Published in final edited form as:

Cochrane Database Syst Rev. 2011 ; 2011(10): . doi:10.1002/14651858.CD009334.

Antenatal interventions for reducing weight in obese women for improving pregnancy outcome

Christine M Furber¹, Linda McGowan¹, Peter Bower², Evangelos Kontopantelis³, Siobhan Quenby⁴, and Tina Lavender¹

¹School of Nursing, Midwifery and Social Work, The University of Manchester, Manchester, UK

²Health Sciences Research Group, Manchester Academic Health Science Centre, University of Manchester, Manchester, UK

³Health Sciences Primary Care Research Group, The University of Manchester, Manchester, UK

⁴Clinical Sciences Research Institute, University of Warwick, Coventry, UK

Abstract

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate the effectiveness of interventions that reduce weight in obese pregnant women.

BACKGROUND

Description of the condition

Obesity is defined as ‘abnormal or excessive fat accumulation that may impair health’ (World Health Organization 2006). The prevalence of obesity is now at epidemic proportions, and is one of the most important challenges of the 21st century.

Body mass index (BMI) is commonly used to measure an individual’s weight in relation to their height. It is expressed as body weight (kg) divided by the square of height (m²). A calculation of 18.5 to 24.9 (kg/m²) is desirable (normal weight), whereas 25 to 29.9 (kg/m²) is ‘overweight’, 30 (kg/m²) or above is ‘obese’ (Zaninotto 2006). The World Health Organization (World Health Organization 2000) has further classified obesity as:

- BMI 30 - 34.9 (kg/m²) - class I obesity,
- BMI 35.0 - 39.9 (kg/m²) - class II or severe obesity,

Copyright © 2011 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Contact address: Christine M Furber, School of Nursing, Midwifery and Social Work, The University of Manchester, Jean McFarlane Building, Oxford Road, Manchester, M13 9PL, UK. christine.furber@manchester.ac.uk.

Editorial group: Cochrane Pregnancy and Childbirth Group.

Publication status and date: New, published in Issue 10, 2011.

CONTRIBUTIONS OF AUTHORS

Christine Furber and Tina Lavender conceived and designed the review.

Christine Furber wrote the protocol.

Tina Lavender, Linda McGowan, Siobhan Quenby, Peter Bower, and Evangelos Kontopantelis contributed significant input to the text and carefully reviewed drafts of this protocol.

DECLARATIONS OF INTEREST

None known.

- BMI 40 (kg/m²) and above - class III or morbid obesity.

The risks related to being obese at the start of pregnancy are substantial, and may involve the pregnancy, birth, and later life for both the woman and her infant.

Risks in pregnancy for obese women—Compared to normal-weight women, obese women are more at risk of pregnancies affected by congenital anomalies, including spina bifida, cardiovascular anomalies, cleft lip and palate, and limb reduction anomalies (Rankin 2010; Stothard 2009). Several studies suggest that gestational diabetes, hypertension, and pre-eclampsia/eclampsia are common pregnancy complications when obese (Baeton 2001; Doherty 2006; Sebire 2001). Also, around one-fifth of women who are obese at the start of the pregnancy give birth to large (macrosomic) babies (defined as greater than 4000 g or larger than 90th centile) (Baeton 2001; Sebire 2001; Zhang 2007).

Risks during birth for obese women—The pregnancies of obese women are longer, and prolonged gestation may lead to complications at birth. Data from the Danish Birth cohort from 1996 to 2004 indicates that post-term birth (pregnancy length longer than 294 days) is correlated with higher pre-pregnancy BMI (Oleson 2006). In clinical practice, prolonged pregnancies are more likely to be induced (Doherty 2008), and inductions may be unsuccessful when obese (Kerrigan 2009).

Caesarean births are more frequent in women who are obese. Heslehurst 2008 carried out a systematic review of the impact of BMI on pregnancy outcomes. The results indicate significantly reduced odds for vaginal birth when overweight, and obese. Operative birth assistance is needed more often for delays in labour when obese and compared to normal-weight women (Kerrigan 2009; Zhang 2007). Fetal distress in labour has also been reported as more likely, and a reason for emergency caesarean birth, in this group of women (Doherty 2006).

Risks after birth for obese women—Complications after birth are more likely for obese women. An increase in the incidence of postpartum haemorrhage and infections (including wound, urinary tract, perineum, chest and breast) have been reported in obese women, when compared with normal-weight women (Heslehurst 2008). Furthermore, excessive weight gained during pregnancy in women who are already obese is likely to be retained after the birth (Rooney 2005), and may lead to health complications such as diabetes and heart disease in later life (Linne 2003).

