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[Intervention Protocol]

Bariatric surgery in adults with obesity and diabetes mellitus: a network meta-analysis

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To investigate comparative medium- and long-term effects and safety, and to obtain a clinically meaningful ranking of different metabolic bariatric surgery procedures (adjustable gastric banding, sleeve gastrectomy, Roux-en-Y gastric bypass, one-anastomosis gastric bypass, gastric plication, biliopancreatic diversion with duodenal switch, and their variations) compared to each other and to non-surgical treatment (e.g. usual care with intensive lifestyle interventions or pharmacotherapy) on outcomes relevant to adults with obesity and type 2 diabetes, by considering both randomised controlled trials and cohort studies.

BACKGROUND

Description of the condition

Obesity is an abnormal or excessive accumulation of body fat that negatively affects health (WHO 2000a). The World Health Organization (WHO) and several other (medical) societies and organisations consider obesity to be a chronic disease (Bray 2017). Longitudinal studies in people with obesity have shown little change in weight loss or reversal of obesity without treatment (Johns 2016; Look AHEAD Research Group 2014; Sjöström 2007), and suggest a high potential for relapse after treatment (Bray 2017; Knowler 2009).

Body mass index (BMI) is the most commonly used measure of obesity. It is calculated as body weight in kilograms divided by height in meters squared (kg/m^2). The WHO defines obesity as $\text{BMI} \geq 30 \text{ kg}/\text{m}^2$. Severe (class II) obesity is classified as BMI between $35 \text{ kg}/\text{m}^2$ and $39.9 \text{ kg}/\text{m}^2$; and morbid obesity (class III) as $\text{BMI} \geq 40 \text{ kg}/\text{m}^2$ (WHO 2000a). As ethnic differences in body composition affect the association between BMI and health risks (Rush 2009, Wulan 2010), cut-off values vary between ethnic groups. For example, lower BMI values define obesity in some Asian populations (WHO 2000b).

Diabetes mellitus is a group of metabolic disorders characterised by a high blood glucose level (hyperglycaemia) over a prolonged period of time (ADA 2019). There are different types of diabetes mellitus: type 1 diabetes, type 2 diabetes (T2D), and gestational diabetes. The commonly used diagnostic method for diabetes mellitus is a test for the glucose content in the blood, using fasting plasma glucose levels ($\text{FPG} \geq 7.0 \text{ mmol}/\text{L}$ ($126 \text{ mg}/\text{dL}$)), two-hour plasma glucose levels after a 75 g oral glucose load during a glucose tolerance test ($\geq 11.1 \text{ mmol}/\text{L}$ ($200 \text{ mg}/\text{dL}$)), or glycosylated haemoglobin (HbA1c; $\geq 48 \text{ mmol}/\text{mol}$ ($\geq 6.5 \%$ (ADA 2019))). If left untreated, diabetes can cause many long-term health complications (van Dieren 2010).

According to the most recent estimates by the WHO, the global prevalence of obesity nearly tripled between 1975 and 2016, with 650 million (13%) adults suffering from obesity in 2016 (WHO 2021a). It is predicted that about 60% (4 billion people) of the global adult population will have overweight or obesity by 2050, compared to 38% in 2010 (Bodirsky 2020). The global prevalence of diabetes is nearly 10% in adults; T2D is the most common type of diabetes (90% to 95% of diabetes cases). An estimated 425 million adults are living with T2D worldwide (Roth 2018). The majority of people with T2D have obesity (Eckel 2011), and an estimated 44% of the global diabetes burden is attributable to overweight and obesity (EASO 2021). The global surge in obesity is closely linked to the substantial increase in T2D in recent decades (Eckel 2011). It has been predicted that by 2045, 700 million adults will have T2D (Cho 2018).

The occurrence of obesity and T2D is closely linked to social determinants of health, conditions into which people are born, grow, live, work, and age, and which have a major impact on health inequities (Cockerham 2022; Hill-Briggs 2021; WHO 2023). The prevalence of both obesity and T2D is disproportionately high in populations with low socioeconomic status who live in deprived neighbourhoods, and in ethnic minorities (Hales 2018; Hayes 2019; Hill-Briggs 2023).

High BMI ($\text{BMI} \geq 25 \text{ kg}/\text{m}^2$) and T2D are amongst the leading global causes of mortality and morbidity (Roth 2018; WHO 2021b). Global mortality attributable to high BMI more than doubled between 1990 and 2017 (Dai 2020). In 2019, overweight and obesity were responsible for five million premature deaths (Murray 2020). Severe and morbid obesity ($\text{BMI} \geq 35 \text{ kg}/\text{m}^2$), in particular, are associated with higher overall mortality rates (Di Angelantonio 2016). People with T2D are at increased risk for many serious health outcomes, including vascular complications, such as stroke and coronary heart disease, and microvascular complications, including neuropathy, nephropathy, or retinopathy, which can all lead to premature death (Peters 2014; Sarwar 2010; Shen 2017; van Dieren 2010). The presence of T2D doubles the risk of mortality, regardless of the absence or presence of cardiovascular diseases (Beckman 2013). According to the International Diabetes Federation, four million people died from diabetes in 2017. Thus, diabetes accounted for 15% of all deaths worldwide (Murray 2020). Total deaths from T2D increased from 2007 to 2017 by nearly 50% (Fry 2018).

According to the Global Burden of Disease study, the number of disability-adjusted life-years (DALYs) attributable to high BMI more than doubled between 1990 and 2017. After cardiovascular diseases, T2D was the leading cause of high BMI-related DALYs (Dai 2020). In 2017, T2D accounted for 57.4 million DALYs, and increased by 35% between 2007 and 2017. High fasting glucose and high BMI were the third and fifth leading risk factors for attributable DALYs in 2019 (Murray 2020). Individuals with severe or morbid obesity are also more likely to have reduced health-related quality of life (HRQoL), and often suffer from depression, anxiety, social stigma, and discrimination (Collins 2016; Kolotkin 2002; Owen-Smith 2014; Wu 2018). The stigma from both weight and diabetes (self-stigma and perceived stigma, by, for example, healthcare professionals) has been shown to be associated with adverse psychological and physiological outcomes, and may negatively affect self-care behaviours as well as the (perceived) quality of health care (Alimoradi 2020; Puhl 2020; Puhl 2022; Wu 2018).

Besides their major impact on DALYs, obesity and T2D lead to substantial costs for the health and social welfare systems. It has been estimated that obesity accounts for 0.7% to 2.8% of a country's total healthcare costs. Direct medical costs for individuals with obesity are 30% higher than those of their peers with normal weight (Withrow 2011). Similarly, T2D and its complications are associated with high direct (medical care) and indirect costs (loss of productivity or earnings). The absolute global economic burden of diabetes in adults will increase from USD 1.3 trillion in 2015 to USD 2.1 to 2.5 trillion by 2030, which corresponds to an increase of up to 92% (Bommer 2018). In 2017, diabetes cost more than USD 727 billion in health expenditure, which is 12% of the global health expenditure (Cho 2018).

Description of the intervention

Contemporary obesity management aims to achieve weight loss by starting with conservative treatments (i.e. lifestyle interventions), followed by pharmacotherapy or surgery (González-Muniesa 2017). However, non-surgical approaches appear to have limited success in achieving desired weight loss (e.g. $\geq 5\%$ of baseline weight) in people with (severe) obesity (Loveman 2011). For people with T2D, especially those receiving pharmacotherapy, a high treatment burden due to negotiating healthcare services, medical expenses,

and mental and physical exhaustion associated with self-care has been described (González-Saldivar 2022; Spencer-Bonilla 2021).

Sustained weight loss and adequate treatment of comorbidities, such as T2D, may be realised through metabolic bariatric surgery (MBS). In people with T2D, MBS is indicated for adults with a BMI ≥ 30 kg/m² (Eisenberg 2022). Potential contraindications for MBS include severe heart failure, unstable coronary artery disease, end-stage lung disease, active cancer, cirrhosis with portal hypertension, uncontrolled drug or alcohol abuse, non-stabilised psychotic disorders, and severely impaired intellectual capacity (Fried 2013; SAGES 2008).

MBS includes procedures aimed at a permanent reduction of food intake. Most MBS procedures combine a reduction of stomach size with a re-routing of the small intestine. The length of the bypassed small intestine and the number of anastomoses vary depending on the approach used (Nguyen 2017). This Cochrane review will consider all existing and commonly used MBS procedures.

(i) Adjustable gastric banding (AGB) is the least invasive bariatric procedure, which technically, is reversible. Food intake is limited by placing an adjustable silicone band around the proximal fundus of the stomach, which creates a small stomach pouch. The band can be adjusted by adding or removing fluid via a subcutaneous port (Colquitt 2014; Nguyen 2017).

