# Diet and exercise interventions for preventing gestational diabetes mellitus (Review)

**Bain E, Crane M, Tieu J, Han S, Crowther CA, Middleton P**


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[Intervention Review]

# Diet and exercise interventions for preventing gestational diabetes mellitus

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## ABSTRACT

### Background

Gestational diabetes mellitus (GDM) is associated with a wide range of adverse health consequences for women and their babies in the short and long term. With an increasing prevalence of GDM worldwide, there is an urgent need to assess strategies for GDM prevention, such as combined diet and exercise interventions.

### Objectives

To assess the effects of combined diet and exercise interventions for preventing GDM and associated adverse health consequences for women and their babies.

### Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (11 February 2014) and reference lists of retrieved studies. We updated the search in February 2015 but these results have not yet been incorporated and are awaiting classification.

### Selection criteria

Randomised controlled trials (RCTs) and cluster-RCTs assessing the effects of interventions that included diet and exercise components. We included studies where combined diet and exercise interventions were compared with no intervention (i.e. standard care).

We planned to also compare diet and exercise interventions with alternative diet and/or exercise interventions but no trials were identified for this comparison.

### Data collection and analysis

Two review authors independently assessed study eligibility, extracted data and assessed the risk of bias of the included studies. Data were checked for accuracy.

**Main results**

We included 13 randomised controlled trials (involving 4983 women and their babies). We assessed the included trials as being of moderate risk of bias overall.

When comparing women receiving a diet and exercise intervention with those receiving no intervention, there was no clear difference in the risk of developing GDM (average risk ratio (RR) 0.92, 95% confidence interval (CI) 0.68 to 1.23; 11 trials, 3744 women), caesarean section (RR 0.92, 95% CI 0.83 to 1.01; seven trials, 3246 women), or large-for-gestational age (RR 0.90, 95% CI 0.77 to 1.05; 2950 infants). Only one trial reported on perinatal mortality, and found no clear difference in the risk of stillbirth (RR 0.99, 95% CI 0.29 to 3.42; 2202 fetuses) or neonatal death (RR 0.99, 95% CI 0.06 to 15.85; 2202 neonates).

Very few differences were shown between groups for the review's secondary outcomes, including for induction of labour, perineal trauma, pre-eclampsia, postpartum haemorrhage and infection, macrosomia, birthweight, small-for-gestational age, ponderal index, neonatal hypoglycaemia requiring treatment, hyperbilirubinaemia requiring treatment, shoulder dystocia, bone fracture or nerve palsy. Women receiving a combined diet and exercise intervention were, however, found to have a reduced risk of preterm birth compared with women receiving no intervention (RR 0.71, 95% CI 0.55 to 0.93; five trials, 2713 women).

A trend towards reduced weight gain during pregnancy was shown for women receiving the combined diet and exercise intervention (mean difference (MD) -0.76 kg, 95% CI -1.55 to 0.03; eight trials, 2707 women; P = 0.06, random-effects); but no clear difference in postnatal weight retention was observed overall.

In relation to adherence to the interventions, a number of trials that reported on behaviour modifications showed benefits in diet- (5/8 trials) and physical activity- (4/8 trials) related behaviours for women receiving the combined diet and exercise intervention, compared with women receiving no intervention; however there was notable variation across trials in outcomes measured and results observed. Only two trials reported on well-being and quality of life of women, and did not observe differences between groups for these outcomes.

Very few trials reported on outcomes relating to the use of health services, although one trial suggested a reduced length of antenatal hospital stay for women receiving a combined diet and exercise intervention (MD -0.27 days, 95% CI -0.49 to -0.05; 2153 women).

No information was available on outcomes for the infant as a child or adult, or for most longer-term outcomes for the mother.

**Authors' conclusions**

There are limitations associated with the available RCT evidence on the effects of combined diet and exercise interventions during pregnancy for preventing GDM. Results from 13 RCTs (of moderate quality) suggest no clear difference in the risk of developing GDM for women receiving a combined diet and exercise intervention compared with women receiving no intervention. However, the ability to draw firm conclusions was limited by variations in the quality of trials, characteristics of the interventions and populations assessed, and outcome definitions between trials.

Based on the data currently available, conclusive evidence is not available to guide practice. Further large, well-designed RCTs, addressing the limitations of previous studies, are needed to assess the effects of combined interventions on preventing GDM and other relevant pregnancy outcomes including caesarean birth, large-for-gestational age and perinatal mortality. Health service utilisation and costs, and longer-term outcomes for mothers and their babies should be included. We identified another 16 trials which are ongoing and we will consider these for inclusion in the next update of this review.

[Note: The 28 records in 'Studies awaiting classification' may alter the conclusions of the review once assessed].

## PLAIN LANGUAGE SUMMARY

### Diet and exercise in pregnancy for preventing gestational diabetes mellitus

Gestational diabetes mellitus (GDM) is high blood glucose (hyperglycaemia) first occurring or first recognised during pregnancy. Between 1% and 14% of pregnant women develop GDM, with some at a higher risk than others (for example, women who are overweight or obese, older, of particular ethnicities, have had GDM previously, or have a family history of type II diabetes). GDM can cause significant health problems for mothers and babies. The babies may grow very large and, as a result, be injured at birth, or cause injury to mothers during birth. Women with GDM have an increased risk of having an induced birth, of their babies being born by caesarean section, and of having a preterm birth (before 37 weeks of pregnancy). Additionally, there can be long-term health problems for mothers and babies, including an increased risk of type II diabetes. Some diets (for example, those with low fibre and high glycaemic

load) and physical inactivity, are potentially modifiable risk factors for GDM. There is evidence that lifestyle interventions in the general population (promoting diet and exercise changes) can prevent type II diabetes, and it has been suggested that these interventions may help prevent GDM in pregnancy.

This review assessed the effects of combined diet and exercise interventions for preventing GDM. We identified 13 randomised controlled trials (involving 4983 women and their babies). The studies were of moderate quality. Women who received diet and exercise interventions were compared with those who received no intervention. No clear differences between the two groups of women were seen in the risks of GDM, caesarean birth, or large-for-gestational age babies. Only one trial reported on deaths of the babies around the time of birth and did not show any difference between groups. Babies born to mothers receiving diet and exercise interventions were less likely to be born preterm, and some women who received the interventions improved their diet and physical activity. Very few other differences were shown between groups. The trials varied in their risk of bias, and also the interventions they evaluated. None of the trials reported on costs of health care, or long-term health of the mothers and babies.

Based on current data, conclusive evidence is not available to guide practice. Further, large, well-designed randomised trials are needed. Sixteen trials are ongoing and will be considered in the next update of this review.

# BACKGROUND

## Description of the condition

### Introduction and definition

Gestational diabetes mellitus (GDM) is a complication of pregnancy that is defined as carbohydrate intolerance resulting in hyperglycaemia (abnormally high blood sugar) of variable severity with onset or first recognition during pregnancy (WHO 1999). GDM defined in this way includes women with undiagnosed pre-existing diabetes, as well as those for whom the first onset is during pregnancy (especially during the third trimester of pregnancy).

### Pathophysiology and symptoms

In normal pregnancy, relative maternal insulin resistance develops, beginning in the second trimester, with a progressive decline in insulin sensitivity until term. This physiological change facilitates the transport of glucose across the placenta to stimulate normal fetal growth and development. For women with GDM, a greater degree of maternal insulin resistance may lead to maternal hyperglycaemia, increased glucose transport across the placenta, fetal hyperinsulinaemia and accelerated growth in the fetus (Setji 2005). Usually, pregnancy-induced maternal insulin resistance resolves promptly after the baby is born.

While many women are asymptomatic, symptoms and signs associated with hyperglycaemia, such as polyuria (increased urinary frequency), polydipsia (increased thirst), blurred vision and fatigue, may be seen where GDM is undetected or poorly controlled (Kjos 1999).

### Risk factors for GDM

Observational studies have helped to identify a multitude of risk factors for GDM; these include maternal body mass index (BMI) of at least 30 kg/m², physical inactivity (Chasan-Taber 2008), advancing maternal age (Morisset 2010), increasing parity, and ethnicity. Diets low in fibre, with a high glycaemic load have been shown to increase the risk of GDM (Zhang 2006). Women are also at an increased risk of GDM who have had a previous macrocosmic baby (birthweight 4000 g or more), have had previous GDM (Petry 2010), have a family history or first-degree relative with diabetes, or have polycystic ovarian syndrome (Reece 2010). Weight gain during pregnancy for women who are overweight or obese has been shown to correlate with GDM risk (Hedderson 2010; Morisset 2010).

### Investigations

The prevalence of GDM is increasing worldwide in parallel with increasing rates of type II diabetes mellitus and maternal obesity (Bottalico 2007; Dabelea 2005). Depending on the population sampled and diagnostic criteria used, reported prevalences range from 1% to 18% (ADA 2004; Coustan 2010; Mulla 2010). Diagnostic methods vary and there are currently no uniformly accepted international diagnostic criteria. The World Health Organization (WHO) recommends a 75 g oral glucose tolerance test (OGTT) at 24 to 28 weeks' gestation. The woman is fasted prior to being given a 75 g glucose load, with measurement of the blood glucose concentration two hours later (WHO 1999). In some parts of the world a 100 g three-hour OGTT is used. Universal screening is encouraged due to an absence of pre-identifiable risk factors in up to 50% of cases (Carr 1998). However, in some parts of the world,

screening is only performed in 'high-risk' women, following an assessment of risk factors. There is currently a lack consistency in regards to screening procedures and diagnostic criteria between and within countries.

The Hyperglycaemia and Adverse Pregnancy Outcome (HAPO) study was designed to clarify risks of adverse outcomes associated with degrees of maternal glucose intolerance (Coustan 2010). Following this study, a task force of the International Association of Diabetes in Pregnancy Study Group (IADPSG) recommended new criteria for the diagnosis of GDM, which diagnoses GDM if any of the following three 75 g OGTT thresholds are met or exceeded: fasting plasma glucose: 5.1 mmol/L (92 mg/dL), one-hour plasma glucose: 10.0 mmol/L (180 mg/dL) or two-hour plasma glucose: 8.5 mmol/L (153 mg/dL) (IADPSG Consensus Panel 2010). Global adoption of these recommendations would lead to substantial change in practice, in some countries, an increase in the diagnosis of GDM, and accordingly significant challenges for healthcare systems. A number of studies have already revealed higher GDM prevalence when using the IADPSG, compared with other (including WHO) criteria (Edwards 2011; Moses 2011; O'Sullivan 2011), and some have confirmed an increase in adverse pregnancy outcomes for the diagnosed women (O'Sullivan 2011). Debate surrounding the risks, costs and benefits of use of these diagnostic criteria is ongoing (Langer 2013).

### Health consequences of GDM

GDM is associated with an increased occurrence of a number of complications during pregnancy including pre-eclampsia (Dodd 2007), and the requirement for induction of labour or caesarean section (Dodd 2007; Reece 2010). Fetal consequences may include macrosomia, which in turn may be associated with adverse maternal outcomes such as uterine rupture, and perineal lacerations (Reece 2010). Women who develop GDM have a significantly increased risk of developing type II diabetes later in life (Bellamy 2009); they are also at an increased risk of developing GDM in future pregnancies (Bottalico 2007).

For the infant, GDM is associated with a range of complications. Babies born to mothers with GDM are more likely to be macrosomic or large-for-gestational age (Crowther 2005; Metzger 2008; Reece 2009; Reece 2010). Large-for-gestational-age infants are at increased risk of birth injury, including perinatal asphyxia, and shoulder dystocia, bone fractures and nerve palsies (Henriksen 2008; Reece 2010). These infants are at increased risk of developing type II diabetes, hypertension, obesity and metabolic syndrome later in life (ADA 2004; Reece 2010; Whincup 2008). In addition, babies born to mothers with GDM are at increased risk of neonatal hypoglycaemia (Dodd 2007), respiratory distress syndrome, polycythaemia (raised red blood cell count), hyperbilirubinaemia, and being born preterm (Metzger 2008; Reece 2009; Reece 2010). Such health consequences together contribute to a need for enhanced neonatal care (Svare 1999). If untreated, GDM may be associated with an increased risk of perinatal mortality.

In randomised controlled trials, the treatment of women with mild GDM (dietary intervention, self-monitoring of blood glucose and insulin therapy if needed) has been shown to significantly reduce the risk of a number of associated complications including fetal overgrowth, shoulder dystocia, and hypertensive disorders (Crowther 2005; Landon 2009). The Cochrane review '*Treatments for gestational diabetes*' concluded that some specific treatments (including dietary advice and insulin) for mild GDM may reduce the risk of maternal and perinatal morbidity (Alwan 2009).

Maternal hyperglycaemia less severe than that associated with a diagnosis of GDM, may also result in clinically important complications for the both mother and her infant (Han 2012a; Metzger 2008). While the risk of adverse maternal and infant pregnancy outcomes appears to increase with increasing levels of glucose impairment (Dodd 2007), the concentration at which pregnancy hyperglycaemia becomes pathological has not been conclusively determined (Metzger 2008; Mulla 2010).

## Description of the intervention

### Dietary interventions

The aim of dietary advice or related interventions in pregnancy is to optimise glycaemic control, thus preventing maternal hyperglycaemia and reducing post-prandial glucose concentrations. Dietary advice may be aimed at ensuring women's diets provide sufficient energy and nutrients to allow normal fetal growth while avoiding accelerated fetal growth patterns, and minimising excessive weight gain (Dornhorst 2002). As glucose is the primary source of energy for fetal growth (Moses 2006), excessive fetal growth is most effectively limited by sustaining low post-prandial glucose concentrations (Dornhorst 2002).

The benefits of low glycaemic index (GI) diets have been shown for individuals being treated for type II diabetes (Brand-Miller 2003), and some evidence exists to suggest similar benefits may be conferred for women with GDM (Cheung 2009). GI quantitatively defines the effect of carbohydrate-based foods on blood glucose concentration (Jenkins 1981). The GI value for a food is determined by comparing the blood glucose response to that food to the response to an equivalent amount of standard glucose (Foster-Powell 2002). Foods with a 'low' GI (less than 55) induce a gradual increase in blood glucose due to slow digestion and absorption, whereas foods that produce a rapid rise in blood glucose concentration are referred to as 'high' GI (greater than 70). Examples of low GI foods are wholegrain bread and dairy foods. High GI foods include potatoes, highly processed carbohydrate foods such as white bread and some breakfast cereals (Atkinson 2008; Jenkins 1981).

Other suggested dietary recommendations for GDM prevention have included the consumption of a high fibre diet (Fraser 1983), and changing the proportion of each macronutrient that makes up the woman's overall intake, for example, increasing the proportion of fat in the diet to compensate for carbohydrate proportion changes (Dornhorst 2002). While high fat diets may have a low GI, they are generally contraindicated due to known associated cardiovascular health risks.

### Exercise interventions

Benefits of exercise during pregnancy are now recognised, and thus women are encouraged to engage in 'light-to-moderate' exercise in the absence of any known pregnancy or medical complications (ACOG 2002; Davies 2003; Dempsey 2005). The Royal College of Obstetricians and Gynaecologists recommend that all women participate in aerobic and strength-conditioning exercise, with the goal of maintaining a good fitness level, as part of a healthy lifestyle during pregnancy (RCOG 2006). Women often reduce their levels of physical activity during pregnancy (Pereira 2007), many due to a perceived risk to maternal or fetal health (Clarke 2004) and the impact of early pregnancy symptoms such as nausea and fatigue (Pereira 2007).

Regular aerobic exercise may lead to lower fasting and postprandial blood glucose concentrations in previously sedentary individuals. Exercise may decrease circulating glucose and insulin during, and for a period of time after, an exercise session (Clapp 1991; Clapp 1998). It has been shown outside of pregnancy that exercise can reduce the risk and delay the onset of the development of type II diabetes mellitus (Jeon 2007). Exercise has been shown to reduce insulin resistance in men and non-pregnant women, leading to effective prevention and management of type II diabetes (Clapp 2006; Knowler 2002; Redden 2011).

Suggested benefits of exercise during pregnancy include a reduction in lower back pain, fluid retention and cardiovascular stress (Schlüssel 2008). Exercise is believed to play a role in reducing the risk of complications such as preterm birth and pre-eclampsia (Dempsey 2005; Schlüssel 2008), and may help prevent excess pregnancy weight gain and postpartum weight retention (Schlüssel 2008). There is increasing evidence from observational studies indicating that pre-pregnancy exercise and exercise in early pregnancy is associated with a reduction in insulin resistance (Reece 2009), and consequently a reduced risk of developing GDM (Jeon 2007; Redden 2011).

## How the intervention might work

### Combined diet and exercise interventions

While dietary advice and exercise interventions alone for the prevention of type II diabetes and GDM have been widely assessed, more recently a shift towards combining such interventions in what may be regarded as 'lifestyle' interventions has been observed. Several randomised controlled trials have established that the progression to type II diabetes can be prevented or postponed with lifestyle interventions in individuals with impaired glucose tolerance in the general population ('high-risk' individuals) (Knowler 2002; Li 2008; Ratner 2008; Tuomilehto 2001). Such studies have focused strongly on combining increased physical activity and dietary modification, along with weight reduction for overweight participants. Long-term follow-up studies of such lifestyle interventions (that lasted for a limited time), have shown sustained beneficial effects on risk factors and diabetes incidence (Tuomilehto 2011). It has been suggested that a key factor in the success of such interventions is the comprehensive approach, addressing and working to correct several lifestyle-related risk factors simultaneously (Tuomilehto 2011).

As it is accepted that a multitude of risk factors may increase the risk of type II diabetes, these randomised trials focused on a number of lifestyle-related factors concurrently. In a Finnish Diabetes Prevention Study, five lifestyle targets were predefined, including: weight loss greater than 5%, intake of fat lower than 30% energy, intake of saturated fats lower than 10% energy, intake of dietary fibre greater than 15 g/1000 kcal, and an increase of physical activity to at least four hours per week (Tuomilehto 2001). These targets were perceived as relatively modest, and it was believed that such lifestyle changes would be feasible to maintain in the long term (Tuomilehto 2011). No 'high-risk' individual with impaired glucose tolerance developed diabetes during the trial if they achieved at least four of the five lifestyle targets (Tuomilehto 2001). This trial was the first of a number to show that type II diabetes may be prevented with lifestyle interventions, and highlighted the importance of addressing multiple lifestyle-related risk factors for optimal benefit (Knowler 2002; Li 2008; Tuomilehto 2001).

Whilst such trials considered type II diabetes and did not focus on pregnant women, they do offer some support for the use of lifestyle interventions in pregnant women for the prevention of GDM. To date, the Cochrane reviews assessing dietary advice alone and exercise interventions alone, for GDM prevention, have revealed inconclusive findings (Han 2012b; Tieu 2008). The review '*Dietary advice in pregnancy for preventing gestational diabetes mellitus*' (Tieu 2008) included three small trials, and concluded that while a low GI diet was shown to be beneficial for some outcomes for the mother (lower maternal fasting glucose concentration) and infant (reduction in risk of large-for-gestational age, and lower ponderal indexes) (Clapp 2006; Moses 2006). The evidence was limited and not of a high quality (Tieu 2008). Similarly, the review '*Exercise for pregnant women for preventing gestational diabetes mellitus*' (Han 2012b) concluded that there was no clear evidence to support exercise during pregnancy for reducing the risk of developing GDM, and no benefits for the infant were seen with increased physical activity (Han 2012b).

As it is widely acknowledged that many factors are associated with

GDM risk, it is considered plausible that lifestyle interventions, aimed at correcting lifestyle-related risk factors, may be effective in preventing GDM. Such lifestyle interventions may combine dietary advice or modifications with exercise interventions.

### Why it is important to do this review

GDM is associated with a wide range of adverse health consequences for women and their babies in the short and long term. Effective strategies are thus required to prevent GDM and the associated complications. This review will complement the existing reviews titled '*Dietary advice in pregnancy for preventing gestational diabetes mellitus*' (Tieu 2008) and '*Exercise for pregnant women for preventing gestational diabetes mellitus*' (Han 2012b), and will assess combined diet and exercise interventions for preventing GDM.

## OBJECTIVES

To assess the effects of dietary interventions in combination with physical exercise interventions for pregnant women for preventing gestational diabetes mellitus (GDM), and associated adverse health consequences for the mother and her infant/child.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

We included all published randomised controlled trials assessing the effects of combined diet and exercise interventions for preventing GDM. We included cluster-randomised trials, and studies published as abstracts only. We planned to exclude quasi-randomised controlled trials and cross-over trials.

#### Types of participants

We included pregnant women regardless of age, gestation, parity or plurality. We excluded studies involving women with pre-existing type I or type II diabetes.

#### Types of interventions

We included interventions that incorporated any type of dietary advice with any type of exercise intervention (i.e. exercise advice, providing exercise sessions). We included studies where such interventions were compared with no intervention (i.e. standard care), and planned to include where they were compared with an alternative dietary and/or exercise intervention.

#### Types of outcome measures

##### Primary outcomes

**Maternal outcomes**

1. GDM (diagnostic criteria as defined in individual trials)
2. Mode of birth (normal vaginal birth, operative vaginal birth, caesarean section)

**Fetal/neonatal outcomes**

1. Large-for-gestational age (as defined in individual trials)
2. Perinatal mortality (fetal and neonatal mortality)

##### Secondary outcomes

**Maternal outcomes**

***Perinatal***

1. Pregnancy hyperglycaemia not meeting GDM diagnostic criteria (diagnostic criteria as dened in individual trials)
2. Induction of labour
3. Augmentation of labour
4. Perineal trauma
5. Pre-eclampsia
6. Weight gain during pregnancy
7. Gestational age at screening for GDM
8. Postpartum haemorrhage
9. Postpartum infection
10. Placental abruption
11. Adherence with intervention
12. Women's sense of well-being and quality of life (as defined in individual trials)
13. Women's view of intervention

***Long-term outcomes***

1. Postnatal weight retention
2. Body mass index (BMI)
3. GDM in subsequent pregnancy
4. Development of type II diabetes mellitus
5. Development of type I diabetes mellitus

6. Impaired glucose tolerance (as defined in individual trials)
7. Insulin sensitivity (as defined in individual trials)

**Fetal/neonatal outcomes**

1. Macrosomia (birthweight greater than 4000 g)
2. Birthweight
3. Small-for-gestational age (as defined in individual trials)
4. Neonatal hypoglycaemia requiring treatment (as defined in individual trials)
5. Gestational age at birth
6. Preterm birth (less than 37 weeks' gestation)
7. Shoulder dystocia
8. Bone fracture
9. Nerve palsy
10. Respiratory distress syndrome
11. Hyperbilirubinaemia requiring treatment (as defined in individual trials)
12. Apgar scores (less than seven at five minutes)
13. Ponderal index
14. Skinfold thickness measurements
15. Neonatal glucose concentrations

**Childhood outcomes**

1. Weight
2. Height
3. BMI
4. Fat mass/fat-free mass
5. Skinfold thickness measurement
6. Blood pressure
7. Impaired glucose tolerance (as defined in individual trials)
8. Development of type I diabetes mellitus
9. Development of type II diabetes mellitus
10. Insulin sensitivity (as defined in individual trials)
11. Dyslipidaemia or metabolic syndrome
12. Neurodisability
13. Educational achievement

**Adulthood outcomes**

1. Weight
2. Height
3. BMI
4. Fat mass/fat-free mass
5. Skinfold thickness measurements
6. Blood pressure
7. Impaired glucose tolerance (as defined in individual trials)
8. Development of type I diabetes
9. Development of type II diabetes
10. Insulin sensitivity (as defined in individual trials)
11. Dyslipidaemia or metabolic syndrome
12. Educational achievement

**Health services cost**

1. Number of hospital visits or health professional visits (e.g. physiotherapist) or antenatal visits for mother
2. Medical physician visits
3. Costs to families in relation to the management provided
4. Length of postnatal stay (mother)
5. Admission to neonatal ward
6. Length of postnatal stay (neonate)
7. Cost of maternal care
8. Cost of offspring care

## Search methods for identification of studies

The following methods section of this review is based on a standard template used by the Cochrane Pregnancy and Childbirth Group.

### Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (11 February 2014). We updated the search on 16 February 2015. Those results have been added to 'Studies awaiting classification', and will be incorporated into the review at the next update.
The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

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

Details of the search strategies for CENTRAL, MEDLINE, Embase and CINAHL, 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 searched the reference lists of retrieved studies.
We did not apply any language or date restrictions.

## Data collection and analysis

### Selection of studies

Two review authors independently assessed for inclusion all the potential studies we identified as a result of the search strategy. We resolved any disagreement through discussion or, if required, we consulted a third review author.

### Data extraction and management

We designed a form to extract data. For eligible studies, two review authors extracted the data using the agreed form. We resolved discrepancies through discussion or, if required, we consulted the third review author. We entered data into Review Manager software (RevMan 2014) and checked for accuracy.

When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

### Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreement by discussion or by involving a third assessor.

#### (1) Random sequence generation (checking for possible selection bias)

We described 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 assessed 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);
- unclear risk of bias.

#### (2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed 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 described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered studies to be at low risk of bias if they were blinded, or if we judged that the lack of blinding would be unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed 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 described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed 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 described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We have stated 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.

We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for 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 described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

- low risk of bias (where it was clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review were reported);
- high risk of bias (where not all the study's pre-specified outcomes were reported; one or more reported primary outcomes were not pre-specified; outcomes of interest were reported incompletely and so could not be used; study failed 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 described for each included study any important concerns we had about other possible sources of bias.

We assessed 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 was risk of other bias.

#### (7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

### Measures of treatment effect

#### Dichotomous data

For dichotomous data, we have presented results as summary risk ratio with 95% confidence intervals.

#### Continuous data

For continuous data, we have used the mean difference where outcomes were measured in the same way between trials. We planned to use the standardised mean difference to combine trials that measured the same outcome, but used different methods.

### Unit of analysis issues

#### Cluster-randomised trials

We included two cluster-randomised trials in the analyses along with individually-randomised trials. We adjusted their sample sizes and event rates using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), using an estimate of the intracluster correlation co-efficient (ICC) derived from another included study (Luoto 2011) of 0.12. We considered it reasonable to combine the results from the cluster-randomised trials and the individually-randomised trials as there was little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit was considered to be unlikely.

We acknowledged heterogeneity in the randomisation unit and performed a subgroup analysis to investigate the effects of the randomisation unit.

#### Cross-over trials

We considered cross-over designs inappropriate for this research question.

#### Multi-arm studies

For multi-arm studies, we planned to use methods as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) to overcome possible unit-of analysis errors, by combining groups to make a single pair-wise comparison (where appropriate), or by splitting the 'shared' group into two (or more) groups with smaller sample sizes, and including the two (or more) comparisons.

### Dealing with missing data

For included studies, we noted levels of attrition. We planned to explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using a sensitivity analysis.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we have attempted to include all participants randomised to each group in the analyses, and all participants were analysed 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 was the number randomised minus any participants whose outcomes were known to be missing.

### Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the $T^2$, $I^2$ and $Chi^2$ statistics. We regarded heterogeneity as substantial where the $I^2$ was greater than 30% and either the $T^2$ was greater than zero, or there was a low P value (less than 0.10) in the $Chi^2$ test for heterogeneity.

### Assessment of reporting biases

Where there were 10 or more studies in a meta-analysis, we investigated reporting biases (such as publication bias) using funnel plots. We assessed funnel plot asymmetry visually. If asymmetry was suggested by a visual assessment, we planned to perform exploratory analyses to investigate it.

### Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2014). We used fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. Where there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or where substantial statistical heterogeneity was detected, we used random-effects meta-analysis to produce an overall summary if an average treatment effect across trials was considered clinically meaningful. The random-effects summary was treated as the average of the range of possible treatment effects and we have discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we would not have combined trials.

Where we have used random-effects analyses, the results have been presented as the average treatment effect with 95% confidence intervals, and the estimates of $T^2$ and $I^2$.

### Subgroup analysis and investigation of heterogeneity

If we had identified substantial heterogeneity, we planned to investigate it using subgroup analyses and sensitivity analyses. We planned to consider whether an overall summary was meaningful, and if it was, use random-effects analysis to produce it.

Maternal characteristics, and characteristics of the dietary advice or exercise interventions assessed were considered likely to affect health outcomes.

We planned to carry out the following subgroup analyses.

- Maternal age (35 years of age or more versus less than 35 years of age).
- Maternal BMI (at or before trial entry) (BMI of 18.5 to 24.9 kg/m$^2$ versus BMI of less than 18.5 kg/m$^2$; versus BMI of 25 to 29.9 kg/m$^2$; versus BMI of 30 kg/m$^2$ to 39.9 kg/m$^2$; and versus BMI of 40 kg/m$^2$ or more).
- Ethnicity (high-risk ethnic groups for GDM versus low-risk ethnic groups for GDM).
- Parity (parity of zero versus one to two; and versus three or more).
- Nature of the exercise intervention (e.g. frequent versus infrequent advice/sessions; short versus long duration of advice/sessions; high intensity verus low intensity of advice/sessions; advice only versus interactive sessions).
- Nature of the dietary intervention (e.g. frequent versus infrequent intervention; short versus long duration of intervention; advice only versus more intensive support).

We were not able to perform subgroup analyses based on maternal age, parity or the nature of the exercise/dietary interventions due to the paucity of data and inability to meaningfully group intervention characteristics.

We used primary outcomes in subgroup analyses.

We assessed subgroup differences by interaction tests available within RevMan (RevMan 2014). We reported the results of subgroup analyses quoting the Chi$^2$ statistic and P value, and the interaction test $I^2$ value.

### Sensitivity analysis

We carried out sensitivity analysis to explore the effects of trial quality assessed by sequence generation and allocation concealment, by omitting studies rated as 'high risk of bias' or 'unclear risk of bias' for these components. We restricted this to the primary outcomes.

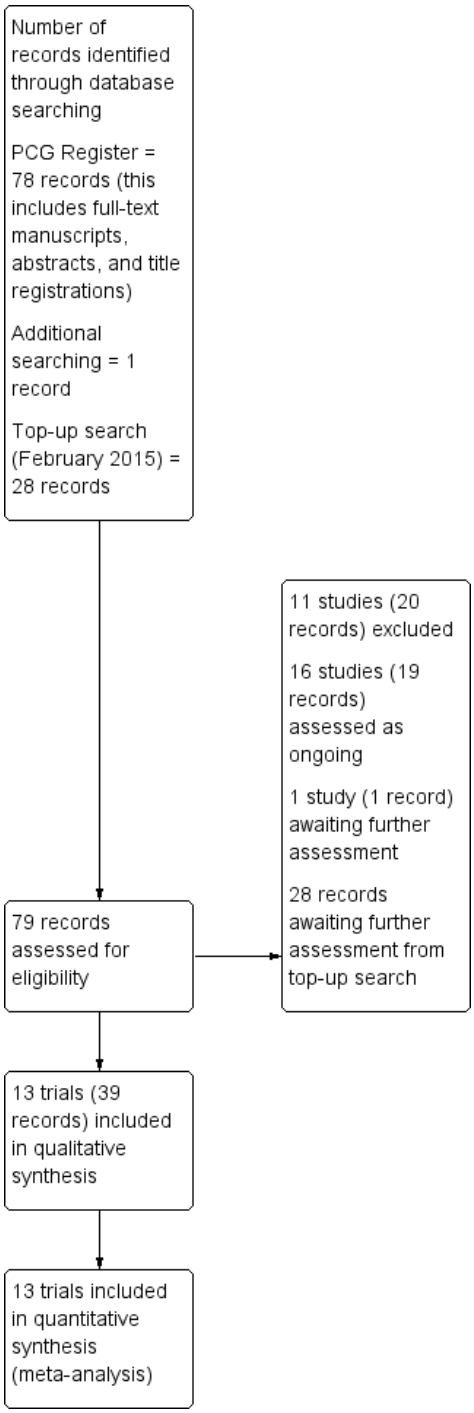
## RESULTS

### Description of studies

#### Results of the search

The search of the Cochrane Pregnancy and Childbirth Group's Trials Register retrieved 79 records relating to 41 studies. We have included 13 trials (39 records) meeting the review's pre-defined inclusion criteria (Asbee 2009; Dodd 2014; El Beltagy 2013; Harrison 2013; Hui 2012; Korpi-Hyovalti 2011; Luoto 2011; Petrella 2013; Phelan 2011; Polley 2002; Poston 2013; Rauh 2013; Vinter 2012). We excluded 11 studies (20 records) (Althuizen 2013; Clapp 1997; Kieffer 2013; Luoto 2010; Marcinkevage 2012; Nascimento 2012; Phelan 2012; Quinlivan 2007; Ruchat 2012; Szmeja 2011; Wilkinson 2012). Sixteen studies (19 records) are currently ongoing (Atkinson 2013; Chasan-Taber 2013; Crowther 2012; Facchinetti 2013; Goldberg 2012; Hivert 2012; Jelsma 2013; McAuliffe 2013; Nagle 2013; Parat 2009; Poston 2009; Roberts 2012; Shen 2008; Skouteris 2012; Umpierrez 2010; Vistad 2009) (see Figure 1). One study (one record) is awaiting classification, pending further information (Mujsindi 2014).