The neonates of obese women are at increased risk of increased morbidity and mortality compared with babies born to normal-weight women. The time to commence spontaneous respiration immediately after birth is longer, more resuscitation is required, and there is more risk of neonatal hypoglycaemia, in babies of obese women (Heslehurst 2008). Furthermore, the children of mothers who are obese at the start of their pregnancy are likely to be overweight at the age of three years (Olson 2009).

Weight management for obese women in pregnancy—There is little robust evidence about optimal weight management in pregnancy for obese women. Pregnancy weight varies between individual women (Carmichael 1997), is not linear (Dawes 1991),

and is related to variables such as maternal age, pre-pregnancy body size, parity, smoking, ethnicity, hypertension, and diabetes (Abrams 1995; Chu 2009).

Guidance on weight gain in pregnancy across all maternal weights is contentious. Over the last 20 years, guidance for clinical staff on weight management in pregnancy has been based on recommendations from the US Institute of Medicine (Medicine 1990). These guidelines have been controversial as they were based on research studies that lacked sufficient rigour to be scientifically sound. These guidelines were based on population-based observational studies (Johnson 1995), and studies that did not account for other confounding variables (Feig 1998). In 2009, the US Institute of Medicine Guidelines were revised, and the new guidance based on a wider review of maternal and fetal outcomes (fetal size, risk of unplanned caesarean birth, and excessive postpartum weight retention) (Rasmussen 2009a). Early guidance recommended that obese pregnant women should gain a minimum of 7 kg (Medicine 1990), but in 2009, the recommendations indicate that obese pregnant women should limit their weight gain to between 5.0 kg and 9.1 kg (Rasmussen 2009b).

Weight loss in obese women in pregnancy—Several observational studies suggest that obese pregnant women gain minimal weight in pregnancy, and even lose weight. A retrospective review of pregnancy outcomes in the US found that 11% of obese women lost weight, or maintained their weight, compared to 0.1% of normal-weight women (Edwards 1996). Bianco 1998 reviewed the outcomes of pregnant women with a BMI > 35 and found that 9% lost weight, or gained no weight, compared to 0.2% of normal-weight women. Two more recent studies show similar results. Data from 136,802 women giving birth to singleton fetuses between 1996 and 2001 across 21 states in the US indicated that low weight gain (less than 0.12 kg/wk) was more common in those obese (8.3%, n = 1315) and morbidly obese (19%, n = 1287), than those normal weight (1.9%, n = 1780) (Dietz 2006). Rode 2007 analysed data from 2248 Danish women of all weights at 37 weeks of gestation and found that 9.7% (n = 15) of obese women (n = 155) gained less than 1 kg at this stage of their pregnancy. Another study reviewing gestational weight gain and the risk of adverse pregnancy outcomes reported that 12 of 328 (not significant) obese women in the total sample of 2011 women lost weight, compared to only one woman in each of the normal weight (n = 1227) and overweight (n = 456) groups (Oken 2009).

More recently published studies exploring gestational weight gain suggest that incidence of weight loss in pregnancy increases as women's weight increases; Bodnar 2010 and Hinkle 2010 found that weight loss in pregnancy was more likely in morbidly obese women.

It is important to note that some women deliberately lose weight in pregnancy. Bish 2009 and Cohen 2009 both reported around 8% of pregnant women of all weights attempting to lose weight using strategies such as limiting calories and fat intake, and increasing exercise. When their data were analysed according to BMI category, the proportions increased to almost 13% of obese women attempting weight loss in pregnancy (Bish 2009; Cohen 2009).

Risks associated with weight loss in obese women during pregnancy—The current evidence related to weight loss and obstetric and neonatal outcomes in all pregnant women is limited.

Maternal dieting and restricting food intake in the first trimester of pregnancy may be associated with increased risk of the fetus developing a neural tube defect (Carmichael 2003). Prolonged periods of fasting (greater than 13 hours) and not eating are also linked to preterm birth and increased maternal corticotropin-releasing hormone concentrations (Herrmann 2001). Furthermore, extreme weight loss (greater than 15% of pre-pregnancy weight) in pregnant women suffering from hyperemesis gravidarum is associated with hospitalisation and the need for parenteral nutrition (Fejzo 2009). These women suffered symptoms including gall bladder and liver dysfunction, renal failure and retinal haemorrhage (Fejzo 2009).

Low maternal weight gain and weight loss in pregnancy have been associated with restrictions in fetal growth. Important evidence is available from Holland during the winter of 1944/1945, when food was severely limited because of a harsh winter and an embargo on food transportation. Many pregnant women at the time had food intakes of less than 1000 kcal/daily for a period of seven months. Analysis of birth records from this period in the western Netherlands indicate that birthweight, fetal crown-heel length, and head circumference decreased after exposure to famine in the third trimester (Stein 2004). An analysis of maternal weight in pregnancy from women based in Amsterdam who gave birth between August 1944 and April 1946 enabled comparisons of birth parameters immediately before famine, during food restriction, and after liberation. Maternal weight loss and weight gain below 0.5 kg/week were associated with reduced birthweight, length and ponderal indices (Stein 1995).