(ii) Gastric plication (GP), also called greater curvature plication/gastric imbrication, is a procedure in which the greater curvature of the stomach is folded and secured with sutures to reduce the gastric volume without gastric resection (Albanese 2015).

(iii) Sleeve gastrectomy (SG) is a non-reversible procedure that reduces the size of the stomach by vertical division. The gastrointestinal passage remains unchanged. Originally, SG was established as the first of a two-step procedure to create a duodenal switch (Colquitt 2014). However, due to its positive effects on body weight, and technical feasibility in people with super obesity, SG was developed as a stand-alone approach. It is now the most commonly used MBS procedure worldwide (Arterburn 2020; Pucci 2019; Ramos 2019). Variations of the SG, which are typically carried out as revision procedures, aim to further improve weight loss and metabolic control. These procedures commonly combine SG with re-routing of the small intestine; sleeve gastrectomy with duodenojejunal bypass (SG-DJB), or single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S).

(iv) Roux-en-Y gastric bypass (RYGB) and its variations (e.g. banded gastric bypass) have long been considered the gold standard of MBS. A RYGB combines a longitudinal gastric pouch with re-routing of the small intestine, bypassing the gastric fundus and 50 cm to 100 cm of the proximal jejunum (Nguyen 2017; Pucci 2019). This anatomical construction leaves a biliopancreatic limb that contains bile and pancreatic enzymes but no nutrients, and an alimentary limb that contains nutrients but no bile or pancreatic enzymes. Whereas nutrient absorption in the alimentary limb is impaired, the common channel is typically 400 cm, and allows undisturbed nutrient absorption. Therefore, there is limited macronutrient malabsorption in a standard RYGB (Fink 2022). The RYGB is one of the most popular MBS procedures (Ramos 2019).

(v) One-anastomosis gastric bypass (OAGB) is a procedure that combines a longitudinal gastric pouch with re-routing of the

small intestine. Compared to the RYGB, the gastric pouch is longer, and the gastrointestinal passage is reconstructed using an omega loop without division of the jejunum. Therefore, this procedure leaves only a biliopancreatic limb and a common channel. Compared to the RYGB, this procedure causes clinically relevant malabsorption of macronutrients, especially when a biliopancreatic limb longer than 150 cm is chosen (Fink 2022). Although often used synonymously, the mini gastric bypass only resembles OAGB.

(vi) Biliopancreatic diversion with duodenal switch (BPD/DS) combines SG with a division of the duodenum and a duodenoileostomy. This procedure creates a very long biliopancreatic limb combined with a very short common channel of approximately 70 cm to 100 cm. Due to partial reabsorption of digestive fluids in the long biliopancreatic limb, and a short length of potentially unimpaired nutrient absorption, this procedure causes highly relevant macro- and micronutrient malabsorption (Biertho 2016; Nguyen 2017). People who undergo this procedure need parenteral vitamin supplementation, and typically experience fatty bowel movements. Delivery of undigested nutrients to the colon provides an energy source for colonic gas-producing bacteria, so people often suffer from bloating.

In general, people who are post-MBS must be monitored for nutritional deficiencies and the potential need for medical adjustments (e.g. diabetes medication). People should receive nutritional advice about the importance of protein intake and the supplementation of micronutrients, and specific meal patterns (Fried 2013).

Adverse effects of the intervention

MBS procedures are generally considered to be safe and effective (Lim 2018; Nguyen 2017). However, as with all surgeries, adverse events may occur. The perioperative mortality rate of MBS ranges from 0.03% to 0.2%, with significant improvement over the last decades (Arterburn 2020). Sleeve gastrectomy and laparoscopic adjustable gastric banding generally have lower rates of serious complications compared to bypass procedures (Biobaku 2020). Biliopancreatic diversion with duodenal switch has the highest rate of serious complications, at 8% (Finks 2011).

Early complications include anastomotic leaks, stenosis, bleeding, wound infection, and venous thromboembolic events (Kassir 2016; Lim 2018). Potential late complications after adjustable gastric banding are band slippage, band erosion, acute obstruction, gastroesophageal reflux disease, and oesophagitis (Lim 2018; McCarty 2022). Late complications after SG mainly refer to acid reflux and oesophagitis (McCarty 2022). Late complications of gastric bypass procedures include marginal ulceration, hernia, bowel obstruction, and dumping syndrome (Kassir 2016; Lim 2018). A recent systematic review including studies with follow-up of at least 10 years reported reoperation rates of 8% to 78% for adjustable gastric banding, 32% to 36% for SG, 8% to 64% for RYGB, and 2% to 14% for OAGB (O'Brien 2019).

Micronutrient deficiencies of, for example, vitamin D, vitamin B₁₂, iron, copper, zinc, or selenium can occur after MBS; the risk varies with the MBS procedure (Bal 2012; Biobaku 2020; Parrott 2017; Via 2017). The reasons relate to a reduced absorption of micronutrients, dumping syndrome, bacterial overgrowth in the

small intestine, maladaptive eating behaviours, and recurrent vomiting (Biobaku 2020).

Depending on the MBS procedure, a decreased bone mineral density and an increased fracture risk have been described, largely due to induced abnormalities in the calciotropic hormones (Biobaku 2020; Rodríguez-Carmona 2014; Zhang 2020). Secondary hyperparathyroidism, which is mainly caused by calcium and vitamin D deficiency, was reported in about 39% of people after RYGB, and can also contribute to bone loss (Gao 2022). In addition, the large weight loss following MBS reduces the mechanical load on the skeleton, which may lead to less bone formation, increased bone resorption, and consequently, a reduction of bone mineral density (Corbeels 2018).

How the intervention might work

MBS aims to achieve and maintain weight loss and related improvements in health outcomes through a permanent reduction of food intake. Observational studies have described various self-reported post-MBS changes, e.g. in appetite, taste, and smell, which may affect food preferences (Zakeri 2018). The underlying biological modulations triggered by MBS may refer to changes in gastrointestinal hormone levels (e.g. reduction of ghrelin and increase in glucagon-like peptide-1 (GLP-1) and peptide YY3-36 (PYY)), composition of bile acids, and the gut microbiome (Lutz 2014; Pucci 2019). These gastrointestinal factors conjointly act on the brain areas that regulate food intake, reward-processing, and executive function, and are associated with favourable changes in eating behaviour (Zakeri 2018). The MBS procedure may impact the extent of these biological modulations (Pucci 2019).

Why it is important to do this review

Obesity and its associated diseases, particularly T2D, have taken on epidemic dimensions globally, and are widely recognised as major public health threats (Cho 2018; WHO 2021a). There is a growing global concern about the rising negative health and socioeconomic consequences of obesity and T2D, such as cardiovascular disease, the leading cause of death worldwide (Beckman 2013; Dai 2020; Effertz 2016; Di Angelantonio 2016; Withrow 2011).

Although several recent randomised controlled trials (RCTs) have shown MBS to be an effective treatment option for weight loss and improvements in T2D (Adams 2017; Courcoulas 2020; Ikramuddin 2018; Mingrone 2015; Schauer 2017; Simonson 2018), global uptake remains very low (0 to 3% annually) compared to the large number of people with obesity and T2D (Dixon 2016; Welbourn 2016). A recent, large RCT comparing MBS with conventional medical therapy in people with obesity and T2D, found surgery to be more effective ($\geq 25\%$ versus 5.5% remission) for the long-term control (10 years) of T2D (Mingrone 2021). The fifth global registry report of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) describes that in many countries, the number of people with T2D is still underrepresented (< 20%) amongst those undergoing MBS (Ramos 2019). As a person's willingness to consider MBS is strongly influenced by information and consultation with healthcare professionals, high quality evidence about the various MBS procedures and their comparative efficacy and safety is important (Ames 2020). This facilitates shared decision-making about MBS, and may result in health and HRQoL improvements, thereby mitigating the (socioeconomic) burden of disease at both an individual and societal level.

A recent systematic review reported MBS to be associated with a reduced risk for all-cause mortality and T2D incidence (Wiggins 2020). Other systematic reviews found MBS to be associated with better weight loss and reduced vascular disease compared to non-surgical treatments in people with (severe) obesity and T2D in the long term (≥ 5 years (Sheng 2017; Yan 2019)). The extent of weight loss, improvements in T2D, and adverse events appear to vary between procedures, resulting in uncertainty about the best MBS procedure for people with obesity and T2D (Arterburn 2020). The results of previous systematic reviews comparing various MBS procedures are inconsistent. A recent systematic review comparing SG and RYGB, found that RYGB resulted in greater weight loss, but no difference in T2D remission compared to SG (Lee 2021); other systematic reviews did not show clear differences between the two procedures (Cresci 2020; Kang 2017).

