentially-relevant ongoing studies including trial identifier in the [Characteristics of ongoing studies](#) table and in [Appendix 5](#) 'Matrix of study endpoints (publications and trial documents)'. We tried to find the protocol for each included study, either in databases of ongoing trials, in publications of study designs, or both. We sent an email request to

the author of the included study to enquire whether further unpublished data relating to the study were available, whether the trial was ongoing and whether they were involved with any new studies in this area ([Appendix 11](#)).

### Dealing with duplicate publications and companion papers

In the event of duplicate publications and companion papers of a primary study, we tried to maximise yield of information by simultaneous evaluation of all available data. In case of doubt, we will give priority to the publication reporting the longest follow-up associated with our primary or secondary outcomes.

### Assessment of risk of bias in included studies

Two review authors (LJE, KR) independently assessed the risk of bias of each included study. Possible disagreements were resolved by consensus, or by consultation with a third review author (EM). In cases of disagreement, the rest of the group was consulted and a judgement was made based on consensus.

We planned to assess risk of bias using the Cochrane risk of bias tool ([Higgins 2011a](#); [Higgins 2011b](#)). We applied the following criteria.

- Random sequence generation (selection bias).
- Allocation concealment (selection bias).
- Imbalances in baseline characteristics (chance bias).
- Blinding (performance bias and detection bias), separated for blinding of participants and personnel and blinding of outcome assessment.
- Incomplete outcome data (attrition bias).
- Selective reporting (reporting bias).
- Other bias.

We evaluated whether imbalances in baseline characteristics existed and how these were addressed ([Egbewale 2014](#); [Riley 2013](#)). We assessed outcome reporting bias by integrating the results of 'Examination of outcome reporting bias' ([Appendix 6](#)), 'Matrix of study endpoints (publication and trial documents)' ([Appendix 5](#)) and 'Outcomes (outcomes reported in abstract of publication)' of the 'Characteristics of included studies' table ([Kirkham 2010](#)). This analysis formed the basis for the judgement of selective reporting (reporting bias) ([Boutron 2014](#); [Mathieu 2009](#)).

We judged risk of bias criteria as 'low risk', 'high risk' or 'unclear risk' and evaluated individual bias items as described in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011a](#)). We report a 'Risk of bias summary' in the results.

We assessed the impact of individual bias domains on study results at endpoint and study levels.

For blinding of participants and personnel (performance bias), detection bias (blinding of outcome assessors) and attrition bias (incomplete outcome data) we evaluated risk of bias separately for each outcome ([Hróbjartsson 2013](#)). We noted whether endpoints were self-reported or investigator-assessed. We considered

the implications of missing outcome data from individual participants per outcome such as high drop-out rates (e.g. above 15%) or disparate attrition rates (e.g. difference of 10% or more between study arms).

We defined the following outcomes as self-reported outcomes.

- BMI and weight loss, if measured by participants.
- Adverse events, if reported by participants.
- Health-related quality of life and self esteem.
- Participants views of the intervention.
- Behaviour change.

We defined the following outcomes as investigator-assessed outcomes.

- BMI, weight loss and measures of body fat distribution, if measured by study personnel.
- Adverse events, if reported by study personnel.
- All-cause mortality.
- Morbidity (changes in disease status).
- Socioeconomic effects.

### Measures of treatment effect

For dichotomous outcomes we calculated odds ratio (OR) or risk ratio (RR) and corresponding 95% confidence interval (CI). For continuous outcomes we calculated the mean difference (MD) and corresponding 95% CI.

### Unit of analysis issues

We planned to take into account the level at which randomisation occurred, such as cross-over trials, cluster-randomised trials and multiple observations for the same outcome.

### Dealing with missing data

If feasible, we obtained relevant missing data from authors. We evaluated important numerical data such as screened, eligible, and randomised patients as well as intention-to-treat (ITT), as-treated and per-protocol (PP) populations. We investigated attrition rates (e.g. drop-outs, losses to follow-up, withdrawals), and we critically appraised issues concerning missing data and imputation methods (e.g. last observation carried forward (LOCF)).

If standard deviations for outcomes were not reported, we would have imputed these values by assuming the standard deviation of the missing outcome to be the average of the standard deviations from those studies where this information was reported. If more than one study were available, we would have investigated the impact of this imputation on the point estimate using a sensitivity analysis.

### Assessment of heterogeneity

If more than one paper had been identified and substantial clinical, methodological or statistical heterogeneity had been identified, we

would not have reported study results as meta-analytically pooled effect estimates. Heterogeneity would have been identified by visual inspection of the forest plots and by using a standard Chi<sup>2</sup> test with a significance level of  $\alpha = 0.1$ , in view of the low power of this test. If more than one study had been identified we would have examined heterogeneity using the I<sup>2</sup> statistic, which quantifies inconsistency across studies to assess the impact of heterogeneity on the meta-analysis (Higgins 2002; Higgins 2003); where an I<sup>2</sup> statistic of 75% or more indicates a considerable level of inconsistency (Higgins 2011a). If heterogeneity had been found, we would have attempted to determine potential reasons for it by examining individual study and subgroup characteristics.

We expected the following characteristics to introduce clinical heterogeneity.

- Differences in the age of study population.
- Differences in the study population demographics.
- Differences in the types of surgery performed.
- Differences in BMI at baseline.

### Assessment of reporting biases

If we included 10 studies or more for a given outcome, we planned to use funnel plots to assess small study effects. Due to several potential explanations for funnel plot asymmetry we planned to interpret results carefully (Sterne 2011).

### Data synthesis

Unless there was good evidence for homogeneous effects across studies we planned to primarily summarise low-risk of bias data by means of a random-effects model (Wood 2008). We planned to interpret random-effects meta-analyses with due consideration of the whole distribution of effects, ideally by presenting a prediction interval (Higgins 2009). A prediction interval specifies a predicted range for the true treatment effect in an individual study (Riley 2011). In addition, if statistical analyses were possible these would have been performed according to the statistical guidelines provided by the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a).

### Subgroup analysis and investigation of heterogeneity

We planned to carry out the following subgroup analyses and wanted to investigate interaction.

- Length of follow-up.
- Impact and nature of maintenance periods.
- The impact of comparator or control: whether concomitant therapy or no treatment (true control).
- The impact of population demographics.

### Sensitivity analysis

We planned to perform sensitivity analyses in order to explore the influence of the following factors (when applicable) on effect size by restricting the analysis to:

- Published studies.
- Taking into account risk of bias, as specified in the [Assessment of risk of bias in included studies](#) section.
- Very long or large studies to establish how much these studies dominate the results.
- Studies using the following filters: diagnostic criteria, language of publication, source of funding (industry versus other), country.

We also tested the robustness of the results by repeating the analysis using different measures of effect size (RR, OR etc) and different statistical models (fixed-effect and random-effects models).

## RESULTS

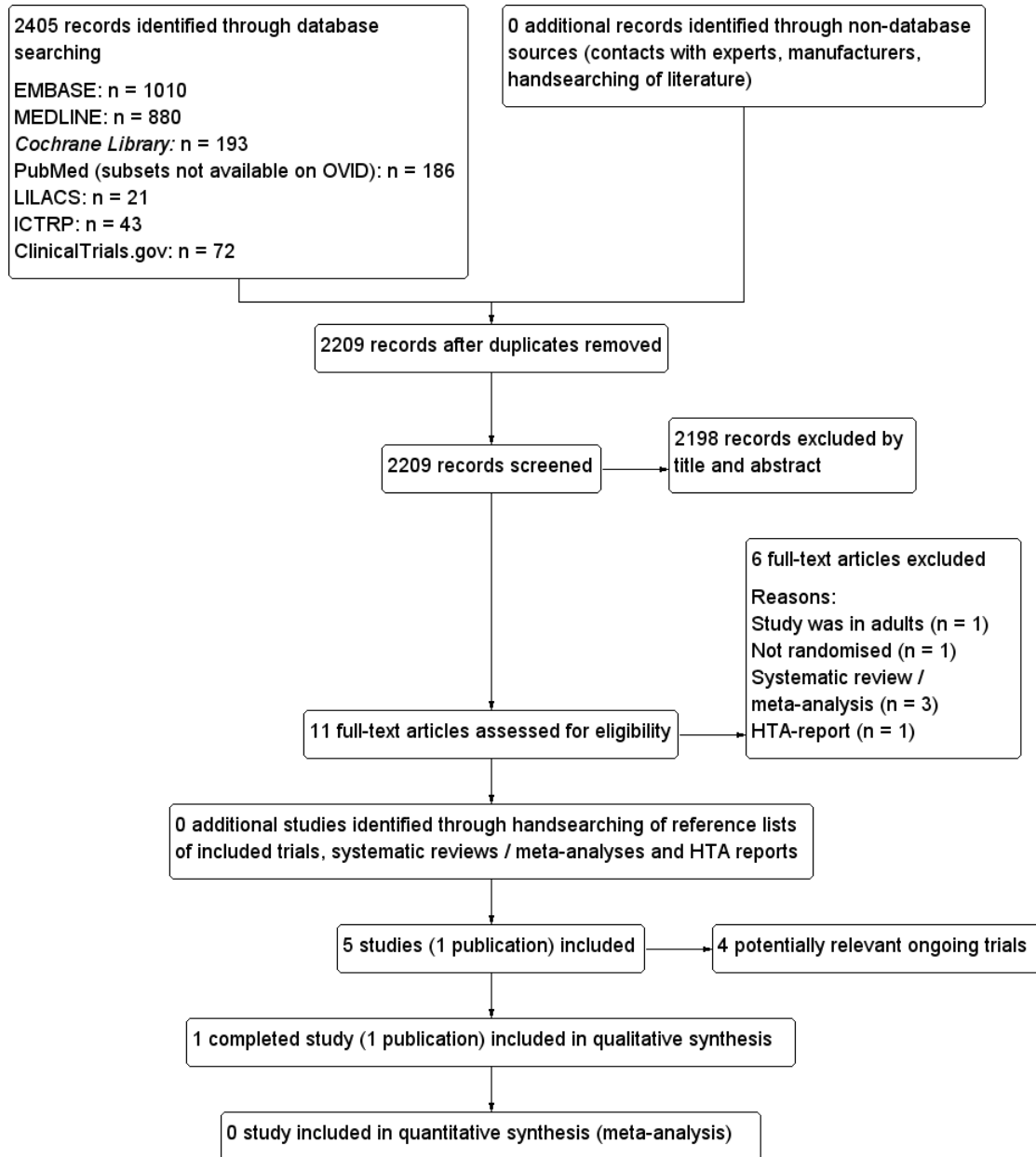
### Description of studies

For a detailed description of studies, see [Characteristics of included studies](#), [Characteristics of excluded studies](#), and [Characteristics of ongoing studies](#).

### Results of the search

The initial search on 30 March 2015 identified 2405 records (2290 from database searches and 115 from trial registry searches); from these, 11 full text publications and protocols were identified for further examination and four trials met the inclusion criteria for ongoing studies. We excluded the other studies because they did not meet the inclusion criteria or were not relevant to the question under study (see [Figure 1](#) for the amended PRISMA (preferred reporting items for systematic reviews and meta-analyses) flow diagram). After screening the full text of the selected publications, one study (one publication) met the inclusion criteria. All studies were published in English. We contacted the author of the published study and received a reply to confirm that no further data were available.