Some studies associate maternal weight loss with risks of preterm birth, small-for-gestational-age infants, and some neonatal complications. Edwards 1996 found that obese women who lost weight, or gained nothing in pregnancy, were significantly more likely to give birth to smaller infants with birthweight less than 3000 g and be small-for-gestational-age compared with obese women who gained pregnancy weight within 1990 guidelines (Medicine 1990). Furthermore, a systematic review suggested that restricting protein/energy intake in overweight pregnant women, or women who were gaining weight excessively, may harm the fetus (Kramer 2003). Dewey 1994 proposed that low energy intakes in pregnancy may result in ketosis that can affect the fetus.

Other studies indicate that weight loss or gaining no weight when obese may be beneficial. Bianco 1998 found that the incidence of low birthweight and small-for-gestational-age births were not increased in women with BMI greater than 35 who either lost weight, or gained nothing, during pregnancy.

Emerging evidence suggests that weight loss in pregnancy for obese women may have substantial benefits for both the mother and infant. Oken 2009 reviewed 2011 mother-child pairs against five adverse outcomes related to gestational weight gain: preterm birth, small-for-gestational-age infant, large-for-gestational-age infant, substantial maternal postpartum weight retention, and child obesity at age of three years. The results indicated that the lowest predicted prevalence of all five adverse outcomes occurred with a weight loss of 0.19 kg/week for obese women, which equates to a total loss of 7.6 kg for obese women over all of the pregnancy (Oken 2009).

For heavier women (BMI greater than 40), weight loss in pregnancy appears to be more advantageous. In an exploration of the outcomes of 120,251 pregnant obese women who delivered full-term live singleton infants where the risks of pre-eclampsia, caesarean birth, small-for-gestation infants and large-for-gestation infants were assessed, the results indicated that a weight loss of up to 9 lbs may have minimal risks for women with BMI greater than 40 (Kiel 2007). The Hinkle 2010 review also indicates that women with BMI greater than 40 who lose weight during pregnancy have better outcomes. The lowest absolute risk of developing pre-eclampsia, caesarean birth, and infant size being either small-for-gestational age or large-for-gestational age for these women was after a weight loss of 0 to 4.1 kg (Hinkle 2010).

Clinical management of pregnancy weight in obese women—Ideally, women with BMI > 30 kg/m² should plan to lose weight before conception according to the National Institute of Health and Clinical Excellence (NICE) (NICE 2010). In the UK, NICE 2010 recommends that pregnant women identified as obese at initial antenatal appointments should be advised about the potential risks of losing weight whilst pregnant, and provided with information and support about appropriate diet and exercise. NICE 2010 guidance discourages dieting when pregnant and obese.

Description of the intervention

Interventions for weight loss—There are many interventions that aim to facilitate weight loss in the non-pregnant population. These interventions are often multi-component, combining one or more techniques. Interventions used pre-conceptionally may include:

Lifestyle interventions—These interventions may use techniques such as ‘information giving’ related to lifestyle, for example, nutrition (calorie restriction and eating behaviour modification) and exercise behaviour modification such as increasing walking (Blackburn 2010). The delivery of information is variable entailing use of written material, Internet, telephone contact and/or mail-based, and group-based or individualised contact (Schroder 2010; Stuart 2005; Witham 2010).

Psychological interventions—Techniques that aim to facilitate behaviour change include self-help, peer support, counselling, cognitive behavioural therapy, problem-solving therapy, goal setting, motivational interview techniques, and therapist contact (Pollak 2010; Warziski 2009).

Complementary therapies—Complementary therapies such as acupuncture and meditation may be incorporated into relevant interventions (Elder 2010; Spadaro 2008).

Pharmacological interventions—Interventions that involve pharmacological agents such as Metformin, Sibutramine and Orlistat that aim to reduce weight (Cannon 2009; Warziski 2009).

Surgical interventions—Interventions that include bariatric procedures such as gastric bypass surgery and laparoscopic adjustable banding (Richens 2010). Health professionals and/or non-trained personnel deliver the interventions.

Interventions for weight loss in the pregnant population—Potential interventions that aim to facilitate weight loss in obese pregnant women may combine one or more techniques of the interventions for non-pregnant populations, excluding surgical techniques.

Why it is important to do this review

There are currently no evidence-based guidelines for clinical staff and women related to weight management when obese and pregnant. Recent recommendations from NICE in the UK state that obese women should not diet when pregnant because of risk of harm to the unborn child (NICE 2010). However, the risks of obesity, to both the mother and infant, are substantial when pregnant.