In recent years, several network meta-analyses (NMA) of RCTs were published, comparing more than two MBS procedures in people with obesity. The NMA by Ding 2020 in people with overweight or obesity and T2D suggested that mini-gastric bypass is more effective in T2D remission than RYGB, SG, or other procedures. In the NMA by Cosentino 2021 in people with obesity, duodenal switch and biliopancreatic diversion appeared to be more effective for weight loss than other procedures, whereas laparoscopic adjustable gastric banding, laparoscopic vertical banded gastroplasty, and greater curvature plication seemed to be less effective. The NMA by Currie 2021 in people with obesity, compared the most commonly performed MBS procedures (RYGB, SG, and OAGB) and concluded that OAGB showed comparable results for weight loss and T2D remission to that seen after RYGB and SG, but lower perioperative complications. Carmona 2021 focussed specifically on people with T2D, and found that laparoscopic OAGB was better for T2D remission, laparoscopic RYGB controlled HDL-cholesterol levels better, and biliopancreatic diversion without duodenal switch was better at lowering diastolic blood pressure. In their NMA, Solé 2022 investigated the efficacy of MBS in T2D management up to five years after surgery, and concluded that no therapeutic procedure offered stable effects on glucose metabolism. The NMA by Matczak 2021 included both RCTs and non-RCTs, and investigated the effects of MBS on HRQoL. They concluded that SG and laparoscopic RYGB improved HRQoL at most time points within five years after surgery. The number of trials included in these systematic reviews varied greatly; the inconsistent results may depend on varying search strategies and eligibility criteria. The majority of these systematic reviews did not use the Cochrane RoB 2 tool to assess risk of bias (Higgins 2023a), or rate the certainty of evidence with GRADE (Brignardello-Petersen 2018).

The only existing Cochrane review on the effects of MBS on adults with obesity found greater improvements with MBS (regardless of the MBS procedure) for weight loss and weight-associated comorbidities compared to non-surgical interventions (Colquitt 2014). However, the authors noted that due to a lack of RCTs on the long-term effects on comorbidities (≥ 24 months; e.g. diabetes complications) and HRQoL, it remained unclear whether the reported benefits continued over time. This Cochrane review was published in 2014 and is outdated (the last literature search was November 2013). They based most findings on RCTs of short duration (i.e. follow-up 12 to 24 months), and did not consider evidence from long-term cohort studies. The review did not specifically focus on people with T2D, did not include a study

investigating the effect of MBS on long-term complications of T2D, and did not undertake an NMA. Therefore, a major question remains unanswered – which bariatric approach offers the greatest long-term benefits to people with obesity and T2D? To answer this question, we will use NMA to identify and rank the most effective and safest MBS procedure on outcomes most relevant to the people affected (Chaimani 2023). We also plan to combine evidence from both RCTs and comparative cohort studies in the NMA, to further improve precision and confidence in our findings, as cohort studies often focus on long-term safety of MBS (Efthimiou 2017).

OBJECTIVES

To investigate comparative medium- and long-term effects and safety, and to obtain a clinically meaningful ranking of different metabolic bariatric surgery procedures (adjustable gastric banding, sleeve gastrectomy, Roux-en-Y gastric bypass, one-anastomosis gastric bypass, gastric plication, biliopancreatic diversion with duodenal switch, and their variations) compared to each other and to non-surgical treatment (e.g. usual care with intensive lifestyle interventions or pharmacotherapy) on outcomes relevant to adults with obesity and type 2 diabetes, by considering both randomised controlled trials and cohort studies.

METHODS

Criteria for considering studies for this review

Types of studies

As the short-term efficacy and safety of metabolic bariatric surgery (MBS) have already been established (Arterburn 2020), we will include randomised controlled trials (RCTs) with individual or cluster randomisation, and prospective or retrospective cohort studies (with at least two study arms) with a minimum follow-up of three years, as recommended by the previous Cochrane review (Colquitt 2014).

We will include cohort studies because we are interested in the long-term effects of MBS. Although cohort studies are generally at a higher risk of bias than RCTs, we will consider this study design due to the expected higher number of participants, longer follow-up times, more information on adverse events, and the inclusion of more generalisable populations (Cameron 2015). Cohort studies are defined as any quantitative studies that estimate the effectiveness of an intervention (harm or benefit) that does not use randomisation to allocate individuals to different groups. This includes studies in which allocation occurs in the course of usual treatment decisions, or according to peoples' choices (often called observational studies).

We will exclude other non-randomised study designs, such as case-control or cross-sectional, case-cross-over, controlled before-after, before-after without control, or ecological studies. We do not consider cross-over studies suitable for our research questions because of expected carry-over effects (Higgins 2023b; Lichtenstein 2021).

Types of participants

We will include studies on adults (≥ 18 years) diagnosed with obesity and type 2 diabetes (T2D), using internationally recognised diagnostic criteria, i.e. the World Health Organization obesity classification system (WHO 2000a), and the American Diabetes

Association classification and diagnostic standards for diabetes (ADA 2021a).

We will define obesity and T2D according to internationally recognised criteria.

- Obesity: defined as a BMI ≥ 30 kg/m²; further subdivided into: class I (BMI 30 kg/m² to 34.9 kg/m²), class II (BMI 35 kg/m² to 39.9 kg/m²), and class III (BMI ≥ 40 kg/m² (WHO 2000a)). For specific ethnic groups, e.g. Asian populations, ethnic-specific BMI cut-off values for obesity will be applied (WHO 2000b);
- Diabetes: defined as glycated haemoglobin (HbA1c) $\geq 6.5\%$ (48 mmol/mol), fasting plasma glucose (FPG) ≥ 126 mg/dL (7.0 mmol/L), or two-hour plasma glucose (PG) ≥ 200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test (ADA 2021a).

We will exclude studies exclusively focusing on these participants.

- Younger than 18 years
- Without obesity or T2D (e.g. participants with type 1 diabetes)
- Participants with abnormal glucose metabolism (FPG 100 mg/dL to 125 mg/dL (5.6 mmol/L to 6.9 mmol/L); HbA1c 5.7% to 6.4% (39 mmol/mol to 47 mmol/mol); or two-hour PG 140 mg/dL to 199 mg/dL (7.8 mmol/L to 11 mmol/L)) during an oral glucose tolerance test, but not diagnosed with T2D
- Pregnant women

If we identify studies in which only a subset of participants (i.e. $\geq 30\%$ with T2D) is relevant for our review, we will contact the study authors to determine if subgroup analyses are available for the relevant subset.

Types of interventions

We will include studies that compare at least one MBS procedure to another, or to non-surgical treatment (i.e. usual care or pharmacotherapy). We will consider MBS procedures currently in use, performed laparoscopically or as open procedures. Details of such interventions are given under the [Description of the intervention](#) section.