**Figure 1. Study flow diagram.**



## Included studies

A detailed description of the characteristics of included studies is presented elsewhere (see [Characteristics of included studies](#) and appendices). The following is a succinct overview:

### Source of data

One published study was included in this review ([O'Brien 2010](#)). Four additional studies were identified from trial registry searches ([ACTRN12609001004257](#); [NCT01172899](#); [NCT01700738](#); [NCT02378259](#)), but these could not be included as outcome data were not yet available. Details of these studies are provided in the [Characteristics of ongoing studies](#) table.

### Comparisons

[O'Brien 2010](#) compared laparoscopic adjustable gastric banding surgery to a multi component lifestyle modification program, consisting of individual calorie reduction diet plans, increased physical activity through pedometer targets, structured exercise schedules, advice to reduce sedentary activity and support through consultation with a health care practitioner every six weeks.

### Overview of study populations

A total of 50 participants were included in the trial, 25 participants were randomised to *intervention* and 25 to *control* groups. Twenty-four (98%) participants finished the study in the *intervention* compared to 18 (72%) participants in the *control* group.

### Study design

The included study was a randomised parallel group superiority trial. Given the nature of the intervention under investigation it was not possible to blind to participants or personnel delivering the interventions. However, outcome assessors were also unblinded. The duration of the intervention was two years, conducted between August 2006 and September 2008. The study was not terminated early.

### Settings

The study was undertaken in a specialist weight management clinic either in the community or the Royal Children's Hospital, Melbourne, with surgery occurring at a private hospital.

## Participants

The participating population consisted of Australian adolescents aged 14 to 18 years, with a mean age of 16.5 and 16.6 years in the banding and lifestyle group respectively. All participants demonstrated substantial physiological maturity with secondary sexual characteristics and most had also completed bone growth. This study contained a higher proportion of girls than boys in each arm of the intervention: 36% of the banding group were males and 28% of the lifestyle group were males. No further demographic information was reported. The mean body mass index (BMI) at baseline was 42.3 (SD 6.1) kg/m<sup>2</sup> in the banding group compared to 40.4 (SD 3.1) kg/m<sup>2</sup> in the lifestyle group. Entry criteria are outlined in the [Characteristics of included studies](#) table. Major exclusion criteria were intellectual disability and syndromic obesity.

### Diagnosis

Participants in the [O'Brien 2010](#) study were required to have a BMI greater than 35 and identifiable medical complications such as metabolic syndrome, physical limitation such as an inability to play a sport, or psycho-social difficulties such as low self-esteem.

### Interventions

This study employed a two month run-in program, which all participants undertook prior to randomisation. The program involved the implementation of best practice guidance on healthy eating and physical activity. The surgical intervention consisted of the gastric band placement followed by detailed guidance on post operative eating and activity.

### Outcomes

The one included study assessed 50 participants, and reported data for all primary and some secondary endpoints. All cause mortality, behaviour change, participants views of the intervention, socioeconomic effects and costs were not reported in this study. For a summary of all outcomes assessed in each study, see [Appendix 5](#).

### Excluded studies

Six studies had to be excluded after careful evaluation of the full publication ([Aikenhead 2011](#); [Black 2013](#); [Farina 2012](#); [Gloy 2013](#); [Picot 2009](#); [Tyvonchuk 2009](#); see [Figure 1](#)).

### Risk of bias in included studies

For details on risk of bias of included studies see [Characteristics of included studies](#). For an overview of review authors' judgments about each risk of bias item for the one included study see [Figure 2](#).





assessors were not blinded.

### Incomplete outcome data

O'Brien 2010 reported on withdrawals and losses to follow-up, with one loss to follow-up in the banding intervention and two losses to follow-up and five withdrawals in the lifestyle intervention (due to family problems, unsatisfied with progress). Intention-to-treat (ITT) analysis was performed for the primary outcome (weight change) only, all secondary outcomes (health-related quality of life outcomes) were assessed by completers analysis as the study was only powered to detect changes in the primary outcome measure. Consequently attrition bias was considered to be low risk for objectively measured outcomes such as the primary outcome weight loss. The primary outcome was analysed using ITT and disparate attrition rates probably did not contribute significantly to this outcome. Bias for subjective measures (health-related quality of life) was considered high as, no ITT analysis was conducted and disparate attrition rates probably influenced this outcome measure.

### Selective reporting

Comparison of the study publication and protocol information in the trial register revealed some differences and reporting bias was therefore judged to be 'unclear'.

### Other potential sources of bias

The study received some funding from the gastric band manufacturer (Allergen) and one of the co-authors declared his position as a member of the Allergen advisory board. However, the authors state that the sponsors had no role in the study design, conduct, data collection and analysis and manuscript preparation.

### Effects of interventions

See: [Summary of findings for the main comparison](#)

### Baseline characteristics

For details of baseline characteristics, see [Appendix 3](#) and [Appendix 4](#).

### Gastric banding program versus lifestyle program

The included study examined the effects of laparoscopic gastric banding surgery compared to a form of lifestyle program (O'Brien 2010). This study measured weight change as the primary outcome.

### Primary outcomes (body mass index (BMI), weight loss, adverse events)

#### BMI, weight loss

The study authors reported a mean reduction in weight of 34.6 kg (95% confidence interval (CI) 30.2 to 39.0) at two years, representing a change in BMI units of 12.7 (95% CI 11.3 to 14.2) for the surgery intervention; and a mean reduction in weight of 3.0 kg (95% CI 2.1 to 8.1) representing a change in 1.3 BMI units (95% CI 0.4 to 2.9) for the lifestyle intervention. The differences between groups was statistically significant for all weight measures at 24 months ( $P < 0.001$ ). All analyses were based on an ITT model.

#### Adverse events

The gastric banding placement occurred without any complications during the perioperative period or within 30 days. The mean length of hospital stay was 26 hrs (range 23 hrs to 32 hrs). A total of 28% of the participants required a revisional procedure. Although we generally considered the risk of performance, detection and attrition bias to be high for adverse events, the risk of these biases was appraised as low for revisional procedures.

Adverse events were reported in both groups, with 13 events reported in 12 participants in the surgery intervention compared to 18 events reported in 11 participants in the lifestyle group. Adverse events in the surgery group included six proximal gastric enlargements, two needlestick injury to tubing, one cholecystectomy, one hospital admission for depression, one lost to follow-up and two unplanned pregnancies. Adverse events in the lifestyle group included one hospital admission for depression and intracranial hypertension, one cholecystectomy, seven loss to follow-up and two unplanned pregnancies.

Over the two year study period the surgical group ( $n = 25$ ) had a mean of 20 visits with a physician (range 10 to 31) per participant and a mean of 9.5 adjustments made to the volume of saline in the band (range 5 to 18) per participant. In the non-surgical group ( $n = 25$ ) adolescents visited the adolescent physician, study dietitian, study nurse practitioner, or other physicians a mean of 16 (range 7 to 31) times. There was also a mean of 5 telephone consultations per participant and each participant had 6 sessions with a personal trainer.

#### Secondary outcomes (health-related quality of life and self esteem; all-cause mortality; morbidity; measures of body fat distribution; behaviour change; participants views of the intervention; socioeconomic effects)

All-cause mortality, behaviour change, self-esteem, participants views of the intervention and socioeconomic effects were either not investigated or reported in the included study.

### Health-related quality of life

Health-related quality of life was assessed by the Child Health Questionnaire™ (CHQ), a family of generic quality of life instruments that have been designed and validated for children 5 to 18 years of age. Parents and children (ages 10 to 18 years) may self-administer the CHQ after instructions from the administrator. The CHQ measures 14 unique physical and psychosocial concepts. The parent form is available in two lengths - 50 or 28 items. Scores can be analysed separately, the CHQ profile scores, or combined to derive an overall physical and psychosocial score, the CHQ summary scores.

Score interpretation: the range on subscales and the overall scale is 0 to 100, where 0 indicates the worst possible health state and 100 the best possible health state. A normative sample was not available for comparison of paediatric patient-reported health-related quality of life. Poor health-related quality of life has been defined as two standard deviations below the mean of the normative sample or a physical functioning or psychosocial health summary score less than 30.

Eight of the subscores of the CHQ are shown in [Appendix 12](#). The subscores for behavioral, emotional, and physical limitations are not shown because these items did not differ from community values at entry into the study and were not different within or between groups over the two-year follow-up period. No statistically significant differences existed in any measures between groups at the commencement of the study. Both groups had six subscores below the community norm at commencement. At two years, the gastric banding group had better physical functioning scores (94 versus 78, community norm 95) and change in health scores (4.4 versus 3.6, community norm 3.5) than the lifestyle group.

### Morbidity

Morbidity was associated with the metabolic syndrome which is a weak surrogate endpoint for illness or harm associated with the intervention or the condition itself. At study entry, 36% of the participants in the gastric banding group and 40% in the lifestyle group were diagnosed with the metabolic syndrome. At 24 months, none of the 24 study completers (0%) in the gastric banding group had the metabolic syndrome compared to four of 18 completers (22%) in the lifestyle group who still had the metabolic syndrome.

### Measures of body fat distribution

Waist circumference was reduced by 28.2 cm in the gastric banding group and by 3.5 cm in the lifestyle group at two years (MD) - 24.7 cm (95% CI -33.1 to -16.3);  $P < 0.001$ .

### Ongoing studies

[NCT01172899](#) and [NCT01700738](#) both report the recruitment of obese 12 to 16 year olds to assess the efficacy of gas-

tric banding in French ([NCT01700738](#)), and Dutch populations ([NCT01172899](#)), with completion anticipated in 2015. [ACTRN12609001004257](#) reports the recruitment of 44 of 50 planned obese 12 to 17 year olds to assess the efficacy of a Bioenterics Intra-gastric Balloon (BIB) in an Australian population. This study started recruitment in 2009 but does not report an end date. [NCT02378259](#) is the most recently registered trial, and aims to recruit 13 to 15 year olds to assess the efficacy of Roux-en-Y gastric bypass in Sweden. This study is due to start in August 2015, with completion anticipated for May 2021.

## DISCUSSION

Only five studies were identified that met the inclusion criteria for this review: four ongoing studies ([ACTRN12609001004257](#); [NCT01172899](#); [NCT01700738](#); [NCT02378259](#)), and one published study ([O'Brien 2010](#)). One ongoing study examined the effect of Bioenterics Intra-gastric Balloon (BIB) insertion over six months compared to a usual care 10 week multidisciplinary lifestyle modification programme in an Australian adolescent population. Another Swedish ongoing study, due to start in August 2015, aims to examine the impact of Roux-en-Y-gastric bypass compared to intensive conservative treatment in 13 to 15 year old adolescents. Three studies investigate the impact of laparoscopic gastric banding in obese adolescents from Australia ([O'Brien 2010](#)), Netherlands ([NCT01172899](#)), and France ([NCT01700738](#)), and measure change in weight status, associated morbidity, adverse events and health-related quality of life. As only one study has reached completion and published findings no further narrative or quantitative comparisons could be made. [O'Brien 2010](#) demonstrated that in a small, predominantly female population of severely obese Australian adolescents both gastric banding and a multi component lifestyle intervention resulted in improved weight and health status. However, gastric banding resulted in significantly greater weight loss than the lifestyle program. Adverse events were reported in both arms of the study, with two unplanned pregnancies and two hospital admissions for depression and cholecystectomy occurring in both groups. An additional eight (28%) admissions for revisional surgery occurred in the banding group, which is a high rate and requires further consideration.