**Figure 1. Study flow diagram.**



The 16 ongoing trials are assessing a variety of lifestyle interventions (many with both diet and exercise components), for preventing adverse maternal and perinatal health outcomes, including, as primary outcomes, the development of GDM (Jelsma 2013; McAuliffe 2013; Nagle 2013; Poston 2009), insulin resistance (Chasan-Taber 2013), the incidence of large-for-gestational-age infants (Crowther 2012), excessive weight gain in pregnancy/gestational weight gain/weight change in pregnancy (Atkinson 2013; Facchinetti 2013; Hivert 2012; Jelsma 2013; Shen 2008; Skouteris 2012; Umpierrez 2010; Vistad 2009), body weight changes for the mother and her infant (Roberts 2012), and children becoming overweight in later life (Parat 2009). The primary outcome of one trial is the achievement of 30 minutes of daily exercise, four or more times each week (Goldberg 2012). The recruitment targets for the trials range from 16 to 1564 women, and they are being conducted across a range of healthcare settings and countries, including in Australia (Crowther 2012; Nagle 2013; Skouteris 2012), the United States (Chasan-Taber 2013; Goldberg 2012; Roberts 2012; Umpierrez 2010), Canada (Atkinson 2013; Hivert 2012; Shen 2008), France (Parat 2009), Italy (Facchinetti 2013), Norway (Vistad 2009), Ireland (McAuliffe 2013) and the United Kingdom (Poston 2009). One trial is being conducted in nine European countries: United Kingdom, Ireland, Netherlands, Belgium, Poland, Italy, Spain, Austria, Denmark (Jelsma 2013).

For further details, *see:* Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies; Figure 1.

Twenty-eight reports from an updated search in February 2015 have been added to the Studies awaiting classification section.

## Included studies

Following application of eligibility criteria, 13 trials (Asbee 2009; Dodd 2014; El Beltagy 2013; Harrison 2013; Hui 2012; Korpi-Hyovalti 2011; Luoto 2011; Petrella 2013; Phelan 2011; Polley 2002; Poston 2013; Rauh 2013; Vinter 2012) were included in this review. Two studies (Luoto 2011; Rauh 2013) were cluster-randomised trials, the other 11 included studies were individually-randomised controlled trials.

A total of 4983 women and their babies were involved in the included trials. Dodd 2014 was the largest study, randomising 2212 women, and Korpi-Hyovalti 2011 and Petrella 2013 were the smallest studies including 60 and 61 women respectively. For the majority of included trials, fewer women were included in the analyses than were randomised (Asbee 2009: 144 women randomised; 100 included in analyses; Dodd 2014: 2212 women randomised; 2152 included in analyses; El Beltagy 2013: 100 women randomised; 96 included in analyses; Harrison 2013: 228 women randomised; 203 included in analyses; Hui 2012: 224 women randomised; 190 women included in analyses; Korpi-Hyovalti 2011: 60 women randomised; 54 women included in analyses; Luoto 2011: 640 women were recruited from the 14 clusters; 399 were included in analyses; Phelan 2011: 401 women randomised; all included in initial analysis; Polley 2002: 120 women randomised; 110 women included in analysis at delivery and 74 followed up postpartum; Poston 2013: 183 women randomised; 154 included in analyses; Rauh 2013: 250 women were recruited from the eight clusters; 235 included in analyses; Vinter 2012: 360 women randomised; 304 women included in analyses).

### Settings

The majority of the trials were conducted in outpatient settings in Western societies. Three trials were conducted in the United States: Asbee 2009 recruited women from the resident obstetric clinic in Charlotte, North Carolina; Polley 2002 recruited women at a clinic for low-income women at Magee Womens Hospital, Pittsburgh, Pennsylvania; and Phelan 2011 recruited women seen in six obstetric offices in Providence, Rhode Island. Two trials were conducted in Finland: one in two rural municipalities: Kauhajoki and Lapua (Korpi-Hyovalti 2011), and the other in maternity clinics of primary healthcare centres of 14 municipalities in south-western Finland (Luoto 2011). Two trials were conducted in Australia: Dodd 2014 recruited women from three major metropolitan maternity hospitals in Adelaide, South Australia; and Harrison 2013 recruited women from three large metropolitan tertiary teaching hospitals in Victoria. In Poston 2013, women were recruited from four hospitals in the United Kingdom (one each in Glasgow and Newcastle and two in London), in urban settings. The remaining trials were conducted in Canada (Hui 2012), Italy (Petrella 2013), Germany (Rauh 2013), Denmark (Vinter 2012) and Egypt (El Beltagy 2013).

### Participants

All study participants were pregnant women, recruited between 2002 and 2011. While in the majority of trials, participants were ethnically diverse, in Asbee 2009 women were predominately of 'high-risk' ethnicities for GDM (with over three-quarters of women being Hispanic or African American); and Dodd 2014, Phelan 2011 and Rauh 2013 included women of predominately 'low-risk' ethnicities for GDM (with 91% being Caucasian in Dodd 2014; over 65% of women being non-Hispanic white in Phelan 2011; and 83% of women being German in Rauh 2013). Vinter 2012 included only Caucasian ('low-risk') women.

In Harrison 2013, 37% of women were born in Australia, 11% in Southeast Asia, and 32% in Southern/Central Asia. Polley 2002 reported that 39% of recruited women were black and 61% were white (with no further details provided regarding ethnicity), and

in Poston 2013, 56% of women were white, 38% black and the remaining women 'Asian/other'. Hui 2012 reported that over 20% of women were First Nation Candadian Aboriginals (however, the ethnicities of the other women were not reported). The ethnicities of women in El Beltagy 2013, Korpi-Hyovalti 2011, Petrella 2013 and Luoto 2011 were not reported.

The ages of women participating in the trials ranged from 18 to 49 with mean ages ranging from 25.5 years in Polley 2002 to 31.7 (control) and 32.4 (intervention) years in Harrison 2013. Multiparous and primiparous patients were included in all studies, and there were roughly equal proportions with the exception of Phelan 2011, where the included women were mostly nulliparous (70%). Gestation at randomisation was similar across studies, with most women being enrolled at approximately 13 to 14 weeks' gestation; however in Poston 2013, women were randomised between 15 and 17 + 6 weeks' gestation.

Pre-pregnancy BMI was similar in Asbee 2009 (mean BMI: 25.5 kg/m² intervention group; 25.6 kg/m² control group); Phelan 2011 (mean BMI: 26.3 kg/m² intervention group; 26.5 kg/m² control group); Hui 2012 (mean BMI: 24.9 kg/m² intervention group; 25.7 kg/m² control group); Korpi-Hyovalti 2011 (mean BMI: 27.3 kg/m² intervention group; 25.5 kg/m² control group); and Luoto 2011 (mean BMI: 26.3 kg/m² intervention group; 26.4 kg/m² control group). In Rauh 2013, the BMI of women at booking was lower (median BMI: 22.2 kg/m² intervention group; 23.3 kg/m² control group).

Dodd 2014 and Harrison 2013 only included overweight and obese women (Dodd 2014 median BMI: 31.1 kg/m²; Harrison 2013 mean BMI: 30.4 kg/m² intervention group; 30.3 kg/m² control group). Vinter 2012 and Poston 2013 included only obese women and thus the median/mean BMI at recruitment/randomisation was higher (Vinter 2012: median BMI: 33.4 kg/m² intervention group; 33.3 kg/m² control group); (Poston 2013: mean BMI: 36.5 kg/m² intervention group; 36.1 kg/m² control group). El Beltagy 2013 also included only obese women, however the BMI at entry was not reported.

Petrella 2013 recruited women with a BMI of greater than 25 kg/m²; however baseline averages of the groups were not reported in the published abstract; and Polley 2002 recruited women with a BMI of over 19 kg/m², however stratified by BMI category ('normal weight' versus 'overweight') (intervention group 'normal weight' mean BMI: 22.8 kg/m²; control group 'normal weight' mean BMI: 22.5 kg/m²; intervention group 'overweight' mean BMI: 31.4 kg/m²; control group 'overweight' mean BMI: 34.1 kg/m²).

### Interventions

Each of the 13 included trials assessed an intervention that included both diet and exercise components and reported on GDM; however the primary focus of many of included trials was on limiting excessive gestational weight gain during pregnancy (Asbee 2009; Harrison 2013; Hui 2012; Luoto 2011; Petrella 2013; Phelan 2011; Polley 2002; Rauh 2013; Vinter 2012).

- In Asbee 2009, a standardised counselling session delivered by a dietitian on physical activity, diet and weight gain (and follow-up at routine visits by the healthcare provider), was compared with routine prenatal care, where the only counselling on diet and exercise was that included in a standard prenatal booklet *"What to do When You're Having a Baby"*.
- Dodd 2014 provided women in the intervention group with a comprehensive dietary and lifestyle intervention that included a combination of dietary, exercise and behavioural strategies, delivered by a research dietitian and trained research assistants face-to-face at entry, 28 and 36 weeks, and on the phone at 22, 24 and 32 weeks. Tailoring of the intervention was informed by stage theories of health decision-making. Women in the control group received standard care, which did not include routine provision of advice related to diet, exercise or gestational weight gain.
- In El Beltagy 2013, women in the intervention group participated in a 12-week mild physical activity and diet control program; control group women did not receive any intervention.
- Harrison 2013 provided women in the intervention group with an individual four-session behaviour change lifestyle intervention based on social cognitive theory. Sessions were provided in the antenatal clinic by a health coach, and aimed to support and empower women to optimise their lifestyle and gestational weight gain. Women in the control group received a brief, single education session based on widely available dietary and physical activity guidelines (and were provided with written pamphlets of the guidelines).
- In Hui 2012, intervention women were provided a community-based exercise program, with weekly group sessions, instructed home exercise (guided by a video) and two dietary counselling sessions, and this was compared with standard prenatal care (which included a package of up-to-date information on physical activity and nutrition from Health Canada).
- Women in the intervention group of Korpi-Hyovalti 2011 were given healthy lifestyle counselling (tailored verbal and written dietary and exercise advice from a nutritionist (six times) and a physiotherapist (six times), based on the number of hours the woman had previously exercised and BMI); while women in the control group (close follow-up group) were given only general information on diet and physical activity, and were followed up in the routine prenatal clinic.
- In Luoto 2011, women in the intervention group received lifestyle counselling related to gestational weight gain (dietary advice (five times) and exercise advice (four times) from trained nurses), which was compared with usual care - where women received no additional counselling beyond standard care (which included some dietary counselling and follow-up of gestational weight; but little physical activity counselling).

- Women in the intervention group of Petrella 2013 received a Therapeutic Lifestyle Changes Program (TLC), which included diet and physical activity recommendations; while women in the control group received no intervention.
- In Phelan 2011, women in the intervention group received a behavioural lifestyle intervention designed to prevent excessive weight gain during pregnancy (including one face-to-face visit with an interventionist with detailed weight gain, dietary and physical activity advice; at least three follow-up phone calls; weekly postcards; weight graphs; and a pedometer). Women in the standard care group in addition to receiving standard nutrition counselling, received a brief face-to-face visit with the study interventionist, and study newsletters at two-month intervals with general information about pregnancy (e.g. maternity clothes) to improve study retention.
- The women in the intervention group of Polley 2002 received education about weight gain, healthy eating, and exercise and individual graphs of their weight gain at regular scheduled clinic visits; with those exceeding weight gain goals given more intensive intervention (stepped-care approach). Women in the control group received only standard nutrition counselling, which emphasised a well-balanced dietary intake and advice on multivitamin/iron supplements.
- In Poston 2013, women in the intervention group attended a one-to-one appointment with a *"Health Trainer"* - and were invited to attend weekly group sessions for eight consecutive weeks from 19 weeks' gestation where they received dietary and physical activity advice. Women in the control group received standard antenatal care.
- The FeLIPO (feasibility of a lifestyle intervention in pregnancy to optimise maternal weight development) intervention in Rauh 2013 had two individual counselling sessions, given by trained researchers during the 20th and 30th weeks of gestation. The counselling focused on nutrition, physical activity and gestational weight gain monitoring, and during both sessions women received feedback on their nutrition and physical activity habits based on seven-day dietary records and physical activity questionnaires. The intervention had three main parts: general information on a healthy lifestyle during pregnancy; promoting self-monitoring (diet, physical activity, weight gain); setting behavioural goals. Women in the control group received routine care, which included an information leaflet with 10 general statements about a healthy lifestyle during pregnancy (but no advice on diet or gaining weight).
- In Vinter 2012, women in the intervention group received a free six-month gym membership and pedometer, exercise classes with a physiotherapy weekly, four to six group coaching sessions, and six dietary counselling sessions with a nutritionist; while women in the control group were provided with information about the study and guidelines for diet and exercise through a web site (in addition to their routine antenatal care).

**Dietary components**

The dietary interventions were primarily implemented by a dietician/nutritionist in Asbee 2009, Dodd 2014, Hui 2012, Korpi-Hyovalti 2011 and Vinter 2012. Dietary counselling was provided by nurses in Luoto 2011 and participants met with a variety of health professionals such as physicians, nurses, nutritionists, and counsellors for the dietary intervention in Phelan 2011. The intervention in Polley 2002 was delivered by masters and doctoral level staff with training in nutrition or clinical psychology; in Rauh 2013 'trained researchers' delivered the intervention; in Harrison 2013, a health coach (exercise physiologist) provided the sessions; and in Poston 2013, the intervention was delivered by health trainers (who did not have pre-specified health professional qualifications, but relevant experience in behaviour modification and conducting group sessions). In El Beltagy 2013, it was not clear who delivered the intervention.

The number of dietary counselling sessions varied between studies, and participants in the intervention group in some individual studies had different regimens of counselling. Women in Asbee 2009 met with a dietician only once at the time of enrolment, and any further guidance on diet was given by a healthcare provider at routine visits based on weight gain. Similarly, women in Phelan 2011 had one face-to-face visit with a study interventionist at enrolment (with dietary advice), however they also received three brief supportive phone calls from the dietitian throughout the intervention; and women who were over or under weight gain guidelines received additional phone calls (two calls per month) that provided structured meal plans, and specific goals.

Women in Hui 2012 had two dietary counselling sessions, one at enrolment and the other at two months after enrolment; and women in Rauh 2013 had also had two individual counselling sessions, however these took place during the 20th and 30th weeks of gestation. Similarly in Dodd 2014, women had two sessions with the dietitian (one planning session, and one session at 28 weeks); however information was reinforced during telephone calls with a research assistant at 22, 24 and 32 weeks, and a face-to-face visit with a research assistant at 36 weeks.

Four visits with a dietician were provided to women in Vinter 2012, at 15, 20, 28, and 35 weeks' gestation. Similarly, four sessions were provided to women in Luoto 2011: one initial dietary counselling session at 16 to 18 weeks' gestation, with three further sessions at later gestations. In Harrison 2013, women received four individual behaviour change sessions for the intervention, scheduled around routine visits (14 to 16, 20, 24, 28 weeks). Six dietary specific counselling sessions were provided to women in Korpi-Hyovalti 2011 throughout their pregnancy. Finally in Poston 2013, women first attended a one-to-one appointment, and then were invited to attend weekly group sessions for eight weeks (or had the session content delivered by phone/email), with each group session delivering a different element of the dietary intervention.

The number of sessions provided to women in El Beltagy 2013

was not stated.

The dietary advice provided to women throughout the trials also varied, with differing recommendations for example on overall energy intake and diet composition.

In Dodd 2014, advice provided to women was consistent with the Australian standards (to maintain balance of carbohydrates, fat and protein; reduce intake of foods high in refined carbohydrates and saturated fats; increase intake of fibre; aim for two servings of fruit, five servings of vegetables and three servings of dairy daily). Women were provided with individualised information (meal plans, healthy recipes, simple food substitutions, options for healthy snacking and eating out, and guidelines for healthy food preparation), and were encouraged to set achievable goals for diet change and asked to self-monitor with a workbook. Harrison 2013 similarly provided women with pregnancy-specific dietary advice and simple healthy eating messages; women also determined goals, such as increasing fruit and vegetable intake, and reducing high fat or convenience food. Women were provided with a pamphlet version of the Australian Dietary Guidelines, and resources promoting optimal health, gestational weight gain and lifestyle. Self-monitoring strategies included use of weight gain charts based on the Institute of Medicine's (IOM) recommendations. In Hui 2012, women were provided with personalised counselling based on results of an interview (using a *"Food Choice Map"*), pregnancy week, weight gain and the Health Canada Guidelines.

In Korpi-Hyovalti 2011 women were encouraged to eat a diet rich in vegetables, berries and fruits, and to use low-fat dairy products, low-fat meat, soft margarines, vegetable oils and wholegrain products. Specific diet composition goals were outlined as: carbohydrate 50 to 55 energy % (E%), fibre 15 g/1000 kcal, fat 30 E%, saturated fat less than 10 E%, and protein 15 to 20 E%. Recommendations for energy intake were dependent on the woman's weight (30 kcal/kg/day for normal weight women and 25 kcal/kg/day for overweight women) (Korpi-Hyovalti 2011). In Luoto 2011 women were also advised to eat a diet rich in vegetables, fruits and berries (at least five portions a day), to select mostly high-fibre bread and wholemeal products and mostly fat-free or low-fat versions of milk and milk products, to eat fish at least twice per week, to use moderate amounts of soft table spreads, and to consume seldom (small-portions) snacks with high levels of sugar and fat. Specific intake goals were set as less than or equal to 10% saturated fat, 5% to 10% polyunsaturated fat, 25% to 30% total fat, less than 10% saccharose of total energy intake, and 25 to 35 g/d fibre (Luoto 2011).

Phelan 2011 educated women to aim for calorie goals (20 kcal/kg), and placed an emphasis on decreasing high-fat foods. Polley 2002 similarly placed an emphasis on decreasing high-fat foods (e.g. fast foods) and substituting healthier alternatives (e.g. fruit and vegetables); a more structured meal plan and individualised calorie goals were only added if this approach did not help women achieve their recommended weight gains. In Rauh 2013 dietary advice also focused on decreasing the intake of energy-dense foods and high-fat foods and substituting them for low-fat alternatives, in addition to improving the quality of fat consumed. General topics such as energy balance (according to the German Nutrition Society) were explained to women, who were also informed about additional energy requirements, and macro and micro nutrition requirements in pregnancy (Rauh 2013).

In Petrella 2013, women were recommended a total caloric limit of 1500 kcal/day, and advised that 25% to 35% of daily total calories should come from fat intake, with less than 7% of daily total calories from saturated fat. Vinter 2012 gave women advice based on the Danish recommendations, and estimated individual energy requirements for women based on weight and level of activity; similarly in Asbee 2009, women were recommended a patient-focused caloric value by the dietitian, however diet was based on 40% carbohydrate, 30% protein, and 30% fat. Rather than limiting energy intake, the exchange of foods was emphasised in Poston 2013. Increased consumption of foods with a low GI, including replacing sugar sweetened beverages with low GI alternatives was recommended; reduction in saturated fats, and replacement with monosaturated and polyunsaturated fats was also a focus. Women were encouraged to set 'SMART' goals, and self-monitor using a log-book.

The specific recommendations for *"diet control"* in El Beltagy 2013 were not provided.

#### Exercise components

The nature of the exercise intervention also differed between studies, with a number of trials offering predominantly advice (Asbee 2009; Dodd 2014; Harrison 2013; Petrella 2013; Phelan 2011; Polley 2002; Poston 2013; Rauh 2013), and others having an increased focus on interactive exercise sessions (Hui 2012; Korpi-Hyovalti 2011; Luoto 2011; Vinter 2012). The individual recommendations for exercise goals also varied between trials.

In Polley 2002, women were given written and oral information regarding physical activity in pregnancy by maters/doctoral level staff at regular clinic visits, with a focus on increasing walking and developing a more active lifestyle (for example, walking rather than driving short distances). Similarly, in Dodd 2014 the focus was on encouraging women to increase walking and incidental activity; women were encouraged to set achievable goals for exercise change, supported to make changes, and asked to self-monitor in a workbook. In Harrison 2013, women received written information (Australian Physical Activity Guidelines), were provided with simple physical activity messages during the sessions with the health coach, and were encouraged to set goals, such as increased physical activity frequency; self-monitoring strategies in Harrison 2013 included the use of pedometers. Women in Poston 2013 were also encouraged to set activity goals, and received a pedometer, a log-book and a DVD of a specifically devised pregnancy exercise regimen. Women were encouraged to increase daily physical activity incrementally, to set goals of incremental step counts

(monitored by pedometers) and to maintain the achieved physical activity level after the intervention period. Recommendations included an emphasis on walking at moderate intensity level (Poston 2013).

Specific recommendations were given to women in Petrella 2013, who were advised to undertake 30 minutes of mild physical activity three days per week. Specific daily goals were also set for women in Phelan 2011 (at the face-to-face visit at study commencement), who were encouraged to undertake 30 minutes of walking most days of the week, and an emphasis was placed on daily self-monitoring, through the use of pedometers. Similarly, in Asbee 2009 specific goals were set (at the an initial visit with the dietitian), with women being encouraged to engage in moderate-intensity exercise, at least three times per week, and preferably five times; if weight gain targets were not met, additional advice on exercise regimen was given by the healthcare provider. Women in Rauh 2013 were also encouraged to engage in 30 minutes of moderate activity on most days of the week, with non weight-bearing/low impact endurance exercises suggested (walking, cycling, swimming, aquatic exercises) (in accordance with guidelines for physical activity in pregnancy from the Society of Obstetricians and Gynaecologists of Canada and the American College of Obstetricians and Gynaecologists). Women were additionally provided with a list of adequate local prenatal physical activity programs and advised to participate in such programs (Rauh 2013).

In Luoto 2011, specific exercise goals were set during five physical activity counselling sessions (with trained nurses), with initial counselling implemented at eight to 12 weeks' gestation, and enhanced at four subsequent visits. The minimum weekly leisure time physical activity dose (entered progressively in the plan) was set as 800 MET (multiples of resting metabolic equivalents) minutes; the aims of the counselling were to increase leisure time for women not fulfilling the recommendations, or to maintain time for women already meeting the recommendations. Though not the focus of the intervention, women in Luoto 2011 were additionally offered participation in monthly thematic meetings, including group exercise.

Women in Korpi-Hyovalti 2011 were encouraged to engage in moderate-intensity physical exercise; the women had six sessions of exercise counselling with a physiotherapist. During the sessions the physiotherapist aimed to motivate the women to continue exercising during pregnancy or to start exercising, and gave written instructions for exercise and self-care. The goal of the exercise intervention was 30 minutes of daily physical activity if the woman previously exercised less than two and a half hours per week, and 45 minutes if the woman already engaged in two and a half hours per week. Recommended types of exercise included brisk walking, Nordic walking, swimming, cycling, and cross-country skiing (if the BMI of the woman was greater than 30 kg/m² and the woman had not been active, exercise was started with 15 minutes per day three times a week). Similar to in Korpi-Hyovalti 2011, women in Luoto 2011 were offered participation group classes - weekly aerobic classes and aqua fit classes.

Women participating in Hui 2012 were delivered a community-based exercise program designed for pregnant women that recommended an exercise regimen three to five times per week (including a weekly exercise session and multiple home sessions) of mild-to-moderate exercise for 30 to 45 minutes per session. Recommended exercise included walking, mild-to-moderate aerobic, stretching and strength exercises. It was advised that the exercise began between 20 to 26 weeks and ended at 36 weeks. The weekly group sessions were held in air-conditioned gymnasia in community centres with a fitness trainer (day- and night-time classes were available), and an exercise instruction video was also given to women to assist with home exercise. In Vinter 2012, similar to Hui 2012, women had weekly closed training classes (with a physiotherapist); and after training, women were grouped four to six times with a physiotherapist using *"coaching-inspired methods"* for improving integration of activity into daily life. Training consisted of aerobic (low-step) exercises, training with light weights and elastic bands, and balance exercises. Women were encouraged to be moderately physically active 30 to 60 minutes per day, and were given a free full-membership to a fitness centre for six months, and a pedometer to improve daily activity.

In El Beltagy 2013 women participated in *"twelve weeks mild physical activity program";* no further details were provided in the published abstract.

### Outcomes

GDM was a primary outcome in four of the included studies (El Beltagy 2013; Korpi-Hyovalti 2011; Luoto 2011; Vinter 2012). Korpi-Hyovalti 2011 assessed GDM based on glucose tolerance at eight to 12 weeks and 26 to 28 weeks, using a modified World Health Organization definition, of fasting plasma glucose of at least 5.6 mmol/L or two-hour plasma glucose of at least 7.8 mmol/L; Luoto 2011 also assessed GDM by OGTT at 26 to 28 weeks' gestation, however used the American Diabetes Association criteria (GDM diagnosed if at least one of the following criteria was met: fasting blood glucose of at least 5.3 mmol/L; one-hour blood glucose of more than 10.0 mmol/L; or two-hour blood glucose of more than 8.6 mmol/L). Vinter 2012 screened for GDM on three occasions using a two-hour OGTT (12 to 14 weeks; 28 to 30 weeks; 34 to 36 weeks) (diagnostic criteria were not reported). GDM was a secondary outcome in the nine other included studies (Asbee 2009; Dodd 2014; Harrison 2013; Hui 2012; Petrella 2013; Phelan 2011; Polley 2002; Poston 2013; Rauh 2013). In Asbee 2009, the primary study outcome was the proportion of women whose gestational weight gain was within the IOM guidelines, and this trial did not report on the methods used for screening and diagnosing GDM. Phelan 2011 and Polley 2002 both studied the proportion of women who exceeded the IOM guidelines for gestational weight gain; however Phelan 2011 also included the proportion of women who returned to pre-pregnancy

weight by six months postpartum as a primary outcome. Neither trial reported on their criteria for diagnosis of GDM (Phelan 2011; Polley 2002). Similarly in Rauh 2013, the primary outcome was the proportion of women exceeding IOM gestational weight gain recommendations; GDM was assessed as a secondary outcome at 24 to 28 weeks using 2010 clinical practice guidelines of the German Society of Gynaecology and Obstetrics. The primary outcome in Hui 2012 was also the prevalence of excessive gestational weight gain, however GDM was similarly assessed at 24 to 28 weeks, diagnosed according to the 2008 guidelines of the Canadian Diabetes Association. Gestational weight gain was the primary outcome in Harrison 2013, who also reported on GDM, assessed at 28 weeks, using the new IADPSG criteria.

In Dodd 2014, the primary outcome was large-for-gestational age, and GDM was assessed at 26 to 28 weeks with an OGTT (using 2012 South Australian Perinatal Practice Guidelines that included modified Australasian Diabetes in Pregnancy Society (ADIPS) recommendations). Poston 2013 (being a pilot randomised trial) focused on a variety of diet- and physical activity-related behaviours and intervention fidelity, however also reported on GDM, assessed at 27 + 0 to 28 + six weeks, using the new IADPSG criteria. The primary outcome of Petrella 2013 was not clear, however GDM was assessed using a two-hour OGTT at 24 to 28 weeks (no further details on diagnostic criteria were given).

### Excluded studies

We excluded 11 trials from this review for a variety of reasons (Althuizen 2013; Clapp 1997; Kieffer 2013; Luoto 2010; Marcinkevage 2012; Nascimento 2012; Phelan 2012; Quinlivan 2007; Ruchat 2012; Szmeja 2011; Wilkinson 2012).

Two trials (Clapp 1997; Quinlivan 2007) were excluded as they are (or are likely to be) included in the Tieu 2008 '*Dietary advice in pregnancy for preventing gestational diabetes mellitus*' Cochrane review, as they assessed a dietary intervention (not a combined diet and exercise intervention). A further two trials (Althuizen 2013; Ruchat 2012) were excluded as they focused on weight gain in pregnancy, and did not report on GDM (and is therefore are likely relevant to the Muktabhant 2012 Cochrane review '*Inteventions for preventing excessive weight gain during pregnancy*). Two trials (Marcinkevage 2012; Nascimento 2012), described in published abstracts only, were excluded as they assessed exercise interventions (not combined diet and exercise interventions), and did not report on GDM. One trial (Szmeja 2011) was excluded as it reported on non-clinical outcomes in a trial assessing the effects of a DVD (focused on dietary advice), and one trial was excluded as it assessed the effects of a lifestyle intervention on reducing depressive symptoms among pregnant Latinas (with only psychological outcomes reported) (Kieffer 2013). One further trial (Wilkinson 2012) was excluded as it assessed a workshop that provided dietary advice and advice regarding physical activity, however did not report on any clinical outcomes, and was focused on improving healthy behaviours. One trial (Phelan 2012), was excluded as it conducted an intervention pre-pregnancy (not during pregnancy as per the review's inclusion criteria), and one final trial was excluded as it was not randomised (Luoto 2010).

## Risk of bias in included studies

For a summary of the risk of bias across the included trials, see Figure 2 and Figure 3.

**Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**

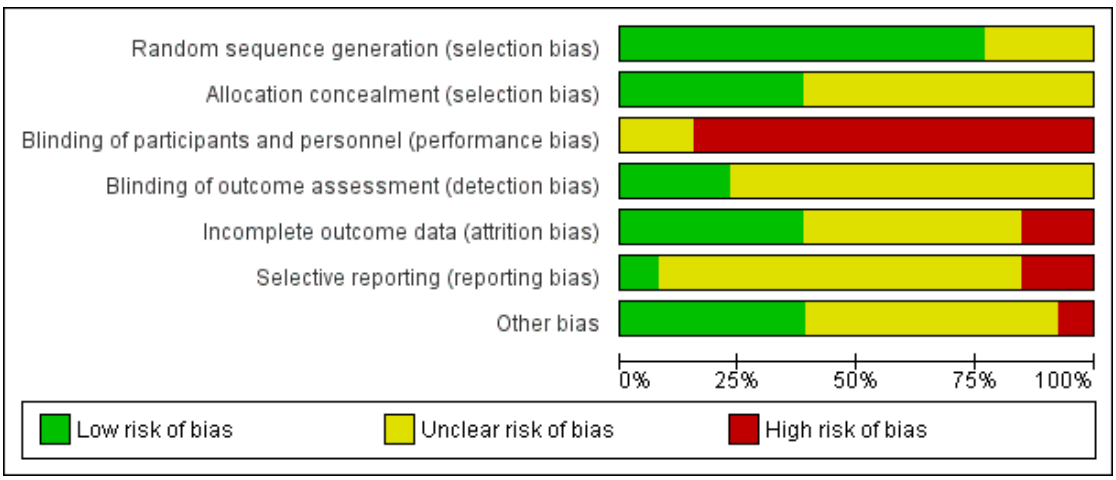
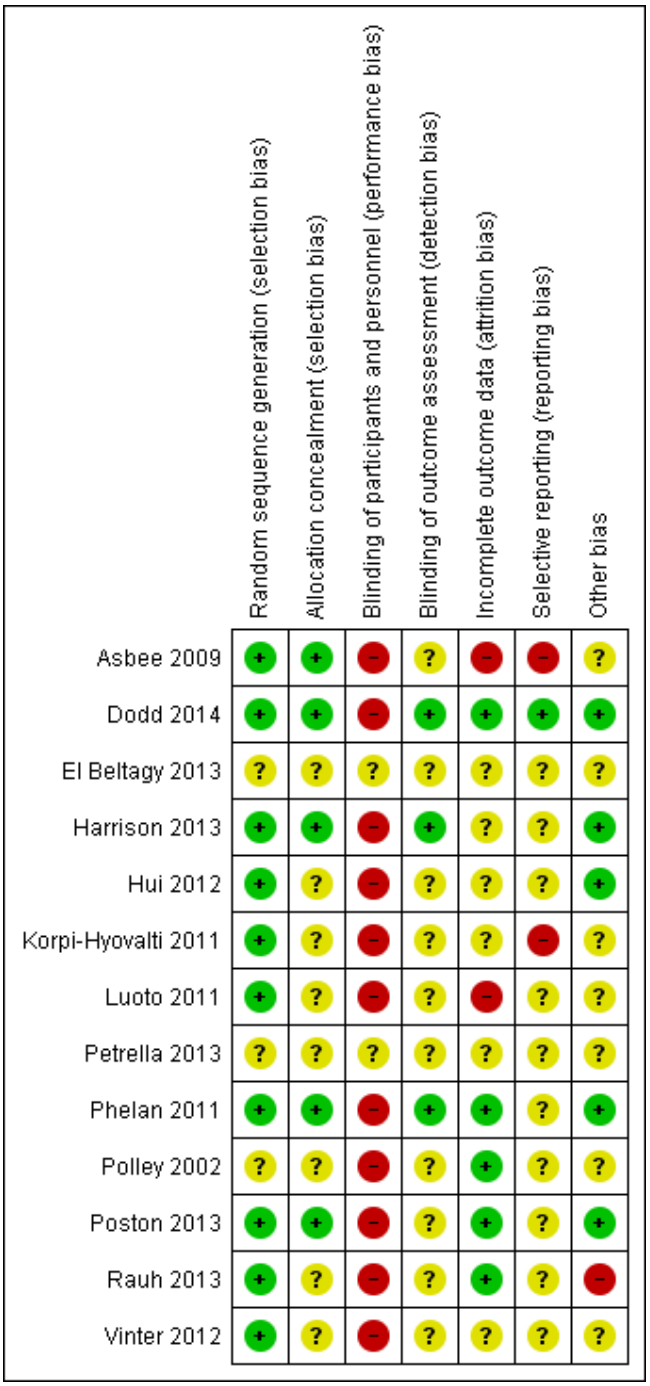


**Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.**



### Allocation

Methods to generate the random sequence were judged to be adequate in 10 of the 13 included trials (Asbee 2009; Dodd 2014; Harrison 2013; Hui 2012; Korpi-Hyovalti 2011; Luoto 2011; Phelan 2011; Poston 2013; Rauh 2013; Vinter 2012), with each trial using computer-generated random numbers. In the remaining three trials (El Beltagy 2013; Petrella 2013; Polley 2002), the risk of selection bias was judged to be unclear, with insufficient information provided.

Five trials (Asbee 2009; Dodd 2014; Harrison 2013; Phelan 2011; Poston 2013) were judged to have used adequate methods for allocation concealment. Of these, three (Asbee 2009; Harrison 2013; Phelan 2011) used consecutive, numbered, sealed, opaque envelopes and two (Dodd 2014; Poston 2013) used centralised phone or online randomisation services.

For the remaining eight trials (El Beltagy 2013; Hui 2012; Korpi-Hyovalti 2011; Luoto 2011; Petrella 2013; Polley 2002; Rauh 2013; Vinter 2012), the risk of bias due to inadequate allocation concealment was judged to be unclear, with no methods detailed, or the methods lacking sufficient detail.

### Blinding

For 11 trials (Asbee 2009; Dodd 2014; Harrison 2013; Hui 2012; Korpi-Hyovalti 2011; Luoto 2011; Phelan 2011; Polley 2002; Poston 2013; Rauh 2013; Vinter 2012), the risk of performance bias due to inadequate blinding of participants and/or research personnel was judged to be high; while for some trials, lack of blinding was stated, for others, no information was provided; however in view of the interventions assessed, it was considered unlikely that blinding would have been successfully achieved.

Two trials (El Beltagy 2013; Petrella 2013) were reported in published abstracts only (and had no information available for assessing performance bias), and thus the risk was judged to be unclear.

Considering blinding of outcome assessors, only three trials (Dodd 2014; Harrison 2013; Phelan 2011) clearly indicated that blinded study personnel were involved in outcome assessment, outcome data collection or outcome data analyses. Hence, these trials were judged to be at low risk of detection bias. For the remaining 10 trials, the risk of detection bias was judged to be unclear (Asbee 2009; El Beltagy 2013; Hui 2012; Korpi-Hyovalti 2011; Luoto 2011; Petrella 2013; Polley 2002; Poston 2013; Rauh 2013; Vinter 2012) with many of the trials not clearly detailing whether it was possible to blind any of the outcome assessments.

### Incomplete outcome data

Five trials (Dodd 2014; Phelan 2011; Polley 2002; Poston 2013; Rauh 2013) were judged to be at a low risk of attrition bias. The trials employed intention-to-treat principles in their analyses and had minimal losses to follow-up, with similar numbers/reasons for losses between groups.

Six trials (El Beltagy 2013; Harrison 2013; Hui 2012; Korpi-Hyovalti 2011; Petrella 2013; Vinter 2012) were judged to be at an unclear risk of attrition bias. While losses were relatively low in Korpi-Hyovalti 2011 and Hui 2012, these studies did not detail from which groups the losses were from post-randomisation, and did not indicate whether the characteristics of the women lost differed from those who were included in the analyses. In Harrison 2013, 15 women from the intervention group and 10 women from the control group were lost to follow-up for variety of reasons, and the numbers of women contributing data for the outcomes of gestational weight gain and physical activity were unclear. In Vinter 2012, outcome data were collected for approximately 80% of all women (56 women dropped out after randomisation for a variety of reasons, and 12 further women failed to attend their last pregnancy appointment, and therefore data were not collected on these women). El Beltagy 2013 and Petrella 2013 were reported in abstract form only, and thus there was insufficient information to determine the risk of attrition bias.

For two trials (Asbee 2009; Luoto 2011), the risk of bias due to incomplete outcome data was judged to be high. In Luoto 2011, of the women considered preliminarily eligible for this trial, who consented to participate, roughly 60% were followed up in each group. Furthermore, for a number of outcomes, *"number missing"* is reported in the tables, however it was not clear from which groups the data were missing. The Asbee 2009 trial excluded 44 women post-randomisation, however did not detail from which groups these women were excluded (and therefore only 100 of the 144 women randomised were included in the analyses).

### Selective reporting

Only one trial (Dodd 2014) was judged at low risk of reporting bias, providing data for all pre-specified outcomes (including from the published protocol).

Ten of the 13 trials were judged to be at an unclear risk of reporting bias (El Beltagy 2013; Harrison 2013; Hui 2012; Luoto 2011; Petrella 2013; Phelan 2011; Polley 2002; Poston 2013; Rauh 2013; Vinter 2012). For most of these trials, there was insufficient information to confidently assess selective reporting (in most cases, there was no access to a published trial protocol).

The remaining two trials (Asbee 2009; Korpi-Hyovalti 2011) were judged to be at a high risk of reporting bias. Outcomes in Asbee 2009 were not clearly pre-specified in the methods. Whilst the results section details a number of secondary outcomes, no outcome data were reported; quote: *"no statistically significant differences were noted between the groups"*. In the study by Korpi-Hyovalti

2011 for the baseline characteristics, and a number of outcomes (such as weight gain; OGTT at 26 to 28 weeks) while data were reported by groups, the P values were reported only as *"NS"* indicating non-significance. For a number of outcomes, the data were not presented, and instead statements made such as *"There was no statistically significant difference between the randomised groups in terms of pre-eclampsia, induction of labor, lacerations, Cesarean deliveries (data not shown)".*

### Other potential sources of bias

Five trials (Dodd 2014; Harrison 2013; Hui 2012; Phelan 2011; Poston 2013) were judged to be at a low risk of other potential sources of bias.

In one trial (Rauh 2013), significant baseline imbalance between groups existed in maternal pre-pregnancy weight, pre-pregnancy BMI and maternal median weight at the first antenatal appointment. In the same trial (Rauh 2013), the authors also reported that it was easier to recruit women for the intervention group clusters than for the control group clusters (and accordingly, the group numbers are imbalanced in a 2:1 ratio). Thus, this trial (Rauh 2013) was judged to be at high risk of other bias.

For the remaining seven trials, the risk of other bias was judged to be unclear, due to, for example, some baseline imbalances between groups (Korpi-Hyovalti 2011; Luoto 2011), or insufficient information available to confidently assess other sources of bias (El Beltagy 2013; Petrella 2013).

## Effects of interventions

### Combined diet and exercise intervention versus control

#### Primary outcomes

**Maternal**

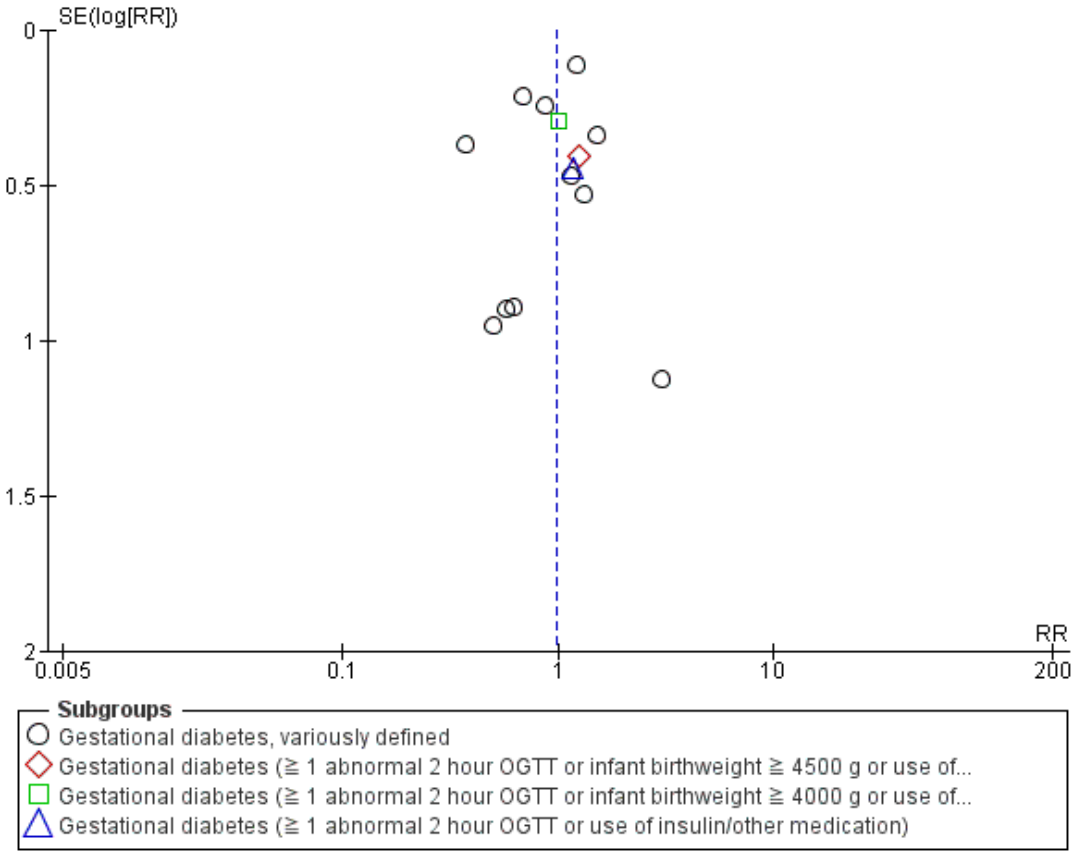
***Gestational diabetes mellitus (GDM)***

Eleven of the 13 included trials reported data on GDM that could be included in a meta-analysis (Dodd 2014; Harrison 2013; Hui 2012; Korpi-Hyovalti 2011; Luoto 2011; Petrella 2013; Phelan 2011; Polley 2002; Poston 2013; Rauh 2013; Vinter 2012). In Hui 2012, Petrella 2013 and Rauh 2013, women were screened for GDM at 24 to 28 weeks' gestation; while in Luoto 2011 and Dodd 2014 women were screened at 26 to 28 weeks, in Poston 2013 at 27 + 0 to 28 + six weeks' gestation, and in Harrison 2013, at 28 weeks' gestation. In Korpi-Hyovalti 2011, women were screened at both eight to 12 weeks and 26 to 28 weeks' gestation; and in Vinter 2012, women were screened on three occasions (at 12 to 14 weeks; 28 to 30 weeks; and at 34 to 36 weeks' gestation). Different GDM diagnostic criteria were used throughout the studies, including the 2008 guidelines of the Canadian Diabetes Association (Hui 2012), the 2010 clinical practice guidelines of the German Society of Gynaecology and Obstetrics (Rauh 2013), modified WHO criteria (Korpi-Hyovalti 2011), the American Diabetes Association criteria (Luoto 2011), the 2012 South Australian Perinatal Practice Guidelines using modified ADIPS recommendations (Dodd 2014), and the new IADPSG criteria (Harrison 2013; Poston 2013) (the criteria used were not specifically stated in Petrella 2013, Phelan 2011, Polley 2002 and Vinter 2012).

No clear difference was seen in the risk of GDM between women receiving the diet and exercise intervention and those receiving no intervention (average risk ratio (RR) 0.92, 95% confidence interval (CI) 0.68 to 1.23; 11 trials, 3744 women; $T^2 = 0.08$; $I^2 = 43\%$) (Analysis 1.1).

We ran a funnel plot to assess the risk of reporting bias, such as publication bias, and we found that studies were equally distributed on either side, with no substantial asymmetry observed (Figure 4).

**Figure 4. Funnel plot of comparison: 1 Diet and exercise versus control, outcome: 1.1 Gestational diabetes.**




The Luoto 2011 trial also reported on GDM based on three variations to the criteria: 1) at least one abnormal value in the two-hour oral glucose tolerance test (OGTT) or birthweight equal or higher than 4500 g or use of insulin or other diabetic medication; 2) at least one abnormal value in the two-hour OGTT or birthweight equal or higher than 4000 g or use of insulin or other diabetic medication; 3) at least one abnormal value in the two-hour OGTT or use of insulin or other diabetic medication. No clear difference between groups was seen when all variations were applied (Analysis 1.1).

While the Asbee 2009 trial did not report data on GDM that could be included in the review's meta-analysis, the trial manuscript reported that *"No statistically significant differences were noted between the groups in... gestational diabetes mellitus"*. Similarly, while the El Beltagy 2013 trial did not report GDM per group, it was reported that *"obese women enrolled in mild physical activity program and diet plan (48 women) had a lower incidence to develop GDM than those participated in neither intervention (48 women) (OR 0.91, 95% CI 0.06-1.02)"*.

***Mode of birth***

In the meta-analysis, no clear difference was seen in the risk of having a caesarean birth between women receiving the diet and exercise intervention and those receiving no intervention (RR 0.92, 95% CI 0.83 to 1.01; seven trials, 3246 women) (Analysis 1.2).

In the Korpi-Hyovalti 2011 study it was reported that *"There was no statistically significant difference between the randomised groups in terms of...Cesarean deliveries (data not shown)"*. Asbee 2009 similarly reported *"No statistically significant differences"* for the rate of caesarean birth and operative vaginal birth, but without providing any data.

Rauh 2013 also reported on the outcomes: spontaneous vaginal birth and vacuum extraction, and found no clear difference between groups for either outcome (RR 1.25, 95% CI 0.70 to 2.23; one trial, 51 women) (Analysis 1.3) and (RR 1.00, 95% CI 0.20 to 4.93; one trial, 51 women) (Analysis 1.4).

### Fetal/neonatal

#### *Large-for-gestational age*

There was no clear difference between the diet and exercise intervention and control groups in the risk of large-for-gestational age on meta-analysis of the results from the six trials that reported on this outcome (Dodd 2014; Hui 2012; Luoto 2011; Poston 2013; Rauh 2013; Vinter 2012) (RR 0.90, 95% CI 0.77 to 1.05; six trials, 2950 infants) (Analysis 1.5).

Petrella 2013 reported that *"Large for gestational age babies were similar among groups".*

#### *Perinatal mortality*

In Dodd 2014, there were six perinatal deaths in each group (RR 0.99, 95% CI 0.32 to 3.07; one trial, 2202 fetuses/neonates) ( Analysis 1.6); there were five stillbirths (at greater than 20 weeks' gestation) in each group (RR 0.99, 95% CI 0.29 to 3.42), and one neonatal death (with no lethal anomaly) in each group (RR 0.99, 95% CI 0.06 to 15.85). Additionally, there were three neonatal deaths due to lethal anomalies (RR 6.95, 95% CI 0.36 to 134.38) in the diet and exercise intervention group (Analysis 1.6).

Vinter 2012 detailed information in the trial manuscript relating to stillbirth, however it was unclear whether one of the three stillbirths occurred in the intervention or control group; and it was additionally unclear as to whether the three stillbirths discussed were the only deaths that occurred: *"One woman had an unexplained stillbirth after induction of labor in GA 42. Two additional women had a preterm delivery with stillborn infants in second trimester of pregnancy, one from each randomization group".*

None of the other trials reported on stillbirth or neonatal death.

### Secondary outcomes

### Maternal outcomes

#### *Induction of labour*

Only two trials provided data relating to induction of labour, and showed no clear difference for this outcome between the diet and exercise intervention and control groups (RR 1.02, 95% CI 0.91 to 1.14; two trials, 2193 women) (Analysis 1.7).

The Korpi-Hyovalti 2011 trial reported that there was no significant difference between groups for this outcome, however they did not provide data.

#### *Perineal trauma*

Dodd 2014 reported on perineal trauma, specifically third- or fourth-degree tears. Dodd 2014 observed no clear difference between groups for this outcome (RR 1.39, 95% CI 0.79 to 2.45; one trial, 2142 women) (Analysis 1.8).

Asbee 2009 indicated that there was no significant difference between groups in the rate of vaginal lacerations, and Korpi-Hyovalti 2011 reported no significant difference in lacerations between groups; however neither trial provided data for this outcome.

#### *Pre-eclampsia*

There was no clear difference in the incidence of pre-eclampsia between women in the diet and exercise intervention and control groups (RR 0.93, 95% CI 0.72 to 1.19; six trials, 3070 women) (Analysis 1.9).

Asbee 2009 and Korpi-Hyovalti 2011 both reported no significant difference in the risk of pre-eclampsia between groups, however did not provide any data.

#### *Weight gain during pregnancy*

There was a trend towards less gestational weight gain for women receiving a diet and exercise intervention compared to women receiving no intervention (average mean difference (MD) -0.76 kg, 95% CI -1.55 to 0.03; eight trials, 2707 women; $T^2 = 0.55$; $I^2 = 41\%$) (P = 0.06) (Analysis 1.10).

Vinter 2012 reported on median weight gain during pregnancy (kg) (that could not be included in the meta-analysis) and found that women receiving the diet and exercise intervention had significantly less weight gain during pregnancy (intervention group: 7.0 kg; control group: 8.6 kg; P = 0.014) (Analysis 1.11). El Beltagy 2013 similarly reported that *"weight gain per week was significantly lower in the diet and exercise group than the other group (p<0.001)".* Poston 2013 however reported that *"There was also no significant difference in gestational weight gain between control and intervention arms (secondary outcome)".*

In relation to gestational weight gain, a number of trials reported on further relevant outcomes.

Both Dodd 2014 and Harrison 2013 reported on rate of weight gain (kg/week). While in Harrison 2013, women in the intervention group had a significantly lower rate of weekly gestational weight gain (MD -0.08 kg/week, 95% CI -0.14 to -0.02; 203 women), in Dodd 2014, no difference between groups was observed (MD 0.00 kg/week, 95% CI -0.03 to 0.03; 1768 women); and on meta-analysis, there was no clear difference between groups (average MD -0.04 kg/week, 95% CI -0.11 to 0.04; two trials, 1971 women; $T^2 = 0.00$; $I^2 = 82\%$) (Analysis 1.12).

Harrison 2013 also reported on gestational weight gain at 26 to 28 weeks, and observed that women in the diet and exercise intervention group, gained significantly less weight, when compared to

control women (RR -0.90 kg, 95% CI -1.75 to -0.05; one trial, 203 women) (Analysis 1.13).

Vinter 2012 reported on weight gain of 5 kg or less during pregnancy and found no clear difference between groups (RR 1.40, 95% CI 0.93 to 2.12; one trial, 292 women) (Analysis 1.14), however found that women receiving the intervention were more likely to gain 9 kg or less during pregnancy (RR 1.21, 95% CI 1.00 to 1.47; one trial, 292 women) (Analysis 1.15).

Both Dodd 2014 and Rauh 2013 reported on excessive and inadequate weight gain according to the IOM recommendations; overall, no clear difference was shown for excessive gestational weight gain (average RR 0.87, 95% CI 0.57 to 1.32; two trials, 1817 women; $T^2 = 0.06$; $I^2 = 60\%$) (Analysis 1.16), nor for inadequate gestational weight gain (RR 1.00, 95% CI 0.86 to 1.18; two trials, 1817 women) (Analysis 1.17).

### *Postpartum haemorrhage*

Dodd 2014 was the only trial to report on postpartum haemorrhage (> 600 mL) and did not observe a difference in the risk of haemorrhage between the diet and exercise intervention group and control group (RR 0.94, 95% CI 0.78 to 1.14; one trial, 2142 women) (Analysis 1.18).

### *Postpartum infection*

Dodd 2014 was the only trial to report data on outcomes relating to postpartum infection, and reported no clear differences between the diet and exercise intervention and standard care groups for wound infection (RR 1.06, 95% CI 0.65 to 1.73; one trial, 2142 women) (Analysis 1.19), endometritis (RR 1.19, 95% CI 0.52 to 2.74; one trial, 2142 women) (Analysis 1.20), and postpartum antibiotic use (RR 1.00, 95% CI 0.77 to 1.31; one trial, 2142 women) (Analysis 1.21).

### *Adherence to the intervention/behaviour modifications (diet and physical activity)*

In relation to adherence to the diet and exercise interventions, a number of trials reported data on specific behaviour modifications (related to diet and/or physical activity).

When considering dietary changes, Hui 2012, found that women receiving diet and exercise interventions at two months after enrolment had significantly lower mean intakes of total calories, carbohydrates, fat, saturated fat and cholesterol (Analysis 1.22), than women in the control group. At two months after enrolment, women receiving the diet and exercise intervention also had a significantly lower mean ratio of fat compared with those in the control group; and their mean carbohydrate and protein ratios were significantly higher (Analysis 1.22). Hui 2012 also found that at two months after enrolment the mean physical activity index of women in the intervention group was significantly higher than for women in the control group (Analysis 1.23).

Phelan 2011 also examined the effect of the diet and exercise intervention on diet- and physical activity-related behaviours, however in late pregnancy, showed no clear difference between the diet and exercise intervention and control groups in mean calorie intake, percentage of calories from fat, carbohydrate, protein or sweets, daily calories from soft drinks, daily saturated fat (g), daily servings of vegetables, fruit/fruit juices, breads, cereals, rice and pasta, milk, yogurt and cheese, daily frequency of fats and oils, sweets and sodas, weekly fast food, daily iron from food (mg), daily calcium from food (mg), total daily fibre (g), daily vitamin D from food (international units (IU)), or daily folate from food (μg) (Analysis 1.24). Phelan 2011 also did not show a clear difference between groups in physical activity (kcal) in late pregnancy, or at six months or 12 months postpartum (Analysis 1.25).

In Poston 2013, at 28 weeks' gestation, women in the diet and exercise intervention group had lower total energy intake (MJ/day), dietary GI (%) and glycaemic load (g/day and % energy), total fat intake (% energy), saturated fat intake (% energy), and higher protein intake (% energy) (Analysis 1.26). No clear differences between groups at 28 weeks were observed for: carbohydrate intake (% energy), protein intake (g), monounsaturated fatty acid intake (% energy), polyunsaturated acid intake (% energy), polyunsaturated fatty acid, saturated fatty acid ratio, or non-starch polysaccharide intake (g). No clear differences between groups were shown for physical activity outcomes assessed by accelerometry and questionnaire at 28 weeks' gestation (minutes/day) (Analysis 1.27).

The Luoto 2011 trial similarly reported on a range of physical activity and dietary changes (the data have not been included in this review, with unclear numbers per group for each outcome), and found that the diet and exercise intervention group significantly reduced their intake of saturated fatty acids and saccharose (from baseline to 26 to 28 weeks at 36 to 37 weeks), and significantly increased their intake of dietary fibre and polyunsaturated fatty acids (from baseline to 36 to 37 weeks). No clear differences were seen for total energy intake, nor for physical activity changes between groups.

In Vinter 2012, 92% of women were reported to have completed all four dietetic counselling sessions, and over 98% completed at least three. Women receiving the diet and exercise interventions were significantly more likely than control women to report that study participation increased their healthy eating habits (RR 4.11, 95% CI 3.00 to 5.63; 304 women) (Analysis 1.29). Women in the intervention group of Vinter 2012 were also more likely to report increased engagement in *"leisure time sporting activities"* as compared with control women (RR 1.19, 95% CI 1.03 to 1.38; 304 women).

Polley 2002 reported that all groups decreased their fat consumption from baseline to 30 weeks, except for normal-weight women in the control group; and noted that there was no effect of treat-

ment on these observed changes in fat intake (P > 0.2). In regards to physical activity changes, Polley 2002 did not report on the changes observed except to note that *"changes in exercise level from recruitment to 30 weeks (P > 0.8) were not related to treatment condition"*.

Rauh 2013 reported that women in the control group increased their daily energy intake from baseline to the end of pregnancy, while women in the intervention group maintained a stable energy intake throughout their pregnancy; no clear difference between groups (with adjustment for clustering) in energy intake (kcal/day) at 36 to 38 weeks' gestation was shown (MD -113.00 kcal/day, 95% CI -399.99 to 173.99; 757 women) (Analysis 1.30). In regards to physical activity, however, while all women significantly decreased their total activity across the course of their pregnancies, in the control group their median total activity (MET-min/week) decreased significantly from baseline to 26 to 28 weeks and to 36 to 38 weeks' gestation (P = 0.019); while no clear reductions for the intervention group in MET over time were shown (P = 0.198) (Analysis 1.31).

In Harrison 2013, at baseline, there was no clear difference between intervention and control groups for mean daily pedometer steps, however at 28 weeks' gestation, while average daily steps declined for both groups, the diet and exercise intervention group had a significantly higher daily step count when compared to the control group (MD 1063.00 steps/day, 95% CI 128.26 to 1997.74; 148 women) (Analysis 1.32).

In the published abstract Petrella 2013 reported that *"Significant changes in eating behavior occurred in TLC group which increased the habit of breakfast and the frequency of snacks. Moreover, intervention increased the rate of women avoiding sugar (from 3.9% to 43.8%) as well as the rate of those that include vegetables in every meal (from 3.9% to 37.5%)"*.

Asbee 2009, Dodd 2014, El Beltagy 2013 and Korpi-Hyovalti 2011 did not report on adherence/related behaviour modifications.

#### *Women's sense of well-being and quality of life*

Phelan 2011 examined the effect of the diet and exercise intervention on stress, sleep and scores on the Edinburgh Depression Scale, and did not show clear differences between the diet and exercise group and control group in late pregnancy, or at six and 12 months postpartum for these outcome (Analysis 1.33). Phelan 2011 also reported that while the intervention group *"had a significantly greater increase in scores of the Edinburgh Depression Scale during the postpartum period than did the standard-care group... multiple logistic regression analyses indicated no significant effects of the intervention compared with standard care on the prevalence of depression... Both groups reported very low depression scores overall"*.

In Poston 2013, there was no clear difference in the numbers of women reporting problems in each of the EurQol quality of life (EQ-5D) questionnaire domains at 28 weeks' gestation (mobility, self-care, usual activity, pain and discomfort and anxiety and depression) (Analysis 1.34). Considering quality of life according to summary index scores (calculated using the time trade-off method, and on the visual analogue scale of health-related quality of life, from 0 to 100, with 0 being the worst imaginable health state), no clear differences between groups were observed (Analysis 1.35). No clear differences between groups were observed for the Edinburgh Post Natal Depression Score (EPDS) mean total, or numbers of women with total score over nine or total score over 12 (Analysis 1.36; Analysis 1.37).

#### *Women's view of the intervention*

Poston 2013 was the only trial to report on women's views of the intervention, specifically reporting on acceptability; *"Women in both arms of the trial found the research processes acceptable, and felt supported by the study midwives. Women in the intervention group were generally willing, in principle, to attend the eight health trainer sessions, and most women who attended valued the group approach, citing opportunities to raise questions and discuss each other's experiences. Some were surprised at the extent of the intervention, having anticipated a less intensive, more advice-based approach...Some women found the information contained in the handbook new, whilst for others it was too basic. The pedometers and step goals were generally well received. Setting and reflecting on weekly goals was motivational for most, but could also invoke feelings of guilt, or a sense of being observed and judges. Women reported having watched the DVD, but few used it regularly"*.

#### *Other perinatal outcomes*

No trials reported on the review's other perinatal outcomes including the following.

- Pregnancy hyperglycaemia not meeting GDM diagnostic criteria
- Augmentation of labour
- Placental abruption

### Longer-term outcomes

#### *Postpartum weight retention*

No clear difference was shown for mean postnatal weight retention between the diet and exercise intervention and control groups overall (average MD -0.72 kg, 95% CI -1.96 to 0.51; three trials, 450 women; $T^2 = 0.65$; $I^2 = 34\%$) (Analysis 1.38). However, considering only women classified as 'normal-weight' at baseline in Phelan 2011, Polley 2002 and Rauh 2013, women in the intervention group were found to retain significantly less weight than

those in the control group (MD -1.31 kg, 95% CI -2.40 to -0.23; three trials, 263 women) (Analysis 1.38); a difference that was not seen for women classified as overweight or obese at baseline (MD 1.05 kg, 95% CI -2.73 to 4.83; two trials, 187 women) (Analysis 1.38). The subgroup interaction test, comparing normal-weight women at baseline with overweight/obese women at baseline was, however, not significant ($Chi^2$ = 1.39; P = 0.24; $I^2$ = 28.1%).

Rauh 2013 additionally reported on postnatal retention of more than 5 kg, however did not show a clear difference between the diet and exercise intervention group and control group (RR 0.58, 95% CI 0.21 to 1.62; one trial, 49 women).

Phelan 2011 reported on weight retention at 12 months postpartum, and did not find a clear difference between the diet and exercise intervention and control groups in the proportion of women at or below their pre-pregnancy weight (RR 1.26, 95% CI 0.91 to 1.73; one trial, 331 women) (Analysis 1.40). Phelan 2011 also compared the proportions of women at or below pre-pregnancy weight at 12 months for 'study completers', and similarly did not show a clear difference between groups (RR 1.28. 95% CI 0.95 to 1.73; one trial, 261 women) (Analysis 1.40). For the 'study completers' net weight retention was shown to be significantly more in the control group than the intervention group at 12 months postpartum (MD -1.60 kg, 95% CI -3.06 to -0.14; one trial, 261 women) (Analysis 1.41), however no clear difference was shown in weight loss since birth (MD 1.10 kg, 95% CI -0.53 to 2.73; one trial, 261 women) (Analysis 1.42).

None of the included trials have reported on maternal BMI postnatally, GDM in subsequent pregnancies, development of type I or II diabetes mellitus, or longer-term impaired glucose tolerance or insulin sensitivity.