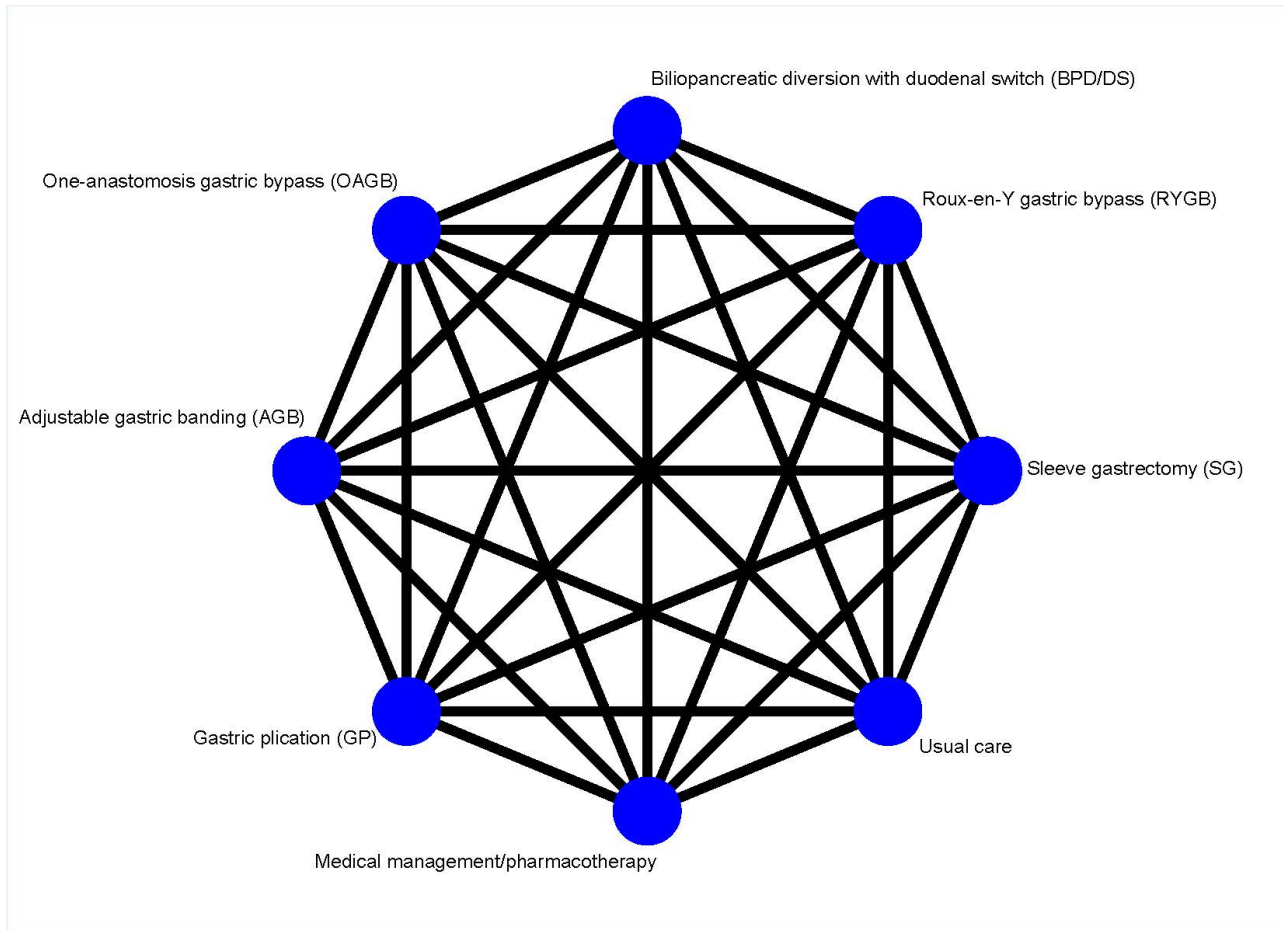
Interventions

- Adjustable gastric banding (AGB)
- Sleeve gastrectomy (SG), including variations (e.g. sleeve gastrectomy with duodenojejunal bypass (SG-DJB), single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S))
- Roux-en-Y gastric bypass (RYGB), including variations (e.g. banded gastric bypass)
- One-anastomosis gastric bypass (OAGB), or mini-gastric bypass
- Gastric plication (GP), also called greater curvature plication/gastric imbrication
- Biliopancreatic diversion with duodenal switch (BPD/DS)

Comparisons

All interventions will be compared to each other in a network meta-analysis (NMA (Figure 1)). Nevertheless, we define the following non-surgical treatments, which are commonly used in clinical practice as comparators, based on the previous Cochrane review (Colquitt 2014), and the ADA's *Obesity Management for the Treatment of Type 2 Diabetes* standards (ADA 2021b).

Figure 1. Theoretical network plot of all possible pairwise comparisons A network plot visualizes the network of treatment comparisons. The blue nodes represent the interventions being compared (e.g. adjustable gastric banding and sleeve gastrectomy) and the black edges, the direct comparisons (evaluated in at least one study) between pairs of interventions. The figure was generated with Stata 15.1.



Non-surgical treatment.

- Usual care, e.g. comprehensive lifestyle intervention, diet, physical activity, and behavioural therapy (ADA 2021b)
- Medical management/pharmacotherapy, e.g. orlistat, lorcaserin, liraglutide, semaglutide (Chukir 2018)

To avoid confounding, we will exclude studies if concomitant interventions differ between intervention and comparator groups. If a study includes multiple arms, we will include any arm that meets the inclusion criteria for this review.

Minimum duration of intervention

Minimum duration of intervention is not relevant for MBS, whereas the duration of non-surgical treatments must be conducted over a period of at least three years.

Minimum duration of follow-up

We are interested in medium-term (≥ 3 to < 5 years) and long-term (≥ 5 years) effects of MBS (Brethauer 2015); therefore, we will include studies with a minimum length of follow-up of three years.

Summary of specific exclusion criteria

We will exclude studies of the following categories of interventions.

- Comparing variations of MBS procedures (e.g. sleeve gastrectomy with duodenojejunal bypass versus single-anastomosis duodeno-ileal bypass with sleeve gastrectomy) rather than different procedures
- Investigational procedures (e.g. vagal blockade, aspiration therapy, endoscopic sleeve gastroplasty, endoscopic gastrointestinal bypass devices)
- Comparing open versus laparoscopic procedures of the same MBS procedure
- Obsolete procedures, which are not currently used (e.g. jejunoileal bypass, vertical banded gastroplasty, horizontal gastroplasty, biliopancreatic diversion without duodenal switch)

Types of outcome measures

We will extract data on the following outcomes, which were chosen based on those prioritised by health professionals and people undergoing, or considering MBS (Coulman 2016); the outcome

reporting standards in metabolic and bariatric surgery (Brethauer 2015); and the outcomes reported in the previous Cochrane review (Colquitt 2014).

Primary outcomes

- Weight loss
- T2D remission
- Serious adverse events

Secondary outcomes

- All-cause mortality
- Morbidity/T2D complications
- Glycaemic control
- T2D recurrence
- T2D medication
- Health-related quality of life
- Reoperations

We will only exclude studies if none of the outcomes relevant to this review were measured, provided there is supporting evidence (e.g. contact with trial authors, access to the original protocol, etc.).

Method of outcome measurement

- Weight loss
 - Measures of weight change: e.g. total weight loss (TWL), per cent total weight loss (%TWL), per cent excess weight loss (%EWL), per cent excess BMI loss (%EBMIL), per cent preoperative weight (%PW), and changes in BMI/body weight (Brethauer 2015; Grover 2019)
 - Measures of fat content/distribution: e.g. waist-hip ratio, waist circumference, per cent body fat
- T2D remission
 - Complete remission: normal measures of glucose metabolism (HbA1c < 6% (42 mmol/mol), FPG < 100 mg/dL (5.6 mmol/L)) without T2D medications (Brethauer 2015)
 - Partial remission: hyperglycaemia below levels diagnostic of diabetes (HbA1c < 6.5% (48 mmol/mol), FPG 100 mg/dL to 125 mg/dL (5.6 mmol/L to 6.9 mmol/L)) without T2D medications (Brethauer 2015)
 - Prolonged remission: complete remission lasting for more than five years (Brethauer 2015; Buse 2009)
- Serious adverse events: according to the outcome reporting standards in metabolic and bariatric surgery, defined as any event that results in a prolonged hospital stay (beyond 7 days), administration of anticoagulants, re-intervention, or reoperation e.g. venous thrombotic event, anastomotic leak, small bowel obstruction, death, myocardial infarction, renal failure, respiratory failure, etc. (Brethauer 2015)
- All-cause mortality: death from any cause
- Morbidity/T2D complications: macrovascular (e.g. coronary artery disease, cerebrovascular disease) and microvascular (e.g. nephropathy, retinopathy, peripheral neuropathy), ketoacidotic coma
- Glycaemic control: HbA1c (mmol/mol;) and FPG (mmol/L)
- T2D recurrence: HbA1c or FPG in the range of T2D (HbA1c ≥ 6.5%; FPG ≥ 126 mg/dL), or the need for T2D medication after any period of complete or partial remission (Brethauer 2015)

- T2D medication: i.e. insulin use, oral medications (e.g. metformin), and GLP-1 analogues
- Health-related quality of life (HRQoL): evaluated by validated instruments, such as the 36 items Short Form survey (SF-36 (Ware 1992)), the Bariatric Analysis Reporting Outcome System (BAROS (Oria 1998)), the Impact of Weight on Quality of Life – Lite (IWQOL-Lite (Kolotkin 2001)) or EuroQoL, 5 dimensions (EQ-5D (Herdman 2011)); and considering global HRQoL (mental, social, emotional, role, and physical functioning (Garratt 2002))
- Reoperations: need for any surgical procedure related to the initial bariatric surgery, e.g. due to complications

Timing of outcome measurement

We are interested in medium-term follow-up, measured ≥ 3 to < 5 years after intervention, and in long-term follow-up, measured ≥ 5 years after intervention (Brethauer 2015).

We will analyse these outcomes as time-to-event during two time points: T2D remission, serious adverse events, all-cause mortality, morbidity/T2D complications, T2D recurrence, T2D medication (dichotomous), and reoperations.

- < 5 years after surgery
- ≥ 5 years after surgery

We will analyse these outcomes at two time points: weight loss, HRQoL, T2D medication (continuous), and glycaemic control.

- ≥ 3 years and < 5 years after surgery
- ≥ 5 years after surgery

If the results of several analyses for the defined time periods are available for the same trial, we will consider the latest measurements within each period.