Eating small meals slowly is central to avoiding problems after the gastric banding procedure. This was repeatedly stressed during the [O'Brien 2010](#) study. For adolescents, additional education and supervision of eating may help reduce the need for revision surgery.

Recruitment methods were used to minimise bias toward one or other treatment but may have drawn on a subset of the community attracted by the availability of free treatment. The [O'Brien 2010](#) study was powered to measure differences in weight outcomes rather than differences in other health measures or adverse events.

Adolescents and parents must understand the importance of careful adherence to recommended eating behaviours and of seeking early consultation if symptoms of reflux, heartburn, or vomiting occur. As importantly, they should be in a setting in which they can maintain contact with health professionals who understand the process of care.

### Summary of main results

This review reports the findings from one RCT (50 participants). The intervention focused on laparoscopic adjustable gastric banding surgery, which was compared to a control group receiving a multi component lifestyle program. The study authors were unable to blind their participants, personnel and outcome assessors which may have resulted in a high risk of performance and detection bias. At 24 months follow-up, the mean change in BMI units was 12.7 (95% CI 11.3 to 14.2) in the surgery group compared to 1.3 (95% CI 0.4 to 2.9) in the control group. Adverse events were reported in 12/25 participants in the intervention group compared to 11/25 in the control group.

### Overall completeness and applicability of evidence

In line with the previous update (Oude Luttikhuis 2009), and the other reviews in this series examining interventions for the treatment of child and adolescent obesity, study design was limited to randomised controlled trials (RCT) to provide the least biased estimate of effect size (Stephenson 1998). Despite the publication of a number of observational studies examining bariatric surgery in young people under 18 years (Black 2013), only one RCT was identified (O'Brien 2010). Whilst this study reported on weight, health-related quality of life and adverse events, further data on the participant socioeconomic status and ethnic origin may have enhanced the wider applicability of the findings. The authors state their uncertainty as to whether the study population is an accurate reflection of the general obese adolescent population, since it may have attracted a subset of the community amenable to the availability of free treatment.

### Quality of the evidence

Whilst the included study was well conducted and provides much needed evidence in this field, further studies are required to strengthen the evidence base. The O'Brien 2010 study would have benefited from outcome assessor blinding for the BMI and health-related quality of life assessment and a cost effectiveness analysis. It would also have been useful if O'Brien 2010 had reported the exact baseline adjusted group difference in change scores.

### Potential biases in the review process

As only one published study was comprehensively assessed in this review, no potential biases in the review process arose.

### Agreements and disagreements with other studies or reviews

The findings from this review agree with the most recent systematic reviews of adolescent obesity surgery (Aikenhead 2011; Black 2013). Both reviews assessed the O'Brien 2010 study alongside a heterogeneous mix of largely underpowered non-RCT studies. Both reviews employed an earlier and less extensive literature search than the search undertaken for this review. The degree of weight loss and improvements to health-related quality of life reported in the O'Brien 2010 study also agree with those reported in recent reviews of adult obesity surgery (Colquitt 2014; Gloy 2013; Picot 2009). However, a much wider range of adverse events were reported in both the adult reviews and recent adolescent reviews.

## AUTHORS' CONCLUSIONS

### Implications for practice

The aim of this review was to assess the effects of surgery for treating obesity in children and adolescents, however, the ability to address this was severely limited by the size of the current evidence base. Whilst an overview of the considerations arising from the included study are provided below, in isolation, this study does not provide sufficient evidence to adequately inform practice.

Compared with a program of lifestyle treatment for obesity, laparoscopic gastric banding led to greater body weight loss in one well conducted study that included 50 patients. However, this study was limited to two years of follow-up, was based on just one small Australian population and was conducted in a private hospital that received funding from the manufacturer of the gastric band. There is currently insufficient evidence to make an informed judgement about efficacy. Whilst one study identified the possible benefits of surgery, there are not enough data to assess efficacy across populations from different countries, socioeconomic and ethnic backgrounds, who may respond differently. There are also insufficient data to examine possible variation according to gender, age, baseline weight status and different surgical procedures.

Twenty-eight per cent of the surgery participants required a revisional procedure. A wider range of adverse events, including mortality were reported in other reviews of non-RCT surgical interventions for obese young people (Aikenhead 2011; Black 2013). Unlike adults, surgery in children and adolescents requires additional considerations, such as a suitable multi-disciplinary paediatric team, pubertal status and degree of physical maturation, the

psychological and nutritional impact of surgery, capacity to consent and undertake the required post operative lifestyle changes, appropriate family support and parental consent (Pratt 2009). Bariatric surgery for young people, as for adults, should not be viewed as a quick fix to weight loss but should be undertaken with due diligence. O'Brien 2010 states that optimal effectiveness requires long term specialist supportive follow-up, with consideration required for the bespoke needs of an adolescent population.

## Implications for research

This systematic review highlights the lack of randomised controlled trials in this field. More high quality studies are required to address the efficacy of bariatric surgery for the treatment obesity in children and adolescents. The four ongoing studies, once completed, will provide additional evidence on bioenteric intragastric balloon and gastric bypass as alternative procedures in Australian and Swedish adolescents respectively, with two further European

studies examining gastric banding. It is important for future studies to address clinical effectiveness across a range of populations, including participants ranging in socio-demographics, ethnicity, baseline weight status and geography. Future studies should assess the impact of the surgical procedure and post operative care to minimise adverse events, including the need for post operative adjustments and revisional surgery. Long term follow-up is also critical to comprehensively assess the impact of surgery as participants enter adulthood. Additional data on cost effectiveness and participants views will also provide constructive evidence to help steer future policy and practice decision making.

## ACKNOWLEDGEMENTS

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#### NCT01172899 {published data only}

**Title:** bariatric surgery in children **Acronym:** BASIC. Ongoing study **Study start date:** July 2010 **Study completion date:** December 2015 (final data collection date for primary outcome measure).

#### NCT01700738 {published data only}

**Title:** evaluation of the effects of laying early a gastric band on the prevention of morbid obesity randomized checked against standard management of obesity in this population **Acronym:** CHADO. Ongoing study **Study start date:** November 2012 **Study completion date:** November 2015.

#### NCT02378259 {published data only}

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\* Indicates the major publication for the study



## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [author-defined order]

O'Brien 2010

Methods	<p><b>Parallel randomised control trial (RCT)</b></p> <p><b>Randomisation ratio:</b> 1:1</p> <p><b>Superiority design</b></p>
Participants	<p><b>Inclusion criteria:</b> age between 14 and 18 years; BMI &gt; 35, identifiable medical complications such as hypertension, metabolic syndrome, asthma, back pain; physical limitations such as an inability to play a sport, difficulties with activities of daily living; or psychosocial difficulties such as isolation or low self-esteem, subject to bullying that stems from obesity and evidence of attempts to lose weight by lifestyle means for more than 3 years</p> <p><b>Key inclusion criteria specified in study register (ACTRN12605000160639):</b> “Have a body mass index greater than 35 kg/m<sup>2</sup> corrected for age, that is a z-score of 3.0 or greater, have had identifiable problems with obesity for more than 3 years, self-motivated with a good grasp of English and able to clearly understand the nature of a randomized treatment program, be able to understand the options and study requirements and comply with both of the management programs, be able to give informed consent to either program, be willing to be randomized, have the support of a parent or guardian who understands the nature and requirements of both treatment arms and is fully supportive of the decision of the adolescent to enter the randomized study, willingness of the parent or guardian to give informed consent to either arm. The subject and parent or guardian partners would understand the requirements of the study itself, including the need for serial simple anthropometric measurements, completion of serial questionnaires and serial biochemical analysis that requires fasting venous sampling.”</p> <p><b>Exclusion criteria:</b> applicants were excluded who had learning disabilities and the Prader-Willi syndrome</p> <p><b>Key exclusion criteria specified in study register (ACTRN12605000160639):</b> “Lack of acceptance of the randomization process, history of previous criteria abdominal surgery which would potentially preclude laparoscopic placement of the band, a history of previous obesity surgery, any contraindication to Lap-Band placement history of previous abdominal surgery which would potentially preclude laparoscopic placement of the band, unsuitability for the Active8 peer support program, medical issues which contraindicated the application of either arm of the study (these would include; acute myocardial infarction within the past 6 months, dementia, active psychosis, concurrent experimental drug use, autoimmune disease, pregnancy, lactation, illicit drug use, excessive alcohol intake, use of drugs known to affect body composition, cytotoxic drugs, internal malignancy or major organ failure) , systemic lupus erythematosus or other auto-immune disease, direct hypothalamic damage as a cause of obesity, inability to understand the risks, realistic benefits and compliance requirements of the Lap-Band intervention and conventional management of severe obesity, Prader-Willi syndrome or other syndromes associated with intellectual disability or hyperphagia”</p> <p><b>Diagnostic criteria:</b> obesity defined as BMI &gt; 35</p>
Interventions	<p><b>Number of study centres:</b> consultations and adjustments of the gastric banding were carried out at a community clinic dedicated to obesity management or at a special clinic at</p>

	<p>the Centre for Adolescent Health, Royal Children's Hospital; gastric banding procedures were conducted at a private hospital</p> <p><b>Treatment before study:</b> see run-in period.</p> <p><b>Intervention</b> (gastric banding program): "participants in the gastric banding group had the procedure performed within a month of randomization. The LAP-BAND Adjustable Gastric Banding system (Allergan, Irvine, California) was used in all cases. Detailed instructions on the requirements for correct eating and exercise after gastric banding were provided by discussion as well as in written form before the procedure. Eating rules centered on having 3 or fewer small (approximately 125 mL), protein-containing meals per day, eaten slowly (1 min/bite) and chewed well. Each participant was encouraged to undertake at least 30 minutes of formal exercise per day and to maintain a high level of activity through the day. Clinical reviews were conducted approximately every 6 weeks for 2 years by experienced medical staff. Adjustments to the volume of fluid in the band were conducted in the office, without use of x-ray imaging, based on weight loss, sense of satiety, and eating pattern and symptoms"</p> <p><b>Comparator</b> (lifestyle programme): "program centered on reduced energy intake (individualized diet plans ranging between 800 and 2000 kcal/d, depending on age and weight status), increased activity (target of 10 000 steps per day on pedometer) with a structured exercise schedule of at least 30 minutes a day and behavioral modification. Compliance was monitored intermittently with food diaries and step counts. Consultation occurred approximately every 6 weeks throughout the 24-month study period by an adolescent physician and a dietitian or exercise consultant, the study nurse coordinator, and a sports medicine physician. The participant's family was included in activities and education where appropriate. Exercise and activity recommendations included decrease of sedentary activities with a limit of 2-hour computer or television screen time, increase of formal exercise including bicycle riding, walking, and swimming plus informal individual and group activities. Group outings to fun parks, bike rides, hiking trips, walking, jogging, kickboxing, indoor bowling, and outdoor reunions were scheduled. A personal trainer was provided to each participant for a 6-week period. Parents were invited to participate in a specific educational program that included sports motivational talks, nutritional education, and discussions of the psychological aspects of adolescence"</p>
<p>Outcomes</p>	<p><b>Outcomes reported in abstract of publication:</b> number of participants which lost more than 50% of excess weight, mean changes in weight loss, excess weight loss, BMI, BMI z score change, number of participants with metabolic syndrome, quality of life, adverse events</p>
<p>Study details</p>	<p><b>Run-in period:</b> "at initial telephone contact, potential participants and their families were invited to attend a patient information session followed by a clinical assessment by 2 physicians experienced in the management of obesity in adolescents. At this time, the nature of the study and the proposed management of the 2 study groups was carefully explained, and the suitability of the participant was clarified. Participants were asked to complete a 2-week food diary, record activity for 2 weeks using a pedometer, and complete several questionnaires. A second consultation occurred no less than 4 weeks later with a detailed clinical assessment, confirmation of satisfactory completion of the tasks, and further discussion of the trial methods. Clinical assessment included measurement of weight and height, neck, waist, and hip circumference; history of the weight disorder; and diet and weight loss efforts. Clinical features of comorbidities of obesity were sought. Laboratory analyses included fasting blood glucose, serum insulin, C-</p>