**Fetal/neonatal outcomes**

***Macrosomia, birthweight, small-for-gestational age, low birthweight (not pre-specified) and ponderal index***

No clear difference was found between babies born to women in the diet and exercise intervention and control groups for macrosomia (RR 0.90, 95% CI 0.77 to 1.05; six trials, 3168 infants) (Analysis 1.43).

Korpi-Hyovalti 2011 did not provide data for this outcome, however reported *"no difference"* between groups.

Similarly, no clear difference was seen for birthweight between babies born to mothers who had received the diet and exercise intervention and those born to mothers from the control group (average MD 28.24 g, 95% CI -78.26 to 134.74; five trials, 737 infants; $T^2$ = 7821.94; $I^2$ = 46%) (Analysis 1.44).

Additional data were provided by Polley 2002 and Vinter 2012 for the outcome birthweight, which could not be included in the meta-analyses (Polley 2002 reported only the mean values by group; Vinter 2012 reported median values and interquartile ranges by group). While Polley 2002 reported no difference in birthweight between the two groups, Vinter 2012 reported a significantly higher birthweight for infants born to mothers who received the diet and exercise intervention (Analysis 1.45).

No clear difference between groups was shown for outcomes: small-for-gestational age (RR 1.02, 95% CI 0.18 to 5.64; two trials, 144 infants) (Analysis 1.46), low birthweight (< 2500 g) (RR 1.00, 95% CI 0.49 to 2.05; two trials, 459 infants) (Analysis 1.47), and ponderal index (MD -0.40, 95% CI -1.36 to 0.56; one trial, 93 infants) (Analysis 1.56).

***Neonatal hypoglycaemia and hyperbilirubinaemia requiring treatment***

Dodd 2014 was the only trial to report on neonatal hypoglycaemia requiring treatment, and hyperbilirubinaemia requiring treatment, and observed no clear differences between groups for either outcome: (hypoglycaemia requiring treatment: RR 1.03, 95% CI 0.80 to 1.33; one trial, 2142 infants) (Analysis 1.48) (hyperbilirubinaemia requiring treatment: RR 0.82, 95% CI 0.61 to 1.11; one trial, 2142 infants) (Analysis 1.55).

***Gestational age at birth and preterm birth***

No clear difference between babies born to mothers who had received the diet and exercise intervention and those born to mothers from the control group was seen for the outcome gestational age at birth (average MD 0.13 weeks, 95% CI -0.24 to 0.50; three trials, 632 infants; $T^2$ = 0.06; $I^2$ = 43%) (Analysis 1.49).

Infants born to mothers from the diet and exercise intervention group were however, found to be significantly less likely to be born preterm (RR 0.71, 95% CI 0.55 to 0.93; five trials, 2713 infants) (Analysis 1.51).

Additional data were provided by Polley 2002 and Vinter 2012 for the outcome gestational age at birth, that could not be included in the review's meta-analysis (Polley 2002 reported only the mean values by group; Vinter 2012 reported median values and interquartile ranges by group). Neither trial found a clear difference in gestational age at birth between groups (Analysis 1.50).

***Shoulder dystocia, bone fracture, nerve palsy***

The Dodd 2014 trial was the only trial to report on shoulder dystocia, bone fracture and nerve palsy, and found no clear differences between the diet and exercise intervention and control groups for these outcomes (shoulder dystocia: RR 1.25, 95% CI 0.81 to 1.93; one trial, 2142 infants) (Analysis 1.52), (bone fracture: RR 1.99, 95% CI 0.36 to 10.82; one trial, 2142 infants) (Analysis 1.53), (nerve palsy: RR 1.99, 95% CI 0.36 to 10.82; one trial, 2142 infants) (Analysis 1.54).

### *Other fetal/neonatal outcomes*

None of the included trials reported data on the other fetal/neonatal outcomes including the following.

- Respiratory distress syndrome
- Apgar score less than seven at five minutes
- Skinfold thickness
- Neonatal glucose concentration

Korpi-Hyovalti 2011 did not provide data for the above outcomes however reported that *"There was no statistically significant difference between the randomized groups in terms of gestational age, admissions to neonatal intensive care unit, jaundice requiring phototherapy or respiratory distress (data not shown)".* Similarly El Beltagy 2013 did not provide data, however indicated that *"there was no adverse neonatal outcome among all the study participants".*

### Childhood and adulthood outcomes

None of the included trials have reported on childhood or adulthood outcomes.

### Health service cost outcomes

### *Antenatal admission, length of antenatal stay and length of postnatal stay for the mother*

For the outcome antenatal hospital admission, Dodd 2014 did not observe a clear difference between groups (RR 0.86, 95% CI 0.71 to 1.04; one trial, 2153 women) (Analysis 1.57). However, women in the diet and exercise intervention group of Dodd 2014 did have a significantly shorter length of antenatal stay (MD -0.27 days, 95% CI -0.49 to -0.05; one trial, 2153 women) (Analysis 1.58).

Considering length of postnatal stay for the mother, Dodd 2014 did not observe a clear difference between the diet and exercise intervention and control groups (MD -0.06 days, 95% CI -0.21 to 0.09; one trial, 2142 women) (Analysis 1.59).

### Neonatal intensive care unit admission

Two trials reported on admission to the neonatal intensive care unit (Dodd 2014; Vinter 2012) and showed no clear difference between babies born to mothers who had received the diet and exercise intervention and those born to mothers from the control group for this outcome (RR 1.01, 95% CI 0.91 to 1.13; two trials, 2446 infants) (Analysis 1.60).

### Other health service cost outcomes

None of the trials reported on the other outcomes relating to health services costs, including: medical physician visits, costs to families in relation to management provided, length of postnatal stay for the neonate/infant, and costs of maternal and offspring care.

## Subgroup analysis

### Subgroup analysis based on study design

Subgroup analysis based on the study designed used (cluster-randomised versus individually-randomised), revealed no clear subgroup differences for the primary outcomes, GDM ($Chi^2$ = 0.09; P = 0.76; $I^2$ = 0%) (Analysis 2.1), caesarean birth ($Chi^2$ = 0.41; P = 0.52; $I^2$ = 0%) (Analysis 2.2), and large-for-gestational age ($Chi^2$ = 0.96; P = 0.33; $I^2$ = 0%) (Analysis 2.3). We were not able to perform a subgroup analysis for perinatal mortality, as only one trial reported on this outcome.

### Subgroup analysis based on baseline BMI

A subgroup analysis was performed based on the baseline BMI of women (considering normal weight women versus overweight/obese women versus mixed (normal or overweight/obese women)). The subgroup analysis revealed no clear subgroup differences for the three primary outcomes, GDM ($Chi^2$ = 0.15, P = 0.93, $I^2$ = 0%) (Analysis 3.1), caesarean birth ($Chi^2$ = 2.78, P = 0.25, $I^2$ = 28.1%) (Analysis 3.2); or large-for-gestational age ($Chi^2$ = 1.55, P = 0.21, $I^2$ = 35.6%) (Analysis 3.3), indicating no clear differential treatment effects for these primary outcomes according to the baseline BMI of the women.

When we excluded the 'mixed' subgroup, similarly no subgroup differences were shown.

### Subgroup analysis based on ethnicity

A subgroup analysis was performed based on the ethnicities of the women (considering majority 'low-risk' ethnicities for GDM versus majority 'high-risk' ethnicities for GDM versus mixed ethnicities/not stated).

This subgroup analysis revealed a possible differential treatment effect for the primary outcome, GDM ($Chi^2$ = 7.80, P = 0.005, $I^2$ = 87.2%) (Analysis 4.1), with trials with women of 'majority low-risk ethnicities' demonstrating a trend towards increased risk of developing GDM for women receiving the diet and exercise intervention (average RR 1.23, 95% CI 1.00 to 1.52; $T^2$ = 0.00; $I^2$ = 0%). In contrast, in the trials with women of 'mixed ethnicities/not stated', a significantly lower risk of developing GDM was observed for women receiving the diet and exercise intervention (average RR 0.72, 95% CI 0.53 to 0.99; $T^2$ = 0.02; $I^2$ = 12%). While this subgroup interaction test was statistically significant,

it is important to highlight the difficulties in interpreting this finding, and inability to draw conclusions based on these data; with no trials including 'high-risk ethnicities' reporting data on this outcome, and due to the nature of the 'mixed ethnicities/not stated' subgroup.

The subgroup analysis for the outcomes caesarean birth ($Chi^2$ = 5.10, P = 0.08, $I^2$ = 60.8%) (Analysis 4.2) and large-for-gestational age ($Chi^2$ = 0.76, P = 0.38, $I^2$ = 0%) (Analysis 4.3), indicated no clear differential treatment effects for these primary outcomes according to ethnicity.

#### Sensitivity analysis

#### Sensitivity analysis by quality rating

The five trials (Asbee 2009; Dodd 2014; Harrison 2013; Phelan 2011; Poston 2013) with a low risk of bias in the domains of sequence generation and allocation concealment were included in this analysis.

No clear beneficial effects of diet and exercise interventions were seen for the primary outcomes, prevention of GDM (average RR 1.01, 95% CI 0.73 to 1.41; four trials, 2884 women; $T^2$ = 0.07; $I^2$ = 59%) (Analysis 5.1), caesarean section (RR 0.92, 95% CI 0.83 to 1.03; three trials, 2591 women) (Analysis 5.2), and large-for-gestational age (RR 0.90, 95% CI 0.76 to 1.07; two trials, 2312 infants) (Analysis 5.3) as in the main analysis. Only Dodd 2014 reported on perinatal mortality, and observed no clear difference between groups (Analysis 5.4).

## DISCUSSION

### Summary of main results

This review included 13 randomised controlled trials (involving 4983 women and their babies) assessing combined diet and exercise interventions that have reported on prevention of gestational diabetes (GDM). On meta-analysis, we did not observe any clear differences between the diet and exercise intervention and control groups when considering the primary outcomes of GDM prevention, caesarean section or large-for-gestational age; only one trial reported on perinatal mortality, and did not show a difference between groups.

Similarly, largely, we did not observe differences between groups for the review's secondary outcomes; including the maternal outcomes: induction of labour, perineal trauma, pre-eclampsia, postpartum haemorrhage and infection; and neonatal outcomes: macrosomia, birthweight, small-for-gestational age, ponderal index, hypoglycaemia requiring treatment, hyperbilirubinaemia requiring treatment, shoulder dystocia, bone fracture or nerve palsy.

The review identified a significant reduction in preterm birth for women receiving the diet and exercise intervention compared with control group women (five trials, 2713 women); the absolute risk reduction was 2.58% (from 8.86% (119/1343) in the control group to 6.28% (86/1370) in the intervention group). While promising, due to the clinical and statistical heterogeneity of the trials combined in this meta-analysis, the result should be interpreted with some caution.

A further potential benefit associated with combined diet and exercise interventions observed in this review, was a trend towards less weight gain during pregnancy; on average, women in the diet and exercise intervention group gained 0.76 kg less than women in the control group (eight trials, 2707 women). In line with this observation, in relation to adherence to the intervention, a number of trials demonstrated improvements in diet (five out of the eight trials reporting on dietary outcomes reported improvements) and physical activity related behaviours (four out of eight trials) for women receiving the combined diet and exercise intervention. There was however, notable variation across trials in the diet- and physical activity-related behaviours measured and also in the results observed; not all trials showed improvements, and where they did, mostly these improvements did not translate into clear health benefits for the mother or her baby.

Only two trials reported on women's well-being and quality of life, and did not observe clear differences between groups for these outcomes.

Finally, very few trials reported on outcomes relating to the use of health services; although one trial (2153 women) did suggest an average reduced length of antenatal hospital stay (of 0.27 days) for women receiving the diet and exercise intervention.

No information was available from the 13 included trials on childhood and adulthood outcomes, and very few trials reported on longer-term outcomes for the mother (and reported on postpartum weight retention only, with no clear difference between groups observed).

The subgroup analyses (based on trial design, baseline BMI, and ethnicity of women) and sensitivity analysis (by trial quality) performed in this review similarly largely revealed no clear differences between groups for primary outcomes, and no clear differential treatment effects according to characteristics of the women/trials.

The subgroup analysis based on ethnicity, however, suggested a possible differential treatment effect for GDM - with trials including women of 'majority low-risk ethnicities' demonstrating a trend towards increased risk of GDM with combined diet and exercise interventions; and conversely trials including women of 'mixed ethnicities/not stated' demonstrating a significantly reduced risk of GDM with the combined diet and exercise interventions. While this finding may suggest that women of different ethnicities could respond differently to diet and exercise interventions for preventing GDM, certainly no conclusions can be based on these data; the nature of the 'mixed ethnicities/not stated' subgroup makes interpretation difficult, and further, no trials including 'high-risk

ethnicities' only reported data on this outcome.

## Overall completeness and applicability of evidence

The evidence for combined diet and exercise interventions during pregnancy for GDM prevention is incomplete.

Although a wide range of diet and exercise interventions have been investigated, for many trials, limited outcome data have been reported. While 11 of the 13 included trials reported on prevention of GDM in a way that allowed the data to be included in a meta-analysis, only seven of the trials reported on caesarean section (Asbee 2009; Dodd 2014; Hui 2012; Phelan 2011; Polley 2002; Rauh 2013; Vinter 2012), six on large-for-gestational age (Dodd 2014; Hui 2012; Luoto 2011; Poston 2013; Rauh 2013; Vinter 2012), and only one on perinatal mortality (stillbirth and neonatal death) (Dodd 2014). Apart from maternal postpartum weight retention, none of the trials have reported on maternal and child longer-term outcomes. Very little data have been reported on health service use and costs. With some secondary outcomes (such as perineal trauma, postpartum infection, postpartum haemorrhage; neonatal hypoglycaemia, shoulder dystocia, bone fracture, nerve palsy, hyperbilirubinaemia), evidence was limited to data from a single trial (Dodd 2014).

The majority of the included trials were conducted in Western societies, in high-income countries (Australia (Dodd 2014; Harrison 2013); Canada (Hui 2012); United States (Asbee 2009; Phelan 2011; Polley 2002); Italy (Petrella 2013); Germany (Rauh 2013), Denmark (Vinter 2012); Finland (Korpi-Hyovalti 2011; Luoto 2011); and the United Kingdom (Poston 2013)); however the El Beltagy 2013 trial was conducted in Egypt. The applicability of the evidence to other settings, particularly to low- and middle-income countries, therefore, is currently limited.

Though we were able to include 13 trials, and almost 5000 women and their babies, in this review, the ability to draw clear conclusions was limited, particularly, by notable variations in characteristics of the interventions across studies, considering the design of both the diet and exercise components of the interventions, and also the characteristics of the populations studied within the trials. While we chose to combine studies in one main comparison, and attempted to explore variation through subgroup analyses, the ability to do this was further limited by the difficulty in meaningfully grouping trials according to their characteristics.

## Quality of the evidence

The risk of bias varied across the 13 included trials. Dodd 2014, the largest trial including 2152 women and their babies, was rated as low risk of bias in six of the seven prespecified domains for assessing risk of bias. The other 12 included trials had at least one domain rated as 'unclear risk of bias', often due to limited information reported (Asbee 2009; El Beltagy 2013; Harrison 2013; Hui 2012; Korpi-Hyovalti 2011; Luoto 2011; Petrella 2013; Phelan 2011; Polley 2002; Poston 2013; Rauh 2013; Vinter 2012).

The potential for performance bias was common across the included trials, due to the nature of the interventions. All trials were rated as high risk of performance bias (Asbee 2009; Dodd 2014; Harrison 2013; Hui 2012; Korpi-Hyovalti 2011; Luoto 2011; Phelan 2011; Polley 2002; Poston 2013; Rauh 2013; Vinter 2012), with the exception of two trials, which received 'unclear' ratings with insufficient information available to confidently assess risk (El Beltagy 2013; Petrella 2013).

Multiple trials were also rated as high risk of bias in other domains assessed. Two trials (Asbee 2009; Luoto 2011) were considered to be high risk of attrition bias due to high rates of post-randomisation exclusions and/or loss to follow-up. Two trials (Asbee 2009; Korpi-Hyovalti 2011) were considered to be at high risk of reporting bias, with multiple outcomes not being reported or statements such as *"no statistically significant differences"* included in the results. One cluster-randomised trial (Rauh 2013) was at high risk of other bias with baseline imbalances existing for pre-pregnancy weight and BMI; and an unexpected 2:1 ratio of recruitment to the intervention and control groups.

## Potential biases in the review process

The search for studies in this area was performed using the Cochrane Pregnancy and Childbirth Group's Trials Register (which is updated weekly to monthly with information from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase, handsearches from 30 journals and conference proceedings of major conferences and alerts for a further 44 journals). It is unlikely that studies that have been conducted have been missed, however unpublished studies, or ongoing studies not registered in clinical trial registries could be missing. Should such studies be identified, we will include them in future updates of the review.

The date of the last search which identified studies that we have included in this review was in February 2014. We are aware of a number of recent studies that have published in this active area of research. While we attempted to conduct a comprehensive search for studies, the fact that 28 reports identified from a more recent search have not yet been incorporated may be a source of potential bias.

We aimed to reduce bias wherever possible by having at least two review authors independently working on study selection, data extraction and 'Risk of bias' assessment.

We explored the potential for publication bias using a funnel plot for the review's primary outcome, GDM, and there was no clear indication of publication bias.

## Agreements and disagreements with other studies or reviews

We found no significant differences in the risks of GDM, caesarean section birth, large-for-gestational age or perinatal mortality between the group of women and babies in the diet and exercise group and the group of women and babies receiving no intervention/standard care. These findings remained unchanged in the sensitivity analyses involving trials with a low risk of bias in the domains of sequence generation and allocation concealment. We found benefits of a reduction in the risk of preterm birth and possibly less weight gain during pregnancy with diet and exercise interventions, as well as some improved diet- and physical activity-related behaviours. We did not see clear differences between women and their babies in the two study groups for any of the other reported secondary outcomes.

Two Cochrane systematic reviews have been conducted to assess diet alone (Tieu 2008) and exercise alone (Han 2012b) for GDM prevention. In Tieu 2008, three small randomised trials with moderate to high risk of bias, involving 107 women and their babies were included. Dietary comparisons studied were high fibre diet compared with standard diet, and low GI diet compared with high GI diet (Tieu 2008). The primary outcome, GDM prevention was not reported by any of the included trials. Tieu 2008 found that women receiving a low GI diet had lower fasting glucose concentrations, fewer large-for-gestational age infants, and infants had lower ponderal indexes. These benefits were not seen in our review, however Tieu 2008 recognised the inconclusive nature of their findings, given the limited number of trials, participants and data, in addition to the between-trial heterogeneity.

In Han 2012b, five randomised trials with moderate risk of bias, involving 1115 women and their babies were included. Exercise interventions included individualised exercise advice, home-based stationary cycling, and regular supervised group exercise sessions (Han 2012b). Similar to our findings, Han 2012b did not find any differences between women who received exercise interventions during pregnancy and those who received standard care for GDM prevention, caesarean section or operative vaginal birth (the trials did not report on large-for-gestational age or perinatal mortality).

A further Cochrane review has assessed the effects of interventions (including dietary advice, physical activity, health education and lifestyle counselling) for preventing excessive weight gain during pregnancy, and included 28 trials involving 3976 women (Muktabhant 2012). Consistent with our review's findings, Muktabhant 2012 reported no clear evidence of differences between groups for a variety of maternal complications (pre-eclampsia, induction of labour, caesarean section, postpartum complications) and adverse neonatal outcomes (large-for-gestational age or birthweight greater than 4000 g; small-for-gestational age or birthweight less than 2500 g; complications related to macrosomia including hypoglycaemia, hyperbilirubinaemia, infant birth trauma (palsy, fracture, shoulder dystocia)). Muktabhant 2012 showed no difference for preterm birth, as was shown in our review. In Muktabhant 2012, similar to in our review, there was evidence from single studies that the interventions had positive effects on diet- and physical activity-related behaviours; however Muktabhant 2012 noted the difficulty in interpreting these results in the absence of blinding. The review showed inconsistent findings for excessive weight gain during pregnancy and mean weight gain in pregnancy, however noted that some interventions (behavioural counselling, an intensive exercise intervention and a combined diet and exercise intervention) seemed to have positive effects on mean weight gain in pregnancy (similar to our review's findings) (Muktabhant 2012).

One recent systematic review assessed a range of interventions (including dietary advice, exercise, metformin, self-monitoring of weight gain, and probiotics) for preventing GDM, including 19 studies (Oostdam 2011). The review reported a significant reduction in GDM compared to standard care with dietary counselling across seven trials (819 women), but noted the very low quality of the evidence for this outcome (Oostdam 2011). This finding was inconsistent with the results from our review and the Tieu 2008 review The Oostdam 2011 review however included data from trials assessing dietary advice published after the Tieu 2008 review, and also included some trials that have been included in this review (Hui 2012; Polley 2002), where exercise advice or sessions were provided in addition to dietary advice. The Oostdam 2011 review did not include a number of additional trials that have been included in this review, that were reported after its publication.

A further systematic review published this year assessed the effects of behaviour modification interventions for the prevention of GDM (Skouteris 2014). The review include nine trials (four of which were included in this review (Asbee 2009; Hui 2012; Luoto 2011; Polley 2002)), and did not pool data from individual studies in meta-analyses. The review however, similarly concluded that there is currently no clear evidence of benefit for prevention of GDM (Skouteris 2014). Importantly, this review documented variations in the characteristics of interventions assessed to date, and highlighted the need for further research to be undertaken to inform the combination of information delivery (written and verbal education; group or individual counselling) and behaviour modification techniques (self-monitoring; goal setting; planning) that may be effective for the prevention of GDM (Skouteris 2014).

In a recent narrative review of the role of lifestyle interventions in the prevention of GDM, it was highlighted that while observational data have shown an association between healthy eating, physical activity, reduced weight gain and reduced rates of GDM, that most randomised controlled trials of lifestyle interventions have been negative; supporting our review's findings (Halperin 2014). The authors suggested that the reasons for negative studies to date may include lack of power and lack of intervention uptake, and stressed the need for future studies to be powered to detect reductions in GDM, to monitor lifestyle changes closely, and to include a psychological component in the intervention (Halperin 2014).

## AUTHORS' CONCLUSIONS

### Implications for practice

There is a limited and incomplete body of evidence from randomised trials assessing the effects of combined diet and exercise intervention for preventing gestational diabetes (GDM), which is insufficient to inform or guide practice.

Results from 13 randomised trials suggested no clear difference in GDM or caesarean birth risk between women receiving an combined diet and exercise intervention and those receiving no intervention/standard care, and no clear difference for their babies in the risk of being born large-for-gestational age, or in the risk of perinatal mortality. The ability to draw clear conclusions however, was limited by variations in the quality of trials, in characteristics of the interventions and populations assessed, and in outcome definitions, particularly considering criteria for GDM diagnosis.

The 28 reports in 'Studies awaiting classification' may alter the conclusions of the review once assessed.

### Implications for research

In light of the limitations associated with the current evidence, further randomised controlled trials are required to determine the effects of combined diet and exercise interventions during pregnancy on prevention of GDM and other relevant adverse health consequences for women and their babies. Future trials must be sufficiently powered, and well-designed to allow important differences in relevant clinical outcomes for the mother and her baby to be detected, and to allow longer-term infant, child and/or adult outcomes to be assessed. The impact on health care requires evaluation.

Sixteen additional trials have been identified as being planned or underway, three in Canada (Atkinson 2013; Hivert 2012; Shen 2008), four in the United States (Chasan-Taber 2013; Goldberg 2012; Roberts 2012; Umpierrez 2010), three in Australia (Crowther 2012; Nagle 2013; Skouteris 2012), one in Italy (Facchinetti 2013), France (Parat 2009), Norway (Vistad 2009), Ireland (McAuliffe 2013), the United Kingdom (Poston 2009), and one in nine European countries (United Kingdom, Ireland, Netherlands, Belgium, Poland, Italy, Spain, Austria, Denmark) (Jelsma 2013). These trials, with recruitment targets ranging from 16 to 1564 women, are assessing a variety of lifestyle interventions (many with clearly defined diet and exercise components), for preventing adverse maternal and perinatal health outcomes, including, as primary outcomes, the development of GDM (Jelsma 2013; McAuliffe 2013; Nagle 2013; Poston 2009).

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* *Indicates the major publication for the study*

# CHARACTERISTICS OF STUDIES

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

**Asbee 2009**

| | |
|---|---|
| Methods | Randomised controlled trial. |
| Participants | 144 women were randomised; 100 women were included in the analyses<br>**Setting:** The Resident Obstetric Clinic in Charlotte, North Carolina, USA (from October 2005 to April 2007)<br>**Inclusion criteria:** women who established prenatal care at 6 to 16 weeks' gestation, were aged between 18 and 49 years, who received all prenatal care at the Resident Obstetrics Clinic, were English-speaking, Spanish-speaking or both, and had a singleton pregnancy were eligible for the trial<br>**Exclusion criteria:** women who established prenatal care at more than 16 weeks' gestation, were non-English or non-Spanish speaking, had a multiple pregnancy, had a BMI of higher than 40 kg/m², had pre-existing diabetes, untreated thyroid disease or hypertension requiring medication, or other medical conditions that might affect body weight were excluded. Women who delivered at an institution other than Carolinas Medical Centre-Main, had a pregnancy ending in premature delivery (less than 37 weeks) or who had limited prenatal care (fewer than 4 visits) were also excluded |
| Interventions | **Intervention group (n = 57)**<br>**Lifestyle counselling:** women underwent a complete history and physical exam with specific attention paid to pre-pregnancy weight, current weight, height and BMI. At the initial visit women met with a registered dietician to receive a standardised counselling session including information on pregnancy specific dietary and lifestyle choices<br>**Dietary counselling:** this consisted of recommendations for a patient-focused caloric value divided in a 40% carbohydrate, 30% protein, and 30% fat fashion<br>**Exercise counselling:** women were instructed to engage in moderate-intensity exercise at least 3 times per week, preferably 5 times<br>Women also received information on the appropriate weight gain during pregnancy using the IOM guidelines. At each routine appointment, the woman's weight was measured and charted on an IOM GWG Grid in front of the woman. The healthcare provider informed the woman whether her weight was at the appropriate level. If the weight gain was appropriate the woman was praised and encouraged to continue her diet and exercise regimen. If the weight gain was not within the guidelines, the regimen was reviewed, and she was advised on increasing/decreasing intake and exercise<br>**Routine prenatal care (n = 43)**<br>Women received routine prenatal care, which included an initial physical examination and history, routine laboratory tests, and routine visits as per ACOG standards. The only counselling of diet and exercise during pregnancy was that included in the standard 'What to do When You're Having a Baby' booklet. At each routine appointment, the woman's weight was measured and recorded |
| Outcomes | Weight gain; adherence to the IOM guidelines (based on initial BMI group); birthweight; pre-eclampsia; GDM; operative vaginal delivery; caesarean delivery (and caesarean due to failure to progress); vaginal lacerations; shoulder dystocia |

**Asbee 2009** (*Continued*)

| | | |
|---|---|---|
| Notes | | |
| ***Risk of bias*** | | |
| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Computer-generated random number sequence. |
| Allocation concealment (selection bias) | Low risk | Allocation was performed using numbered, sealed, opaque envelopes (used in a consecutive order) |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | While blinding (or the absence of) was not described, it seems unlikely that the participants and the study personnel were blinded, given the nature of the intervention |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | Blinding was not described. |
| Incomplete outcome data (attrition bias)<br>All outcomes | High risk | 44 participants were excluded after randomisation. It was unclear which groups the excluded women had been randomised to. No other losses to follow-up were reported |
| Selective reporting (reporting bias) | High risk | Outcomes were not clearly pre-specified in the methods (only total weight gain and BMI change from pre-pregnancy to before delivery were discussed in the methods). Whilst the results section details secondary outcomes including operative vaginal delivery, neonatal weight, pre-eclampsia, GDM, vaginal/perinatal lacerations and shoulder dystocia, no outcome data were reported; quote: *"no statistically significant differences were noted between the groups"*. |
| Other bias | Unclear risk | The study was terminated early due to time restrictions involved with completing a resident research project |

**Dodd 2014**

| | |
|---|---|
| Methods | Multi-centred, randomised controlled trial. |
| Participants | 2212 women were randomised.<br>**Setting:** 3 major metropolitan maternity hospitals in Adelaide, South Australia (June 2008 to December 2011)<br>**Inclusion criteria**: women with a BMI of at least 25 kg/m², with a singleton pregnancy at 10 + 0 to 20 + 0 weeks' gestation<br>**Exclusion criteria:** women with a multiple pregnancy, or type I or II diabetes diagnosed |

| | |
|---|---|
| | prior to pregnancy |
| Interventions | **Intervention group (n = 1108 randomised)**<br>Women participated in a comprehensive dietary and lifestyle intervention that included dietary, exercise and behavioural strategies delivered by a research dietician and trained research assistants. Women attending a planning session with the dietician and were provided with individualised information (meal plans, healthy recipes, simple food substitutions, options for healthy snacking and eating out and guidelines for healthy food preparation). Women were encouraged to set achievable goals for diet and exercise change, supported to make changes, and asked to self-monitor with a workbook; they were also asked to identify barriers and assisted to develop strategies to overcome these. The information was reinforced during a visit with the dietician at 28 weeks, and during telephone calls with a research assistant at 22, 24 and 32 weeks, and a face-to-face visit with a research assistant at 36 weeks<br>**Dietary advice**: advice was consistent with the Australian standards (maintain balance of carbohydrates, fat and protein; reduce intake of foods high in refined carbohydrates and saturated fats; increase intake of fibre; aim for 2 servings of fruit, 5 servings of vegetables and 3 servings of dairy daily)<br>**Exercise advice:** advice encouraged women to increase walking and incidental activity<br>**Control group (n = 1104 randomised)**<br>Women received their pregnancy care according to state-wide perinatal practice and local guidelines, which did not include routine provision of diet or exercise advice, or advice regarding GWG |
| Outcomes | Primary outcomes: large-for-gestational-age (defined as birthweight $\geq$ 90th centile for gestational age)<br>Secondary outcomes for the infant: preterm birth; mortality (stillbirth after 20 weeks' gestation, before birth; and infant death before hospital discharge including lethal congenital anomalies); infant birthweight > 4000 g; hypoglycaemia requiring intravenous treatment; admission to neonatal intensive care unit, or special care baby unit; hyperbilirubinaemia requiring phototherapy; nerve palsy; fracture; birth trauma; shoulder dystocia<br>Secondary outcomes for mother: maternal hypertension and pre-eclampsia, GDM (defined as a positive OGTT with fasting blood glucose level $\geq$ 5.5 mmol/L, or 2-hour blood glucose level $\geq$ 7.8 mmol/L); need for and length of antenatal hospital stay; antepartum haemorrhage requiring hospitalisation; preterm and term prelabour ruptured membranes; chorioamnionitis requiring antibiotic use during labour; need for induction of labour; any antibiotic use during labour; caesarean section; postpartum haemorrhage (defined as blood loss > 600 mL); perineal trauma; wound infection; endometritis; use of postnatal antibiotics; length of postnatal hospital stay; thromboembolic disease; maternal death<br>Post hoc analysis: GWG (difference in weight measured between 36 weeks' gestation, or closest to birth and the antenatal booking visit); and the proportion of women with weight gain below, within or above IOM recommendations |
| Notes | |