Search methods for identification of studies

Electronic searches

An information specialist (MIM) will search the following sources from the inception of each database to the date of search, with no restrictions on the language of publication:

- Cochrane Central Register of Controlled Trials (CENTRAL; year, issue) in the Cochrane Library;
- MEDLINE Ovid (MEDLINE ALL 1946 to Daily Update);
- Cumulative Index to Nursing and Allied Health Literature (CINAHL EBSCOhost);
- Science Citation Index and Emerging Citation Index Web of Science via Clarivate;
- Latin American and Caribbean Health Sciences Literature (LILACS; bvsalud.org/en/);
- BASE (Bielefeld Academic Search Engine; www.base-search.net);
- World Health Organization International Clinical Trials Registry Platform (ICTRP; www.who.int/trialsearch/);
- ClinicalTrials.gov (www.clinicaltrials.gov).

We will not include Embase in our search, as RCTs indexed in Embase are now prospectively added to CENTRAL via a highly sensitive screening process (Cochrane 2022).

For detailed search strategies, see [Appendix 1](#).

Searching other resources

We will attempt to identify other potentially eligible studies or ancillary publications by searching the reference lists of included studies, systematic reviews, and meta-analyses identified during the electronic searches. We will also contact the authors of the included studies to request additional information on the retrieved studies, and establish whether we may have missed further studies. To retrieve grey literature, we will search BASE.

We will not use abstracts or conference proceedings for data extraction unless full data are available from study authors, because this information source does not fulfil the CONSORT requirements ([CONSORT 2022](#); [Scherer 2018](#)). We will present information on abstracts or conference proceedings in the characteristics of studies awaiting classification table.

Data collection and analysis

Selection of studies

We will use Cochrane's Screen4Me workflow to help assess the search results. Screen4Me comprises three components: known assessments – a service that matches records in the search results to records that have already been screened by Cochrane Crowd and been labelled as an RCT or not an RCT; the RCT classifier – a machine-learning model that distinguishes RCTs from non-RCTs; and Cochrane Crowd (crowd.cochrane.org) – Cochrane's citizen science platform in which the Crowd helps to identify and describe health evidence. Recently, this service has been expanded to classify cohort studies, and we will also use this new component to assess this study design. More detailed information regarding evaluations of the Screen4Me components can be found here: [Marshall 2018](#); [Noel-Storr 2020](#); [Noel-Storr 2021](#); [Thomas 2021](#).

Two review authors (CS, EK, JS, LS) will independently screen the abstract, title, or both, of every record retrieved through the literature searches. We will obtain the full text of all potentially relevant records, and two review authors (CS, EK, JS, LS) will independently screen these. We will resolve disagreements through consensus, or by recourse to a third review author (GM, JF). If we cannot resolve a disagreement, we will categorise the study as awaiting classification and contact the study authors for clarification. We will present an adapted PRISMA flow diagram (including Cochrane's Screen4Me workflow) to show the process of study selection ([Page 2021](#)). After a full-text assessment, we will list key excluded articles that the reader might expect to find in the Cochrane review in a characteristics of excluded studies table, and provide the reasons for exclusion ([Lefebvre 2023](#); [Page 2021](#)). We will use Covidence software for study selection ([Covidence 2022](#)).

Data extraction and management

Two reviewers (EK, JS, CS, LS) will independently extract the following information for each included study (for RCTs and cohort studies separately) using standardised and piloted data extraction sheets from the Cochrane Metabolic and Endocrine Disorders (CMED) Group.

- Study design/methods: first author, publication year, study registration, setting, study design, study duration, follow-up duration, sample size, dropouts, etc.

- Participants: mean baseline age, sex, ethnicity, socioeconomic status/education, number of cases, mean baseline BMI and HbA1c, definition and duration of obesity and T2D, etc.
- Intervention(s)/comparator(s): specification of MBS procedure(s), specification of co-intervention(s), control group(s) and comparator(s), etc. We will describe interventions according to the Template for intervention description and replication (TIDieR) checklist ([Hoffmann 2014](#); [Hoffmann 2017](#)).
- Outcomes: outcome description, assessment instrument used, measurement time point, outcome assessor, and effect estimates with measure of uncertainty for all outcomes
- Adjusted and unadjusted outcome measures with measures of uncertainty (for cohort studies)
- Confounders: uncontrolled confounders and list of variables the authors have included in the analyses for adjusted estimates (for cohort studies)
- Methods used to control for confounders (for cohort studies)
- Funding source and conflict of interests

If relevant data are missing, we will contact the corresponding authors of the studies via e-mail and try to obtain missing data.

We will resolve disagreements by discussion or, if required, by consultation with a third review author (GM, JF).

We will provide information, including the study identifier for potentially relevant ongoing trials in the characteristics of ongoing trials table and in a joint appendix entitled Matrix of study endpoint (publications and trial documents).

Dealing with companion publications

In the event of companion documents or multiple reports of a primary study, we will maximise the information yield by collating all available data, and we will use the most complete data set aggregated across all known publications. If discrepancies in data across publications occur, we will contact the authors in an attempt to resolve the issues. In cases of no response, we will use the most up-to-date data. We will list companion documents, reports of a primary study, and trial documents of included trials (such as trial registry information) as secondary references under the study ID of the included study.

Data from clinical trials registers

If data from included studies are available as study results in clinical trial registers, such as ClinicalTrials.gov or similar sources, we will make full use of this information and extract the data. If there is also a full publication of the study, we will collate and critically appraise all available data. If an included study is marked as completed in a clinical trial register but no additional information is available (study results or publication, or both), we will add this study to the characteristics of studies awaiting classification table.

Assessment of risk of bias in included studies

We will assess the risk of bias for all predefined primary and secondary outcomes measured ≥ 5 years after MBS. Time-to-event outcomes will be considered in the RoB assessment if the follow-up after MBS was ≥ 5 years.

Two review authors (EK, JS, CS) will independently assess the risk of bias. We will resolve disagreements by consensus, or by consulting a third review author (LS). If adequate information is unavailable

from the study publications, study protocols, or other sources, we will contact the study authors to request missing data on risk of bias items.

Randomised controlled trials

We will use RoB 2, the Cochrane risk of bias tool, to evaluate individual bias items, described in the guidance paper and the *Cochrane Handbook for Systematic Reviews of Interventions*, according to the criteria and associated categorisations contained therein (Flemyng 2023; Higgins 2023a).

The RoB 2 tool evaluates these domains.

- Bias arising from the randomisation process
- Bias due to deviations from the intended interventions
- Bias due to missing outcome data
- Bias in measurement of the outcome
- Bias in the selection of the reported results

Within each domain, signalling questions provide information about features of the study that are relevant to the risk of bias. We are mainly interested in the effect of assignment to the interventions at baseline, regardless of whether the interventions are received as intended (the intention-to-treat effect). Possible answers to the signalling questions are yes, probably yes, probably no, no, and no information. After answering the signalling questions and following the domain-specific algorithms, we will make a judgement about the risk of bias, assigning one of three levels to each domain (low risk of bias, some concerns, high risk of bias). Based on these results, we will make summary assessments of the risk of bias for each predefined outcome (across domains), within and across studies (Higgins 2023a).

We will use the RoB 2 Excel tool to manage the data supporting the answers to the signalling questions and risk of bias judgements (available at www.riskofbias.info/). All data will be publicly available as supplementary material in a public repository.

Cohort studies

Risk of bias for cohort studies will be assessed using the Risk Of Bias In Non-randomised Studies - of Interventions (ROBINS-I) tool, taking into account these domains (Sterne 2011; Sterne 2019).

- Bias due to confounding
- Bias in selection of participants into the study
- Bias in classification of the intervention
- Bias due to deviations from the intended intervention
- Bias due to missing data
- Bias in measurement of outcomes
- Bias in selection of the reported result

We will judge these domains as being at low, moderate, serious, critical, or unclear risk of bias; we will document reasons for each bias classification. We used the ROBINS-I Stage 1 tool at the protocol stage to prespecify the review question, confounding domains, and co-interventions/exposures, as follows:

Review question

Which MBS intervention is the most effective in the treatment of people with obesity and T2D?

Confounding factors

We defined these confounders as relevant to interfere with all or most outcomes.

- Age
- Gender
- Ethnicity
- Education/socioeconomic status
- Baseline BMI
- Blood pressure
- Glycaemic control (e.g. duration of diabetes, HbA1c, perioperative insulin treatment)
- Comorbidity
- Year of surgery

Co-interventions

To avoid confounding, we will exclude studies if concomitant interventions differ between intervention and comparator groups.

Assessment of bias in conducting the systematic review

We will conduct the review according to this published protocol and will report any deviations from it in the Differences between protocol and review section of the completed review.