	<p>peptide, hemoglobin A1c, iron status, liver function tests, lipids, and thyroid function tests. Potential participants undertook a 2-month program that involved best practice recommendations around eating and physical activity. At a third clinical appointment, the randomization process was again explained and the consent form was signed by the participant and the parent or guardian. After a cooling-off period of 7 days, the desire to enter the study was reconfirmed ...”</p> <p><b>Study terminated before regular end (for benefit / because of adverse events):</b> no</p>	
Publication details	<p><b>Language of publication:</b> English  <b>Funding:</b> commercial funding and non-commercial funding  <b>Publication status:</b> peer review journal</p>	
Stated aim for study	<p><b>Quote from publication:</b> “we hypothesized that gastric banding would induce more weight loss and would provide greater health benefits and better improvement in the quality of life of obese adolescents than the optimal application of the currently available lifestyle approaches. To test this hypothesis, we conducted a prospective, randomized controlled trial in a group of severely obese adolescents”</p>	
Notes	<p>First author’s failure to report financial disclosure information was corrected in a letter to the editor</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	<p><b>Quote from publication:</b> “Randomization was performed using a computer-derived random allocation sequence to allow orderly admission into both programs. There was no stratification or blocking.”</p> <p><b>Information specified in study register (ACTRN12605000160639):</b> “Subjects were block randomized into 3 unequal blocks. Each block contained equal numbers in both treatment arms. The sequence within blocks was determined by the staff member in control of concealment by drawing the allocation out of a hat and the number in each blocking group was known only to this staff member”</p> <p><b>Comment:</b> unclear risk because of mismatch of information between publication and study register</p>
Allocation concealment (selection bias)	Low risk	<p><b>Quote from author (via email):</b> “The trial coordinator went over the trial details with the prospective participant (and parent) , had the informed consent for the trial signed, phoned the allocation centre, re-</p>

		<p>ceived the allocation and informed the participant immediately”</p> <p><b>Information specified in study register</b> (ACTRN12605000160639): “Intervention recorded and stored in numbered, sealed opaque envelopes organized and maintained by staff member not involved in patient care or scheduling and opened in sequence as randomized.”</p> <p><b>Comment:</b> allocation was concealed</p>
Baseline imbalance (chance bias)	Low risk	Comment: none detected
Blinding of participants and personnel (performance bias) Adverse events	High risk	<p><b>Quote from publication:</b> “The study was not blinded”</p> <p><b>Information specified in study register</b> (ACTRN12605000160639): “Open (masking not used)”</p> <p><b>Comment:</b> lack of blinding may pose a high risk to this outcome measure</p>
Blinding of participants and personnel (performance bias) BMI, weight loss, measures of body fat distribution	Unclear risk	<p><b>Quote from publication:</b> “The study was not blinded”</p> <p><b>Information specified in study register</b> (ACTRN12605000160639): “Open (masking not used)”</p> <p><b>Comment:</b> unclear if blinding would affect performance bias</p>
Blinding of participants and personnel (performance bias) Health-related quality of life, self-esteem	High risk	<p><b>Quote from publication:</b> “The study was not blinded”</p> <p><b>Information specified in study register</b> (ACTRN12605000160639): “Open (masking not used)”</p> <p><b>Comment:</b> lack of blinding may pose a high risk to this outcome measure</p>
Blinding of participants and personnel (performance bias) Morbidity	Unclear risk	<p><b>Quote from publication:</b> “The study was not blinded”</p> <p><b>Information specified in study register</b> (ACTRN12605000160639): “Open (masking not used)”</p> <p><b>Comment:</b> unclear if blinding would affect performance bias</p>
Blinding of outcome assessment (detection bias) Adverse events	High risk	<p><b>Quote from publication:</b> “The study was not blinded”</p> <p><b>Comment:</b> outcomes assessors were not blinded, therefore detection bias may have</p>

		occurred
Blinding of outcome assessment (detection bias) BMI, weight loss, measures of body fat distribution	Unclear risk	<b>Quote from publication:</b> "The study was not blinded" <b>Comment:</b> outcomes assessors were not blinded
Blinding of outcome assessment (detection bias) Health-related quality of life, self-esteem	High risk	<b>Quote from publication:</b> "The study was not blinded" <b>Comment:</b> outcomes assessors were not blinded, therefore detection bias may have occurred
Blinding of outcome assessment (detection bias) Morbidity	Unclear risk	<b>Quote from publication:</b> "The study was not blinded" <b>Comment:</b> outcomes assessors were not blinded
Incomplete outcome data (attrition bias) Adverse events	High risk	<b>Quote from publication:</b> "We analysed the weight change data according to the patient's randomly assigned program (intention-to-treat analysis) and used completer's analysis for the health and quality of life data"; "The laboratory and questionnaire represent data provided by only those who completed"; "The laboratory and questionnaire represent data provided by only those who completed"; "All observed data were considered for analysis, with the mixed-effects models assuming non informative dropout such that the probability of dropout may depend on a participant's previous response but not on current or future responses" <b>Comment:</b> outcomes were assessed using completers analysis
Incomplete outcome data (attrition bias) BMI, weight loss, measures of body fat distribution	Low risk	<b>Quote from publication:</b> "We analysed the weight change data according to the patient's randomly assigned program (intention-to-treat analysis) and used completer's analysis for the health and quality of life data"; "The laboratory and questionnaire represent data provided by only those who completed"; "All observed data were considered for analysis, with the mixed-effects models assuming non informative dropout such that the probability of dropout may depend on a participant's previous response

		but not on current or future responses” <b>Comment:</b> intention-to-treat analysis was used, however this was for only one measured outcome (weight change) which was the primary outcome measure
Incomplete outcome data (attrition bias) Health-related quality of life, self-esteem	High risk	<b>Quote from publication:</b> “We analysed the weight change data according to the patient’s randomly assigned program (intention-to-treat analysis) and used completer’s analysis for the health and quality of life data”; “The laboratory and questionnaire represent data provided by only those who completed”; “The laboratory and questionnaire represent data provided by only those who completed”; “All observed data were considered for analysis, with the mixed-effects models assuming non informative dropout such that the probability of dropout may depend on a participant’s previous response but not on current or future responses” <b>Comment:</b> outcomes were assessed using completers analysis
Incomplete outcome data (attrition bias) Morbidity	Unclear risk	<b>Quote from publication:</b> “We analysed the weight change data according to the patient’s randomly assigned program (intention-to-treat analysis) and used completer’s analysis for the health and quality of life data”; “The laboratory and questionnaire represent data provided by only those who completed”; “The laboratory and questionnaire represent data provided by only those who completed”; “All observed data were considered for analysis, with the mixed-effects models assuming non informative dropout such that the probability of dropout may depend on a participant’s previous response but not on current or future responses” <b>Comment:</b> outcomes were assessed using completers analysis
Selective reporting (reporting bias)	Unclear risk	<b>Comment:</b> mismatch between outcome measures stated in trial register and publication
Other bias	Low risk	<b>Comment:</b> none detected

Note: where the judgement is 'Unclear' and the description is blank, the study did not report that particular outcome.  
 BMI: body mass index

### Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Aikenhead 2011	Systematic review
Black 2013	Systematic review
Farina 2012	Participants were adults
Gloy 2013	Systematic review
Picot 2009	Health-technology assessment report
Tyvonchuk 2009	Participants were 'young adults'; probably not a randomised controlled trial

### Characteristics of ongoing studies *[ordered by study ID]*

ACTRN12609001004257

Trial name or title	<p><b>Title:</b> randomised controlled trial of the Bioenterics Intra-gastric Balloon (BIB) versus lifestyle intervention alone on weight loss and reversal of weight related diseases in obese adolescents</p> <p><b>Acronym:</b> BIB study</p>
Methods	<p><b>Type of study:</b> interventional; randomised controlled trial</p> <p><b>Allocation:</b> randomised</p> <p><b>Intervention model:</b> parallel assignment</p> <p><b>Masking:</b> open</p> <p><b>Primary purpose:</b> treatment</p>
Participants	<p><b>Condition:</b> obesity</p> <p><b>Enrollment:</b> 50</p> <p><b>Inclusion criteria:</b> males and females aged 12 to 17 years; participants must be living in metropolitan Perth and willing to attend outpatient appointments, and have no significant weight loss despite 3 months attempted lifestyle improvements. Participants must also have a BMI Z-score &gt;+3 or a BMI Z-score &gt;+2 and 2 or more of the following co-morbidities: hyperlipidaemia; impaired glucose tolerance/hyperinsulinaemia; hepatitis steatosis; hypertension; polycystic ovarian syndrome; obstructive sleep apnoea; benign intracranial hypertension; degenerative joint disease</p> <p><b>Exclusion criteria:</b> previous gastrointestinal resections; structural abnormalities of the gastrointestinal tract; psychiatric/eating disorder; rural dwelling; active oesophagitis (grade1) / active gastric ulcer or its previous complications/hiatus hernia (&gt; 5 cm); pregnancy; type 2 diabetes; patient on anticoagulants or non-steroidal anti-inflammatory drugs gastric irritants, unwilling to make lifestyles changes or attend regular clinic appointments; unwilling to accept the probability of nausea and vomiting in the postoperative period; physical</p>

	inability to maintain regular follow-up; obstructive sleep apnoea requiring a continuous positive airway pressure (CPAP) machine
Interventions	<p><b>Intervention:</b> Bioenterics Intra-gastric Balloon (BIB) for a duration of six months, plus detailed post operative dietary plan</p> <p><b>Comparator:</b> usual care multidisciplinary lifestyle intervention: changes in lifestyle are successful in partnership (CLASP) program. The program runs for 10 weeks (two and a half sessions held once a week) and aims to achieve: a healthy diet, learning how to self-monitor, behavioural changes and improving physical activities, through a series of participant and parent/guardian individual and group sessions</p>
Outcomes	<p><b>Primary outcome:</b> body mass index (BMI) raw score and Z score measured at baseline, six and 18 months</p> <p><b>Secondary outcomes:</b> biochemical tests, clinical symptoms and signs of obesity complications, assessed through clinic visits and biochemical markers, fitness, physical activity and sedentary behaviour, using validated questionnaires. Fitness will be assessed by the 6-minute walk test, step test and balance test, dietary habits and intake changes, using a three-day food diary and an eating habits questionnaire, psychological scores on validated questionnaires, blood pressure, measured using a handheld aneroid sphygmomanometer all assessed at baseline, six and eighteen months. Tolerance and adverse events, including nausea, vomiting and abdominal pain. This will be measured by assessing the postoperative requirement for antiemetics and documentation of symptoms, measured at one week, two weeks, four weeks, 10 weeks, six months</p>
Starting date	1/10/2009
Contact information	<p>Scientific queries to: Dr Jacqueline Curran Princess Margaret Hospital for Children Department of Endocrinology and Diabetes Roberts Road Subiaco, WA 6008 jacqueline.curran@health.wa.gov.au</p>
Notes	<p>When identified the study was currently recruiting participants Funding source: National Health and Medical Research Council 20 April 2015 (information from study authors): "Currently we have 23 in the control arm and 21 in the intervention arm ... we will continue to recruit until 50"</p>