***Risk of bias***

**Dodd 2014** (*Continued*)

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | A computer-generated randomisation scheduled was used (with balanced variable blocks in a 1:1 ratio; with stratification for parity, BMI at antenatal booking and collaborating centre) |
| Allocation concealment (selection bias) | Low risk | A central telephone randomisation service was used. |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Due to the nature of the intervention it was not possible to blind women, nor the study personnel |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | After birth, a research assistant not involved in providing the intervention and blinded to group allocation obtained information relating to antenatal, birth and infant outcomes from case notes |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | 2212 women were randomised; 10 withdrew consent to use data. Of the 1108 women in the intervention group, there were 25 miscarriages/terminations before 20 weeks, 3 women withdrew consent to use data, there was 1 maternal death, 4 neonatal deaths (3 due to lethal anomalies) and 5 stillbirths. Therefore, there were 1080 women included in the intervention group analyses and 1075 infants (excluding miscarriages, stillbirths and withdrawn consents). Of the 1104 women in the control group, there were 25 miscarriages/terminations before 20 weeks, 7 women withdrew consent to use data, there was 1 maternal death, 1 neonatal death and 5 stillbirths. Therefore, there were 1072 women included in the analyses, and 1067 infants (excluding miscarriages, stillbirths and withdrawn consents). Intention-to-treat analyses were performed, with multiple imputation performed separately by treatment group (sensitivity analyses with available data and different imputation models produced similar results) |

**Dodd 2014** (*Continued*)

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|---|---|---|
| Selective reporting (reporting bias) | Low risk | No evidence of selective reporting; data for pre-specified outcomes (according to published trial protocol) have been reported |
| Other bias | Low risk | No other source of bias identified. |

**El Beltagy 2013**

| | |
|---|---|
| Methods | Randomised controlled trial. |
| Participants | 100 women were randomised.<br>**Setting:** Egypt.<br>**Inclusion criteria:** obese women at risk of GDM at their first antenatal visit.<br>**Exclusion criteria:** none detailed. |
| Interventions | **Intervention group (assumed that 50 randomised, 48 analysed)**<br>Women participated in a 12-week mild physical activity program and diet control<br>**Control group (assumed that 50 randomised, 48 analysed)**<br>Not detailed. Assumed that women received standard care. |
| Outcomes | Abstract reports on: GDM, weight gain per week, *"adverse neonatal outcome".* |
| Notes | Information taken from published abstract only. |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | Not described in abstract. |
| Allocation concealment (selection bias) | Unclear risk | Not described in abstract. |
| Blinding of participants and personnel (performance bias)<br>All outcomes | Unclear risk | Not described in abstract. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | Not described in abstract. |
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | Insufficient information to determine. 100 women were enrolled, however in the abstract, data are reported for 48 women per group |
| Selective reporting (reporting bias) | Unclear risk | Insufficient information to determine. |

| | | |
|---|---|---|
| Other bias | Unclear risk | Insufficient information to determine. |

**Harrison 2013**

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|---|---|
| Methods | Randomised controlled trial. |
| Participants | 228 women were randomised.<br>**Setting:** 3 large metropolitan tertiary teaching hospitals in Victoria, Australia<br>**Inclusion criteria:** women at 12 to 15 weeks' gestation, who were overweight (BMI 25 or 23 kg/m² if high-risk ethnicity) or obese (BMI 30 kg/m²), and were at increased risk for developing GDM according to a validated risk prediction tool (based on first trimester data of women attending the hospital). Women had to agree to complete an OGTT at 28 weeks (rather than a standard GCT at GDM screening)<br>**Exclusion criteria:** women with multiple pregnancies, diagnosed with type I or II diabetes, BMI 45 kg/m², pre-existing chronic medical condition, non-English speaking |
| Interventions | **Intervention group (n = 121 women randomised)**<br>Women allocated to the intervention received 4 individual sessions of a behavioural-change lifestyle intervention, based on social cognitive theory. Sessions were provided in the antenatal clinic, scheduled around routine visits (14-16, 20, 24, 28 weeks), by a health coach (exercise physiologist); however was, designed to be delivered by generic health-care providers. The sessions provided pregnancy-specific dietary advice, simple healthy eating and physical activity messages. Simple behavioural change strategies were practices to identify short-term goals, increase self-efficacy and self-monitoring. Goals were determined by participants, informed by the lifestyle messages, and included goals such as increasing fruit and vegetable intake, reducing high fat or convenience foot, increased physical activity frequency. Self-monitoring strategies included use of pedometers and weight gain charts based on IOM recommendations. Women received the same written information as controls, in addition to resources promoting optimal health, GWG and lifestyle<br>**Control group (n = 107 women randomised)**<br>Women received a brief, single education session based on the widely available generic Australian Dietary and Physical Activity Guidelines. Written pamphlet versions were provided. GWG was not discussed and there was no further study support<br>All women received standard maternal care with the study integrated with routine maternity visits |
| Outcomes | Primary outcome: GWG.<br>Secondary outcomes: GDM; physical activity; risk perception. |
| Notes | |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|

**Harrison 2013** (*Continued*)

| | | |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Women were randomly assigned to intervention or control through a computer-generated randomisation sequence |
| Allocation concealment (selection bias) | Low risk | Allocation concealment was achieved through the use of sealed, opaque envelopes |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Due to the nature of the intervention, it was not possible to blind women, though *"pedometers were sealed to blind participants to their step count"*. Blinding of study personnel is unclear, as although the authors stated: *"Care providers, investigators, and outcome data analyzers were blinded to group allocation"* it is unclear how this would have been successfully achieved for care providers, given women's knowledge of their group allocation |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | Quotes: "*outcome data analyzers were blinded to group allocation;" "height measured by a registered nurse unaware of participant allocation".* |
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | 121 women allocated to intervention, 15 were lost to follow-up, and therefore 106 analysed. Reasons for loss to follow-up: miscarriage (1 woman), premature birth < 26 weeks (3 women), change in circumstance (3 women) , unavailable at 28 weeks (2 women), lost contact (6 women). 107 women allocated to control, 10 were lost to follow-up, and therefore 97 analysed. Reasons for loss to follow-up: miscarriage (2 women), premature birth < 26 weeks (1 woman), change in circumstance (1 woman) , unavailable at 28 weeks (4 women), lost contact (2 women). The numbers of women, per group, used to calculate weight gain and physical activity outcomes are unclear (given that data are not reported in tables, rather only in text, with means, standard deviations and P values, and not *"n"* values). |
| Selective reporting (reporting bias) | Unclear risk | While outcomes were described in the methods, with no access to a trial protocol, it is not possible to confidently assess selective reporting |
| Other bias | Low risk | No other obvious sources of bias identified. |

**Hui 2012**

| | |
|---|---|
| Methods | Randomised controlled trial. |
| Participants | 224 women were randomised.<br>**Setting:** Winnipeg, Manitoba, Canada (from July 2004 to February 2010)<br>**Inclusion criteria:** non-diabetic pregnant women (at less than 26 weeks' gestation), attending prenatal classes or community clinics in Winnipeg<br>**Exclusion criteria:** women with medical or obstetric contraindications to exercise during pregnancy |
| Interventions | **Intervention group (n = 112 randomised, n = 102 analysed)**<br>**Exercise:** women were given a community-based exercise programme designed for pregnant women. Recommended exercise included walking, mild-to-moderate aerobic, stretching and strength exercises. An exercise regimen (3 to 5 times per week; including a weekly exercise session and multiple home sessions) of mild-to-moderate exercise for 30 to 45 minutes per session was recommended. It was recommended that the exercise began between 20 to 26 weeks and ended at 36 weeks. The group sessions were held in air-conditioned gymnasia in community centres (day time and night time classes were available). An exercise instruction video was given to women to assist with home exercise. Activity logbooks were collected weekly by the project co-ordinator from the women<br>**Diet:** dietary interviews and counselling were provided twice to each woman by a registered dietician - 1 at enrolment, and 1, 2 months after enrolment. The interview was assisted with a 'Food Choice Map' (a computerised dietary interview tool, which consisted of a map, 91 magnetic stickers with pictures of common foods and bar codes and software modified for pregnant women). Women recalled their food intakes in a typical week, and women and dieticians placed stickers on the maps - bar codes and locations of stickers on the map represented the frequency, types and quantities of food intakes - which were scanned into the computer at the end of the interview to allow analysis instantly of calories and nutrients. Dieticians provided personalised counselling based on the interview results, pregnancy week, weight gain and Health Canada Guidelines<br>**Control group (n = 112 randomised, n = 88 analysed)**<br>Women received standard prenatal care recommended by the SOGC, and were provided with a package of up-to-date information on physical activity and nutrition from Health Canada. No exercise instruction or dietary intervention were provided |
| Outcomes | Prevalence of excessive GWG; food intake; physical activity; prevalence of large-for-gestational age; GDM (according to the 2008 Guidelines of the Canadian Diabetes Association); weight-related obstetrics procedures (induction, forceps or caesarean section); GWG; birthweight |
| Notes | |

***Risk of bias***

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | A computer-generated randomisation allocation table was used |

**Hui 2012** (*Continued*)

| | | |
|---|---|---|
| Allocation concealment (selection bias) | Unclear risk | Women received a sealed envelope labelled with the assigned randomisation number, with instructions for participants |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Due to the nature of the intervention, there was no blinding of participants or clinicians |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | Blinding of outcome assessors was not described. |
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | 4 women were excluded from analyses due to miscarriage (1 in the control group, 3 in the intervention group). 23 women discontinued the study in the control group and 7 in the intervention group (due to relocation, work/study, and loss to follow-up). Therefore, 88/112 women from the control group and 102/112 women from the intervention group were analysed. (Some suggestion of more women discontinuing the study in the control group.) |
| Selective reporting (reporting bias) | Unclear risk | Outcome data for induction and forceps deliveries were not reported (though the outcomes were pre-specified in the methods). No other evidence of selective reporting, though no published protocol was available for thorough assessment |
| Other bias | Low risk | Baseline characteristics similar between groups. No other obvious risk of bias identified |

**Korpi-Hyovalti 2011**

| | |
|---|---|
| Methods | Randomised controlled trial. |
| Participants | 60 women were randomised.<br>**Setting:** multi-centre study, with 2 rural municipalities: Kauhajoki and Lapua in Finland (from April 2005 to May 2006)<br>**Inclusion criteria:** a 2-hour OGTT was offered to all women at their first contact with maternal healthcare units during gestational weeks 8 to 12. Women who had 1 or more risk factors for GDM (BMI of greater than 25 kg/m², previous history of GDM, previous child born at more than 4.5 kg, aged greater than 40 years, family history of diabetes), or who had a venous plasma glucose concentration after 12 hours of fasting in the morning of 4.8 to 5.5 mmol/L, and a 2-hour OGTT plasma glucose of less than 7.8 mmol/L were eligible<br>**Exclusion criteria:** women with GDM (fasting plasma glucose of at least 5.6 mmol/L or 2-hour plasma glucose of at least 7.8 mmol/L), and women that did not want to participate in the trial for personal or professional reasons were excluded |

| | |
|---|---|
| Interventions | **Intervention group (n = 30 randomised; n = 27 analysed)**<br>**Dietary counselling:** dietary advice tailored to each subject individually on 6 occasions was provided; the nurse in the healthcare centres had on average 13 appointments with the intervention women. Women were encouraged to eat a diet rich in vegetables, berries and fruits, and to use low-fat dairy products, low-fat meat, soft margarines and vegetable oils and wholegrain products (with a goal of carbohydrate 50 to 55 energy %, fibre 15 g/1000 kcal, fat 30% energy %, saturated fat less than 10 energy %, and protein 15-20 energy %). Recommendation for energy intake was 30 kcal/kg/day for normal weight women and 25 kcal/kg/day for overweight women<br>**Exercise counselling:** moderate-intensity physical exercise during pregnancy was encouraged; the women had 6 sessions of exercise counselling with the physiotherapist. During the sessions the physiotherapist motivated the women individually to continue exercising during pregnancy or to start exercising, and gave written instructions for exercise and self-care. The goal of the exercise intervention was 30 minutes of daily physical activity if the woman previously exercised less than 2.5 hours per week, and 45 minutes if the woman already engaged in 2.5 hours per week. Recommended types of exercise included brisk walking, Nordic walking, swimming, cycling, and cross-country skiing. (If the BMI of the woman was greater than 30 kg/m² and the woman had not been active, exercise was started with 15 minutes per day 3 times a week)<br>**Control group (n = 30 randomised; n = 27 analysed)**<br>All women were given general information on diet and physical activity to decrease the risk of GDM during pregnancy as part of routine care. Women were followed up in the prenatal clinical at 1 month intervals according to standard care<br>For all women, dietary information was collected 3 times during pregnancy, and women returned a self-reported exercise history twice, and a monthly questionnaire of activity |
| Outcomes | Glucose tolerance at 26 to 28 weeks (fasting glucose; OGTT 1-hour glucose; OGTT 2-hour glucose; area under the curve); GDM (modified from the WHO as a fasting plasma glucose 5.6 mmol/L or 2-hour plasma glucose 7.8 mmol/L); need for insulin therapy; maternal weight gain; weight at the end of pregnancy; pre-eclampsia; induction of labour; lacerations; caesarean deliveries; birthweight; macrosomia; gestational age; admission to the neonatal intensive care unit; jaundice requiring phototherapy; respiratory distress |
| Notes | |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | A computer randomisation list was used. |
| Allocation concealment (selection bias) | Unclear risk | The study physician in the Central Hospital used the computed randomisation list. The healthcare nurses who scheduled the study visits did not have access to the randomisation list |

**Korpi-Hyovalti 2011** (*Continued*)

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| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | No blinding, trial described as *"open"*. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | Trial described as *"open"*. Unclear as to whether any outcome assessment was performed blind |
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | 60 women were randomised; 54 women were analysed. 3 women dropped out from each group (4 due to early miscarriage, 1 with a twin pregnancy, and 1 woman moved away). No detail of whether the characteristics of the women lost to follow-up differed from those analysed |
| Selective reporting (reporting bias) | High risk | For the baseline characteristics, and a number of other outcomes, data were reported by groups, with the P values reported as "NS" (indicating non-significance). For a number of outcomes, the data were not presented |
| Other bias | Unclear risk | Pre-pregnancy weight in the intervention group tended to be higher (P = 0.061) with *"all women weighing over 100 kg"* being in the intervention group. Women in the control group (close follow-up group) tended to have a higher educational status (P = 0.080) |

**Luoto 2011**

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| Methods | Cluster-randomised controlled trial. |
| Participants | 14 municipalities, with 640 women, were randomised.<br>**Setting:** maternity clinics of primary healthcare centres of 14 municipalities in Pirkanmaa region in south-western Finland. All 14 municipalities with at least 70 annual deliveries were recruited to the study<br>**Inclusion criteria:** women were eligible if they were pregnant and had at least 1 of the following risk factors: BMI of at least 25 kg/m² based on measured height and self-reported pre-pregnancy weight; GDM or any signs of glucose intolerance or newborn macrosomia in any earlier pregnancy; type I or II diabetes in first or second degree relatives; age of at least 40 years<br>**Exclusion criteria:** women were excluded if they: had at least 1 of 3 baseline OGTT measurements abnormal (fasting blood glucose of at least 5.3 mmol/L, more than 10. 0 mmol/L at 1-hour, and more than 8.6 mmol/L at 2 hours); had pre-pregnancy type I or II diabetes; were unable to speak Finnish; were less than 18 years old; had a multiple pregnancy; had a physical restriction preventing physical activity; had substance abuse; had treatment or clinical history of psychiatric illness |
| Interventions | **Intervention group (n = 7 municipalities)**<br>The intervention continued from the first maternity clinic (8 to 12 weeks) to 37 weeks' gestation. At the first visit, recommendations for GWG were discussed and an appro- |

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| | priate weight gain graph selected to guide the woman in her weight gain. The primary physical activity counselling was implemented at 8 to 12 weeks, and the primary dietary counselling session at 16 to 18 weeks. Physical activity counselling was enhanced at 4, and diet counselling at 3, subsequent visits. If the OGTT at 26 to 28 weeks was pathological, women were referred to other healthcare specialists<br>**Physical activity counselling:** aims were to increase leisure time for those women not fulfilling recommendations, or to adjust/maintain time for women who were fulfilling recommendations. The minimum weekly leisure time physical activity dose in the plan was 800 MET (multiples of resting metabolic equivalents) minutes<br>**Dietary counselling:** The goal of dietary counselling was to help women achieve a healthy diet (less than or equal to 10% saturated fat, 5% to 10% polyunsaturated fat, 25% to 30% total fat, and less than 10% saccharose of total energy intake, and 25 to 35 g/d fibre). Women were advised to consume vegetables, fruits and berries of at least 5 portions a day, to select mostly high-fibre bread and wholemeal products, to select mostly fat-free or low-fat versions of milk and milk products, to eat fish at least twice per week, to use moderate amounts of soft table spreads on bread, oil-based salad dressings in salad and oil in cooking/baking, to consume seldom (small-portions) of foods high in fat, and to consume seldom (small-portions) snacks with high levels of sugar and fat. Counselling cards helped nurses to standardise counselling. The women used follow-up notebooks to set their individualised plans and to keep a record of adherence<br>**Control group (n = 7 municipalities)**<br>Women received no counselling beyond usual care - which included some dietary counselling and follow-up of GWG, but little on physical activity |
| Outcomes | GDM (based on 25 to 28 week OGTT: at least 1 of the following criteria were met: fasting blood glucose of at least 5.3 mmol/L, more than 10.0 mmol/L at 1 hour, and more than 8.6 mmol/L at 2 hours); birthweight (adjusted for gestational age); glucose intolerance; insulin resistance; newborn sex; macrosomia (at least 4500 g); large-for-gestational age (birthweight above the 90th percentile adjusted gestational age); small-for-gestational age (birthweight below the 10th percentile adjusted gestational age); gestational age at birth; birthweight standard deviation score; crown-heel length and crown heel length standard deviation score; ponderal index (birthweight in kg divided by the cube of the crown-heel length in metres); newborn head circumference; GWG (based on self-reported pre-pregnancy weight and the last measured weight during pregnancy); the need for insulin or other diabetic medication from 26 to 28 weeks on; child weight development after delivery (to be reported in a separate article); pre-eclampsia; changes in physical activity and diet (intake of total fat, saturated and polyunsaturated fatty acids, saccharose, and fibre); adverse effects (nausea, bleeding, painful contractions, dizziness, breathlessness, headache, chest pain, tiredness/fatigue, calf pain, musculoskeletal problems) |
| Notes | |

***Risk of bias***

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | The unit of randomisation was municipality. In the randomisation process, participating municipalities were first pair-wise matched with regards |

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| | | to annual number of births, size and socio-economic status of the population, estimated incidence of GDM and urbanity level. Municipalities were randomised by computer; within each pair they were randomised to a trial and control municipality |
| Allocation concealment (selection bias) | Unclear risk | No further details regarding concealment of allocation was provided |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Due to the nature of the intervention, there was no blinding of participants or clinicians |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | It was not explicitly stated that the outcome collection was not conducted blind - however due to the nature of the trial (cluster-randomised), blinding was considered unlikely |
| Incomplete outcome data (attrition bias)<br>All outcomes | High risk | For the outcomes *"n Missing"* is reported in the tables - it is unclear however from which groups the missing data are from (for example, gestation weight gain *"n Missing"* = 31, and it is unclear if these women are from the intervention or usual care groups)<br>14 clusters were randomised and all included in the analyses. Of the 343 women in the intervention group and 297 women in the usual care group that agreed to participate (after having been screened for eligibility), 81 (24%) in the intervention group and 93 (31%) in the usual care group were excluded due to abnormal OGTT results at baseline (and 16 and 8 respectively due to miscarriage). The final number of participants in the analyses, after further loss to follow-up (27 in the intervention group and 16 in the usual care group) was 219 in the intervention group and 180 in the control group. Thus of the women considered preliminarily eligible, who consented to participate, 64% (219/343) were followed up in the intervention group, and 60% (180/297) in the usual care group; of the women who received the allocated intervention 89% (219/246) were followed up in the intervention group and 92% (180/196) in the usual care group |
| Selective reporting (reporting bias) | Unclear risk | The published trial protocol indicates that data for a number of additional outcomes including other perinatal outcomes (caesarean section and |

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| | | need for induction of labour), maternal quality of life, and direct and indirect costs during pregnancy have been (or will be) collected; however outcome data for these outcomes were not reported in this manuscript. In addition, one-year follow-up data are expected, however the manuscript does indicate that these will be published in a later report |
| Other bias | Unclear risk | There were more women in the intervention group with high education than in the usual care group. The trial's statistical methods appear to take clustering into account, and a number of individual level characteristics such as education (unadjusted and adjusted analyses were performed) |

**Petrella 2013**

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| Methods | Randomised controlled trial. |
| Participants | 61 women were randomised.<br>**Setting:** Modena, Italy.<br>**Inclusion criteria:** women with a BMI of greater than 25 kg/m² at first trimester<br>**Exclusion criteria:** women with chronic disorders. |
| Interventions | **Intervention group (n = 33)**<br>Therapeutic Lifestyle Changes Program: including **diet** (1500 kcal per day) and mild **physical activity** (30 minutes per day, 3 times per week).<br>**Control group (n = 28)**<br>No intervention.<br>Prenatal care was similar in both groups. |
| Outcomes | GDM (75 g OGTT at 24-28 weeks); gestational hypertension; weight gain; preterm birth; large-for-gestational age; eating habits |
| Notes | Information taken from a published abstract only. |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | Women *"were randomized to no intervention (28 cases) or a Therapeutic Lifestyle Changes (TLC) Program"*. No further detail. |
| Allocation concealment (selection bias) | Unclear risk | No information provided. |

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| Blinding of participants and personnel (performance bias)<br>All outcomes | Unclear risk | No information provided. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | No information provided. |
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | Insufficient information to determine attrition bias. |
| Selective reporting (reporting bias) | Unclear risk | Insufficient information to determine reporting bias. |
| Other bias | Unclear risk | Socio-demographic features were similar between groups. Insufficient other information to determine other risk of bias |

**Phelan 2011**

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|---|---|
| Methods | Randomised controlled trial. |
| Participants | 401 women were randomised.<br>**Setting:** 6 obstetric offices in Providence, Rhode Island, USA. (from 2006 to 2008)<br>**Inclusion criteria:** women with a gestational age between 10 to 16 weeks; a BMI between 19.8 to 40 kg/m²; who were non-smoking adults (at least 18 years); who were fluent in English; who had access to a telephone; and who had a singleton pregnancy were included<br>**Exclusion criteria:** women with self-reported major health or psychiatric disease; women with weight loss during pregnancy; or women with a history of at least 3 miscarriages were excluded |
| Interventions | **Intervention group (n = 201)**<br>Women in the intervention group received all aspects of standard care plus a behavioural lifestyle intervention designed to prevent excessive weight gain during pregnancy; no intervention was provided postpartum. The intervention included 1 face-to-face visit with an interventionist at the onset of treatment who discussed appropriate weight gain during pregnancy.There was an emphasis on decreasing high-fat foods, increasing physical activity and daily self-monitoring of eating, exercise, and weight. Women received 3 brief supportive phone calls from the dietitian during the intervention. Women who were over or under weight gain guidelines during any 1 month interval received additional phone calls (2 calls per month) that provided structured meal plans, and specific goals<br>**Physical activity recommendation:** 30 minutes walking most days of the week<br>**Dietary recommendation:** calorie goals (20 kcal/kg).<br>**Control group (n = 200)**<br>Women attended regular scheduled visits to prenatal care providers, occurring monthly until 28 weeks' gestation, bi-weekly from 28 to 36 weeks' gestation, weekly until delivery, and at 6 weeks postpartum. Women received standard nutrition counselling provided |

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| | by physicians, nurses, nutritionists, and counsellors. Women were weighed by nurses at each visit, and attended a brief (15 minute) face-to-face visit at study entry with the study interventionist and received study newsletters at 2-month intervals during pregnancy and postpartum, providing information about pregnancy related issues (prenatal vitamins and maternity clothes), to improve retention in the study |
| Outcomes | Pre-pregnancy weight was based on a self-report at time of study enrolment, and was compared with weight at the last clinic visit before delivery; excessive GWG was based on the 1990 IOM guidelines; women at (± 0.9 kg) or below their pre-pregnancy weights at 6 months postpartum. Total GWG; postpartum weight; changes in demographics; breastfeeding status; maternal and fetal complications |
| Notes | |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Computer-generated randomisation by varying block sizes and stratified by clinic and BMI category |
| Allocation concealment (selection bias) | Low risk | Allocation was concealed in opaque envelopes prepared by the study statistician |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Women were not blinded. Due to the nature of the intervention it is unclear how *"clinic staff and physicians were blinded to subject randomisation to prevent contamination"*. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | *"Postpartum weight, changing in demographics, and breastfeeding status...were obtained by a blinded research assistant at the 6-month postpartum visit"*. Obstetric records were *"abstracted"* after delivery for maternal and fetal complication - somewhat unclear if this was performed blind, and unclear if the height and weight measurements by research staff were performed blind |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | An intention-to-treat analysis was conducted assuming all losses to follow-up were treatment failures. Of the 401 participants randomly assigned into the intervention (n = 201) and control groups (n = 200), 176 intervention women and 182 control women were included in the 6-month postpartum analysis (25 women were excluded from the intervention group and 18 from the standard care group at follow-up) |
| Selective reporting (reporting bias) | Unclear risk | While outcomes were described in the methods, with no access to a trial protocol, and as the trial registration detailed the primary outcome and 1 secondary outcome |

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| | | only, it is not possible to confidently assess selective reporting |
| Other bias | Low risk | *"The 2 study groups did not significantly differ on key baseline measures."* Completers of the 6-month postpartum assessment were significantly older than non-completers, but no other significant differences were shown |

**Polley 2002**

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|---|---|
| Methods | Randomised controlled trial. |
| Participants | 120 women were randomised.<br>**Setting**: Obstetric clinic for low-income women at a hospital in Pittsburgh, Pennsylvania, USA<br>**Inclusion criteria:** women at less than 20 weeks' gestation, who gave informed consent<br>**Exclusion criteria:** underweight women (BMI less than 19.8 kg/m²) based on self-reported height and pre-pregnancy weight; age < 18 years; women whose first prenatal visit was less than 12 weeks' gestation; high-risk pregnancy (i.e. drug abuse, chronic health problems, previous complications during pregnancy, or current multiple gestation) |
| Interventions | **Intervention group (n = 61 randomised; n = 57 followed to delivery)**<br>The intervention was delivered by staff with training in nutrition/clinical psychology at regular scheduled clinic visits. Women were given written and oral information regarding: appropriate weight gain during pregnancy; exercise during pregnancy; healthy eating during pregnancy. Newsletters were mailed bi-weekly. Between clinic visits women were contacted by phone to discuss progress towards the goals set at the previous visit. After each clinic visit, women were sent a personalised graph of their weigh gain - women whose weight gains exceeded the recommended levels were given additional individualised nutrition/behavioural counselling using 6 steps (review of weight gain chart; assessment of current eating and exercise based on 24-hour recall or review of self-monitoring records)<br>**Diet:** the primary focus of the intervention was on decreasing high-fat foods, and substituting healthier alternatives. If these approached did not help the woman achieve the recommended weight, a more structure meal plan and individualised calorie goals were set<br>**Exercise:** the intervention focused on increasing walking and developing a more active lifestyle<br>**Control group (n = 59 randomised; n = 53 followed to delivery)**<br>Women received standard care, including standard nutrition counselling provided by the physicians, nutritionists and WIC counsellors at Magee-Women's Hospital. This counselling emphasised a well-balanced dietary intake and advice to take a multivitamin/iron supplement. No information or counselling was provided by the research staff |
| Outcomes | Excessive GWG; total GWG during pregnancy based on self-reported pre-pregnancy weight and weight at the last clinic visit; infant birthweight (and low birthweight) and complications during pregnancy and/or delivery, including macrosomia; preterm birth; caesarean birth; pre-eclampsia; weight retention at 4 weeks postpartum |

**Polley 2002** (*Continued*)

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| Notes | |

***Risk of bias***

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | Women were randomly assigned to the standard care control group or to the intervention - no further detail provided |
| Allocation concealment (selection bias) | Unclear risk | No information provided. |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Whilst blinding (or the absence of) was not described, it seems unlikely that the participants and the study personnel were blinded, given the nature of the intervention. Difficult to ascertain whether a lack of blinding would have impacted outcomes |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | No information provided. |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | Minimal losses to follow-up during the pregnancy period: in the intervention group, 2 women moved out of the area, 1 had a miscarriage, and 1 withdrew; in the control group, 4 women moved out of the area and 2 had miscarriages. Analyses were intention-to-treat |
| Selective reporting (reporting bias) | Unclear risk | Whilst outcomes were described in the methods, with no access to a trial protocol, it is not possible to confidently assess selective reporting |
| Other bias | Unclear risk | Rates of refusal to participate were higher among black women (28/74 refused) than among white women (16/90 refused) ($P < 0.005$) and higher in overweight blacks (16/37 refused) than in any of the other 3 weight-by-race categories ($P < 0.02$) |

**Poston 2013**

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|---|---|
| Methods | Randomised controlled trial. |
| Participants | 183 women were randomised.<br>**Setting:** 4 hospital in the UK (Glasgow, Newcastle, London), in urban settings (March 2010 to May 2011)<br>**Inclusion criteria:** BMI of at least 30 kg/m²; singleton pregnancy; gestational age over 15 weeks, and less than 17 + 6 weeks<br>**Exclusion criteria:** unable or unwilling to give informed consent; gestation less than 15 |

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| | weeks and more than 17 + 6 weeks; pre-existing diabetes; pre-existing essential hypertension (treated); pre-existing renal disease; multiple pregnancy; systemic lupus erythematosus; antiphospholipid syndrome; sickle cell disease; thalassaemia; coeliac disease; prescribed metformin; thyroid disease or current psychosis |
| Interventions | **Intervention group (n = 94 randomised)**<br>Women in the intervention group attended a one-to-one appointment with a *"Health Trainer"* (no specific health professional qualification, but experience in behaviour modification and conducting group sessions) - and were invited to attend weekly group sessions for 8 consecutive weeks from 19 weeks' gestation. The intervention was informed by psychological models of health behaviour. SMART (specific, measurable, achievable, relevant, time specific) diet and activity goals were set, with behaviours recorded in a log-book. Identification of benefits and overcoming barriers to behaviour change, and increasing self-efficacy were included; social support was facilitated through the group format. For women unable to attend, the session content was delivered by phone or email. At the initial one-to-one appointment, women received a participant handbook, a pedometer, a log-book (for weekly SMART goals and related behaviours) and a DVD of a specifically devised pregnancy exercise regimen. Each group session delivered a different element of the dietary and physical activity intervention; goals from the previous week were reviewed and goals set for the following week<br>**Dietary advice:** the focus on the advice was on increased consumption of foods with a low GI, including replacing sugar sweetened beverages with low GI alternatives; reduction in saturated fats, and replacement with monosaturated and polyunsaturated fat was recommended; exchange of foods was emphasised - high GI food for low GI food - rather than limiting energy intake<br>**Physical activity advice:** women were encouraged to increase daily physical activity incrementally, setting goals of incremental step counts (monitored by pedometers) and maintaining the achieved physical activity level after the intervention period. Recommendations included an emphasis on walking at moderate intensity level<br>**Control group (n = 89 randomised)**<br>Women in the control group received standard antenatal care, and returned for data collection appointments with the study midwife at 27 to 28 + 6 weeks and 34 to 36 + 6 weeks (where possible with coinciding antenatal visits)<br>All women attended routine antenatal care appointments and received advice regarding diet and physical activity according to local policies, which draw on UK NICE guidelines |
| Outcomes | Outcomes from attitudinal assessment questionnaire; health status and mental health outcomes; outcomes related to dietary and physical activity assessment (change in GI, GL, and energy intake from saturated fatty acids; total energy intake; proportion of energy derived from macronutrients; increase in minutes per day of MVPA (recorded by accelerometry)); process evaluation outcomes<br>Clinical outcome data: maternal primary outcome for the subsequent trial: GDM; neonatal primary outcome for the subsequent trial: large-for-gestational age. Other clinical outcomes (*"recorded but not reported"*): GDM; pre-eclampsia; GWG; mode of birth; blood loss at birth; maternal inpatient nights; detailed clinical and family history; health in current pregnancy; early pregnancy data; blood pressure; routine maternal blood results; gestational age at birth; birthweight; anthropometry; neonatal inpatient nights |
| Notes | |