Summary assessment of risk of bias

We will present a risk of bias graph and a risk of bias summary figure. We will distinguish between participant-reported outcomes, observer-reported outcomes not involving judgement, observer-reported outcomes involving some judgement, outcomes reflecting decisions made by intervention providers, and composite outcomes (Sterne 2019).

We will consider:

- Health-related quality of life (participant-reported);
- Serious adverse events, morbidity/T2D complications, T2D medication, reoperation (reflecting decisions made by intervention providers);
- All-cause mortality, T2D remission, T2D recurrence (observer-reported outcomes not involving judgement);
- Weight loss, glycaemic control (observer-reported outcomes not involving judgement).

Risk of bias for an outcome within a study and across domains

We will assess the risk of bias for an outcome measure by including all entries relevant to that outcome (i.e. both study-level entries and outcome-specific entries). For each specific outcome, we will establish an overall risk of bias judgement using the following criteria:

- Low risk of bias: the study was judged to be at low risk of bias for all domains for this result;
- Some concerns: the study was judged to raise some concerns in at least one domain for this result, but not to be at high risk of bias for any domain;
- High/serious risk of bias: the study was either judged to be at high risk of bias in at least one domain for this result, or the study was judged to raise some concerns in multiple domains in a way that substantially lowered confidence in the result;

- Critical risk of bias (relevant only for cohort studies): the study was judged to be at critical risk of bias in at least one domain.

Risk of bias for an outcome across studies and across domains

To facilitate our assessment of the certainty of evidence for key outcomes, we will assess the risk of bias across studies and domains for the outcomes included in the summary of findings tables. We will define the evidence as being at low risk of bias when most information comes from studies at low risk of bias, some concerns when most information comes from studies at low risk of bias or with some concerns, high risk of bias when a sufficient proportion of information comes from studies at high risk of bias, and critical risk of bias (relevant only for cohort studies) when a sufficient proportion of information comes from studies at critical risk of bias.

Measures of treatment effect

If NMA is possible, we will express dichotomous data (e.g. all-cause mortality) as a risk ratio (RR) with 95% credible interval (CrI), and time-to-event data as a hazard ratio (HR) with 95% CrI according to the Bayesian approach (Deeks 2023). If only pairwise meta-analysis can be performed, we will present dichotomous data as a RR or HR with 95% confidence interval (CI (Deeks 2023)). For continuous outcomes measured on the same scale (e.g. body weight in kg), we will estimate the intervention effect using the mean difference (MD) with corresponding standard deviation (SD) and 95% CrI (in the case of pairwise meta-analysis, 95% CI). For continuous outcomes that measure the same underlying concept (e.g. HRQoL) but use different measurement scales, we will calculate the standardised mean difference (SMD). The magnitude of the SMD will be interpreted according to Cohen (small/minor SMD: 0.2 or less, medium SMD: 0.2 to 0.8, large SMD: 0.8 or greater (Cohen 2013)).

For cohort studies, we will extract both adjusted and unadjusted outcomes. If feasible, we will use the adjusted effect for our evidence synthesis. We will enter data presented as a scale with a consistent direction of effect. Skewed data reported as medians and interquartile ranges will be narratively described.

Unit of analysis issues

For dichotomous outcomes, we will use participants, rather than events, as the unit of analysis (i.e. number of participants with an adverse event, rather than number of adverse events).

For RCTs, we will take into account the level at which randomisation occurred, i.e. individually randomised or cluster randomised, and multiple observations for the same outcome.

If cluster-RCTs have appropriately adjusted for potential clustering of participants within clusters, we will use the reported estimates. We will attempt to reanalyse cluster-RCTs that did not include appropriate adjustments in their analyses. We will inflate the variance of the intervention effects by a design effect; calculation of a design effect involves estimation of an intracluster correlation coefficient (ICC). We will obtain estimates of ICCs by contacting study authors, or by imputing ICC values, using either estimates from other included studies that report ICCs, or external estimates from empirical research (e.g. Bell 2013).

For cohort studies, we will also use participants as the unit of analysis. If multiple studies investigated the same cohort and

reported the same outcomes and follow-ups, we will use the most recent results of the cohort of interest for analyses.

Dealing with missing data

If possible, we will obtain missing data from the authors of the included studies. If data cannot be obtained, we will use the information reported in the publication. If both available case analysis and analysis with imputed data are presented, we will use the estimates with imputed data for the NMA. We will carefully evaluate important numerical data, such as the number of people screened, included, and analysed. We will investigate attrition rates (e.g. dropouts, losses to follow-up, and withdrawals) and critically appraise issues concerning missing data and use of imputation methods (e.g. last observation carried forward).

For studies in which either the SD of the outcome is not available at follow-up, or we cannot recalculate it, we will impute the median of the pooled baseline SD from studies that reported this information. When included studies do not report means and SDs for outcomes, and we do not receive the requested information from study authors, we will impute these values by estimating the sample mean from the sample size, median, mid-range, and mid-quartile range, where possible (Luo 2018). We will investigate the impact of imputation on meta-analyses by performing sensitivity analyses, and for every outcome, we will report which studies had imputed means and SDs.

Assessment of heterogeneity

In the event of substantial clinical or methodological heterogeneity, we will not report pooled effect estimates in an NMA. We will assess the assumption of transitivity, implying that studies comparing different groups of interventions are sufficiently similar to allow valid indirect conclusions, by comparing the distribution of potential effect modifiers (e.g. age, duration of diabetes, and baseline BMI) across the available direct comparisons. As the time of establishing the surgical procedure might determine the possible length of follow-up, we will inspect the aspect of timing across groups of interventions in the assessment of the transitivity assumption. We will assess statistical heterogeneity and inconsistency globally by decomposing the Q statistic into heterogeneity (within designs) and inconsistency (between designs). When we identify heterogeneity, we will attempt to determine possible reasons for this by examining individual characteristics of studies and subgroups. In addition, we will assess inconsistencies locally, by looking at differences between direct and indirect effect estimates, using the SIDE (Separating Indirect from Direct Evidence) approach (Dias 2010).

Assessment of reporting biases

If we include 10 studies or more that investigate a particular outcome, considering both RCTs and cohort studies, we will evaluate the presence of small-study effects by drawing comparison-adjusted funnel plots that account for the fact that different studies compare different sets of interventions (Chaimani 2013).

Data synthesis

We will use an NMA to synthesise all available evidence from RCTs and cohort studies. We will exclude studies at critical risk of bias from analysis. An NMA combining evidence from RCTs and cohort studies is only conducted if (i) NMA results are consistent with

randomised evidence, and (ii) no substantial disagreement exists between randomised and cohort study evidence (Efthimiou 2017). Otherwise, we will undertake separate NMAs for RCTs and cohort studies.

We will use a Bayesian approach to combine evidence from randomised and cohort studies, namely, bias-adjusted model 2 (Hamza 2023a), which is an extension of the model from Verde 2021. The model is based on a mixture of two random-effects distributions for treatment and bias effects.

We will undertake a Bayesian random-effects NMA to determine the summary effect of each intervention relative to any other intervention/control arm. We will present the available direct comparisons between different interventions and control groups using a network plot for each outcome (Figure 1).

We will assess model convergence using established methods, including Gelman Rubin diagnostics and inspection of Monte Carlo errors. We will choose initial sampling values (burnin) that are sufficiently large to allow for convergence of the posterior distribution, and re-run the models long enough to get stable credible intervals. We will use non-informative prior distributions for all relative effect parameters. We will use vague uniform priors for the SD of the heterogeneity, except in sparse data sets, where we will formulate informative priors based on other meta-analyses with similar outcomes (Turner 2019).

We will assess model fit by comparing residual deviance to the number of data points. We will assess heterogeneity by inspecting the size of the between-study SD, and by comparing the deviance information criteria (DIC) for random-effects and common-effect models.

To summarise NMA results, we will present effect estimates with their 95% CrIs in league tables and forest plots. We will generate cumulative ranking curves, and rank treatments by the surface under the cumulative ranking curve (SUCRA (Salanti 2011)). SUCRAs are values between 0 and 1, where a value of 1 means that a treatment always ranks best, and a value of 0 means that a treatment always ranks worst. In addition, we will calculate mean and median ranks with 95% CrIs.

We will conduct statistical analyses in R, using the `crossnma` (Hamza 2023b), and `netmeta` (Rücker 2024) packages.

If we are unable to undertake an NMA, for example, due to violations of the assumption of transitivity, we will undertake a pairwise random-effects meta-analysis in R, using the `meta` package (Balduzzi 2019; Balduzzi 2019a).

If meta-analysis is not possible for certain outcomes, we will describe the results in tables ordered by study ID, using the guidance in the *Cochrane Handbook* (McKenzie 2023).