## NCT01172899

Trial name or title	<p><b>Title:</b> bariatric surgery in children <b>Acronym:</b> BASIC</p>
Methods	<p><b>Type of study:</b> interventional; randomised controlled trial <b>Allocation:</b> randomised <b>Intervention model:</b> parallel assignment <b>Masking:</b> single blind (outcomes assessor) <b>Primary purpose:</b> treatment</p>
Participants	<p><b>Condition:</b> obesity; morbid <b>Enrollment:</b> estimated 60 <b>Inclusion criteria:</b> aged 12 to 16 years; age and sex adjusted BMI &gt; 40 kg/m<sup>2</sup> or &gt; 35 kg/m<sup>2</sup> with associ-</p>



NCT01172899 (Continued)

	<p>ated comorbidity (associated comorbidity includes: glucose intolerance, type 2 diabetes, hypertension, pseudotumour cerebri, acanthosis nigricans, obstructive sleep apnoea syndrome, depression, arthropathies, non-alcoholic steatohepatitis and dyslipidaemia); &gt; 1 year multidisciplinary organized weight reducing attempts with less than 5% weight loss; demonstrate decisional capacity</p> <p><b>Exclusion criteria:</b> psychologically not suitable; pre-menarche or bone age &lt;15 years in boys; obesity associated to other disorders such as hypothyroidism; syndromal disorders such as Prader-Willi syndrome; severe cardiorespiratory impairment (ASA class 3 or higher); Insufficiently fluid in the Dutch language; unwillingness to adhere to follow-up programmes</p>
Interventions	<p><b>Intervention:</b> laparoscopic gastric band placement + combined lifestyle interventions</p> <p><b>Comparator:</b> combined lifestyle interventions</p>
Outcomes	<p><b>Primary outcome(s):</b> weight loss, excess weight loss and loss of excess BMI</p> <p><b>Secondary outcome(s):</b> body composition; pubertal development; metabolic and endocrine changes; Inflammatory status; cardiovascular abnormalities; non-alcoholic fatty liver disease; quality of life; behaviour changes; operative complications; effects on sleep architecture; brain development; physical activity; behavior towards food</p> <p><b>Other outcome(s):</b> not reported</p>
Starting date	<p><b>Study start date:</b> July 2010</p> <p><b>Study completion date:</b> December 2015 (final data collection date for primary outcome measure)</p>
Contact information	<p><b>Responsible party/principal investigator:</b> Maastricht University Medical Center. LWE van Heurn, Professor: +31433877477. e.van.heurn@mumc.nl Givan F Paulus, PhD student: +31620727692. g.paulus@mumc.nl.</p>
Notes	<p>When the study was identified they were currently recruiting participants ClinicalTrials.gov Identifier: <a href="#">NCT01172899</a>. Study sponsor: Maastricht University Medical Center</p>

NCT01700738

Trial name or title	<p><b>Title:</b> evaluation of the effects of laying early a gastric band on the prevention of morbid obesity randomized checked against standard management of obesity in this population</p> <p><b>Acronym:</b> CHADO</p>
Methods	<p><b>Type of study:</b> interventional; randomised controlled trial</p> <p><b>Allocation:</b> randomised</p> <p><b>Intervention model:</b> parallel assignment</p> <p><b>Masking:</b> open label</p> <p><b>Primary purpose:</b> treatment</p>
Participants	<p><b>Condition:</b> obesity</p> <p><b>Enrollment:</b> estimated 200</p> <p><b>Inclusion criteria:</b> adolescents 12 to 16 years and with BMI and weight gain according to sex and age is greater than IMCZ-score &gt; 4 DP&gt; 8 kg; obesity “common” non-syndromic; medical decision of surgical placement of laparoscopic gastric banding; adolescent and family who understand and accept the need for medical and surgical follow long term; adolescent and family who fully understood the oral and written</p>

NCT01700738 (Continued)

	<p>information explaining the study and the need for prolonged follow-up; obtention of oral and written consent of the adolescent and the parents; parents and adolescents affiliated with the social security system</p> <p><b>Exclusion criteria:</b> intellectual deficit; psychiatric contraindication of surgical placement of laparoscopic gastric banding; obesity with severe binge eating; pregnancy or wishes of pregnancy in the following year; non accession adolescent and / or family in the process of medical care before inclusion; predictable post surgical monitoring difficulties; suspicion of physical abuse, verbal or negligence / deficiency in care of the family; participation in a clinical study evaluating a treatment during the 2 years of the study; anesthetic contra indication for placement of a gastric laparoscopic; IMC &gt; 50 kg/m<sup>2</sup> the day of inclusion</p>
Interventions	<p><b>Intervention:</b> gastric ring surgery</p> <p><b>Comparator:</b> nutritional help</p>
Outcomes	<p><b>Primary outcome(s):</b> BMI Z-score evolution in 2 years</p> <p><b>Secondary outcome(s):</b> evolution of quality of life scales; evolution of BMIZ-score; evaluation of alimentary troubles and psychiatric troubles; evolution of round-waist; evolution of bodily composition; evolution of metabolic syndrome parameters; evolution of respiratory parameters: polysomnography; determination of success factors of the ring; study of tolerance of the gastric ring</p> <p><b>Other outcome(s):</b> not reported</p>
Starting date	<p><b>Study start date:</b> November 2012</p> <p><b>Study completion date:</b> November 2015</p>
Contact information	<p><b>Responsible party/principal investigator:</b> Regis Coutant, University Hospital of Angers. Email: rcoutant@chu-angers.fr</p>
Notes	<p>When the study was identified it was not yet open for participant recruitment</p> <p>Study sponsor: University Hospital, Angers.</p> <p>ClinicalTrials.gov Identifier: <a href="https://clinicaltrials.gov/ct2/show/study/NCT01700738">NCT01700738</a></p>

NCT02378259

Trial name or title	<p><b>Title:</b> randomized controlled trial; intensive conservative treatment or bariatric surgery for adolescents (13-15 y) with severe obesity (AMOS-RCT)</p>
Methods	<p><b>Type of study:</b> interventional; randomised controlled trial</p> <p><b>Allocation:</b> randomised</p> <p><b>Intervention model:</b> parallel assignment</p> <p><b>Masking:</b> open label</p> <p><b>Primary purpose:</b> treatment</p>
Participants	<p><b>Condition:</b> obesity</p> <p><b>Enrollment:</b> estimated 50</p> <p><b>Inclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>• Age 13-15 years</li> <li>• BMI &gt;35</li> <li>• Failed comprehensive treatment for obesity &gt; 1 year</li> <li>• Passing assessment of psychologist</li> <li>• Tanner stage 3 or more</li> </ul>

	<p><b>Exclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>• Monogenic obesity (for example Prader Willis, Laurence Moon-Bardet-Biedl)</li> <li>• Obesity secondary to brain injury</li> <li>• Severely mentally disabled</li> <li>• Not eligible for general anesthesia</li> <li>• Psychotic or other major psychiatric illness</li> <li>• Previous major gastrointestinal surgery</li> </ul>
Interventions	<p><b>Intervention:</b> Roux-en-Y gastric bypass surgery</p> <p><b>Comparator:</b> intensive conservative treatment</p>
Outcomes	<p><b>Primary outcome measures:</b> body mass index (time frame: 2, 7, 12 and 17 years after treatment initiation)</p> <p><b>Secondary outcome measures:</b></p> <p>Metabolic control (time frame: 2, 7, 12 and 17 years after treatment initiation); glucose control (fP-Glc, fs-Insulin, HbA1c, oral glucose tolerance test); blood lipids (HDL, LDL, TG, Apo A, Apo B); blood pressure (systolic and diastolic); inflammation (LPK, CRP, Adiponectin, IL-6, TNF-alfa); liver function tests (AST, ALT, ALP, Bil)</p> <p>Quality of life (time frame: 2, 7, 12 and 17 years after treatment initiation), mental and physical QoL</p> <p>Socioeconomic development (time frame: 7, 12 and 17 years after treatment initiation), education, civil status, number of children, income, sick leave (from national registries)</p> <p>Health care consumption (time frame: 2, 7, 12 and 17 years after treatment initiation), in-hospital care, outpatient care, prescribed medications (from national registries)</p> <p>Skeletal maturation and quality (time frame: 2, 7, 12 and 17 years after treatment initiation), bone mineral content and bone mineral density will be assessed as well as blood markers for bone formation and resorption</p> <p>Addictive behavior (time frame: 2, 7, 12, 17 years after treatment initiation), alcohol consumption, blood markers for alcohol consumption, drugs, brain response to visual stimuli</p> <p>Mental health (time frame: 2, 7, 12 and 17 years after treatment initiation ) [ Designated as safety issue: Yes ] Depression, anxiety, self esteem, stability in neuropsychiatric disease (ADHD, ADD), psychiatric illness, OCD</p> <p>Adverse events (time frame: 2, 7, 12 and 17 years after treatment initiation), any adverse event (physical, mental or other)</p> <p>Eating function (time frame: 2, 7, 12 and 17 years after treatment initiation), assessment of meal pattern, dietary composition and gastrointestinal symptoms in relation to eating</p> <p>Energy expenditure (time frame: 2 and 7 years after treatment initiation, doubly labelled water, basic metabolic rate, 24h energy expenditure chamber after 7 years)</p> <p><b>Other outcome measures:</b> cancer or precancerous lesions (time frame: 17 years after treatment initiation and later), as this parameter is hard to foresee we might need to extend the time for assessment longer than 17 years</p>
Starting date	<p><b>Study start date:</b> August 2015</p> <p><b>Study completion date:</b> May 2021</p>
Contact information	<p><b>Responsible party/principal investigator:</b> Torsten Olbers, Göteborg University</p>
Notes	<p>When identified this study was not yet recruiting participants</p> <p>Study sponsor: Göteborg University</p> <p>Clinical trials identifier: <a href="#">NCT02378259</a></p> <p>Other study ID number: 578-13</p>

## DATA AND ANALYSES

This review has no analyses.