**Poston 2013** (*Continued*)

| *Risk of bias* | | |
|---|---|---|
| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | The randomised treatment was allocated automatically, balanced by minimisation for maternal age, centre, ethnicity, parity and BMI |
| Allocation concealment (selection bias) | Low risk | Randomisation was performed online. |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | No mention of blinding. In view of the nature of the intervention, blinding of participants and study personnel was considered unlikely |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | No mention of blinding of outcome assessors. |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | 94 women were allocated to the intervention group; 15 women and 9 neonates were lost to follow-up; 4 women discontinued the intervention and 4 withdrew. 89 women were allocated to the control group: 14 women and 5 neonates were lost to follow-up. Therefore, for the intervention group, 79 women (84%) and 85 (90%) neonates were included in the analysis, and 75 women (84%) and 84 neonates (94%) in the control group. Intention to treat analyses performed, and no exclusions for analysis of primary outcome, other than those lost to follow-up |
| Selective reporting (reporting bias) | Unclear risk | With no access to a trial protocol, it is not possible to determine selective reporting. The methods specify a number of clinical outcomes for which data were *"recorded but not reported".* |
| Other bias | Low risk | No other source of bias identified. |

**Rauh 2013**

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| Methods | Cluster-randomised controlled trial. |
| Participants | 250 women from 8 gynaecological practices.<br>**Setting:** gynaecological practices in Munich, German (February 2010 to August 2011)<br>**Inclusion criteria:** pregnant women, older than 18 years, with a singleton pregnancy, prior to their 18th week of pregnancy, with a BMI of at least 18 kg/m², with *"sufficient"* German language.<br>**Exclusion criteria:** women with any condition preventing physical activity (cervical incompetence, placenta praevia, persistent bleeding); pre-pregnancy diabetes, uncontrolled |

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| | chronic diseases that could affect weight development (thyroid dysfunction, psychiatric diseases) |
| Interventions | **Intervention group (4 practices: 83 women recruited, 74 analysed)**<br>The FeLIPO (feasibility of a lifestyle intervention in pregnancy to optimise maternal weight development) intervention had 2 individual counselling sessions, given by trained researchers during the 20th (lasting up to 60 minutes, and including the main components of the intervention) and 30th (lasting 30 minutes, repeating topics from the first, with a 'problem-oriented' manner) week of gestation. The counselling focused on nutrition, physical activity and GWG monitoring, and during both sessions women received feedback on their nutrition and physical activity habits based on 7-day dietary records and physical activity questionnaires. The intervention had 3 main parts: general information on a healthy lifestyle during pregnancy; promoting self-monitoring (diet, physical activity, weight gain); setting behavioural goals<br>**Diet:** general topics such as energy balance and health nutrition (according to the German Nutrition Society) were explained; women were informed about additional energy requirements, and macro and micro nutrition requirements in pregnancy. The advice aimed to decrease the intake of energy-dense foods and high-fat foods and substitute them for low-fat alternatives, and aimed to increase consumption of fruit, vegetables and wholegrain products. The advice also focused on improving the quality of fat consumed (increasing fish consumption; choosing the correct fat/oil for cooking)<br>**Exercise:** the advice given was in accordance with current guidelines for physical activity in pregnancy from the SOGC and the ACOG. The recommendations used the FITT (frequency, intensity, time, type) criteria: 30 minutes of moderate intensity activity on most days, at an appropriate heart-rate zone. Non weight-bearing/low-impact endurance exercises were suggested (walking, cycling, swimming, aquatic exercises). Women were additionally provided with a list of adequate local prenatal physical activity programs and advised to participate in such programs<br>Each woman received a weight gain chart personalised according to her baseline BMI group, which incorporates the IOM's weight gain recommendations. Women were asked to use their chart to monitor their weight development, weekly<br>**Control group (4 practices: 167 women recruited, 152 analysed)**<br>Women in the control group received routine care, which included an information leaflet with 10 general statements about a healthy lifestyle during pregnancy (but no advice on diet or gaining weight) |
| Outcomes | GWG (including total weight gain; and excessive GWG or inadequate GWG according to IOM guidelines); postpartum weight retention (including total weight retention, and substantial weight retention (> 5 kg)); GDM or impaired glucose tolerance; birth mode: spontaneous birth; caesarean birth; vacuum extraction; induced birth; birthweight; birth length; large-for-gestational age; SGA; preterm birth; behavioural change outcomes (daily energy intake (kcal/day) at baseline, 26-28th week and 36-38th week; total physical activity (MET-min/week) at baseline, 26-28th week and 36-38th week) |
| Notes | The sample size calculations did not take into account clustering |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|

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|---|---|---|
| Random sequence generation (selection bias) | Low risk | The gynaecological practices were randomised using a computer-generated randomisation allocation table |
| Allocation concealment (selection bias) | Unclear risk | Quote: *"Randomization was performed by a research not involved in the study design thereby preventing allocation bias".* |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | The trial was *"open-label"* with no blinding. Quote: *"The nature of the study meant that participants and study staff were not blinded to the types of interventions".* |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | As above; no additional mention of blinding of outcome assessment |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | 83 women were recruited to the control group; and 167 to the intervention group. 4 women from the control group withdrew (relocation, personal reasons, unable to contact) and 8 women in the intervention group withdrew (personal reasons, complications in pregnancy). A further 3 women in the intervention group were considered 'drop-outs' (miscarriages, and late-term abortion). Women who gave birth preterm (5 in the control group; 4 in the intervention group) were excluded from the GWG analysis. 72 (87%) women in the control group and 152 (91%) in the intervention group could be contacted at 4-month follow-up |
| Selective reporting (reporting bias) | Unclear risk | Outcomes (particularly pregnancy and fetal outcomes) were not clearly pre-specified in the methods of the manuscript; further, with no access to a trial protocol, it is not possible to confidently assess selective reporting |
| Other bias | High risk | Quote: *"During recruitment, however it turned out that it was easier to recruit women for the intervention group than for the control group, yielding a 2:1 ratio".* The authors speculated that this may have been due to unmotivated gynaecologists/ practice staff recruiting women, or low numbers of pregnant women among the control practices; they acknowledge that as practice staff and women were not blinded, knowledge of the 'control group' status of these practices may have in- |

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| | | fluence recruitment and participation rates, raising the possibility of post-randomisation selection. Pre-pregnancy weight and BMI were *"although slightly"* significantly higher in the control group, compared to the intervention group (with more overweight and obese women in the control group); median weight at the first antenatal visit was also higher among women in the control group |

**Vinter 2012**

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| Methods | Randomised controlled trial. |
| Participants | 360 women were randomised.<br>**Setting:** 2 university hospitals in Denmark: Odense and Aarhus University Hospital (from October 2007 to October 2010)<br>**Inclusion criteria:** women aged 18 to 40 years at 10 to 14 weeks' gestation were recruited, with a BMI of 30 to 45 kg/m² as calculated from pre-pregnancy weight or first measured weight in pregnancy<br>**Exclusion criteria:** prior serious obstetric complications; chronic diseases (e.g. hypertension and diabetes); positive OGTT in early pregnancy; alcohol or drug abuse; Non-Danish speaking; multiple pregnancy |
| Interventions | **Intervention group (n = 180 randomised, n = 150 analysed)**<br>Dietary counselling was performed by trained dieticians on 4 separate occasions, at 15, 20, 28 and 35 weeks' gestation, to limit GWG to 5 kg. The counselling included advice based on the official Danish recommendations<br>**Dietary component:** energy requirements were individually estimated according to weight and level of activity<br>**Exercise component:** women were encouraged to be moderately physically active 30 to 60 minutes daily and were equipped with a pedometer to motivate and improve daily activity. They also had free full membership to a fitness centre for 6 months where they had closed training classes with physiotherapists for 1 hour each week. Training consisted of aerobic (low-step), training with light weights and elastic bands, and balance exercises. After training women were grouped 4 to 6 times with a physiotherapist using coaching-inspired methods for improving integration of activity into daily life<br>**Control group (n = 180 randomised, n = 154 analysed))**<br>Women in the control group received the same initial information about the purpose and content of the study, including access to a web site with advice about dietary habits and physical activities in pregnancy, but no additional intervention<br>Weight was measured at all antenatal visits, all women had the same follow-up program including repeated monitoring of blood pressure and 2 additional ultrasounds in third trimester |
| Outcomes | GWG (weight at 35 weeks visit minus measured weight at inclusion); pre-eclampsia; pregnancy-induced hypertension; GDM (2-hour OGTT $\geq$ 9 mmol/L); caesarean section; macrosomia (birthweight more than 4 kg); large-for-gestational age (above or equal to the 90th percentile) and admission to neonatal intensive care unit |

| | | |
|---|---|---|
| Notes | | |
| ***Risk of bias*** | | |
| **Bias** | **Authors' judgement** | **Support for judgement** |
| Random sequence generation (selection bias) | Low risk | Women were randomised 1:1 by computer-generated numbers. |
| Allocation concealment (selection bias) | Unclear risk | Women were randomised by the computer-generated numbers *"in closed envelopes;"* no further details provided. |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Trial described as *"open"* in registration. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | Trial described as *"open"* in registration. Not clear whether outcome assessment was conducted blind |
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | Of the 360 women who were enrolled in the study, 56 women dropped out. 30 in the intervention group (GDM: 9, withdrew: 18, missed miscarriage: 1, misclassification: 2) and 26 in the Control group (GDM: 3, withdrew: 14, twins: 2, missed miscarriage: 4, abortion: 3). 12 of the 304 women failed to attend the last appointment in pregnancy so data were not collected |
| Selective reporting (reporting bias) | Unclear risk | With no access to a published protocol, it is difficult to assess selective reporting. The trial registration lists *"Metabolic Markers"* as secondary outcome measures, however data were not reported for these outcomes |
| Other bias | Unclear risk | The groups did not differ significantly on any maternal baseline characteristics, although there were more smokers in the control group despite stratified randomisation (11.7% versus 7.3%).The drop-out group was older and had a higher percentage with a BMI of at least 40 kg/m², and a higher percentage of smokers, compared with the completing group (though not statistically significant) |

ACOG: American College of Obstetricians and Gynecologists
BMI: body mass index
GDM: gestational diabetes mellitus
GI: glycaemic index
GL: glycaemic load
GCT: glucose challenge test

GWG: gestational weight gain
IOM: Institute of Medicine
MET: multiples of resting metabolic equivalents
MVPA: moderate and vigorous physical activity
NICE: National Institute for Health and Care Excellence
OGTT: oral glucose tolerance test
SOGC: Society of Obstetricians and Gyncacologists Canada
WHO: World Health Organization

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

| Study | Reason for exclusion |
|---|---|
| Althuizen 2013 | This randomised controlled trial focuses on preventing excessive weight gain during pregnancy, and did not report on GDM (and therefore is of relevance to the Muktabhant 2012 review *'Interventions for preventing excessive weight gain during pregnancy'*). Women receiving 4 face-to-face counselling sessions (weight, physical activity, diet) and 1 session by telephone were compared to a randomised control group |
| Clapp 1997 | This randomised controlled trial is included in the review *'Dietary advice in pregnancy for preventing gestational diabetes mellitus'* (Tieu 2008), and compares a high GI/cafeteria diet to a low GI/Aboriginal diet |
| Kieffer 2013 | This randomised controlled trial assessed effects of culturally and linguistically tailored lifestyle intervention program (by providing diet and exercise information sessions) on reducing depressive symptoms among pregnant Latinas. Women in the control group received no lifestyle interventions. Only maternal psychological outcomes were reported, no data were reported on GDM or any other maternal and child clinical outcomes |
| Luoto 2010 | This was a non-randomised trial (n = 160) that recruited women while they were pregnant and postpartum. The intervention included individual counselling on diet and physical activity during 5 routine visits to a public health nurse in primary health care. The counselling focused on promoting healthy dietary and physical activity habits. The participants in the intervention clinics had also an option to participate in group exercise sessions once a week. The participants of the control clinics received usual care |
| Marcinkevage 2012 | A published abstract describes a randomised trial that was focused on physical activity (women are randomly assigned to receive regular care or regular care plus a lifestyle intervention - monthly meetings focused on reducing sedentary behaviour and increasing levels of moderate physical activity). GDM was not reported on in the abstract for this trial |
| Nascimento 2012 | This published abstract detailed a secondary analysis of a randomised clinical trial (n = 82) that randomised overweight pregnant women to an exercise intervention (not a combined diet and exercise intervention). The intervention group were instructed to exercise under supervision and received home exercise counselling. GDM was not reported on in the abstract for this trial |
| Phelan 2012 | This ongoing randomised controlled trial is recruiting and randomising women pre-conception (not during pregnancy, as per this review's inclusion criteria), and is assessing a behavioural weight loss program prior to pregnancy to reduce GDM recurrence |
| Quinlivan 2007 | This randomised controlled trial is included in the review *'Dietary advice in pregnancy for preventing gestational diabetes mellitus'* (Tieu 2008), and compares a 4-step multidisciplinary approach to the management of obese |

(*Continued*)

| | |
|---|---|
| | pregnant women (continuity of care, assessing weight gain at each visit, a brief intervention by a food technologist before each visit, and assessment by a clinical psychologist), with standard obstetric antenatal care |
| Ruchat 2012 | This randomised controlled trial evaluated the effect of an exercise program with 2 different intensities (low-intensity versus moderate intensity), plus nutrition program (women in both study groups received same nutrition intervention) on GWG and maternal weight retention at 2 months postpartum. In this trial, a third group of 45 women were recruited at 2 months postpartum as a historical control group (non-randomised). No data were reported on GDM or maternal metabolic outcomes and therefore is of relevance to the Muktabhant 2012 review *'Interventions for preventing excessive weight gain during pregnancy'*. |
| Szmeja 2011 | This is a brief abstract of a randomised controlled trial with overweight and obese pregnant women (n = 193) . The intervention was a DVD incorporating dietary advice (no detail of any exercise advice provided). The outcome measures were self-reported knowledge and satisfaction with care, and GDM was not reported |
| Wilkinson 2012 | This randomised controlled trial evaluated a workshop: usual care women (n = 182) received a nutrition resource, and intervention women also attended a 1-hour Healthy Start to Pregnancy Workshop (n = 178). This trial evaluated dietary intake, physical activity levels, GWG knowledge, smoking cessation and intention to breast feed, and did not assess clinical outcome data such as GDM |

GDM: gestational diabetes mellitus
GI: glycaemic index
GWG: gestational weight gain

## Characteristics of studies awaiting assessment *[ordered by study ID]*

**Bo 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Briley 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |

**Briley 2014** (*Continued*)

| | |
|---|---|
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Dodd 2014a**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Dodd 2014b**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Dodd 2014c**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Farajzadegan 2013**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Harrison 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Harrison 2014a**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Hawkins 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |

| | |
|---|---|
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Hayes 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Hui 2010**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Hui 2011**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Hui 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | |

**Kieffer 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**McGowan 2013**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Mujsindi 2014**

| | |
|---|---|
| Methods | Randomised controlled trial. |
| Participants | 79 obese women with singleton pregnancies. |
| Interventions | Intervention: *"pregnancy, exercise and nutrition (PEN) program"*. The intervention consisted of 5 dietary/nutrition sessions during pregnancy and at 3 months postpartum (food records, pedometers and logs, pregnancy activity questionnaire and food frequency questionnaires were used; anthropometric measures were collected throughout pregnancy and postpartum)<br>Control: standard care. |

**Mujsindi 2014** (*Continued*)

| | |
|---|---|
| Outcomes | Primary outcome: GWG; postpartum weight retention.<br>Secondary outcomes: obstetric, delivery and neonatal outcomes |
| Notes | This trial has been reported in abstract form only, and GDM was not reported in this abstract. We have contacted the trial authors (23/06/2014) with no response to date |

**Peacock 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Petrella 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Rauh 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Rono 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Schneeberger 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Szmeja 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Tanvig 2015**

| | |
|---|---|
| Methods | Not known. |
| Participants | |
| Interventions | |
| Outcomes | |

**Tanvig 2015** (*Continued*)

| | |
|---|---|
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Teede 2012**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Uauy 2013**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Vesco 2012**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Vinter 2011**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Vinter 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

**Youngwanichsetha 2014**

| | |
|---|---|
| Methods | |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | This trial report was identified in our February 2015 updated search - it will be assessed and incorporated into the review when it is updated |

GDM; gestational diabetes mellitus
GWG: gestational weight gain

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

### Atkinson 2013

| | |
|---|---|
| Trial name or title | Be healthy in pregnancy (B-HIP): a randomised clinical trial to study nutrition and exercise approaches for healthy pregnancy |
| Methods | Randomised controlled trial. |
| Participants | **Setting:** Canada.<br>**Inclusion criteria:** healthy pregnant females > 18 years of age with singleton pregnancies (either nulliparous or multiparous); less than 20 weeks' gestation; pre-pregnancy BMI of > 25 and < 40 kg/m²; plans to deliver at a Hamilton Health Sciences, St Joseph's Healthcare Hamilton, Joseph Brant Hospital or by home birth but willing to attend research visits at the McMaster University Medical Centre site; approval of primary care provider; and able to provide signed informed consent<br>**Exclusion criteria:** unable to understand some English; currently breastfeeding previous child; pregnancy resulting from in vitro fertilization; known contraindications to exercise as recommended by the Canadian clinical practice guidelines for pregnancy; severe chronic gastrointestinal diseases or conditions; refusal to consume dairy foods due to intolerance or dislike; any significant heart, kidney, liver or pancreatic diseases; pre-existing diabetes; or a depression score above 10 on the validated Edinburgh Depression scale as that is indicative of severe depression and should be referred for treatment; currently smoking |
| Interventions | **Intervention group:** a high protein (25% energy) diet providing low fat dairy foods and individualised to energy needs and aerobic exercise (walking)<br>**Control group**: usual prenatal care. |
| Outcomes | **Primary outcome**: GWG within IOM guidelines.<br>**Other outcomes**: mother and infants bone outcomes at 6 months postpartum. |
| Starting date | July 2012. |
| Contact information | Dr Stephanie A Atkinson: satkins@mcmaster.ca<br>McMaster University Medical Centre,Hamilton, Ontario, Canada, L8S 4K1 |
| Notes | Recruitment target: 110 women. |

### Chasan-Taber 2013

| | |
|---|---|
| Trial name or title | Lifestyle intervention in overweight and obese pregnant Hispanic women |
| Methods | Randomised controlled trial. |
| Participants | **Setting**: United States.<br>**Inclusion criteria**: Hispanic women; overweight or obese before pregnancy (BMI > 25 kg/m²); 16-45 years old<br>**Exclusion Criteria:** History of type II diabetes, heart disease, or chronic renal disease; contraindications to participation in moderate physical activity or to a low-fat/ high-fibre diet (e.g. Crohn's disease, ulcerative colitis); inability to read English or Spanish at a sixth grade level; > 20 weeks' gestation; current medications which adversely influence glucose tolerance; not planning to continue to term or deliver at the study site; pregnant with twins or triplets; preterm birth (< 34 weeks), a miscarriage, or a stillbirth after enrolment or a |

**Chasan-Taber 2013** (*Continued*)

| | |
|---|---|
| | stillbirth; women who become pregnant again in the year following delivery will be censored at the time of their positive pregnancy test |
| Interventions | **Intervention group:** stage-matched physical activity and diet intervention materials and health education<br>**Control group:** standard care, no lifestyle intervention. |
| Outcomes | **Primary outcome:** maternal insulin resistance. |
| Starting date | January 2014. |
| Contact information | Professor Lisa Chasan-Taber: lct@schoolph.umass.edu<br>Baystate Medical Center, Springfield, Massachusetts, United States, 01199 |
| Notes | Recruitment target: 333 women. |

**Crowther 2012**

| | |
|---|---|
| Trial name or title | The IDEAL study: investigation of dietary advice and lifestyle for women with borderline GDM: a randomised controlled trial |
| Methods | Multi-centre, randomised controlled trial. |
| Participants | **Setting:** Australia.<br>**Inclusion criteria:** women between 24 and 34 + 6 weeks' gestation with a singleton pregnancy, a positive OGTT (venous plasma glucose ≥ 7.8 mmol/L) and a normal oral 75 g OGTT (fasting venous plasma glucose < 5.5 mmol/L and a 2-hour glucose < 7.8 mmol/L) with written, informed consent<br>**Exclusion criteria:** Women with known diabetes mellitus, previously treated GDM, active chronic systemic disease or a multiple pregnancy |
| Interventions | **Intervention group:** women will be advised that their OGTT results are normal but that they have borderline glucose intolerance. They will receive obstetric care by the attending obstetric team, which will include dietary and lifestyle advice, monitoring of blood glucose and further treatment if appropriate<br>**Control group:** women will be advised that their OGTT results are normal. They will receive routine obstetric care by the attending obstetric team |
| Outcomes | **Primary outcomes:** incidence of large-for-gestational age infants.<br>**Other outcomes:** death or serious health outcomes for the infant; other causes of infant morbidity (many defined); serious health outcomes up to 6 weeks postpartum for the mother; other adverse health outcomes for the mother; maternal diet and exercise outcomes |
| Starting date | 8/01/2008. |
| Contact information | Professor Caroline Crowther: caroline.crowther@adelaide.edu.au<br>The University of Adelaide, Obstetrics and Gynaecology, Women's and Children's Hospital Level 1, Queen Victoria Building 72 King William Road North Adelaide SA 5006 |
| Notes | Recruitment target: 682 women. |

**Facchinetti 2013**

| | |
|---|---|
| Trial name or title | Pregnancy complications in women with BMI > 25 kg/m² enrolled in a healthy lifestyle and eating habits program: a randomised controlled trial |
| Methods | Randmoised controlled trial. |
| Participants | **Setting:** Italy.<br>**Inclusion criteria:** BMI ≥ 25 kg/m²; age > 18 years; singleton pregnancy; first trimester<br>**Exclusion criteria:** twin pregnancies; chronic diseases (i.e., diabetes mellitus, chronic hypertension, untreated thyroid diseases); GDM in previous pregnancies; smoking during pregnancy; dietary supplements or herbal products known to affect body weight; other medical conditions that might affect body weight; to plan to deliver outside of the Birth Center |
| Interventions | **Intervention group**: specific Therapeutic Lifestyle Changes (TLC) program includes diet and mild physical activity. The TLC comprises 1500 kcal/day (3 main meals and 3 snacks) composed of 55% carbohydrate, 20% protein, and 25% fat. The dietitian adds an 200 kcal/day for obese or 300 kcal/day for overweight. The exercise intervention is focused on increasing walking. All participants are advised to participate in 30 minutes of moderate intensity activity at least 3 days a week. Subjects wear a pedometer waist during walking session for the assessment of the adherence to the physical activity program. Women are told to consider using the *"talk test"* (being able to maintain a conversation during activity) to monitor exercise intensity, and to record the frequency and duration of the activity on a diary. Follow-up is performed at 16, 20, 28, 36 weeks<br>**Control group**: receives only a simple nutritional booklet about a lifestyle and healthy diet during pregnancy without explicit caloric restriction, in accordance with Italian Guidelines for a healthy diet during pregnancy, compatible with a recommended nutritional intake. A 30 minute counselling session about the appropriate GWG at term for each different BMI category is performed. Moreover, the importance of the limited GWG for preventing unfavourable maternal-neonatal outcomes related to excessive weight gain is explained. Women are scheduled to have a follow-up at 16, 20, 28, 36 weeks |
| Outcomes | **Primary outcome**: total GWG at term and maternal body composition assessed by bioimpedance analyser<br>**Other outcomes:** 75-g 2-hour OGTT result; maternal blood pressure; maternal adherence to exercise program assessed by SenseWear system armband and Pedometer |
| Starting date | October 2012. |
| Contact information | Dr Fabio F Facchinetti: facchi@unimore.it<br>Mother-Infant Department, University of Modena and Reggio Emilia, Italy, 41124 |
| Notes | Recruitment target: 400 women. |

**Goldberg 2012**

| | |
|---|---|
| Trial name or title | Randomised control pilot of a behaviour-based exercise and diet intervention to reduce risk factors for GDM among otherwise healthy pregnant women |
| Methods | Randomised controlled trial. |
| Participants | **Setting:** United States<br>**Inclusion criteria:** healthy first trimester pregnant women.<br>**Exclusion criteria:** hypertension, diabetes, known cardiopulmonary disease; orthopedic problems or other conditions that would prevent regular physical activity |

| | |
|---|---|
| Interventions | **Intervention group:** pregnant women will participate in 20 educational sessions designed to promote daily exercise, vegetable and fruit intake, maintain a diet that is relatively lower in fat and rich in whole grains<br>**Control group:** standard medical care. |
| Outcomes | **Primary outcome:** achieving 30 minutes of daily exercise, 4 or more times each week<br>**Other outcomes:** eating 5 or more servings of vegetables and/or fruits each day; pregnancy weight gain; haemoglobinA1C |
| Starting date | November 2012. |
| Contact information | Dr Linn Goldberg: goldberl@ohsu.edu<br>Oregon Health and Science University, Portland, Oregon, United States, 97239 |
| Notes | Recruitment target: 30 women. |

**Hivert 2012**

| | |
|---|---|
| Trial name or title | Intervention en Changement Des Habitudes de Vie Par l'Activité Physique et un Support Nutritionnel Durant la Grossesse en Estrie |
| Methods | Randomised controlled trial. |
| Participants | **Setting:** Canada<br>**Inclusion criteria:** aged ≥ 18 years; have a pre-pregnancy BMI ≥ 25 kg/m²; at risk of developing GDM (a history of GDM or glucose 1-hour post-50 g > 7.1 mmol/L<br>**Exclusion criteria:** pre-pregnancy diabetes detected in the first trimester (A1c > 6.5%, fasting glucose > 7.0 mmol/L, random blood glucose > 11.1 mmol/L, glucose > 10.3 mmol/L 1-hour post-50 g); twin pregnancy; taking medications that can affect blood sugar or weight; practice ≥ 150 minutes of physical activity per week; against formal-indication for physical activity |
| Interventions | **Intervention group:** a nutritional counselling every 2 weeks by a nutritionist until week 36 of gestation; a physical activity group session once a week lead by a kinesiologist until week 36 of gestation; 2 sessions of physical activity counselling (weeks 12 and 24)<br>**Control group:** in addition to the standard antenatal care for pregnancy, women will receive information about the recommended weight gain during pregnancy and an evaluation about of their nutritional and physical activity habits |
| Outcomes | **Primary outcome:** weight change during pregnancy.<br>**Other outcomes:** levels of maternal and fetal adipokines; maternal and fetal glycaemic control; determine whether the adoption of healthy lifestyle in pregnancy is associated with epigenetic changes that influence the levels of adipokines and glucose regulation during pregnancy and in newborns; optimise the intervention before measuring its impact on the prevention of GDM on a larger scale |
| Starting date | December 2011. |

| | |
|---|---|
| Contact information | Dr Marie-France Hivert<br>Centre Hospitalier Universitaire de Sherbrooke, Sherbrooke, Quebec, Canada, J1H5N4 |
| Notes | Recruitment target: 16 women. |

**Jelsma 2013**

| | |
|---|---|
| Trial name or title | DALI: Vitamin D and lifestyle intervention for GDM prevention: an European multi-centre, randomised trial |
| Methods | Multi-centre, randomised controlled trial. |
| Participants | **Setting:** 9 European countries: United Kingdom, Ireland, Netherlands, Belgium, Poland, Italy, Spain, Austria, Denmark<br>**Inclusion criteria:** pregnant women with a pre-pregnancy BMI $\geq$ 29 kg/m$^2$; before 19 + 6 days of gestation, singleton pregnancy and aged $\geq$ 18 years<br>**Exclusion criteria:** are diagnosed with GDM on OGTT, before randomisation, using IADPSG criteria defined as fasting venous plasma glucose $\geq$ 5.1 mmol/L and/or 1-hour glucose $\geq$ 10 mmol/L and/or 2-hour glucose $\geq$ 8.5 mmol/L at baseline measurement; have pre-existing diabetes; are not able to walk at least 100 meter safely; require complex diets; have chronic medical conditions (e.g. valvular heart disease); have significant psychiatric disease; are unable to speak major language of the country of recruitment fluently or are unable to converse with the lifestyle coach in another language for which translated materials exist. For the vitamin D arm, 2 additional exclusion criteria apply: current or past abnormal calcium metabolism, e.g. hypo/hyperparathyroidism, nephrolithiasis,<br>hypercalciuria; have hypercalciuria (> 0.6 mmol/mmol creatinine in spot morning urine) or hypercalcaemia (> 10.6 mg/dL, 2.65 mmol/L) detected at baseline measurement |
| Interventions | This study will have intervention arms using a 2×(2×2) factorial design:<br>1. Healthy eating:<br>• Setting up 7 dietary objectives for each participant to achieve or to maintain: 1) *"Replace sugary drinks"*: To reduce intake of sugary drinks (e.g. replace with water); 2) *"Eat more non-starchy vegetables"*: To eat more non-starchy vegetables; 3) *"Increase fibre consumption"*: To choose high-fibre, over low fibre products ($\geq$ 5 g fibre/100 g); 4) *"Watch portion size"*: To be conscious about the amount of food eaten each meal; 5) *"Eat protein"*: To increase intake of proteins (e.g. meat, fish, beans); 6) *"Reduce fat intake"*: To reduce fat intake (e. g. snack, fast food, fried foods); 7) *"Eat less carbohydrates"*: To reduce intake of carbohydrates (e.g. potatoes, pasta, rice, snacks, candy).<br>• Participant manual including information about: 1) healthy eating; 2) how to read a food labels, 3) an adapted food pyramid (which is concurrent with the dietary objectives); 4) detailed information about the above-mentioned 7 dietary topics.<br>• Action plan for improving dietary behaviour: will be made during the first intervention session and evaluated in subsequent sessions.<br>• Intervention sessions will be delivered by 5 1-to-1, face-to-face sessions of approximately 30-45 minutes duration and 4 optional phone booster sessions of up to 20 minutes that occur between the face-to-face sessions. All lifestyle intervention sessions will be carried out by specifically trained lifestyle coaches.<br>2. Physical activity:<br>• Each participant will be advised by attractive messages to: 1) *"Be active every day"*: Incorporate light and moderate physical activity as much as possible into their daily life (e.g. by parking further away from destination or undertake special activities for pregnant women). 2) *"Sit less"*: Reduce sedentary time. 3) |

**Jelsma 2013** (*Continued*)

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| | *"Build your strength"*: Incorporate upper and/or lower limb resistance exercise as PA. 4) "Take more steps": To increase the number of steps taken per day. 5) *"Be more active at weekends"*: To be more active during the weekends.<br>• Participant manual including information about: 1) upper and/or lower limb resistance exercises; 2) a list of helpful places where pregnant women can go for physical activity classes; 3) an adapted FITT. model (frequency, intensity, time, type) based on ACOG guidelines and information about the above mentioned physical activity advice.<br>• Action plan for increasing physical activity levels: will be made during the first intervention session and evaluated in subsequent sessions.<br>• Providing pedometers to provide feedback on women's behaviour and progress.<br>• Additional (training) video on upper and/or lower limb resistance exercises.<br>• Providing flexible elastic dynabands to encourage upper and/or lower limb resistance exercises at home.<br>• Intervention sessions will be delivered by 5 1-to-1, face-to-face sessions of approximately 30-45 minutes duration and 4 optional phone booster sessions of up to 20 minutes that occur between the face-to-face sessions. All lifestyle intervention sessions will be carried out by specifically trained lifestyle coaches.<br>3. Vitamin D alone: each vitamin D tablet contains 400 IU, and participants are asked to take 4 tablets/day until delivery<br>4. Placebo alone: placebo tablets are identical to the vitamin D tablets in appearance, are packed in identical bottles with identical labels as the vitamin D bottles. The women will be asked to take 4 tablets daily. Placebo manufacturer will provide the results of the batch analysis of the placebo's after producing those<br>5. Control: no lifestyle intervention or vitamin D/placebo. Women will receive usual care from their midwife or obstetrician during pregnancy<br>6. Healthy eating and physical activity.<br>7. Healthy eating and physical activity and vitamin D.<br>8. Healthy eating and physical activity and placebo. |
| Outcomes | **Primary outcome:** maternal GWG, fasting glucose levels and insulin sensitivity<br>**Other outcomes:** cost-effectiveness of the intervention. |
| Starting date | February 2013. |
| Contact information | Mireille NM van Poppel: mnm.vanpoppel@vumc.nl<br>Department of Public and Occupational Health, EMGO+—Institute for Health and Care Research, VU University Medical Centre, Van der Boechorststraat 7, 1081BT Amsterdam, the Netherlands |
| Notes | Recruitment target: 880 women. |