Some obese women lose weight when pregnant (Bianco 1998; Bish 2009; Cohen 2009; Dietz 2006; Edwards 1996; Oken 2009), and especially those who are heaviest (Hinkle 2010). There is insufficient evidence of the known benefits of weight loss when obese and pregnant, or the harm that may occur to the unborn baby.

Deliberate attempts to lose weight are common among the non-pregnant reproductive-aged population (Bish 2005). It is possible therefore that some women may be dieting around the time of conception, and for the weeks prior to pregnancy being confirmed (Cohen 2009). Furthermore, for some women pregnancy is an opportunity to evaluate their lifestyle, and many adjust their diet to eat more healthily for the sake of the child (Gross 2007). Eating healthier when obese may result in weight loss. There is a possibility that some obese women may not disclose their attempts at weight loss when pregnant because they are aware that it is socially unacceptable (Cohen 2009).

As it is clearly apparent that some obese women deliberately try to lose weight in pregnancy (Bish 2009; Cohen 2009), the maternal and neonatal outcomes of weight loss in pregnancy when obese need to be established.

If weight loss in obese pregnant women is beneficial, maternal and infant outcomes may be improved. Postnatal weight retention will be limited and this may lead to greater control over weight management in this group in the future. This may improve health outcomes of future pregnancies. If weight loss is beneficial to obese pregnant women, the development of feasible and acceptable interventions designed to facilitate weight loss may result in decreased costs to health services.

If weight loss is harmful for the obese pregnant woman, the effects should be identified so that appropriate information and advice can be developed.

OBJECTIVES

To evaluate the effectiveness of interventions that reduce weight in obese pregnant women.

METHODS

Criteria for considering studies for this review

Types of studies—We will consider all published and unpublished randomised and quasi-randomised controlled trials, comparing a weight loss intervention with routine care or more than one weight loss intervention. We will include cluster-randomised trials.

Types of participants—Obese pregnant women with a BMI equal to, or greater than 30 (kg/m²).

Types of interventions—All interventions that aim to reduce weight in pregnant women who are obese.

Interventions may be in any setting.

We will include studies where the intervention is introduced in pregnancy.

We will undertake the following comparisons:

- one intervention versus no intervention;
- one intervention versus another intervention.

Types of outcome measures—We will undertake outcome measures on obese pregnant women and their infants.

Primary outcomes

1. Serious maternal morbidity (admission to high dependency care) and/or death.
2. Neonatal admission to neonatal intensive care.
3. Perinatal death (including stillbirth).

Secondary outcomes

Maternal outcomes

1. Gestational diabetes.
2. Fetal distress in pregnancy or labour.
3. Postpartum haemorrhage.
4. Caesarean birth.
5. Infection (including wound, urinary tract, perineum, chest and breast).
6. Weight (loss/gain/no change).

Neonatal outcomes

1. Birthweight less than 2500 g and less than the 10th centile for gestational age and sex.

2. Birth weight greater than 4000 g or larger than the 90th centile for gestational age and sex.
3. Preterm birth (birth less than 37 completed weeks of pregnancy).
4. Apgar scores less than seven at five minutes.
5. Hypoglycaemia - as defined by trialists.

Long-term outcomes

1. Maternal weight postpartum.
2. Childhood weight.

Search methods for identification of studies

Electronic searches—We will contact the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register. The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of EMBASE;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and EMBASE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

Searching other resources—We will not apply any date restrictions.

We will not apply any language restrictions.

We will include abstracts if sufficient data and detail are available. Where necessary, we will contact the authors of abstracts to obtain further information.

We will use our professional contacts to seek further trial data.

Data collection and analysis

Selection of studies—Three review authors (Christine Furber (CF), Tina Lavender (TL), and Linda McGowan (LMcG)) will independently assess for inclusion all the potential studies we identify as a result of the search strategy. We will resolve any disagreement through discussion.

Data extraction and management—We will design a form to extract data. For eligible studies, at least two review authors will extract the data using the agreed form. We will resolve discrepancies through discussion or, if required, we will consult a third person. We will enter data into Review Manager software (RevMan 2011) and check for accuracy. When information regarding any of the above is unclear, we will attempt to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies—Three review authors (CF, TL, and LMcG) will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve any disagreement by discussion.

(1) Random sequence generation (checking for possible selection bias): We will describe for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We will assess the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number); or
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias): We will describe for each included study the method used to conceal allocation to interventions prior to assignment and will assess whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We will assess the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias): We will describe for each included study the methods used, if any, to blind study

participants and personnel from knowledge of which intervention a participant received. We will consider that studies are at low risk of bias if they were blinded, or if we judge that the lack of blinding would be unlikely to affect results. We will assess blinding separately for different outcomes or classes of outcomes.