Subgroup analysis and investigation of heterogeneity

We will restrict subgroup analyses for the NMA (Hamza 2023b), or if an NMA is not possible, for pairwise meta-analyses, to primary outcomes with at least ten studies, to provide data with sufficient power.

For pairwise meta-analysis, we will test subgroup differences according to Borenstein 2013. Subgroup analyses are based on the

previous Cochrane review (Colquitt 2014). We expect the following characteristics to introduce clinical heterogeneity, for which we plan to carry out subgroup analyses.

- Age (< 50 versus ≥ 50 years)
- Sex
- Baseline BMI (30 kg/m² to < 35 kg/m² (obesity) versus 35 kg/m² to < 40 kg/m² (severe obesity) versus 40 kg/m² to 50 kg/m² (morbid obesity) versus > 50 kg/m² (super obesity))
- Follow-up duration (< 10 years versus ≥ 10 years)
- Duration of T2D (< 10 years versus ≥ 10 years)

Sensitivity analysis

We will restrict sensitivity analyses for the NMA, or if an NMA is not possible, for pairwise meta-analyses, to primary outcomes with at least ten studies to provide data with sufficient power. When applicable, we plan to explore the influence of important factors on effect sizes, by performing sensitivity analyses in which we restrict the analyses to the following.

- Studies that were published
- Studies at low risk of bias, as specified in the [Assessment of risk of bias in included studies](#) section
- Very large studies, to establish the extent to which they dominate the results
- Studies without imputed SDs
- RCTs only
- Studies with ≤ 20% missing data

Summary of findings and assessment of the certainty of the evidence

Certainty of the evidence

We will present the overall certainty of the evidence for each outcome specified below, according to the GRADE approach for NMA (Brignardello-Petersen 2018). Two review authors (EK, JS) will independently rate the certainty of evidence for each outcome. We will resolve any differences in assessment by discussion or by consultation with a third review author (LS).

We will rate the certainty of evidence for each of the direct, indirect, and network estimates. We will rate the direct evidence based on risk of bias, inconsistency, indirectness, and publication bias. If the certainty of direct evidence is high, and its contribution is at least as much as that of the indirect evidence, we will not rate the indirect evidence (Brignardello-Petersen 2018). If rating of indirect evidence is necessary, we will use the certainty of direct estimates to inform indirect estimates, considering the lowest of the ratings of the two direct comparisons forming the most dominant first-order loop. In the presence of serious intransitivity, we will downgrade the certainty of the indirect estimate. To address the certainty of network estimates, we will compare the ratings for direct and indirect estimates. We will choose the estimate with the higher contribution, and downgrade it in case of incoherence or imprecision (Brignardello-Petersen 2018).

If NMA or pairwise meta-analyses are not possible, we will present the results in a narrative format in the summary of findings tables. We will justify all decisions to downgrade the certainty by using

informative footnotes, and we will make comments to aid the reader's understanding of the Cochrane review when necessary.

Summary of findings table

We will present a summary of the evidence in a summary of findings table. This will provide key information about the best estimate of the magnitude of effect, in relative terms and as absolute differences, for each relevant comparison of alternative management strategies; the numbers of participants and studies addressing each important outcome; and a rating of overall certainty in effect estimates for each outcome. We will create the summary of findings tables using the methods described in the *Cochrane Handbook* (Schünemann 2023), and according to the GRADE summary of findings table format that displays the critical information from an NMA (Yepes-Nuñez 2019).

We will present the interventions (i.e. adjustable gastric banding, sleeve gastrectomy, Roux-en-Y gastric bypass, one-anastomosis gastric bypass, gastric plication, biliopancreatic diversion with duodenal switch) in one summary of findings table. The comparators will be usual care with lifestyle interventions or pharmacotherapy. In the summary of findings tables, we will also report the results separately by study design (pooled RCTs and cohort studies; RCTs only; and cohort studies only).

We will report the following long-term outcomes (≥ 5 years after metabolic bariatric surgery), listed according to priority.

- Weight loss
- T2D remission
- Serious adverse events
- All-cause mortality
- Morbidity/T2D complications
- Glycaemic control

- Health-related quality of life

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Editorial and peer-reviewer contributions

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The following people conducted the editorial process for this article:

- Sign-off Editor (final editorial decision): Brenda Bongaerts, Institute of General Practice, Medical Faculty of the Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany
- Managing Editor (selected peer reviewers, collated peer-reviewer comments, provided editorial guidance to authors, edited the article): Juan Victor Ariel Franco, Institute of General Practice, Medical Faculty of the Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany
- Copy Editor (copy-editing and production): Victoria Pennick, Cochrane Central Production Service
- Peer-reviewers (provided comments and recommended an editorial decision): Yuan Chi, Cochrane Campbell Global Ageing Partnership; Maria A Willis Department of General, Visceral, Thorax and Vascular Surgery, University Hospital Bonn, Bonn, Germany

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APPENDICES

Appendix 1. Search strategies

Cochrane CENTRAL (Cochrane Library)

1. [mh ^"Bariatric Surgery"]
2. [mh ^"Gastric Bypass"]
3. [mh ^"Biliopancreatic Diversion"]
4. [mh ^"Anastomosis, Roux-en-Y"]
5. ((obes* or "weight loss" or "weight reduction" or antiobes* or metabolic) next surg*):ti,ab,kw
6. (bariatric next (surg* or operation* or procedure*)):ti,ab,kw
7. (malabsorpti* next (procedure* or surg*)):ti,ab,kw
8. (gastric next (bypass or band* or imbrication* or plication* or sleeve)):ti,ab,kw
9. ("greater curvature plication"):ti,ab,kw
10. ((gastroileal or jejunal or duodeno or ileal or biliopancreatic or "bilio pancreatic" or SASI or SADI or "SADI-S") next bypass):ti,ab,kw
11. ((sleeve next gastrectom*) or "banded sleeve"):ti,ab,kw
12. (("bilio pancreatic" or biliopancreatic) next diversion):ti,ab,kw
13. (scopinaro):ti,ab,kw
14. (lap next band*):ti,ab,kw
15. (RYGB* or "Roux-en-Y"):ti,ab,kw
16. (duodenal next switch*):ti,ab,kw
17. {or #1-#16}
18. [mh ^"Diabetes Mellitus"]
19. [mh "Diabetes Mellitus, Type 2"]
20. (NIDDM or T2DM or T2D):ti,ab,kw

(Continued)

21. diabet*:ti,ab,kw
22. {or #18-#21}
23. #17 and #22

MEDLINE Ovid

Bariatric Procedures

1. Bariatric Surgery/
2. Gastric Bypass/
3. Biliopancreatic Diversion/
4. Anastomosis, Roux-en-Y/
5. ((obes* or weight loss or weight reduction or antiobes* or metabolic) adj surg*).mp.
6. (bariatric adj (surg* or procedure*)).mp.
7. (malabsorpti* adj (procedure* or surg*)).mp.
8. (gastric adj (bypass or band* or imbrication* or plication* or sleeve)).mp.
9. (greater curvature plication).mp.
10. ((gastroileal or jejunal or duodeno or ileal or biliopancreatic or bilio pancreatic or SASI or SADI or SADI-S) adj bypass).mp.
11. (sleeve gastrectom* or banded sleeve).mp.
12. ((bilio pancreatic or biliopancreatic) adj diversion).mp.
13. (scopinaro).mp.
14. (lap band*).mp.
15. (RYGB* or Roux-en-Y).mp.
16. (duodenal switch*).mp.
17. or/1-16

Population

18. Diabetes Mellitus/
19. exp Diabetes Mellitus, Type 2/
20. (NIDDM or T2DM or T2D).mp.
21. diabet*.mp.
22. or/18-21

Intervention + Population

23. 17 and 22

RCTs [Cochrane Handbook 2022 RCT filter - sensitivity max. version, without “drug therapy.fs”]

24. randomized controlled trial.pt.
25. controlled clinical trial.pt.
26. randomi?ed.ab.

(Continued)

27. placebo.ab.

28. randomly.ab.

29. trial.ab.

30. groups.ab.

31. or/24-30

32. exp animals/ not humans/

33. 31 not 32

Intervention + Population + RCTs

34. 23 and 33

University of Texas School of Public Health. Search filters for case-control studies, cohort studies, cross-sectional studies, clinical trials, epidemiological studies. Accessed 06 Dec 2013. [Ovid – Cohort studies]

35. cohort studies/ or longitudinal studies/ or follow-up studies/ or prospective studies/ or retrospective studies/ or cohort.ti,ab. or longitudinal.ti,ab. or prospective.ti,ab. or retrospective.ti,ab.