## ADDITIONAL TABLES

Table 1. Overview of study populations

	Intervention(s) and comparator(s)	Sample size <sup>a</sup>	Screened/eligible [N]	Randomised [N]	Safety [N]	ITT/analysed [N]	Finishing study [N]	Randomised finishing study [%]	Follow-up <sup>b</sup>
<b>O'Brien 2010</b>	I: gastric banding procedure + lifestyle advice	The study was powered assuming that, using an intention-to treat analysis, more than 60% of patients of the gastric banding group would achieve an excess weight loss of more than 50% at 2 years and that less than 10% of the lifestyle group would achieve this weight loss <sup>c</sup> . Using these expected proportions, study	163/84	25	25	25/25 <sup>d</sup>	24	96	24 months

**Table 1. Overview of study populations** (Continued)

		authors required 17 participants in each the study group to provide an 80% power and a 2-sided P value of 0.05. On the basis of a possible loss of 30% after randomisation, 50 adoles-						
	C: lifestyle programme		25	25	25/25 <sup>d</sup>	18	72	
	<b>total:</b>		50	50	50/50	42	84	
<b>Grand total</b>	<b>All interventions</b>		25			24		
	<b>All comparators</b>		25			18		
	<b>All interventions and comparators</b>		50			42		

<sup>a</sup>According to power calculation in study publication or report

<sup>b</sup>Duration of intervention or follow-up, or both, under randomised conditions until end of study

<sup>c</sup>Actual numbers were 84% in the intervention and 12% in the comparator group

<sup>d</sup>Primary analysis only (weight change data)

"-" denotes not reported

ITT: intention-to-treat

## APPENDICES

### Appendix I. Search strategies

#### Cochrane Library (Wiley)

- #1 [mh Ôbesity]
- #2 [mh ^“Obesity, Morbid”]
- #3 [mh ^“Obesity, Abdominal”]
- #4 [mh ^“Pediatric Obesity”]
- #5 [mh Ôverweight]
- #6 [mh ^“Weight Loss”]
- #7 (adipos\* or obes\*):ti,ab,kw
- #8 (overweight\* or “over weight\*”):ti,ab,kw
- #9 (“weight” near/4 (reduc\* or los\* or control\* or gain\*)):ti,ab,kw
- #10 (“body mass ind\*” or “BMI” or “waist hip ratio” or “skinfold thickness”):ti,ab,kw
- #11 {or #1-#10}
- #12 [mh ^“Bariatric Surgery”]
- #13 [mh ^“Gastric Bypass”]
- #14 [mh ^Gastroplasty]
- #15 [mh ^“Jejunioleal Bypass”]
- #16 [mh ^Lipectomy]
- #17 [mh ^Gastroenterostomy]
- #18 [mh ^Gastrectomy]
- #19 [mh ^“Biliopancreatic Diversion”]
- #20 [mh ^“Gastric Balloon”]
- #21 [mh ^“Vagotomy, Truncal”]
- #22 [mh ^Stomach/SU]
- #23 [mh ^“Anastomosis, Roux-en-Y”]
- #24 [mh ^Laparoscopy]
- #25 ((obes\* or “weight loss” or “weight reduction” or antiobes\* or “metabolic” or “gastric” or laparoscop\*) next surg\*):ti,ab,kw
- #26 (“bariatric” next (surg\* or operation\* or procedure\*)):ti,ab,kw
- #27 (surg\* next (procedure\* or intervention\* or treatment\* or “management”)):ti,ab,kw
- #28 (“gastric” near/4 (band\* or imbrication\* or plication\* or “sleeve” or stapl\* or resection\* or reduction\* or “stimulation”)):ti,ab,kw
- #29 ((“gastroileal” or “jejunoileal” or “biliopancreatic” or “gastric” or “stomach”) next “bypass”):ti,ab,kw
- #30 gastrojejunosom\*:ti,ab,kw
- #31 gastrectom\*:ti,ab,kw
- #32 gastroplast\*:ti,ab,kw
- #33 “biliopancreatic diversion”:ti,ab,kw
- #34 (malabsorpti\* next (procedure\* or surg\*)):ti,ab,kw
- #35 “lap band”:ti,ab,kw
- #36 “LAGB”:ti,ab,kw
- #37 “LSG”:ti,ab,kw
- #38 (RYGB\* or “roux en y”):ti,ab,kw
- #39 “duodenal switch”:ti,ab,kw
- #40 “stomach stapl\*”:ti,ab,kw
- #41 “scopinaro”:ti,ab,kw
- #42 ((“mason” or “rose” or “stomaphyx”) next “procedure”):ti,ab,kw
- #43 ((“gastric” or “intra gastric”) next balloon\*):ti,ab,kw

(Continued)

#44 (“endoluminal” or “bypass”) next “sleeve”):ti,ab,kw  
#45 “endobarrier”:ti,ab,kw  
#46 “truncal vagotomy”:ti,ab,kw  
#47 {or #12-#46}  
#48 #11 and #47  
#49 [mh Adolescent]  
#50 [mh Child]  
#51 [mh “Young Adult”]  
#52 [mh Pediatrics]  
#53 “minors”:ti,ab,kw  
#54 (“boy” or “boys” or “boyhood”):ti,ab,kw  
#55 girl\*:ti,ab,kw  
#56 (“kid” or “kids”):ti,ab,kw  
#57 (child\* or schoolchild\*):ti,ab,kw  
#58 adolescen\*:ti,ab,kw  
#59 juvenil\*:ti,ab,kw  
#60 youth\*:ti,ab,kw  
#61 (teen\* or preteen\*):ti,ab,kw  
#62 (underage\* or “under age\*”):ti,ab,kw  
#63 pubescen\*:ti,ab,kw  
#64 (paediatric\* or pediatric\*):ti,ab,kw  
#65 {or #49-#64}  
#66 #48 and #65

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#### MEDLINE (Ovid SP)

---

1 Obesity/  
2 Obesity, Morbid/  
3 Obesity, Abdominal/  
4 Pediatric Obesity/  
5 Overweight/  
6 Weight Loss/  
7 (adipos\* or obes\*).tw.  
8 (overweight\* or over weight\*).tw.  
9 (weight adj3 (reduc\* or los\* or control\* or gain\*)).tw.  
10 (body mass ind\* or BMI or waist hip ratio or skinfold thickness).tw.  
11 or/1-10  
12 Bariatric Surgery/  
13 Gastric Bypass/  
14 Gastroplasty/  
15 Jejunioleal Bypass/  
16 Lipectomy/  
17 Gastroenterostomy/  
18 Gastrectomy/  
19 Biliopancreatic Diversion/  
20 Gastric Balloon/  
21 Vagotomy, Truncal/  
22 Stomach/su [Surgery]  
23 Anastomosis, Roux-en-Y/

(Continued)

- 24 Laparoscopy/
- 25 ((obes\* or weight loss or weight reduction or antiobes\* or metabolic or gastric or laparoscop\*) adj1 surg\*).tw.
- 26 (bariatric adj1 (surg\* or operation? or procedure?)).tw.
- 27 (surg\* adj1 (procedure? or intervention? or treatment? or management)).tw.
- 28 (gastric adj3 (band\* or imbrication? or plication? or sleeve or stapl\* or resection? or reduction? or stimulation)).tw.
- 29 ((gastroileal or jejunoileal or biliopancreatic or gastric or stomach) adj1 bypass).tw.
- 30 gastrojejunostom\*.tw.
- 31 gastrectom\*.tw.
- 32 gastroplast\*.tw.
- 33 biliopancreatic diversion.tw.
- 34 (malabsorpti\* adj1 (procedure\* or surg\*)).tw.
- 35 lap band.tw.
- 36 LAGB.tw.
- 37 LSG.tw.
- 38 (RYGB\* or roux en y).tw.
- 39 duodenal switch.tw.
- 40 stomach stapl\*.tw.
- 41 scopinaro.tw.
- 42 ((mason or rose or stomaphyx) adj1 procedure).tw.
- 43 ((gastric or intragastric) adj1 balloon).tw.
- 44 ((endoluminal or bypass) adj1 sleeve).tw.
- 45 endobarrier.tw.
- 46 truncal vagotomy.tw.
- 47 or/12-46
- 48 11 and 47
- [49-65 Ovid SP adaptation of pediatric filter for PubMed by Leclercq 2013]
- 49 Adolescent/
- 50 Child/
- 51 Young Adult/
- 52 Pediatrics/
- 53 minors.tw.
- 54 (boy or boys or boyhood).tw.
- 55 girl\*.tw.
- 56 (kid or kids).tw.
- 57 (child\* or schoolchild\*).tw.
- 58 adolescen\*.tw.
- 59 juvenil\*.tw.
- 60 youth\*.tw.
- 61 (teen\* or preteen\*).tw.
- 62 (underage\* or under age\*).tw.
- 63 pubescen\*.tw.
- 64 p?ediatric\*.tw.
- 65 or/49-64
- 66 48 and 65
- [Lefebvre 2011 Cochrane Handbook 2008 RCT filter - sensitivity maximizing version, without "drug therapy.fs"]
- 67 randomized controlled trial.pt.
- 68 controlled clinical trial.pt.
- 69 randomi?ed.ab.
- 70 placebo.ab.



(Continued)

71 randomly.ab.  
72 trial.ab.  
73 groups.ab.  
74 or/67-73  
75 exp animals/ not humans/  
76 74 not 75  
77 66 and 76

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**PubMed**

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#1 adipos\*[tw] OR obes\*[tw] OR overweight\*[tw] OR over weight\*[tw] OR weight reduc\*[tw] OR weight los\*[tw] OR weight control\*[tw] OR weight gain\*[tw]  
#2 bariatric[tw] OR gastric[tw] OR band\*[tw] OR sleeve\*[tw] OR resection\*[tw] OR jejunoileal[tw] OR biliopancreatic[tw] OR bypass[tw] OR gastrojejunostom\*[tw] OR gastrectom\*[tw] OR gastroplast\*[tw] OR malabsorpti\*[tw] OR "lap band"[tw] OR LAGB[tw] OR LSG[tw] OR RYGB\*[tw] OR "roux en y"[tw] OR "duodenal switch"[tw] OR stomach stapl\*[tw] OR balloon\*[tw] OR endobarrier[tw] OR "truncal vagotomy"[tw]  
#3 #1 AND #2  
#4 minors[tw] OR boy[tw] OR boys[tw] OR boyhood[tw] OR girl\*[tw] OR kid[tw] OR kids[tw] OR child\*[tw] OR schoolchild\*[tw] OR adolescen\*[tw] OR juvenil\*[tw] OR youth\*[tw] OR teen\*[tw] OR preteen\*[tw] OR underage\*[tw] OR under age\*[tw] OR pubescen\*[tw] OR paediatric\*[tw] OR pediatric\*[tw]  
#5 #3 AND #4  
#6 #5 not medline[sb] not pmcbook

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**EMBASE (Ovid SP)**

---

1 Obesity/  
2 Morbid Obesity/  
3 Abdominal Obesity/  
4 Childhood Obesity/  
5 Overnutrition/  
6 Weight Reduction/  
7 (adipos\* or obes\*).tw.  
8 (overweight\* or over weight\*).tw.  
9 (weight adj3 (reduc\* or los\* or control\* or gain\*)).tw.  
10 (body mass ind\* or BMI or waist hip ratio or skinfold thickness).tw.  
11 or/1-10  
12 Bariatric Surgery/  
13 Biliopancreatic Bypass/  
14 Gastric Banding/  
15 Sleeve Gastrectomy/  
16 Stomach surgery/  
17 Gastrectomy/  
18 Stomach Bypass/  
19 Gastroenterostomy/  
20 Intestine Bypass/  
21 Jejunioleal Bypass/  
22 Intestine anastomosis/  
23 Roux Y anastomosis/  
24 Gastroenterostomy/

(Continued)