We will assess the methods as:

- low, high, or unclear risk of bias for participants;
- low, high, or unclear risk of bias for personnel.

(3.2) Blinding of outcome assessment (checking for possible detection bias): We will describe for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We will assess blinding separately for different outcomes or classes of outcomes.

We will assess methods used to blind outcome assessment as:

- low, high, or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data): We will describe for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We will state whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or can be supplied by the trial authors, we will re-include missing data in the analyses which we undertake.

We will assess methods as:

- low risk of bias (e.g. 20% or less missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. greater than 20% missing data; missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias): We will describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We will assess the methods as:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes

of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);

- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by 1 to 5 above): We will describe for each included study any important concerns we have about other possible sources of bias.

We will assess whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias: We will make explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we will assess the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. We will explore the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

Measures of treatment effect

Dichotomous data: For dichotomous data, we will present results as summary risk ratio with 95% confidence intervals.

Continuous data: For continuous data, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome, but use different methods. If there is evidence of skewness, we will report this in the text.

Unit of analysis issues

Cluster-randomised trials: We will include cluster-randomised trials in the analyses along with individually randomised trials. We will adjust their sample sizes using the methods described in the *Handbook* using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely. We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Crossover trials: We will not include crossover trials as these are not an appropriate study design for the interventions in this review.

Other unit of analysis issues

Studies with multiple pregnancies: If we include studies including multiple pregnancies, we will treat the infants as independent and note effects of estimates of confidence intervals in the review.

Studies with more than two treatment groups: If we include studies using one or more treatment groups (multi-arm studies), where appropriate, we will combine groups to create a single pair-wise comparison. We will use methods described in the *Handbook* (Higgins 2011) to ensure that we do not double count participants.

Dealing with missing data—For included studies, we will note levels of attrition. We will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, we will carry out analyses, as far as possible, on an intention-to-treat basis, i.e. we will attempt to include all participants randomised to each group in the analyses, and analyse all participants in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity—We will assess statistical heterogeneity in each meta-analysis using the T^2 , I^2 and Chi^2 statistics. We will regard heterogeneity as substantial if T^2 is greater than zero and by either I^2 estimates (low if $I^2 = 25\%$, moderate if $I^2 = 50\%$ and high if $I^2 = 75\%$) or there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases—If there are 10 or more studies in the meta-analysis we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually, and use formal tests for funnel plot asymmetry. For continuous outcomes we will use the test proposed by Egger 1997, and for dichotomous outcomes we will use the test proposed by Harbord 2006. If we detect asymmetry in any of these tests or by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis—We will carry out statistical analysis using the Review Manager software (RevMan 2011). We will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect: i.e. where trials are examining the same intervention, and the trials' populations and methods are judged sufficiently similar. If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if we detect substantial statistical heterogeneity, we will use random-effects meta-analysis to produce an overall summary if an average treatment effect across trials is considered clinically meaningful. We will treat the random-effects summary as the average range of possible treatment effects and

we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful we will not combine trials.

If we use random-effects analyses, we will present the results as the average treatment effect with its 95% confidence interval, and the estimates of T^2 and I^2 .

Subgroup analysis and investigation of heterogeneity—If we identify substantial heterogeneity, we will investigate it using subgroup analyses and sensitivity analyses. We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it.

We plan to carry out the following subgroup analyses.

1. Pre-pregnancy BMI (morbidly obese versus obese).
2. Primigravidae versus multigravidae.
3. Women under 20 years of age versus those over 20 years of age.
4. Low-income settings versus high income settings.

We will use the following outcomes in subgroup analysis:

- serious maternal and neonatal morbidity/death;
- weight (loss/gain/no change).

For fixed-effect inverse variance meta-analyses we will assess differences between subgroups by interaction tests. For random-effects and fixed-effect meta-analyses using methods other than inverse variance, we will assess differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals indicate a statistically significant difference in treatment effect between the subgroups.

Sensitivity analysis—We will carry out sensitivity analyses as appropriate to evaluate the effect of trial quality.

Acknowledgments

As part of the pre-publication editorial process, this protocol has been commented on by three peers (an editor and two referees who are external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

SOURCES OF SUPPORT

Internal sources

- The University of Manchester, UK.