Intervention + Population + Cohorts

36. 23 and 35

Intervention + Population + (RCTs or Cohorts)

37. 34 or 36

CINAHL EbscoHost

S1. MH "Bariatric Surgery"

S2. MH "Gastric Bypass"

S3. MH "Jejunioileal Bypass"

S4. MH "Anastomosis, Roux-en-Y"

S5. TI ((obes* OR "weight loss" OR "weight reduction" OR antiobes* OR metabolic) N1 surg*) OR AB ((obes* OR "weight loss" OR "weight reduction" OR antiobes* OR metabolic) N1 surg*)

S6. TI (bariatric N1 (surg* OR operation* OR procedure*)) OR AB (bariatric N1 (surg* OR operation* OR procedure*))

S7. TI (malabsorpti* N1 (procedure* OR surg*)) OR AB (malabsorpti* N1 (procedure* OR surg*))

S8. TI (gastric N1 (bypass OR band* OR imbrication* OR plication* OR sleeve)) OR AB (gastric N1 (bypass OR band* OR imbrication* OR plication* OR sleeve))

S9. TI ("greater curvature plication") OR AB ("greater curvature plication")

S10. TI ((gastroileal OR jejunal OR duodeno OR ileal OR biliopancreatic OR "bilio pancreatic" OR SASI OR SADI OR "SADI-S") N1 bypass) OR AB ((gastroileal OR jejunal OR duodeno OR ileal OR biliopancreatic OR "bilio pancreatic" OR SASI OR SADI OR "SADI-S") N1 bypass)

S11. TI (("sleeve gastrectom*") OR "banded sleeve") OR AB (("sleeve gastrectom*") OR "banded sleeve")

S12. TI (("bilio pancreatic" OR biliopancreatic) N1 diversion) OR AB (("bilio pancreatic" OR biliopancreatic) N1 diversion)

S13. TI (scopinaro) OR AB (scopinaro)

S14. TI ("lap band*") OR AB ("lap band*")

(Continued)

S15. TI (RYGB* OR "Roux-en-Y") OR AB (RYGB* OR "Roux-en-Y")

S16. TI ("duodenal switch*") OR AB ("duodenal switch*")

S17. S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16

S18. MH "Diabetes Mellitus"

S19. MH "Diabetes Mellitus, Type 2"

S20. TI (NIDDM OR T2DM OR T2D) OR AB (NIDDM OR T2DM OR T2D)

S21. TI (diabet*) OR AB (diabet*)

S22. S18 OR S19 OR S20 OR S21

S23. S17 AND S22

[S24: Wong et al. 2006 "therapy studies" filter - SDSSGS version]

S24. MH "treatment outcomes+" OR MH "experimental studies+" or random*

S25. S23 AND S24

[S26: adapted text words from University of Texas School of Public Health. Search filters for case-control studies, cohort studies, cross-sectional studies, clinical trials, epidemiological studies.]

S26. TI (cohort OR longitudinal OR prospective OR retrospective) OR AB (cohort OR longitudinal OR prospective OR retrospective)

S27. S23 AND S26

S28. S25 OR S27

Science Citation Index and Emerging Citation Index Web of Science

#1

AB=((((obes* OR "weight loss" OR "weight reduction" OR antiobes* OR metabolic) NEAR/0 surg*) OR (bariatric NEAR/0 (surg* OR operation* OR procedure*)) OR (malabsorpti* NEAR/0 (procedure* OR surg*)) OR (gastric NEAR/0 (bypass OR band* OR imbrication* OR plication* OR sleeve)) OR "greater curvature plication" OR ((gastroileal OR jejunal OR duodeno OR ileal OR biliopancreatic OR "bilio pancreatic" OR SASI OR SADI OR "SADI-S") NEAR/0 bypass) OR ("sleeve gastrectom*" OR "banded sleeve") OR (("bilio pancreatic" OR biliopancreatic) NEAR/0 diversion) OR scopinaro OR "lap band*" OR RYGB* OR "Roux-en-Y" OR "duodenal switch*") OR TI=((obes* OR "weight loss" OR "weight reduction" OR antiobes* OR metabolic) NEAR/0 surg*) OR (bariatric NEAR/0 (surg* OR operation* OR procedure*)) OR (malabsorpti* NEAR/0 (procedure* OR surg*)) OR (gastric NEAR/0 (bypass OR band* OR imbrication* OR plication* OR sleeve)) OR "greater curvature plication" OR ((gastroileal OR jejunal OR duodeno OR ileal OR biliopancreatic OR "bilio pancreatic" OR SASI OR SADI OR "SADI-S") NEAR/0 bypass) OR ("sleeve gastrectom*" OR "banded sleeve") OR (("bilio pancreatic" OR biliopancreatic) NEAR/0 diversion) OR scopinaro OR "lap band*" OR RYGB* OR "Roux-en-Y" OR "duodenal switch*")

#2

AB=(NIDDM OR T2DM OR T2D OR diabet*) OR TI=(NIDDM OR T2DM OR T2D OR diabet*)

#3

#1 AND #2

#4

AB=(random* OR placebo OR trial OR groups) OR TI=(random* OR placebo OR trial OR groups)

#5

#3 AND #4

#6

(Continued)

AB=(cohort OR follow-up OR longitudinal OR prospective OR retrospective) OR TI=(cohort OR follow-up OR longitudinal OR prospective OR retrospective)

#7

#3 AND #6

#8

#5 OR #7

LILACS BVSalud

((obes\$ OR "weight loss" OR "weight reduction" OR antiobes\$ OR metabolic) AND surg\$) OR (bariatric AND (surg\$ OR operation\$ OR procedure\$)) OR (malabsorpti\$ AND (procedure\$ OR surg\$)) OR (gastric AND (bypass OR band\$ OR imbrication\$ OR plication\$ OR sleeve)) OR "greater curvature plication" OR ((gastroileal OR jejunal OR duodeno OR ileal OR biliopancreatic OR "bilio pancreatic" OR SASI OR SADI OR "SADI-S") AND bypass) OR ("sleeve gastrectomy" OR "banded sleeve") OR (("bilio pancreatic" OR biliopancreatic) AND diversion) OR scopinaro OR "lap band" OR "lap banding" OR RYGB\$ OR Roux OR "duodenal switch") AND (NIDDM OR T2DM OR T2D OR diabet\$) AND ((random\$ OR placebo OR trial OR groups) OR (cohort OR follow-up OR longitudinal OR prospective OR retrospective))

Bielefeld Academic Search Engine (BASE; advanced search)

tit:diabet* AND tit:(bariatric OR "obesity surgery" OR gastric OR plication OR bypass OR sleeve OR diversion OR scopinaro OR lap OR RYGB OR Roux OR "duodenal switch") doctype:(13 14 183 19) - Exakte Suche: An

WHO ICTRP (standard search)

((gastric AND (bypass OR band* OR imbrication* OR plication* OR sleeve)) OR "greater curvature plication" OR ((gastroileal OR jejunal OR duodeno OR ileal OR biliopancreatic OR "bilio pancreatic" OR SASI OR SADI OR "SADI-S") AND bypass) OR "sleeve gastrectomy" OR "banded sleeve" OR (("bilio pancreatic" OR biliopancreatic) AND diversion) OR scopinaro OR "lap band" OR "lap banding" OR RYGB* OR Roux OR "duodenal switch") AND (NIDDM OR T2DM OR T2D OR diabet*))

ClinicalTrials.gov (**expert** search)

AREA[ConditionSearch] (NIDDM OR T2DM OR T2D OR diabetes OR diabetic) AND AREA[InterventionSearch] EXPAND[Concept] ("gastric bypass" OR "gastric band" OR "gastric banding" OR "gastric imbrication" OR "gastric plication" OR "gastric sleeve" OR "greater curvature plication" OR "gastroileal bypass" OR "jejunal bypass" OR "ileal bypass" OR "biliopancreatic bypass" OR "bilio pancreatic bypass" OR "SASI bypass" OR "SADI bypass" OR "SADI-S bypass" OR "sleeve gastrectomy" OR "banded sleeve" OR "bilio pancreatic diversion" OR "biliopancreatic diversion" OR scopinaro OR "lap band" OR "lap banding" OR RYGB OR Roux OR "duodenal switch")

CONTRIBUTIONS OF AUTHORS

All review authors read and approved the final review draft.

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Bariatric surgery in adults with obesity and diabetes mellitus: a network meta-analysis (Protocol)

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DECLARATIONS OF INTEREST

EK: none known

JS: none known

GS: none known

GM: none known

JF: none known

CS: none known

MIM: none known. MIM is a member of the CMED Group, but she was excluded from the editorial processing of this protocol.

SD: none known

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NOTES

We based parts of the [Methods](#) and [Appendix 1](#) of this Cochrane protocol on a standard template established by the Cochrane Metabolic and Endocrine Disorders Group.