**McAuliffe 2013**

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| Trial name or title | Pregnancy, exercise and nutrition research study with app support: a randomized controlled trial |
| Methods | Randomised controlled trial. |
| Participants | **Setting:** Ireland.<br>**Inclusion criteria:** 1) singleton pregnancies with a live fetus; 2) smart phone; 3) women between the ages of 18 and 45 at 10-15 weeks' gestation with an early pregnancy BMI $\geq$ 25 kg/m$^2$) women with adequate understanding of the English language and an understanding of the study to enable them to give informed consent to participate<br>**Exclusion criteria:** 1) multiple pregnancy; 2) women < 18 or > 45 years of age; 3) those with pre GDM or |

**McAuliffe 2013** (*Continued*)

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| | early onset GDM or past history of GDM; 4) fetal anomaly; 5) previous stillbirth / perinatal death; 6) those whose English is inadequate or those who are unable to understand the study adequately to participate; 7) those with a medical disorder requiring medication |
| Interventions | **Intervention group:** 1)**w**omen will receive a *"Healthy lifestyle package"* which consists of targeted advice on a low GI eucaloric diet, individualised exercise goals and a specially designed smart phone application containing daily information about nutrition, and exercise delivered in a motivational way; 2) women will have individual and group education sessions on the healthy lifestyle package at randomisation; 3) research team will contact women in the intervention group every 2 weeks to support adherence to exercise goals and low GI diet<br>**Control group:** women will receive routine antenatal care which does not include specific nutritional advice nor specific advice on GWG |
| Outcomes | **Primary outcome:** incidence of GDM according to the HAPO criteria.<br>**Other outcomes:** GWG; maternal GI value; maternal activity levels in the third trimester |
| Starting date | 7/1/2013. |
| Contact information | Prof Fionnuala McAuliffe: fionnuala.mcauliffe@ucd.ie.<br>National Maternity Hospital, Holles St, Dublin, Ireland. |
| Notes | Recruitment target: 500 women. |

**Nagle 2013**

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|---|---|
| Trial name or title | Primary prevention of GDM for women who are overweight and obese: a randomised controlled trial |
| Methods | Randomised controlled trial. |
| Participants | **Setting:** Australia.<br>**Inclusion criteria:** pregnant women at less than 14 weeks' gestation, with a singleton pregnancy, a BMI of at least 25 kg/m², who are able to give informed consent in English<br>**Exclusion criteria:** diabetes or a history of GDM. |
| Interventions | **Intervention group:** from recruitment in the first trimester until birth, women in the intervention group will receive a telephone-based program informed by the Theory of Self-efficacy and employing Motivational Interviewing. Brief phone contact will alternate each week with a text message/email and this contact will involve goal setting, behaviour change reinforcement with weekly self weighing and charting, and the provision of health information<br>**Control group:** usual pregnancy care |
| Outcomes | Primary outcome: GDM.<br>Other outcomes: large-for-gestational age; self-efficacy related to healthy lifestyle changes in diet and exercise; anxiety; depression |
| Starting date | 20/02/2013. |

**Nagle 2013** (*Continued*)

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| Contact information | Dr Cate Nagle: cate.nagle@deakin.edu.au<br>Deakin University School of Nursing and Midwifery Waterfont Campus 1 Gheringhap St Geelong Victoria 3220, Australia |
| Notes | Recruitment target: 370. |

**Parat 2009**

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|---|---|
| Trial name or title | Impact of Pregnant Women Education in Case of Overweight or Obesity on Risk of Child Overweight and Pregnancy Outcome |
| Methods | Randomised controlled trial. |
| Participants | **Setting:** France.<br>**Inclusion criteria:** pregnant women who agree the study; have a BMI > 25 kg/m²; are no more that 21 weeks of gestation; have social security<br>**Exclusion criteria:** women younger than 18 years, with a multiple gestation, a high-risk pregnancy, a psychiatric pathology, with diabetes diagnosed before the inclusion, with fetal malformation, or with a history of obesity surgery will be excluded. Women with no understanding of the French language or planning to move to another area will also be excluded |
| Interventions | **Intervention group:** women will be provided with education, at regularly scheduled sessions (20 weeks, 28 weeks, 35 weeks, and 2 months after delivery) and 2 dietary consults. The sessions will provided information about healthy eating and modest exercise, and will include several women (no more than 10)<br>**Control group:** women will be managed with standard care. |
| Outcomes | Primary outcomes: 30% reduction of rapid infancy weight gain at 2 years defined as > + 0.67 change in weight SD score<br>Other outcomes: reduction of rapid infancy weight gain between 0 and 6 months; reduction of the number of children with BMI over 19 kg/m² at 2 years; reduction of incidence of GDM; pre-eclampsia; hypertension during pregnancy; caesarean; fetal macrosomia; reduction of spontaneous feeding at 4 months; increase in breastfeeding (number of women and duration); reduction 1 and 2 years after pregnancy of maternal weight and BMI; reduction of abnormality of lipid and glycaemia test in women 2 years after the pregnancy |
| Starting date | September 2008. |
| Contact information | Dr Sophie Parat.<br>Assistance Publique - Hôpitaux de Paris, France. |
| Notes | Recruitment target: 800. |

**Poston 2009**

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| Trial name or title | Improving pregnancy outcome in obese women; a multi-centre randomised controlled trial: (UK Pregnancies Better Eating and Activity Trial) |
| Methods | Multi-centre randomised controlled trial. |
| Participants | **Setting:** United Kingdom.<br>**Inclusion criteria:** women who are willing and able to give informed consent; are pregnant with a booking BMI greater than or equal to 30 kg/m²; and have a singleton pregnancy<br>**Exclusion criteria:** women who are unwilling or unable to give informed consent; have a booking BMI less than 30 kg/m²; have a multiple pregnancy; have pre-existing diabetes mellitus; have pre-existing hypertension requiring treatment; have pre-existing thyroid and renal disease, current psychosis, sickle cell disease, thalassaemia, or coeliac disease |
| Interventions | **Intervention group:** women receive an intervention delivered by a health trainer in weekly sessions between 20 and 28 weeks' gestation which focusses on changing the diet (lowering the glycaemic load, free sugars and saturated fat intake) with advice on increasing mild-to-moderate physical activity. Each session comprises a targeted dietary and physical activity change with individualised SMART goals.<br>**Control group:** women in the control arm will receive standard antenatal care. All women have an OGTT at 28 weeks |
| Outcomes | Primary outcomes: GDM by HAPO criteria; macrosomia (> 90th customised birthweight centile)<br>Other outcomes: maternal: complications in pregnancy (GDM, pre-eclampsia, depression, quality of life), physical activity, diet, GWG, maternal body composition (skin folds), mode of delivery, hospital admissions. Health economic assessment. Infant: adverse outcomes, neonatal unit admissions, small-for-gestational age, large-for-gestational age, body composition (skin folds). At 6 months postpartum: maternal and child diet and physical activity, maternal general health (depression, quality of life). maternal and child body composition, childhood modifiers/modulators of obesity. At 3 years: to be confirmed; measures of maternal and child body composition, diet, physical activity. childhood mental health, cardiovascular function |
| Starting date | 01/11/2008. |
| Contact information | Professor Lucilla Poston: lucilla.poston@kcl.ac.uk<br>Maternal and Foetal Research Unit, 10th Floor North Wing, St Thomas' Hospital, Westminster Bridge Road, London, UK |
| Notes | Recruitment target: 1564. |

**Roberts 2012**

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|---|---|
| Trial name or title | Interventions to reduce excess weight gain in pregnancy in overweight and obese mothers |
| Methods | Randomised controlled trial. |
| Participants | **Setting:** United States.<br>**Inclusion criteria:** aged 15/46 years; in first trimester; willing not to join any other weight control program while in the study; BMI 25 to 40 kg/m²; willingness and ability to attend support group meetings either in person or via web; must be able to read, speak, and understand English<br>**Exclusion criteria:** carrying multiple fetuses; GDM at study entry; type II diabetes mellitus or blood glucose > 125 mg/dL at screening; self reported current substance abuse; current smoking; alcohol consumption of |

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| | more than 1 drink per day; pre-existing medical conditions (includes bariatric surgery) or use of medications that would impact study involvement or outcomes testing; eating disorder in the past 2 years; depression or diagnosis of bipolar disorder; concurrent participation in any other research study that would impact participation in this investigation |
| Interventions | **Intervention group:** meetings with a nutrition counsellor and/or psychologist where individualised eating plans will be developed and reviewed, and regular group meetings during which information about healthy eating for weight management will be discussed<br>**Control group:** routine clinical care and no additional interventions. |
| Outcomes | **Primary outcome:** maternal body weight change from first trimester to 1 year postpartum; infant weight change from birth to 1 year old<br>**Other outcomes:**<br>1) Infant outcomes: body composition changes through the first year; characteristics at birth including Apgar score, gestational age; dietary intake and food preferences at 1 year<br>2) maternal outcomes: caesarean delivery; gestational hypertension/pre-eclampsia; preterm birth; birth complications; fasting blood glucose and insulin concentrations throughout pregnancy; body composition and energy requirements at baseline and 24-28 weeks of pregnancy; total energy expenditure at 24-28 weeks of pregnancy; rate of breastfeeding and breastfeeding practices at 1, 3, 6, and 12 months postpartum |
| Starting date | July 2012. |
| Contact information | Dr Susan B Roberts: susan.robers@tufts.edu.<br>Tufts University Human Nutrition Research Center on Aging, Boston, Massachusetts, United States, 02111 |
| Notes | Recruitment target: 75 women. |

**Shen 2008**

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|---|---|
| Trial name or title | Impact of a Community-based Obesity and Diabetes Prevention Program on Pregnant Outcomes in Pregnant Women: (Impact of Diet and Exercise Activity on Pregnancy Outcomes (IDEA)) |
| Methods | Randomised controlled trial. |
| Participants | **Setting:** Canada.<br>**Inclusion criteria:** pregnancy < 20 weeks; expressed interest in study and willingness to consent to participate in the study<br>**Exclusion criteria:** obstetric or medical contraindications for exercise according to 2002 SOCG guideline (ruptured membranes, preterm labor, incompetent cervix, hypertensive disorders of pregnancy, growth restricted fetus, placenta previa, persistent bleeding in 2nd or 3rd trimester, significant metabolic, cardiovascular, respiratory or systemic disorder) (5, 6). Pre-existing diabetes (except a history of GDM, but not in current pregnancy). Multiple gestations |
| Interventions | **Intervention group:** women will receive exercise and dietary education, recommending aerobic exercise or walking for 3 to 5 times/day for 30-45 minutes from 20 weeks to 36 weeks of pregnancy. Women will also be given dietary education on nutrition for healthy pregnancy through weekly classes during pregnancy |

**Shen 2008** (*Continued*)

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| Outcomes | Primary outcome: excessive GWG during pregnancy.<br>Other outcomes: macrosomia, requirement of delivery procedures |
| Starting date | July 2004. |
| Contact information | Dr Garry Shen: gshen@ms.umanitoba.ca<br>University of Manitoba, Winnipeg, Manitoba, Canada. |
| Notes | Recruitment target: 500. |

**Skouteris 2012**

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|---|---|
| Trial name or title | Health In Pregnancy and Post Birth: The HIPP Study. |
| Methods | Randomised controlled trial. |
| Participants | **Setting:** Australia.<br>**Inclusion criteria:** pregnant women who have a BMI of over 18.5 kg/m² (American IOM cut-off for normal weight), are 18 years of age or older, English speaking, and less than 18 weeks' gestation<br>**Exclusion criteria:** history of disordered eating or diabetes, non-English speaking, greater than 18 weeks' gestation |
| Interventions | **Health coaching:** women will take part in a Health Coaching intervention program, which has 2 components: (1) 1-on-1 sessions with a Health Coach, and (2) educational group sessions lead by a Health Coach<br>**Education alone:** women will only receive 2 education group sessions run by an educator<br>**Usual care:** women will receive standard care. |
| Outcomes | Primary outcome: BMI.<br>Other outcomes: readiness to change; motivation to change; general distress and psychopathology; body dissatisfaction; physical activity; food intake |
| Starting date | 1/05/2011. |
| Contact information | Associate Professor Helen Skouteris: helen.skouteris@deakin.edu.au<br>School of Psychology, Deakin University, 221 Burwood Highway, Burwood, Victoria 3125 Australia |
| Notes | Recruitment target: 220. |

**Umpierrez 2010**

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|---|---|
| Trial name or title | Lifestyle intervention to limit excessive weight gain during pregnancy in minority women |
| Methods | Randomised controlled trial. |
| Participants | **Inclusion criteria:** 1) Blacks and Hispanic; 2) women between 18-45 years of age; 3) overweight and obese (BMI > 25 kg/m²); 4) have a sedentary lifestyle (< 30 minutes/day of moderate physical activity); 5) prenatal care established at less than 20 weeks of gestation; 5) with a singleton pregnancy |

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| | **Exclusion criteria:** 1) age < 18 or > 45 years; 2) > 20 weeks' gestation; 3) history of diagnosis of type II diabetes, hypertension, cardiovascular disease, chronic renal disease, and active liver disease (AST > 3 ULN) ; 4) anaemia (haemoglobin < 10 g, hematocrit < 32%); 5) current medications which adversely influence glucose tolerance (corticosteroids); 6) multiple pregnancy; 7) women not planning to continue pregnancy to term, 7) contraindications to participate in regular physical activity; 8) patients with mental conditions rendering them unable to understand the nature, scope, and possible consequences of the study |
| Interventions | **Intervention group:** women will participate in a lifestyle program based on diet and moderate physical activity implemented shortly after first recognition of pregnancy. These women will attend monthly nutrition and physical activity educational sessions, and receive booster every 2 weeks<br>**Control group:** women will receive counselling routinely provided to all prenatal care women as recommended by the IOM for appropriate nutrition and weight gain and ACOG guidelines for appropriate physical activity during pregnancy |
| Outcomes | **Primary outcome:** maternal GWG assessed against the IOM recommendations.<br>**Other outcomes:** maternal carbohydrate intolerance, GDM, and other maternal and fetal complications |
| Starting date | April 2010. |
| Contact information | Professor Guillermo Umpierrez<br>Grady Memorial Hospital, Atlant, Georgia, United States, 30303 |
| Notes | Recruitment target: 57 women. |

**Vistad 2009**

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|---|---|
| Trial name or title | Fit for delivery: a study of the effect of exercise intervention and nutritional counselling on pregnancy outcome |
| Methods | Randomised controlled trial. |
| Participants | **Setting:** Norway.<br>**Inclusion criteria:** 1) expecting first child; 2) gestational weeks 12-20; 3) residence in 1 of the following towns: Kristiansand, Søgne, Sogndalen, Vennesla, Lillesand, Mandal<br>**Exclusion criteria:** 1) twin or other multiple pregnancy; 2) pre-existing diabetes; 3) physical handicap which precludes participation in exercise groups; 4) ongoing drug addiction; 5) serious mental disorder; 6) BMI at or below 19 kg/m² before pregnancy; 7) inability to read/write Norwegian or English |
| Interventions | **Intervention group:** women will receive 2 telephone consultations on nutritional topics and twice-weekly exercise groups. Access to a password-protected Internet site with information on healthy lifestyle during pregnancy. 2 evening meetings with information on healthy pregnancy lifestyle<br>**Control group:** routine pregnancy care. |
| Outcomes | **Primary outcome:** maternal GWG in pregnancy; weight of the newborn; maternal fasting serum glucose level; incidences of caesarean section and operative vaginal delivery; maternal body composition<br>**Other outcomes:** maternal weight retention at 12 months postpartum; serum levels of hormones which regulate serum glucose levels, in both the pregnant woman and her newborn baby; incidence of women with serum glucose levels > 7.8 mmol/L after 2-hour GCT; incidence of delivery complications; proportion of newborns with birthweight over the 90th percentile for gestational age |

**Vistad 2009** (*Continued*)

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| Starting date | September 2009. |
| Contact information | Dr. Ingvild Vistad<br>Sorlandet Hospital, Kristiansand, Vest Agder, Norway, 4604. |
| Notes | Recruitment target: 600 women. |

ACOG: American College of Obstetricians and Gynecologists
BMI: body mass index
GDM; gestational diabetes mellitus
GI: glycaemic index
GWG: gestational weight gain
HAPO: Hyperglycaemia and Adverse Pregnancy Outcome
IADPSG: International Association of the Diabetes and Pregnancy Study Groups
IOM: Institute of Medicine
OGTT: oral glucose tolerance test
SOGC: Society of Obstetricians and Gyncacologists Canada

## DATA AND ANALYSES

### Comparison 1. Combined diet and exercise versus control

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Gestational diabetes | 11 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 1.1 Gestational diabetes, variously defined | 11 | 3744 | Risk Ratio (M-H, Random, 95% CI) | 0.92 [0.68, 1.23] |
| 1.2 Gestational diabetes (≧ 1 abnormal 2 hour OGTT or infant birthweight ≧ 4500 g or use of insulin/other medication) | 1 | 93 | Risk Ratio (M-H, Random, 95% CI) | 1.24 [0.56, 2.74] |
| 1.3 Gestational diabetes (≧ 1 abnormal 2 hour OGTT or infant birthweight ≧ 4000 g or use of insulin/other medication) | 1 | 93 | Risk Ratio (M-H, Random, 95% CI) | 1.0 [0.56, 1.78] |
| 1.4 Gestational diabetes (≧ 1 abnormal 2 hour OGTT or use of insulin/other medication) | 1 | 93 | Risk Ratio (M-H, Random, 95% CI) | 1.18 [0.49, 2.82] |
| 2 Caesarean birth | 7 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 2.1 Caesarean birth | 7 | 3246 | Risk Ratio (M-H, Fixed, 95% CI) | 0.92 [0.83, 1.01] |
| 2.2 Planned caesarean birth | 1 | 304 | Risk Ratio (M-H, Fixed, 95% CI) | 1.68 [0.82, 3.44] |
| 2.3 Emergency caesarean birth | 1 | 304 | Risk Ratio (M-H, Fixed, 95% CI) | 0.81 [0.48, 1.34] |
| 3 Spontaneous vaginal birth | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 4 Vacuum extraction | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 5 Large-for-gestational age | 6 | 2950 | Risk Ratio (M-H, Fixed, 95% CI) | 0.90 [0.77, 1.05] |
| 6 Perinatal mortality | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 6.1 Perinatal mortality overall | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 6.2 Stillbirth > 20 weeks | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 6.3 Neonatal death (no lethal anomalies) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 6.4 Neonatal death (lethal anomalies) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 7 Induction of labour | 2 | 2193 | Risk Ratio (M-H, Fixed, 95% CI) | 1.02 [0.91, 1.14] |
| 8 Perineal trauma (third or fourth degree) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 9 Pre-eclampsia | 6 | 3070 | Risk Ratio (M-H, Fixed, 95% CI) | 0.93 [0.72, 1.19] |
| 10 Weight gain during pregnancy (kg) | 8 | 2707 | Mean Difference (IV, Random, 95% CI) | -0.76 [-1.55, 0.03] |
| 10.1 All women | 5 | 486 | Mean Difference (IV, Random, 95% CI) | -1.57 [-2.61, -0.52] |
| 10.2 Normal weight women | 2 | 241 | Mean Difference (IV, Random, 95% CI) | -0.92 [-2.12, 0.29] |
| 10.3 Overweight or obese women | 3 | 1980 | Mean Difference (IV, Random, 95% CI) | 0.28 [-1.13, 1.69] |
| 11 Weight gain during pregnancy (kg) | | | Other data | No numeric data |

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| 12 Weight gain during pregnancy (kg/week) | 2 | 1971 | Mean Difference (IV, Random, 95% CI) | -0.04 [-0.11, 0.04] |
| 13 Weight gain during pregnancy (at 26-28 weeks) (kg) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Subtotals only |
| 14 Weight gain during pregnancy ≤ 5 kg | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 15 Weight gain during pregnancy ≤ 9 kg | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 16 Excessive gestational weight gain (IOM) | 2 | 1817 | Risk Ratio (M-H, Random, 95% CI) | 0.87 [0.57, 1.32] |
| 17 Inadequate gestational weight gain (IOM) | 2 | 1817 | Risk Ratio (M-H, Fixed, 95% CI) | 1.00 [0.86, 1.18] |
| 18 Postpartum haemorrhage (> 600 mL) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 19 Postpartum infection (wound infection) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 20 Postpartum infection (endometritis) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 21 Postpartum infection (postpartum antibiotics) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 22 Adherence with the intervention (data on diet) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 22.1 Total calorie intake at 2 months after enrolment | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 22.2 Carbohydrate intake (g) at 2 months after enrolment | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 22.3 Protein intake (g) at 2 months after enrolment | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 22.4 Fat intake (g) at 2 months after enrolment | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 22.5 Saturated fat intake (g) at 2 months after enrolment | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 22.6 Cholesterol intake (mg) at 2 months after enrolment | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 22.7 Fibre intake (g) at 2 months after enrolment | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 22.8 Carbohydrate ratio (%) at 2 months after enrolment | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 22.9 Protein ratio (%) at 2 months after enrolment | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 22.10 Fat ratio (%) at 2 months after enrolment | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 23 Adherence with the intervention (data on physical activity) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 23.1 Physical activity index at 2 months after enrolment | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24 Adherence with the intervention (data on diet) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 24.1 Calorie intake (late pregnancy) | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |

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| 24.2 Percentage of calories from fat (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.3 Percentage of calories from carbohydrates (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.4 Percentage of calories from protein (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.5 Percentage of calories from sweets (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.6 Daily calories from soft drinks (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.7 Daily saturated fat (late pregnancy) (g) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.8 Daily servings of vegetables (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.9 Daily servings of fruit and fruit juices (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.10 Daily servings of breads, cereals, rice, pasta (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.11 Daily servings of milk, yoghurt, cheese (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.12 Daily frequency of fats, oils, sweets, sodas (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.13 Weekly fast food (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.14 Daily iron from food (late pregnancy) (mg) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.15 Daily calcium from food (late pregnancy) (mg) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.16 Total daily dietary fibre (late pregnancy) (g) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.17 Daily vitamin D from food (late pregnancy) (IU) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 24.18 Daily folate from food (late pregnancy) (µg) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 25 Adherence with the intervention (data on physical activity) | 1 | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 25.1 Physical activity (late pregnancy) (kcal) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 25.2 Physical activity (6 months postpartum) (kcal) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 25.3 Physical activity (12 months postpartum (kcal) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 26 Adherence with the intervention (data on diet) | 1 | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 26.1 Total energy at 28 weeks (MJ/day) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |

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| 26.2 Dietary glycaemic index at 28 weeks (%) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 26.3 Dietary glycaemic load at 28 weeks (g/day) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 26.4 Glycaemic load at 28 weeks (% energy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 26.5 Carbohydrate at 28 weeks (% energy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 26.6 Protein at 28 weeks (% energy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 26.7 Protein at 28 weeks (g) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 26.8 Total fat at 28 weeks (% energy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 26.9 Saturated fatty acid at 28 weeks (% energy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 26.10 Monounsaturated fatty acid at 28 weeks (% energy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 26.11 Polyunsaturated acid at 28 weeks (% energy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 26.12 Polyunsaturated fatty acid, saturated fatty acid ratio at 28 weeks | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 26.13 Non-starch polysaccharide at 28 weeks (g) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 27 Adherence with the intervention (data on physical activity) | 1 | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 27.1 By accelerometer: active at 28 weeks (minutes/day) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 27.2 By accelerometer: light at 28 weeks (minutes/day) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 27.3 By accelerometer: moderate and/or vigorous at 28 weeks (minutes/day) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 27.4 By RPAQ questionnaire: active at 28 weeks (minutes/day) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 27.5 By RPAQ questionnaire: light at 28 weeks (minutes/day) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 27.6 By RPAQ questionnaire: moderate and/or vigorous at 28 weeks (minutes/day) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 28 Adherence with the intervention (data on physical activity) | 1 | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 28.1 By accelerometer: sedentary at 28 weeks (minutes/day) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 28.2 By RPAQ questionnaire: sedentary at 28 weeks (minutes/day) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |

| | | | |
|---|---|---|---|
| 29 Adherence with the intervention | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 29.1 Increase in healthy eating habits (self-reported) | 1 | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 29.2 Engagement in 'leisure time sporting activities' | 1 | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 30 Adherence with intervention (data on energy intake) | 1 | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 30.1 Energy intake [kcal/day] at 36-38th week | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 31 Adherence with the intervention (data on physical activity) | | Other data | No numeric data |
| 32 Adherence with the intervention (data on physical activity) | 1 | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 32.1 Daily step count (28 weeks) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 33 Well-being and quality of life | 1 | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 33.1 Stress (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 33.2 Stress (6 months postpartum) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 33.3 Stress (12 months postpartum) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 33.4 Sleep score (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 33.5 Sleep score (6 months postpartum) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 33.6 Sleep score (12 months postpartum) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 33.7 Depression scale (late pregnancy) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 33.8 Depression scale (6 months postpartum) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 33.9 Depression scale (12 months postpartum) | 1 | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 34 Well-being and quality of life (EQ-5D) | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 34.1 Mobility problems at 28 weeks | 1 | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 34.2 Self-care problems at 28 weeks | 1 | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 34.3 Usual activity problems at 28 weeks | 1 | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 34.4 Pain and discomfort problems at 28 weeks | 1 | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 34.5 Anxiety and depression problems at 28 weeks | 1 | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 35 Well-being and quality of life (EQ-5D) | 1 | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |

| | | | | |
|---|---|---|---|---|
| 35.1 'Time Trade-Off' health state rating at 28 weeks | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 35.2 'Visual Analogue Scale' of health related quality of life at 28 weeks | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 36 Well-being and quality of life (EPDS) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 36.1 Total at 28 weeks | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 37 Well-being and quality of life (EPDS) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 37.1 Total score > 9 at 28 weeks | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 37.2 Total score > 12 at 28 weeks | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 38 Postnatal weight retention | 3 | 450 | Mean Difference (IV, Random, 95% CI) | -0.72 [-1.96, 0.51] |
| 38.1 Normal weight women | 3 | 263 | Mean Difference (IV, Random, 95% CI) | -1.31 [-2.40, -0.23] |
| 38.2 Overweight or obese women | 2 | 187 | Mean Difference (IV, Random, 95% CI) | 1.05 [-2.73, 4.83] |
| 39 Postnatal weight retention > 5 kg | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 40 Weight retention (12 months postpartum) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 40.1 At or below pre-pregnancy weight (ITT) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 40.2 At or below pre-pregnancy weight (study completers) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 41 Weight retention (12 months postpartum) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 41.1 Net weight retention (study completers) (kg) | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 42 Weight retention (12 months postpartum) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 42.1 Weight loss since birth (study completers) (kg) | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 43 Macrosomia | 6 | 3168 | Risk Ratio (M-H, Fixed, 95% CI) | 0.90 [0.77, 1.05] |
| 44 Birthweight (g) | 5 | 737 | Mean Difference (IV, Random, 95% CI) | 28.24 [-78.26, 134.74] |
| 44.1 Born to all women | 4 | 388 | Mean Difference (IV, Random, 95% CI) | 24.82 [-148.19, 197.84] |
| 44.2 Born to normal weight women | 1 | 182 | Mean Difference (IV, Random, 95% CI) | 96.00 [-38.53, 230.53] |
| 44.3 Born to overweight or obese women | 1 | 167 | Mean Difference (IV, Random, 95% CI) | -12.0 [-206.19, 182.19] |
| 45 Birthweight (g) | | | Other data | No numeric data |
| 46 Small-for-gestational age | 2 | 144 | Risk Ratio (M-H, Fixed, 95% CI) | 1.02 [0.18, 5.64] |
| 47 Low birthweight (< 2500 g) | 2 | 459 | Risk Ratio (M-H, Fixed, 95% CI) | 1.00 [0.49, 2.05] |
| 48 Neonatal hypoglycaemia requiring treatment | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 49 Gestational age at birth (weeks) | 3 | 632 | Mean Difference (IV, Random, 95% CI) | 0.13 [-0.24, 0.50] |
| 49.1 All women | 2 | 283 | Mean Difference (IV, Random, 95% CI) | 0.09 [-0.26, 0.44] |

| | | | | |
|---|---|---|---|---|
| 49.2 Normal weight women | 1 | 182 | Mean Difference (IV, Random, 95% CI) | 0.60 [0.06, 1.14] |
| 49.3 Overweight or obese women | 1 | 167 | Mean Difference (IV, Random, 95% CI) | -0.30 [-1.04, 0.44] |
| 50 Gestational age at birth (days or weeks) | | | Other data | No numeric data |
| 51 Preterm birth | 5 | 2713 | Risk Ratio (M-H, Fixed, 95% CI) | 0.71 [0.55, 0.93] |
| 52 Shoulder dystocia | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 53 Bone fracture | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 54 Nerve palsy | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 55 Hyperbilirubinaemia requiring treatment | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 56 Ponderal index (weight, kg/height, m3) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Subtotals only |
| 57 Antenatal admission | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 58 Length of antenatal stay (days) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Subtotals only |
| 59 Length of postnatal stay (mother) (days) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Subtotals only |
| 60 Admission to neonatal intensive care unit (or special care) | 2 | 2446 | Risk Ratio (M-H, Fixed, 95% CI) | 1.01 [0.91, 1.13] |

**Comparison 2. Diet and exercise versus control (subgroups based on unit of randomisation)**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Gestational diabetes | 11 | 3744 | Risk Ratio (M-H, Random, 95% CI) | 0.92 [0.68, 1.23] |
| 1.1 Individually-randomised | 9 | 3603 | Risk Ratio (M-H, Random, 95% CI) | 0.90 [0.65, 1.25] |
| 1.2 Cluster-randomised | 2 | 141 | Risk Ratio (M-H, Random, 95% CI) | 1.05 [0.42, 2.60] |
| 2 Caesarean birth | 7 | 3246 | Risk Ratio (M-H, Fixed, 95% CI) | 0.92 [0.83, 1.01] |
| 2.1 Individually-randomised | 6 | 3195 | Risk Ratio (M-H, Fixed, 95% CI) | 0.92 [0.83, 1.02] |
| 2.2 Cluster-randomised | 1 | 51 | Risk Ratio (M-H, Fixed, 95% CI) | 0.71 [0.33, 1.54] |
| 3 Large-for-gestational age | 6 | 2950 | Risk Ratio (M-H, Fixed, 95% CI) | 0.90 [0.77, 1.05] |
| 3.1 Individually-randomised | 4 | 2806 | Risk Ratio (M-H, Fixed, 95% CI) | 0.92 [0.78, 1.07] |
| 3.2 Cluster-randomised | 2 | 144 | Risk Ratio (M-H, Fixed, 95% CI) | 0.59 [0.25, 1.40] |