25 Lipectomy/  
26 Gastric Balloon/  
27 Gastric Band/  
28 Truncus vagotomy/  
29 ((obes\* or weight loss or weight reduction or antiobes\* or metabolic or gastric or laparoscop\*) adj1 surg\*).tw.  
30 (bariatric adj1 (surg\* or operation? or procedure?)).tw.  
31 (surg\* adj1 (procedure? or intervention? or treatment? or management)).tw.  
32 (gastric adj3 (band\* or imbrication? or plication? or sleeve or stapl\* or resection? or reduction? or stimulation)).tw.  
33 ((gastroileal or jejunoileal or biliopancreatic or gastric or stomach) adj1 bypass).tw.  
34 gastrojejunosom\*.tw.  
35 gastrectom\*.tw.  
36 gastroplast\*.tw.  
37 biliopancreatic diversion.tw.  
38 (malabsorpti\* adj1 (procedure\* or surg\*)).tw.  
39 lap band.tw.  
40 LAGB.tw.  
41 LSG.tw.  
42 (RYGB\* or roux en y).tw.  
43 duodenal switch.tw.  
44 stomach stapl\*.tw.  
45 scopinaro.tw.  
46 ((mason or rose or stomaphyx) adj1 procedure).tw.  
47 ((gastric or intragastric) adj1 balloon).tw.  
48 ((endoluminal or bypass) adj1 sleeve).tw.  
49 endobarrier.tw.  
50 truncal vagotomy.tw.  
51 or/12-50  
52 11 and 51  
53 Juvenile/  
54 Adolescent/  
55 Child/  
56 Young adult/  
57 Pediatrics/  
58 minors.tw.  
59 (boy or boys or boyhood).tw.  
60 girl\*.tw.  
61 (kid or kids).tw.  
62 (child\* or schoolchild\*).tw.  
63 adolescen\*.tw.  
64 juvenil\*.tw.  
65 youth\*.tw.  
66 (teen\* or preteen\*).tw.  
67 (underage\* or under age\*).tw.  
68 pubescen\*.tw.  
69 p?ediatric\*.tw.  
70 or/53-69  
71 52 and 70  
[Wong 2006 "sound treatment studies" filter - BS version]  
72 random\*.tw. or clinical trial\*.mp. or exp health care quality/

(Continued)

73 71 and 72  
74 limit 73 to embase

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**LILACS (IAHx)**

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(MH:“Bariatric Surgery” OR MH:“Gastroenterostomy” OR MH:“Obesity/surgery” OR MH:“Obesity, Morbid/surgery” OR MH:“Obesity, Abdominal/surgery” OR ((bariatric\$ OR obes\$ OR gastric\$) AND (surg\* OR cirug\* OR cirurg\*)) OR (gastr\$ AND (band\$ OR bypass OR sleeve OR vertic\$ OR derivac\$)) OR gastrojejun\$ OR (biliopancreatic AND (diversion OR derivac\$ OR bypass)) OR gastroplast\$) AND (MH:“Adolescent” OR MH:“Child” OR MH:“Young Adult” OR MH:“Pediatrics” OR boy OR boys OR girl\$ OR kid OR kids OR child\$ OR schoolchild\$ OR adolescen\$ OR juvenil\$ OR youth\$ OR teen\$ OR preteen\$ OR underage\$ OR pubescen\$ OR paediatric\$ OR pediatri\$ OR joven\$ OR jovem\$ OR juvenil\$ OR niños OR niñas OR criancas OR menin\$)  
+ Filter “Controlled Clinical Trial”

---

**ICTRP trial register (Standard search)**

---

bariatric AND child\* OR  
bariatric AND adolesc\* OR  
bariatric AND young\* OR  
obes\* AND surg\* AND child\* OR  
obes\* AND surg\* AND adolesc\* OR  
obes\* AND surg\* AND young\* OR  
obes\* AND bypass\* AND child\* OR  
obes\* AND bypass\* AND adolesc\* OR  
obes\* AND bypass\* AND young\* OR  
obes\* AND gastr\* AND child\* OR  
obes\* AND gastr\* AND adolesc\* OR  
obes\* AND gastr\* AND young\* OR  
obes\* AND biliopancreatic AND child\* OR  
obes\* AND biliopancreatic AND adolesc\* OR  
obes\* AND biliopancreatic AND young\* OR  
obes\* AND jejun\* AND child\* OR  
obes\* AND jejun\* AND adolesc\* OR  
obes\* AND jejun\* AND young\* OR  
obes\* AND band\* AND child\* OR  
obes\* AND band\* AND adolesc\* OR  
obes\* AND band\* AND young\* OR  
obes\* AND endoluminal AND child\* OR  
obes\* AND endoluminal AND adolesc\* OR  
obes\* AND endoluminal AND young\* OR  
obes\* AND endobarrier AND child\* OR  
obes\* AND endobarrier AND adolesc\* OR  
obes\* AND endobarrier AND young\*

---

**ClinicalTrials.gov trial register (Advanced search)**

---

**Conditions:** adiposity OR adipose OR obese OR obesity OR overweight OR “over weight”

**Interventions:** surgery OR surgical OR bariatric OR gastroenterostomy OR gastrojejunostomy OR gastrectomy OR gastroplasty OR gastric OR band OR banding OR balloon OR roux OR lipectomy OR bypass OR LAGB OR LSG OR RYGB OR duodenal OR sleeve OR endobarrier

(Continued)

Age Group: Child

## Appendix 2. Description of interventions

	Intervention(s)	Comparator(s)
<b>O'Brien 2010</b>	Gastric banding procedure (LAP-BAND® adjustable gastric banding system) Lifestyle advice (eating rules and physical activity)	Lifestyle program (dietary and exercise advice (assessed by pedometers and food diary), behavioural modification, group outings and a personal trainer for 6 weeks)

## Appendix 3. Baseline characteristics (I)

	Intervention(s) and comparator(s)	Duration of intervention (duration of follow-up)	Participating population	Study period [year to year]	Country	Setting	Duration of obesity [mean years (SD)]	Comedications / Cointerventions	Comorbidities
<b>O'Brien 2010</b>	I: gastric banding procedure + lifestyle advice	After the procedure clinical reviews were conducted approximately every 6 weeks for 2 years (24 months)	Severely obese adolescents with identifiable medical complications, physical limitations or psychosocial difficulties	May 2005 to September 2008	Melbourne, Australia	Community clinic or Centre for Adolescent Health, Royal Children's Hospital Gastric banding procedures were conducted at a private hospital	-	-	Identifiable medical complications such as hypertension, metabolic syndrome, asthma, back pain; physical limitations such as an inability to play a sport, difficulties with activities

(Continued)

										of daily living; psychosocial difficulties such as isolation or low self-esteem, and subject to bullying that stems from obesity
	C: lifestyle programme	Consultation occurred approx. every 6 weeks throughout the 24-month study period; a personal trainer was provided to each participant for a 6-week period (24 months)								
<p>“-” denotes not reported  C: comparator; I: intervention; SD: standard deviation</p>										

#### Appendix 4. Baseline characteristics (II)

	Intervention(s) and comparator(s)	Sex [female %]	Age [mean years (SD)]	BMI [mean kg/m <sup>2</sup> (SD)]	BMI score (SD)	z-	Weight [mean kg (SD)]	Waist circumference [mean cm (SD)]	BP systolic [mean mm Hg (SD)]	BP diastolic [mean mm Hg (SD)]
O'Brien 2010	I: gastric banding procedure + lifestyle advice	64	16.5 (1.4)	42.3 (6.1)	2.54 (31)	(0.	120.7 (25.3)	120.8 (14.2)	122 (14)	72 (8)
	C: lifestyle programme	72	16.6 (1.2)	40.4 (3.1)	2.46 (22)	(0.	115.4 (14.0)	118.1 (10.6)	133 (16)	77 (11)

“-” denotes not reported

BMI: body mass index; BMI z-score (BMI standard deviation score): measure of relative weight adjusted for child age and sex; BP: blood pressure; C: comparator; I: intervention; SD: standard deviation

## Appendix 5. Matrix of study endpoints (publications and trial documents)

	Endpoints quoted in trial document(s) (ClinicalTrials.gov, FDA/EMA document, manufacturer's web site, published design paper) <sup>a</sup>	Study results posted in trial register (publications specified in trial register)	Endpoints quoted in publication(s) <sup>b,c</sup>	Endpoints quoted in abstract of publication(s) <sup>b,c</sup>
O'Brien 2010	Source: AC-TRN12605000160639 (retrospectively registered) Primary outcome measure(s): at the end of the 2-year period following randomization: % of participants who achieve a weight loss of 50% of excess BMI corrected for age; the initial BMI will be adjusted for age (z-score)	No (yes - O'Brien 2010)	Primary outcome measure(s): the primary endpoint was whether participants could lose 50% excess weight	Primary outcome measure(s): weight loss (% loss of excess weight, kg, BMI, BMI z-score)

(Continued)

	<p><b>Secondary outcome measure(s):</b>          difference in weight, height, skinfolds at triceps, minimal abdominal, maximal gluteal circumferences and neck circumference at the upper border of the thyroid cartilage (at 24 months); functional status using SF36, multi-dimensional body-self relation questionnaire, Beck depression inventory, child health questionnaire, binge eating scale, step fitness (pedometers) - at 6,12, and 24 months; relationship of primary outcome with University of Rhode Island change assessment (URICA) scale - at 2 years; changes in comorbidities (including hypertension, impaired fasting glucose, hyperinsulinaemia, insulin resistance and pancreatic beta cell function, dyslipidaemia, clinical polycystic ovary syndrome, markers for obesity related liver dysfunction (NAFLD), obstructive sleep apnoea, excessive daytime sleepiness and asthma) - at 6,12 and 24 months; side effects of treatment with emphasis on compliance, peri-operative problems, postoperative vomiting, need for revisional procedures, cost of therapy for both arms - at 24 months</p>		<p><b>Secondary outcome measure(s):</b>          health (health status was documented by clinical assessment and investigations at the initial assessment before randomization, and at 12 and 24 months after randomization); quality of life (using the child health questionnaire (CHQ CF-50)); adverse events resulting from treatment or from failure of compliance with the protocol</p>	<p><b>Secondary outcome measure(s):</b>          metabolic syndrome, quality of life, adverse outcomes</p>
	<p><b>Other outcome measure(s):</b>          -</p>		<p><b>Other outcome measure(s):</b>          total weight loss (kg), per-</p>	<p><b>Other outcome measure(s):</b></p>

(Continued)

			centage of total weight lost, percentage of excess weight lost, change in BMI and BMI z score; anthropometric measures included neck, waist, and hip circumference; metabolic syndrome (defined by the age-specific adolescent criteria of Joliffe and Janssen linked to the Adult Treatment Panel III 21 criteria); hypertension (adjusted for age); insulin sensitivity and pancreatic $\beta$ -cell function (homeostatic model assessment (HOMA); adverse events included perioperative complications, revisional or other gastric banding procedures, protocol violations, adverse drug or treatment effects, hospitalizations, new disease diagnoses, and loss to follow-up	
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- denotes not reported

<sup>a</sup>Trial document(s) refers to all available information from published design papers and sources other than regular publications (e.g. FDA/EMA documents, manufacturer's web sites, trial registers)

<sup>b</sup>Publication(s) refers to trial information published in scientific journals (primary reference, duplicate publications, companion documents or multiple reports of a primary study)

<sup>c</sup>Other outcome measures refer to all outcomes not specified as primary or secondary outcome measures  
BMI: body mass index; EMA: European Medicines Agency; FDA: Food and Drug Administration (US)