External sources

- No sources of support supplied

HISTORY

Protocol first published: Issue 10, 2011

Additional references

- Abrams 1995 . Abrams B, Selvi S. Maternal weight gain pattern and birth weight. *Obstetrics & Gynecology*. 1995; 86:163–9. [PubMed: 7617344]
- Baeton 2001 . Baeten JM, Bukusi EA, Lambe M. Pregnancy complications and outcomes among overweight and obese nulliparous women. *American Journal of Public Health*. 2001; 91(3):436–40. [PubMed: 11236410]
- Bianco 1998 . Bianco AT, Smilen SW, Davis Y, Lopez S, Lapinski R, Lockwood CJ. Pregnancy outcome and weight gain recommendations for the morbidly obese woman. *Obstetrics & Gynecology*. 1998; 91:97–102. [PubMed: 9464729]
- Bish 2005 . Bish CL, Blanck HM, Serdula MK, Marcus M, Kohl HW 3rd, Khan LK. Diet and physical activity behaviors among Americans trying to lose weight: 2000 Behavioral Risk Factor Surveillance System. *Obesity Research*. 2005; 13(3):596–607. [PubMed: 15833946]
- Bish 2009 . Bish CL, Chu SY, Shapiro-Mendoza CK, Sharma AJ, Blanck HM. Trying to lose or maintain weight during pregnancy - United States, 2003. *Maternal Child Health Journal*. 2009; 13:286–92. [PubMed: 18449630]
- Blackburn 2010 . Blackburn GL, Wollner S, Heynsfield SB. Lifestyle interventions for the treatment of class III obesity: a primary target for nutrition medicine in the obesity epidemic. *American Journal of Clinical Nutrition*. 2010; 91(Suppl):289S–292S. [PubMed: 19906805]
- Bodnar 2010 . Bodnar LM, Siega-Riz AM, Simhan N, Himes KP, Abrams B. Severe obesity, gestational weight gain, and adverse birth outcomes. *American Journal of Clinical Nutrition*. 2010; 91:1642–8. [PubMed: 20357043]
- Cannon 2009 . Cannon CP, Kumar A. Treatment of overweight and obesity: lifestyle, pharmacologic, and surgical options. *Clinical Cornerstone*. 2009; 9(4):55–71. [PubMed: 19789064]
- Carmichael 1997 . Carmichael S, Abrams B, Selvin S. The pattern of maternal weight gain in women with good pregnancy outcomes. *American Journal of Public Health*. 1997; 87(12):1984–8. [PubMed: 9431288]
- Carmichael 2003 . Carmichael SL, Shaw GM, Schaffer DM, Laurent C, Selvin S. Dieting behaviors and risk of neural tube defects. *American Journal of Epidemiology*. 2003; 158:1127–31. [PubMed: 14652296]
- Chu 2009 . Chu SY, Callaghan WM, Bish CL, D'Angelo D. Gestational weight gain by body mass index among US women delivering live births, 2004–2005: fuelling future obesity. *American Journal of Obstetrics and Gynecology*. 2009; 200(3):271.e1–271.e7. [PubMed: 19136091]
- Cohen 2009 . Cohen JH, Kim H. Sociodemographic and health characteristics associated with attempting weight loss during pregnancy. *Preventing Chronic Disease*. 2009; 6(1):A07. [PubMed: 19080013]
- Dawes 1991 . Dawes MG, Grudzinskas JG. Patterns of maternal weight gain in pregnancy. *British Journal of Obstetrics and Gynaecology*. 1991; 98:195–201. [PubMed: 2004057]
- Dewey 1994 . Dewey KG, McCrory MA. Effects of dieting and physical activity on pregnancy and lactation. *American Journal of Clinical Nutrition*. 1994; 59(Suppl):446S–535S. [PubMed: 8304282]
- Dietz 2006 . Dietz PM, Callaghan WM, Cogswell ME, Morrow B, Ferre C, Schieve LA. Combined effects of prepregnancy body mass index and weight gain during pregnancy on the risk of preterm delivery. *Epidemiology*. 2006; 17(2):170–7. [PubMed: 16477257]
- Doherty 2006 . Doherty DA, Magann EF, Franxis J, Morrison JC, Newnham JP. Pre-pregnancy body mass index and pregnancy outcomes. *International Journal of Gynecology & Obstetrics*. 2006; 95:242–7. [PubMed: 17007857]
- Doherty 2008 . Doherty L, Norwitz ER. Prolonged pregnancy: when should we intervene? *Current Opinion in Obstetrics and Gynecology*. 2008; 20(6):519–27. [PubMed: 18998240]
- Edwards 1996 . Edwards LE, Hellerstedt WL, Alton IR, Story M, Himes JH. Pregnancy complications and birth outcomes in obese and normal-weight women: effects of gestational weight change. *Obstetrics & Gynecology*. 1996; 87:389–94. [PubMed: 8598961]