## Appendix 6. Examination of outcome reporting bias according to ORBIT classification

	Outcome	High risk of bias (category A) <sup>a</sup>	High risk of bias (category D) <sup>b</sup>	High risk of bias (category E) <sup>c</sup>	High risk of bias (category G) <sup>d</sup>
<b>O'Brien 2010</b>	N/A				

<sup>a</sup>Clear that outcome was measured and analysed; trial report states that outcome was analysed but only reports that result was not significant  
(Classification 'A', table 2, [Kirkham 2010](#))

(Classification 'A', table 2, [Kirkham 2010](#))

<sup>b</sup>Clear that outcome was measured and analysed; trial report states that outcome was analysed but no results reported



(Continued)

(Classification 'D', table 2, [Kirkham 2010](#))

<sup>c</sup>Clear that outcome was measured; clear that outcome was measured but not necessarily analysed; judgement says likely to have been analysed but not reported because of non-significant results

(Classification 'E', table 2, [Kirkham 2010](#))

<sup>d</sup>Unclear whether the outcome was measured; not mentioned but clinical judgement says likely to have been measured and analysed but not reported on the basis of non-significant results

(Classification 'G', table 2, [Kirkham 2010](#))

N/A: not applicable

## Appendix 7. Definition of endpoint measurement (I)

	Body mass index	Adverse events	Health-related quality of life and self-esteem	All-cause mortality	Morbidity
<b>O'Brien 2010</b>	Expressed as change in BMI (kg/m <sup>2</sup> ) and BMI z score (reference: Centers for Disease Control and Prevention (CDC) growth charts)	Adverse events included perioperative complications, revisional or other gastric banding procedures, protocol violations, adverse drug or treatment effects, hospitalisations, new disease diagnoses, and loss to follow-up. A serious/severe adverse event was not defined	Quality of Life - measured using the Child Health Questionnaire (CHQ CF-50) The questionnaire was administered to each adolescent alone, prior to randomisation, and at 2 years after entry. The CHQCF-50 has 11 validated subscores. Each item was scored and transformed into 10 final subscores with values ranging from 0 to 100, and 1 subscore (change of health) with 5 levels	N/I	Health status was documented by clinical assessment and investigations at the initial assessment before randomisation, and at 12 and 24 months after randomisation: metabolic syndrome, defined by the age-specific adolescent criteria linked to the Adult Treatment Panel III hypertension was adjusted to age and defined using the 2004 report of the National High Blood Pressure Education Program Working Group on High Blood

(Continued)

						Pressure in Children and Adolescents	
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BMI: body mass index; BMI z-score (BMI standard deviation score): measure of relative weight adjusted for child age and sex; N/D: not defined; N/I: not investigated

## Appendix 8. Definition of endpoint measurement (II)

	Measures of body fat distribution	Behaviour change	Participants views of the intervention	Socioeconomic effects
<b>O'Brien 2010</b>	Anthropometric measures included neck, waist, and hip circumference - no reference; total weight loss (kg), percentage of total weight lost	N/I	N/I	N/I

N/D: not defined; N/I: not investigated

## Appendix 9. Adverse events (I)

	Intervention(s) and comparator(s)	Randomised or safety population [N]	Deaths [N (%)]	Participants with reoperations [N]	Participants with reoperations [%]	Participants with adverse events [N]	Participants with adverse events [%]	Participants with severe/serious adverse events [N(%)]	Participants discontinuing study due to adverse events
<b>O'Brien 2010</b>	I: gastric banding procedure + lifestyle program	25	0 (0)	7	28	12	48	-	0 (0)
	C: lifestyle programme	25	0 (0)	N/A	N/A	11	44	-	0 (0)

(Continued)

	all:	50	0 (0)	N/A	N/A	23	46	-	0 (0)
<p>“-” denotes not reported          C: comparator; I: intervention; N/A: not applicable</p>									

## Appendix 10. Adverse events (II)

	Intervention (s) and comparator(s)	Randomised or safety population [N]	Participants hospitalised [N]	Participants hospitalised [%]	Participants with specific adverse events [description]	Participants with specific adverse events [N]	Participants with specific adverse events [%]
O'Brien 2010	I: gastric banding procedure + lifestyle program	25	9	36	(1) Proximal gastric enlargements (2) Needle stick injury to tubing (3) Acute cholecystitis (+ cholecystectomy) (4) Hospital admission for depression (5) Lost to follow-up (6) Unplanned pregnancy	(1) 6 (2) 2 (3) 1 (4) 1 (5) 1 (6) 2	(1) 24 (2) 8 (3) 4 (4) 4 (5) 4 (6) 8
	C: lifestyle programme	25	2	8	(1) Hospital admission for depression and intracranial hypertension (2) Cholelithiasis (+ cholecystectomy) (3) Lost to follow-up (4) Un-	(1) 1 (2) 1 (3) 7 (4) 2	(1) 4 (2) 4 (3) 28 (4) 8

(Continued)

					planned pregnancy		
	all:	50	11	22			

“-” denotes not reported  
C: comparator; I: intervention

## Appendix 11. Survey of authors providing information on included trials

	Study author contacted [DD/MM/YY]	Study author replied [DD/MM/YY]	Study author asked for additional information [short summary]	Study author provided data [short summary]
<b>O'Brien 2010</b>	24/01/2014 24/04/2014	24/01/2014 30/04/2014	Asked to provide data on outpatient visits for adverse events table and to describe how allocation was concealed	Author provided data on number of outpatient visits but stressed that these were not adverse events. He also confirmed allocation was concealed
<b>AC-TRN12609001004257</b>	31/03/2015	20/04/2015	Asked on the current status of the trial and whether results were published	Currently 23 participants in the control arm and 21 participants in the intervention arm. Recruitment will continue until 50 participants are included

## Appendix 12. Health-related quality of life: instruments

	Name [type of measurement]	Dimensions (sub-scales)	Validated instrument	Answer options	Scores	Minimum score Maximum score	Weighting of scores	Direction of scales	Minimal important difference
	Child Health Questionnaire (G)	BE - global behaviour BEHAV BP - bodily pain	Multidimensional generic measure of HrQoL;	Likert rating scale	Scores can be analysed separately, the CHQ	Scores are transformed to a 0-100 scale, with	None	Range on sub-scales and the overall scale is 0-	Poor HRQoL has been defined as 2 SDs be-

(Continued)

		CH - change in health FA - family activities FC - family cohesion GH - general health MH - mental health PE - parental impact emotional PF - physical functioning PT - parental impact time REB - role social-emotional behaviour RP - role social-physical SE - self-esteem	validated		profile scores, or combined to derive an overall physical and psychosocial score, the CHQ summary scores; the CHQ measures 14 unique physical and psychosocial concepts (physical functioning, role/social-physical, general health perceptions, bodily pain, parental time impact, parental emotional impact, parental emotional impact, role/social-emotional/behavioural, self-esteem, mental health,	a mean of 50 and an SD of 10		100, where 0 = worst possible health state and 100 = best possible health state; individual or population means of can be compared to a normative sample	low the mean of the normative sample or a physical functioning or psychosocial health summary score <30
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(Continued)

					general behaviour, family activities, family cohesion, change in health); the parent form is available in 2 lengths - 50 or 28 items							
O'Brien 2010		LAGB (initial) [SD/median and interquartile range] N = 25	LAGB (final) [SD] N = 24	Intra-group value	P	Lifestyle (initial) [SD/median and interquartile range] N = 25	Lifestyle (final) [SD] N = 18	Intra-group value	P	Inter-group value	P	Community norms
	BE	59.1 (19)	64.0 (21)	0.42		58.0 (19)	58.6 (19)	0.80		0.27		77.5
	FA	70.5 (23)	85.6 (16)	0.006		73.1 (18)	80.2 (23)	0.60		0.12		72.5
	FC	52.8 (24)	50.8 (32)	0.76		62.8 (23)	70.8 (23)	0.48		0.52		71.2
	GH	47.8 (17)	65.7 (21)	0.003		47.1 (15)	53.7 (15)	0.044		0.37		68.1
	MH	75.0 (65-81)	73.0 (3.3)	0.66		65.6 (56-75)	67.0 (2.5)	0.90		0.69		74.9
	PF	73.1 (18)	94.4 (6.6)	<.001		80.4 (20)	78.1 (24)	0.79		0.002		94.8
	SE	55.9 (18)	70.3 (21)	0.012		60.5 (15)	62.7 (22)	0.94		0.21		74.6
	CH	2.48 (0.8)	4.38 (0.8)	<.001		2.96 (0.8)	3.56 (1.2)	0.094		0.006		3.54

CHQ: child health questionnaire; G: generic; HrQoL: health-related quality of life; LABG: laparoscopic adjustable gastric banding; SD: standard deviation

## WHAT'S NEW

Last assessed as up-to-date: 30 March 2015.

Date	Event	Description
23 July 2014	Amended	Given the rapid growth in the treatment of child and adolescent obesity, the original review formerly published as "Interventions for treating obesity in children and adolescents" has now been split into six separate reviews (see <a href="#">Differences between protocol and review</a> ).

## CONTRIBUTIONS OF AUTHORS

Louisa J Ells (LJE): search strategy development, acquiring trial reports, trial selection, data extraction, data analysis, data interpretation, review draft and update draft.

Emma Mead (EM): search strategy development, acquiring trial reports, trial selection, data extraction, data analysis, data interpretation, review draft and update draft.

Greg Atkinson (GA): search strategy development, trial selection, data extraction, data analysis, data interpretation, review draft and update draft.

Louise Baur (LB): search strategy development, trial selection, data interpretation, review draft and update draft.

Eva Corpeleijn (EC): search strategy development, trial selection, data interpretation, review draft and update draft.

Russell Viner (RV): interpretation, review draft and update draft.

Kath Roberts (KR): trial selection, data extraction, data analysis, data interpretation, review draft and update draft.

Maria-Inti Metzendorf (MIM): search strategy development, update draft.

Bernd Richter (BR): acquiring trial reports, trial selection, data extraction, data analysis, data interpretation, review draft and update draft.

## DECLARATIONS OF INTEREST

LJE: none known.

EM: none known.

GA: none known.

LB: none known.

EC: none known.

RV: none known.

KR: none known.

MIM: none known.

BR: none known.

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Given the rapid growth in the treatment of child and adolescent obesity, the original review has now been split into six separate reviews, with a specific intervention and age focus.

1. Diet, physical activity and behavioural interventions for the treatment of overweight or obesity in adolescents aged 12 to 17 years.
2. Diet, physical activity and behavioural interventions for the treatment of overweight or obesity in children aged 5 to 11 years.
3. Diet, physical activity and behavioural interventions for the treatment of overweight or obesity in infants aged 0 to 4 years.
4. Drug interventions for the treatment of obesity in children and adolescents.
5. Parent only interventions for childhood overweight or obesity.
6. Surgery for the treatment of obesity in children and adolescents.

A new search strategy was developed (see [Appendix 1](#)) to reflect advances in bariatric surgery that may not have been adequately captured by the original search strategy.

## NOTES

Part of the background, the methods section, the appendices, additional tables, [Figure 1](#) and [Figure 2](#) of this review are based on a standard template established by the CMED Group.

## INDEX TERMS

### Medical Subject Headings (MeSH)

Australia; Gastroplasty [\*methods]; Life Style; Pediatric Obesity [\*surgery]; Quality of Life; Randomized Controlled Trials as Topic; Weight Loss

### MeSH check words

Adolescent; Child; Female; Humans; Male