- Egger 1997 . Egger M, Davey Smith G, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *BMJ*. 1997; 315(7109):629–34. [PubMed: 9310563]
- Elder 2010 . Elder C, Gallison C, Lindberg NM, DeBar L, Funk K, Ritenbaugh C, et al. Randomized trial of Tapas Acupressure Technique for weight loss maintenance: rationale and study design. *Journal of Alternative & Complementary Medicine*. 2010; 16(6):683–90.
- Feig 1998 . Feig DS, Naylor CD. Eating for two: are guidelines for weight gain during pregnancy too liberal? *Lancet*. 1998; 351:1054–5. [PubMed: 9546528]
- Fejzo 2009 . Fejzo MS, Poursharif B, Korst LM, Munch S, MacGibbon KW, Romero R, et al. Symptoms and pregnancy outcomes associated with extreme weight loss among women with hyperemesis gravidarum. *Journal of Women's Health*. 2009; 18(12):1981–7.
- Gross 2007 . Gross, H.; Pattison, H. *Sanctioning Pregnancy. A Psychological Perspective on the Paradoxes and Culture of Research*. Routledge; London and New York: 2007.
- Harbord 2006 . Harbord RM, Egger M, Sterne JA. A modified test for small-study effects in meta-analyses of controlled trials with binary endpoints. *Statistics in Medicine*. 2006; 25(20):3443–57. [PubMed: 16345038]
- Herrmann 2001 . Herrmann TS, Siega-Riz AM, Hobel CJ, Aurora C, Dunkel-Schetter C. Prolonged periods without food intake during pregnancy increase risk for elevated maternal corticotropin-releasing hormone concentrations. *American Journal of Obstetrics and Gynecology*. 2001; 185(2):403–12. [PubMed: 11518900]
- Heslehurst 2008 . Heslehurst N, Simpson L, Ells J, Rankin J, Wilkinson J, Lang R, et al. The impact of maternal BMI on pregnancy outcomes with immediate short-term obstetric resource implications: a meta-analysis. *Obesity*. 2008; 9:635–83.
- Higgins 2011 . Higgins, JPT.; Green, S., editors. *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]*. The Cochrane Collaboration; 2011. Available from www.cochrane-handbook.org
- Hinkle 2010 . Hinkle SN, Sharma AJ, Dietz PM. Gestational weight gain in obese mothers and associations with fetal growth. *American Journal of Clinical Nutrition*. 2010; 92:644–51. [PubMed: 20631201]
- Johnson 1995 . Johnson JW, Yancey MK. A critique of the new recommendations for weight gain in pregnancy. *American Journal of Obstetrics and Gynecology*. 1995; 174:254–8. [PubMed: 8572016]
- Kerrigan 2009 . Kerrigan AM, Kingdon C. Maternal obesity and pregnancy: a retrospective study. *Midwifery*. 2010; 26(1):138–46. [PubMed: 19195748]
- Kiel 2007 . Kiel DW, Dodson EA, Artal R, Boehner TK, Leet TL. Gestational weight gain and pregnancy outcomes in obese women. *Obstetrics & Gynecology*. 2007; 110(4):752–8. [PubMed: 17906005]
- Kramer 2003 . Kramer MS, Kakuma R. Energy and protein intake in pregnancy. *Cochrane Database of Systematic Reviews*. 2003; (4) DOI: 10.1002/14651858.CD000032.
- Linne 2003 . Linne Y, Dye L, Barkelin B, Rossner S. Weight development over time in parous women: The SPAWN study: 15 years follow-up. *International Journal of Obesity*. 2003; 27:1516–22. [PubMed: 14634683]
- Medicine 1990 . Institute of Medicine. *Nutrition During Pregnancy*. National Academy Press; Washington DC: 1990.
- NICE 2010 . National Institute for Health and Clinical Excellence. *Weight Management Before, During and After Pregnancy*. National Institute for Health and Clinical Excellence; London: 2010.
- Oken 2009 . Oken E, Kelnman KP, Belfort MB, Hammitt JK, Gillman MW. Associations of gestational weight gain with short and longer-term maternal and child health outcomes. *American Journal of Epidemiology*. 2009; 170(2):173–80. [PubMed: 19439579]
- Oleson 2006 . Oleson AW, Westergaard JG, Olsen J. Prenatal risk indicators of a prolonged pregnancy: the Danish Birth Cohort 1998–2001. *Acta Obstetrica et Gynecologica Scandinavica*. 2006; 85(11):1338–41. [PubMed: 17091414]

- Olson 2009 . Olson CM, Strawderman MS, Dennison BA. Maternal weight gain during pregnancy and child weight at age 3 years. *Maternal and Child Health Journal*. 2009; 13:839–46. [PubMed: 18818995]
- Pollack 2010 . Pollack KI, Alexander SC, Coffman CJ, Tulskey JA, Lyna P, Dolor RJ, et al. Physician communication techniques and weight loss in adults Project CHAT. *American Journal of Preventive Medicine*. 2010; 39(4):321–8. [PubMed: 20837282]
- Rankin 2010 . Rankin J, Tennant PWG, Stothard KJ, Bythell M, Summerbell CD, Bell R. Maternal body mass index and congenital anomaly risk: a cohort study. *International Journal of Obesity*. 2010; 34:1371–80. [PubMed: 20368710]
- Rasmussen 2009a . Rasmussen KM, Catalano PM, Yaktine AL. New guidelines for weight gain during pregnancy: what obstetricians/gynaecologists should know. *Current Opinion in Obstetrics and Gynecology*. 2009; 21:521–6. [PubMed: 19809317]
- Rasmussen 2009b . Rasmussen, KM.; Yaktine, AL., editors. *Weight Gain During Pregnancy: Reexamining the Guidelines*. The National Academies Press; Washington DC: 2009.
- RevMan 2011 . The Nordic Cochrane Centre. The Cochrane Collaboration. Review Manager (RevMan). 5.1. The Nordic Cochrane Centre, The Cochrane Collaboration; Copenhagen: 2011.
- Richens 2010 . Richens, Y.; Fiennes, A. Bariatric surgery and care of pregnant women. In: Richens, Y.; Lavender, T., editors. *Care for Pregnant Women Who Are Obese*. Quay Books; London: 2010. p. 19-27.
- Rode 2007 . Rode L, Heggard HK, Kjaergaard H, Moller LF, Tabor A, Ottesen B. Association between maternal weight gain and birth weight. *Obstetrics & Gynecology*. 2007; 109(6):1309–15. [PubMed: 17540802]
- Rooney 2005 . Rooney BL, Schauburger CW, Mathiason MA. Impact of perinatal weight change on long-term obesity and obesity-related illnesses. *Obstetrics & Gynecology*. 2005; 106(6):1349–56. [PubMed: 16319262]
- Schroder 2010 . Schroder KEE. Computer-assisted dieting: effects of a randomised controlled intervention. *Psychology and Health*. 2010; 25:519–34. [PubMed: 20204974]
- Sebire 2001 . Sebire N, Jolly M, Harris J, Wadsworth J, Joffe M, Beard R, et al. Maternal obesity and pregnancy outcome: a study of 287,213 pregnancies In London. *International Journal of Obesity and Related Metabolic Disorders*. 2001; 25(8):1175–82.
- Spadaro 2008 . Spadaro, KC. *Weight loss: exploring self-regulation through mindfulness meditation* [PhD dissertation]. University of Pittsburgh; Pittsburgh: 2008.
- Stein 1995 . Stein AD, Ravelli ACJ, Lumey LH. Famine, third-trimester pregnancy weight gain, and intrauterine growth: the Dutch famine birth cohort study. *Human Biology*. 1995; 67(1):135–49. [PubMed: 7721275]
- Stein 2004 . Stein AD, Zybert PA, Van der Bor M, Lumer LH. Intrauterine famine exposure and body proportions at birth: the Dutch hunger winter. *International Journal of Epidemiology*. 2004; 33:831–6. [PubMed: 15166208]
- Stothard 2009 . Stothard KJ, Tennat PWG, Bell R, Rankin J. Maternal overweight and obesity and the risk of congenital anomalies. *JAMA*. 2009; 3016:636–50. [PubMed: 19211471]
- Stuart 2005 . Stuart WP, Broome ME, Smith BA, Weaver M. An integrative review of interventions for adolescent weight loss. *Journal of School Nursing*. 2005; 21(2):77–85. [PubMed: 15801873]
- Warziski 2009 . Warziki M, Yang K, Hravnak M, Sereika SM, Ewing LJ, Burke LE. Randomized clinical trials of weight loss maintenance. *Journal of Cardiovascular Nursing*. 2009; 24(1):58–80.
- Witham 2010 . Witham MD, Avenell A. Interventions to achieve long-term weight loss in obese older people. A systematic review and meta-analysis. *Age and Ageing*. 2010; 39:176–84. [PubMed: 20083615]
- World Health Organization 2000 . World Health Organization. *Obesity: preventing and managing the global epidemic*. World Health Organization; Geneva: 2000.
- World Health Organization 2006 . World Health Organization. *Overweight and obesity. Fact sheet N °311*. World Health Organization; Geneva: 2006.
- Zaninotto 2006 . Zaninotto, P.; Wardle, H.; Samakakis, E.; Mindell, J.; Head, J. *Forecasting obesity to 2010*. Department of Health; London: 2006.

Zhang 2007 . Zhang J, Bricker L, Wray S, Quenby S. Poor uterine contractility in obese women. BJOG: An International Journal of Obstetrics and Gynaecology. 2007; 114:343–8. [PubMed: 17261121]

* *Indicates the major publication for the study*