**Comparison 3. Diet and exercise versus control (subgroups based on baseline BMI)**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Gestational diabetes | 11 | 3744 | Risk Ratio (M-H, Random, 95% CI) | 0.93 [0.71, 1.23] |
| 1.1 Normal weight | 2 | 243 | Risk Ratio (M-H, Random, 95% CI) | 0.91 [0.19, 4.24] |
| 1.2 Overweight or obese | 7 | 3116 | Risk Ratio (M-H, Random, 95% CI) | 0.90 [0.63, 1.29] |
| 1.3 Mixed (normal and overweight/obese) | 4 | 385 | Risk Ratio (M-H, Random, 95% CI) | 1.06 [0.50, 2.27] |
| 2 Caesarean birth | 7 | 3246 | Risk Ratio (M-H, Fixed, 95% CI) | 0.92 [0.83, 1.01] |
| 2.1 Normal weight | 2 | 243 | Risk Ratio (M-H, Fixed, 95% CI) | 0.92 [0.58, 1.45] |

| | | | | |
|---|---|---|---|---|
| 2.2 Overweight or obese | 4 | 2662 | Risk Ratio (M-H, Fixed, 95% CI) | 0.93 [0.84, 1.04] |
| 2.3 Mixed (normal and overweight/obese) | 3 | 341 | Risk Ratio (M-H, Fixed, 95% CI) | 0.59 [0.34, 1.00] |
| 3 Large-for-gestational age | 6 | 2950 | Risk Ratio (M-H, Fixed, 95% CI) | 0.90 [0.77, 1.05] |
| 3.1 Overweight or obese | 3 | 2616 | Risk Ratio (M-H, Fixed, 95% CI) | 0.93 [0.79, 1.09] |
| 3.2 Mixed (normal and overweight/obese) | 3 | 334 | Risk Ratio (M-H, Fixed, 95% CI) | 0.65 [0.38, 1.12] |

**Comparison 4. Diet and exercise versus control (subgroups based on ethnicity)**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Gestational diabetes | 11 | 3744 | Risk Ratio (M-H, Random, 95% CI) | 0.92 [0.68, 1.23] |
| 1.1 Majority low-risk ethnicities | 4 | 2854 | Risk Ratio (M-H, Random, 95% CI) | 1.23 [1.00, 1.52] |
| 1.2 Mixed ethnicities/not stated | 7 | 890 | Risk Ratio (M-H, Random, 95% CI) | 0.72 [0.53, 0.99] |
| 2 Caesarean birth | 7 | 3246 | Risk Ratio (M-H, Fixed, 95% CI) | 0.92 [0.83, 1.01] |
| 2.1 Majority low-risk ethnicities | 4 | 2846 | Risk Ratio (M-H, Fixed, 95% CI) | 0.94 [0.85, 1.04] |
| 2.2 Majority high-risk ethnicities | 1 | 100 | Risk Ratio (M-H, Fixed, 95% CI) | 0.50 [0.23, 1.12] |
| 2.3 Mixed ethnicities/not stated | 2 | 300 | Risk Ratio (M-H, Fixed, 95% CI) | 0.42 [0.17, 1.06] |
| 3 Large-for-gestational age | 6 | 2950 | Risk Ratio (M-H, Fixed, 95% CI) | 0.90 [0.77, 1.05] |
| 3.1 Majority low-risk ethnicities | 3 | 2497 | Risk Ratio (M-H, Fixed, 95% CI) | 0.93 [0.79, 1.09] |
| 3.2 Mixed ethnicities/not stated | 3 | 453 | Risk Ratio (M-H, Fixed, 95% CI) | 0.73 [0.45, 1.20] |

**Comparison 5. Diet and exercise versus control (sensitivity analysis)**

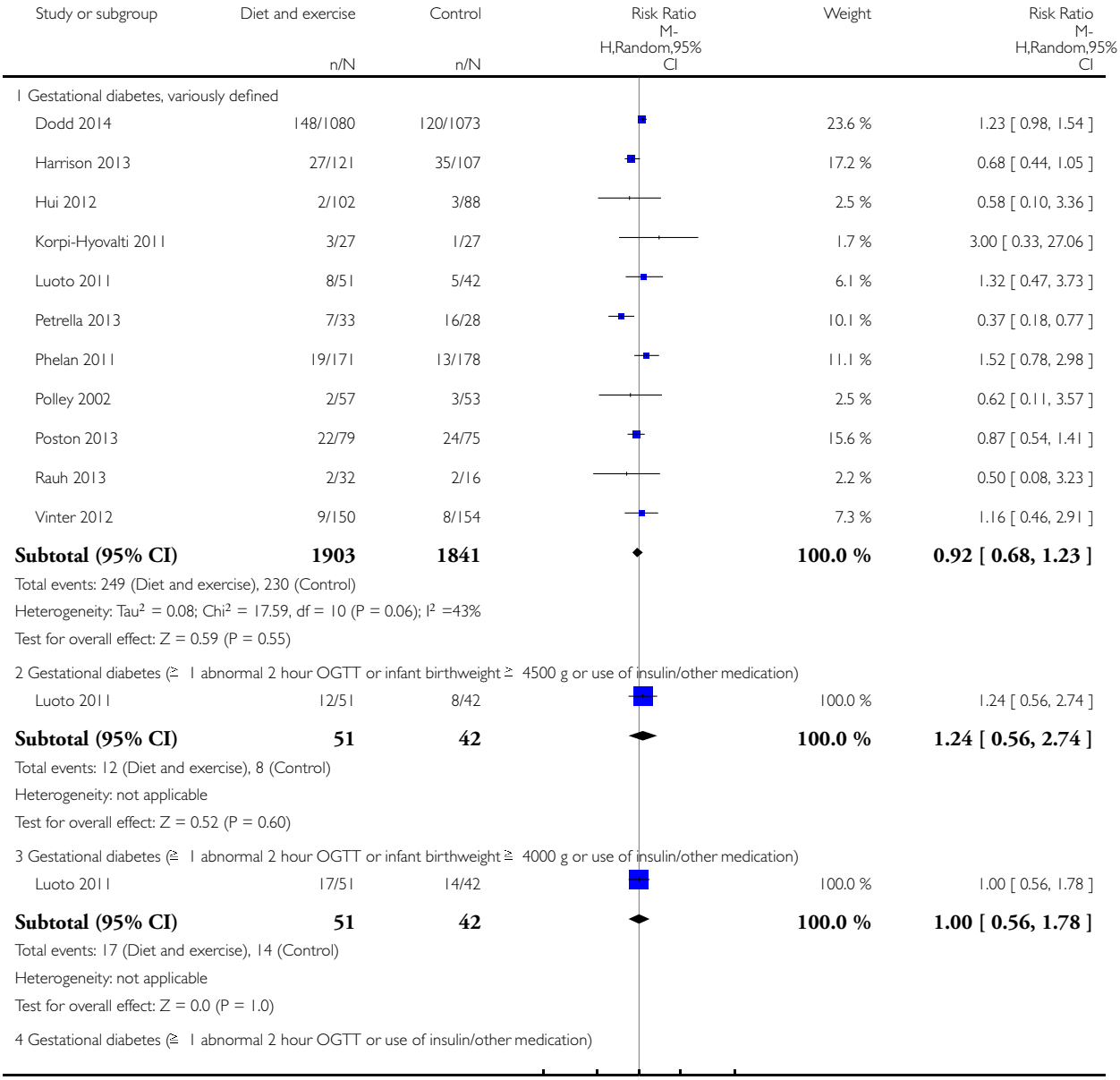
| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Gestational diabetes | 4 | 2884 | Risk Ratio (M-H, Random, 95% CI) | 1.01 [0.73, 1.41] |
| 2 Caesarean birth | 3 | 2591 | Risk Ratio (M-H, Fixed, 95% CI) | 0.92 [0.83, 1.03] |
| 3 Large-for-gestational age | 2 | 2312 | Risk Ratio (M-H, Fixed, 95% CI) | 0.90 [0.76, 1.07] |
| 4 Perinatal mortality | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |

## Analysis 1.1. Comparison 1 Combined diet and exercise versus control, Outcome 1 Gestational diabetes.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 1 Gestational diabetes

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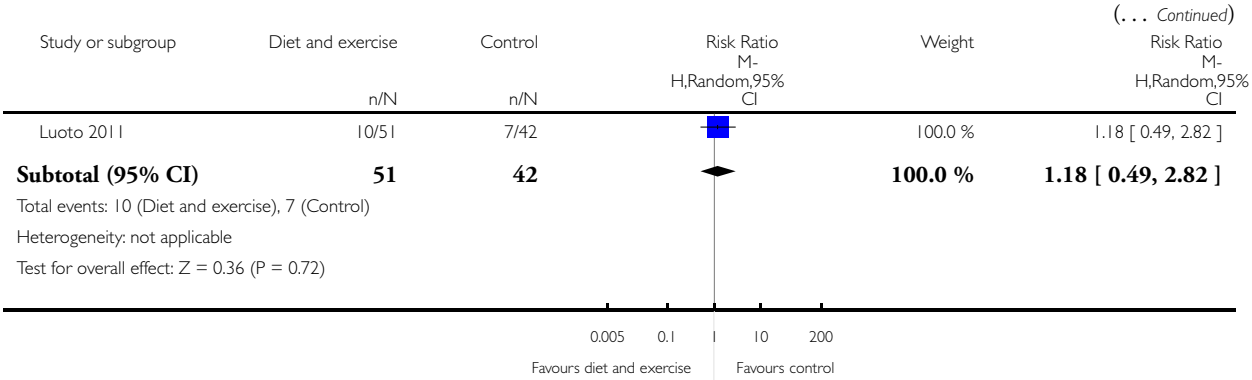
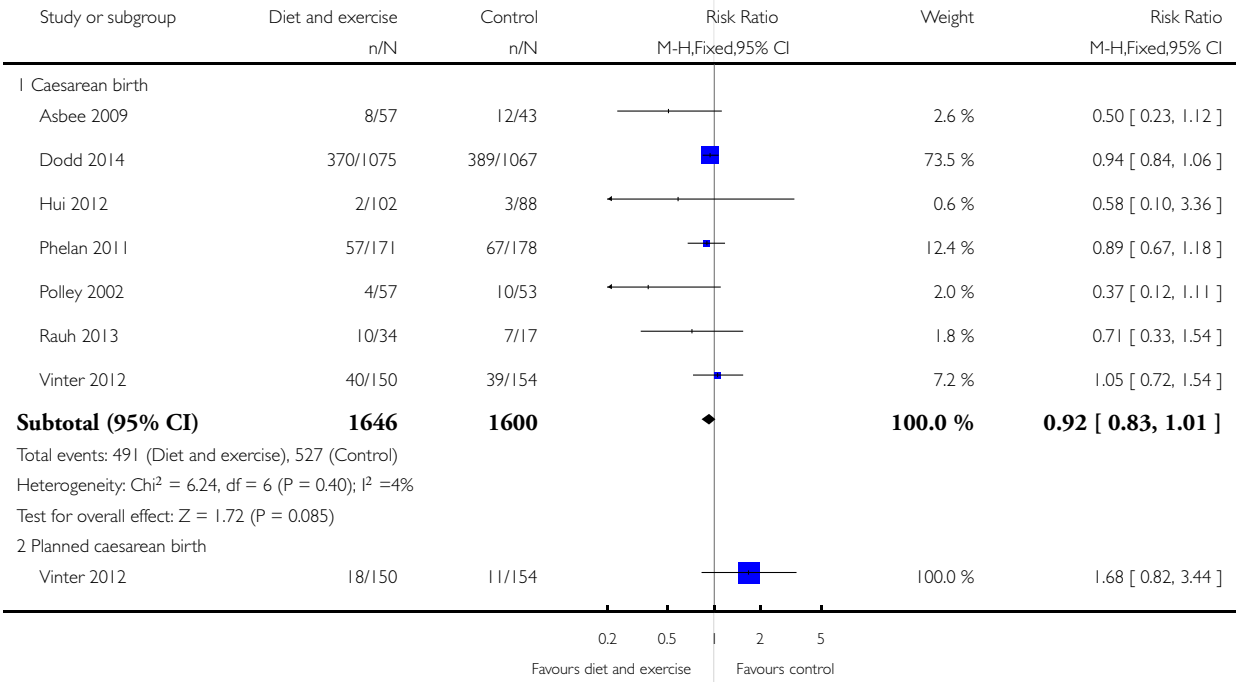



**Analysis 1.2. Comparison 1 Combined diet and exercise versus control, Outcome 2 Caesarean birth.**

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 2 Caesarean birth

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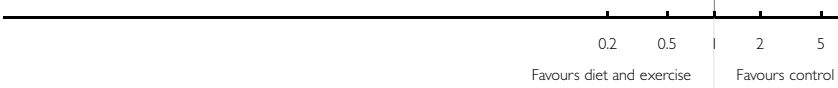
| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| **Subtotal (95% CI)** | **150** | **154** | | **100.0 %** | **1.68 [ 0.82, 3.44 ]** |
| Total events: 18 (Diet and exercise), 11 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 1.42 (P = 0.16) | | | | | |
| 3 Emergency caesarean birth | | | | | |
| Vinter 2012 | 22/150 | 28/154 | | 100.0 % | 0.81 [ 0.48, 1.34 ] |
| **Subtotal (95% CI)** | **150** | **154** | | **100.0 %** | **0.81 [ 0.48, 1.34 ]** |
| Total events: 22 (Diet and exercise), 28 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 0.82 (P = 0.41) | | | | | |




**Analysis 1.3. Comparison 1 Combined diet and exercise versus control, Outcome 3 Spontaneous vaginal birth.**

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 3 Spontaneous vaginal birth

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Rauh 2013 | 20/34 | 8/17 | | | 1.25 [ 0.70, 2.23 ] |
| **Subtotal (95% CI)** | **0** | **0** | | | **0.0 [ 0.0, 0.0 ]** |
| Total events: 20 (Diet and exercise), 8 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 0.0 (P < 0.00001) | | | | | |
| Test for subgroup differences: Not applicable | | | | | |

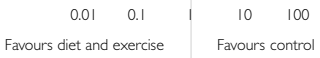
### Analysis 1.4. Comparison 1 Combined diet and exercise versus control, Outcome 4 Vacuum extraction.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 4 Vacuum extraction

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Rauh 2013 | 4/34 | 2/17 | | | 1.00 [ 0.20, 4.93 ] |
| **Subtotal (95% CI)** | **0** | **0** | | | **0.0 [ 0.0, 0.0 ]** |
| Total events: 4 (Diet and exercise), 2 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 0.0 (P < 0.00001) | | | | | |
| Test for subgroup differences: Not applicable | | | | | |



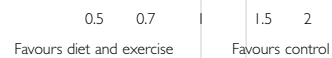

### Analysis 1.5. Comparison 1 Combined diet and exercise versus control, Outcome 5 Large-for-gestational age.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 5 Large-for-gestational age

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 203/1075 | 224/1067 | | 81.1 % | 0.90 [ 0.76, 1.07 ] |
| Hui 2012 | 12/102 | 15/88 | | 5.8 % | 0.69 [ 0.34, 1.39 ] |
| Luoto 2011 | 6/51 | 8/42 | | 3.2 % | 0.62 [ 0.23, 1.64 ] |
| Poston 2013 | 7/86 | 7/84 | | 2.6 % | 0.98 [ 0.36, 2.66 ] |
| Rauh 2013 | 2/34 | 2/17 | | 1.0 % | 0.50 [ 0.08, 3.25 ] |
| Vinter 2012 | 23/150 | 18/154 | | 6.4 % | 1.31 [ 0.74, 2.33 ] |
| **Total (95% CI)** | **1498** | **1452** | | **100.0 %** | **0.90 [ 0.77, 1.05 ]** |
| Total events: 253 (Diet and exercise), 274 (Control) | | | | | |

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| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Heterogeneity: Chi² = 3.17, df = 5 (P = 0.67); I² =0.0% | | | | | |
| Test for overall effect: Z = 1.30 (P = 0.19) | | | | | |
| Test for subgroup differences: Not applicable | | | | | |

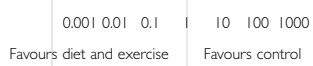

### Analysis 1.6. Comparison 1 Combined diet and exercise versus control, Outcome 6 Perinatal mortality.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 6 Perinatal mortality

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Perinatal mortality overall | | | | |
| Dodd 2014 | 6/1105 | 6/1097 | | 0.99 [ 0.32, 3.07 ] |
| 2 Stillbirth > 20 weeks | | | | |
| Dodd 2014 | 5/1105 | 5/1097 | | 0.99 [ 0.29, 3.42 ] |
| 3 Neonatal death (no lethal anomalies) | | | | |
| Dodd 2014 | 1/1105 | 1/1097 | | 0.99 [ 0.06, 15.85 ] |
| 4 Neonatal death (lethal anomalies) | | | | |
| Dodd 2014 | 3/1105 | 0/1097 | | 6.95 [ 0.36, 134.38 ] |

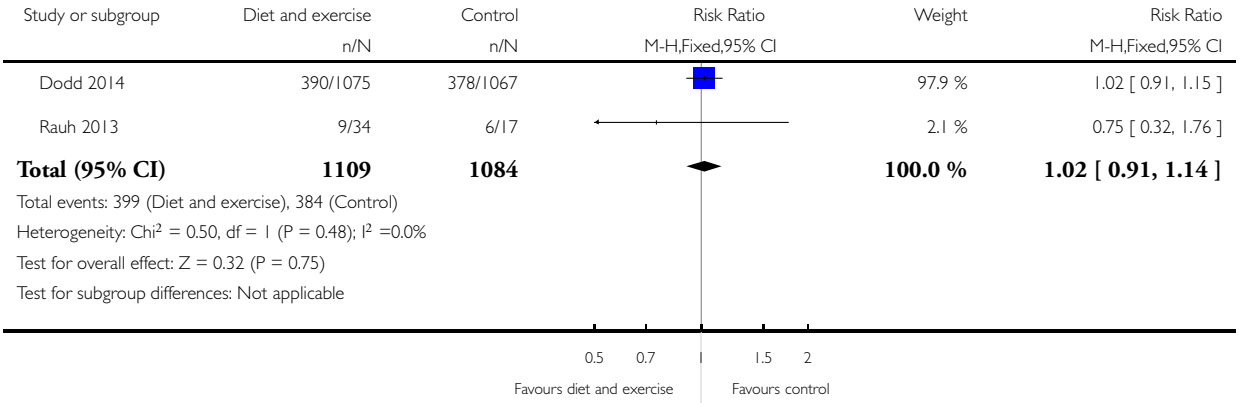


### Analysis 1.7. Comparison 1 Combined diet and exercise versus control, Outcome 7 Induction of labour.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 7 Induction of labour




### Analysis 1.8. Comparison 1 Combined diet and exercise versus control, Outcome 8 Perineal trauma (third or fourth degree).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 8 Perineal trauma (third or fourth degree)

### Analysis 1.9. Comparison 1 Combined diet and exercise versus control, Outcome 9 Pre-eclampsia.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 9 Pre-eclampsia

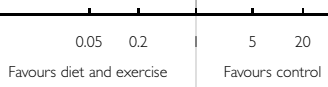
| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 56/1080 | 53/1073 | | 46.9 % | 1.05 [ 0.73, 1.51 ] |
| Luoto 2011 | 3/51 | 2/42 | | 1.9 % | 1.24 [ 0.22, 7.05 ] |
| Petrella 2013 | 1/33 | 7/28 | | 6.7 % | 0.12 [ 0.02, 0.93 ] |
| Phelan 2011 | 20/171 | 20/178 | | 17.3 % | 1.04 [ 0.58, 1.87 ] |
| Polley 2002 | 2/57 | 3/53 | | 2.7 % | 0.62 [ 0.11, 3.57 ] |
| Vinter 2012 | 23/150 | 28/154 | | 24.4 % | 0.84 [ 0.51, 1.40 ] |
| **Total (95% CI)** | **1542** | **1528** | | **100.0 %** | **0.93 [ 0.72, 1.19 ]** |

Total events: 105 (Diet and exercise), 113 (Control)

Heterogeneity: $Chi^2$ = 4.88, df = 5 (P = 0.43); $I^2$ =0.0%

Test for overall effect: Z = 0.58 (P = 0.56)

Test for subgroup differences: Not applicable

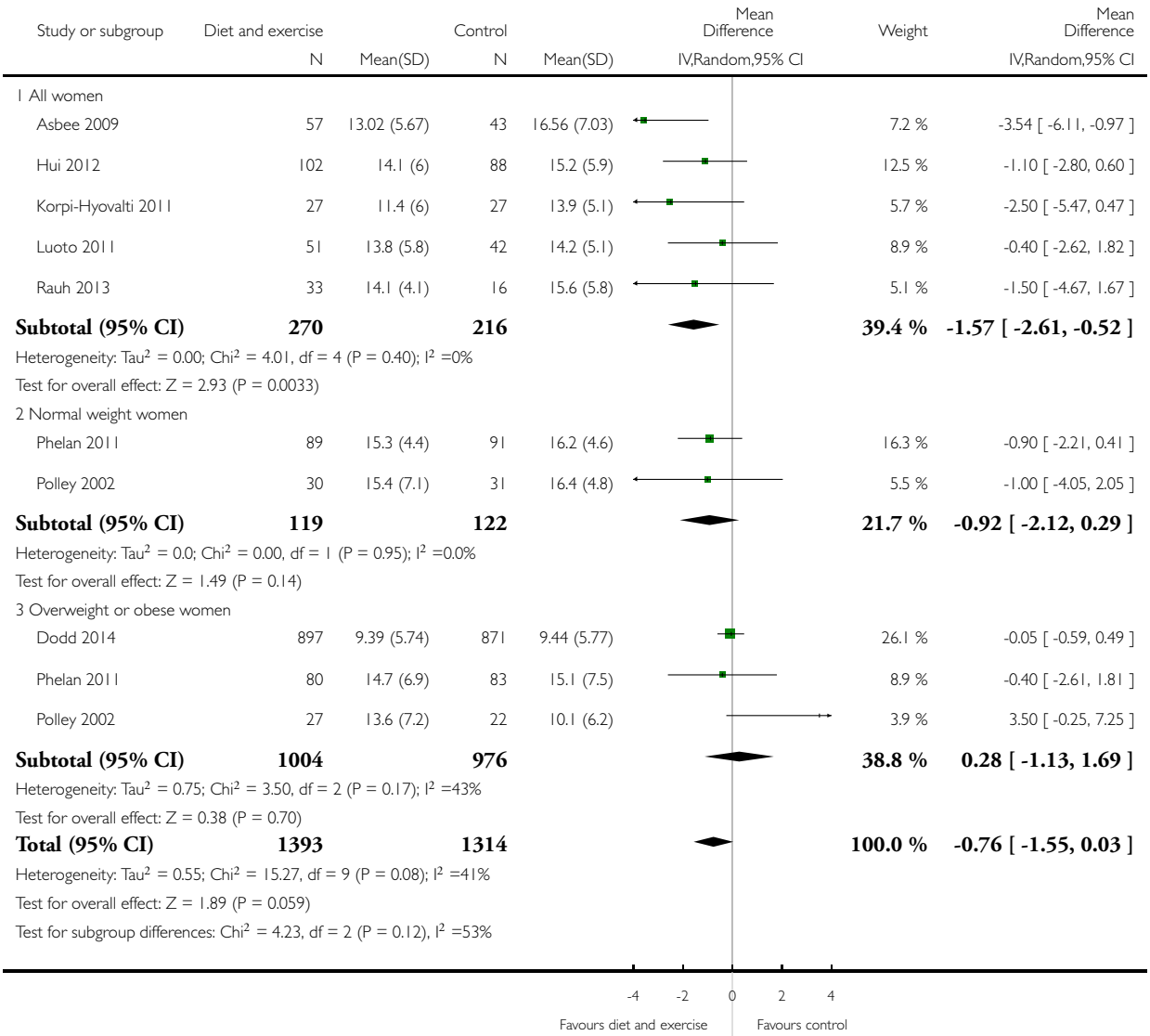


## Analysis 1.10. Comparison 1 Combined diet and exercise versus control, Outcome 10 Weight gain during pregnancy (kg).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 10 Weight gain during pregnancy (kg)



### Analysis 1.11. Comparison 1 Combined diet and exercise versus control, Outcome 11 Weight gain during pregnancy (kg).

**Weight gain during pregnancy (kg)**

| Study | Intervention group (n = 144) | Control group (n = 148) | P value |
|---|---|---|---|
| Vinter 2012 | Median: 7.0 kg<br>Range: 4.7 to 10.6 kg | Median: 8.6 kg<br>Range: 5.7 to 11.5 kg | 0.014 |

### Analysis 1.12. Comparison 1 Combined diet and exercise versus control, Outcome 12 Weight gain during pregnancy (kg/week).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

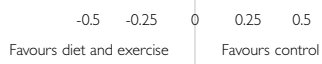
Outcome: 12 Weight gain during pregnancy (kg/week)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Random,95% CI | Weight | Mean Difference IV,Random,95% CI |
|---|---|---|---|---|---|---|---|
| Dodd 2014 | 897 | 0.45 (0.28) | 871 | 0.45 (0.28) | | 56.1 % | 0.0 [ -0.03, 0.03 ] |
| Harrison 2013 | 106 | 0.43 (0.22) | 97 | 0.51 (0.22) | | 43.9 % | -0.08 [ -0.14, -0.02 ] |
| **Total (95% CI)** | **1003** | | **968** | | | **100.0 %** | **-0.04 [ -0.11, 0.04 ]** |

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 5.65$, df = 1 (P = 0.02); $I^2 = 82\%$

Test for overall effect: Z = 0.88 (P = 0.38)

Test for subgroup differences: Not applicable



### Analysis 1.13. Comparison 1 Combined diet and exercise versus control, Outcome 13 Weight gain during pregnancy (at 26-28 weeks) (kg).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

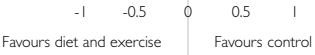
Outcome: 13 Weight gain during pregnancy (at 26-28 weeks) (kg)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Weight | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|---|
| Harrison 2013 | 106 | 6 (2.8) | 97 | 6.9 (3.3) | | | -0.90 [ -1.75, -0.05 ] |
| **Subtotal (95% CI)** | **0** | | **0** | | | | **0.0 [ 0.0, 0.0 ]** |

Heterogeneity: not applicable

Test for overall effect: Z = 0.0 (P < 0.00001)

Test for subgroup differences: Not applicable




### Analysis 1.14. Comparison 1 Combined diet and exercise versus control, Outcome 14 Weight gain during pregnancy ≤ 5 kg.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 14 Weight gain during pregnancy ≤ 5 kg

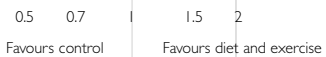
| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Vinter 2012 | 41/144 | 30/148 | | | 1.40 [ 0.93, 2.12 ] |
| **Subtotal (95% CI)** | **0** | **0** | | | **0.0 [ 0.0, 0.0 ]** |

Total events: 41 (Diet and exercise), 30 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 0.0 (P < 0.00001)

Test for subgroup differences: Not applicable

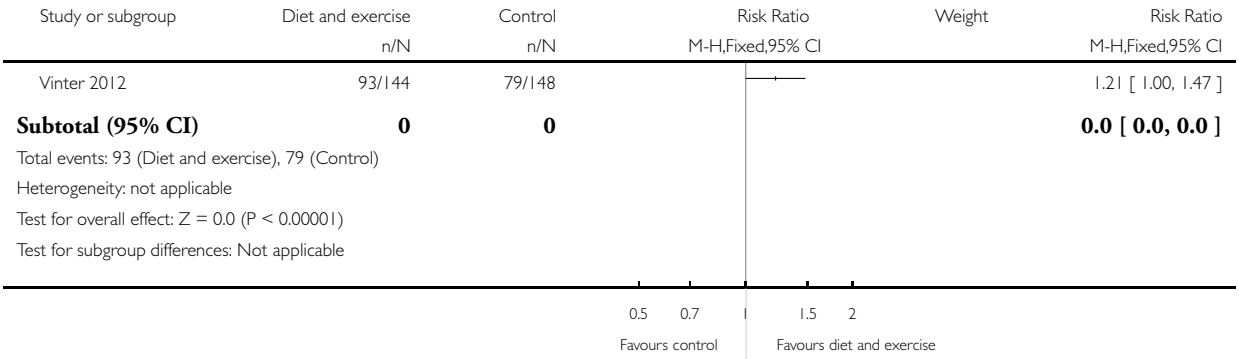


### Analysis 1.15. Comparison 1 Combined diet and exercise versus control, Outcome 15 Weight gain during pregnancy ≤ 9 kg.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 15 Weight gain during pregnancy ≤ 9 kg

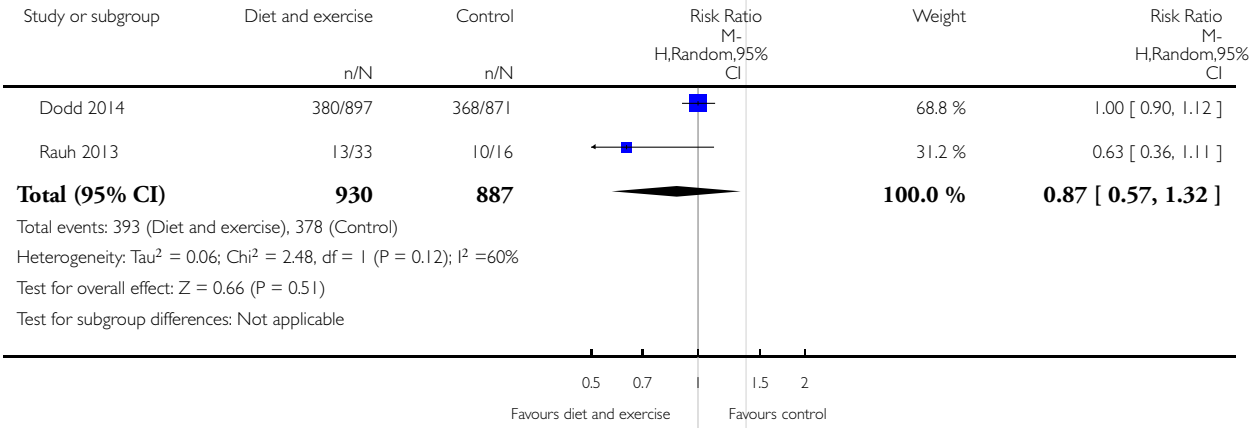



### Analysis 1.16. Comparison 1 Combined diet and exercise versus control, Outcome 16 Excessive gestational weight gain (IOM).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 16 Excessive gestational weight gain (IOM)

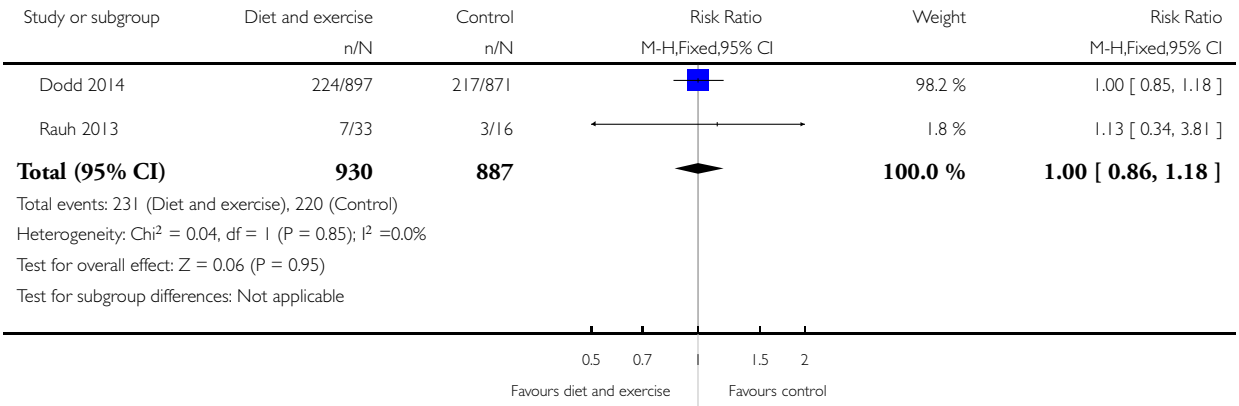


### Analysis 1.17. Comparison 1 Combined diet and exercise versus control, Outcome 17 Inadequate gestational weight gain (IOM).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 17 Inadequate gestational weight gain (IOM)

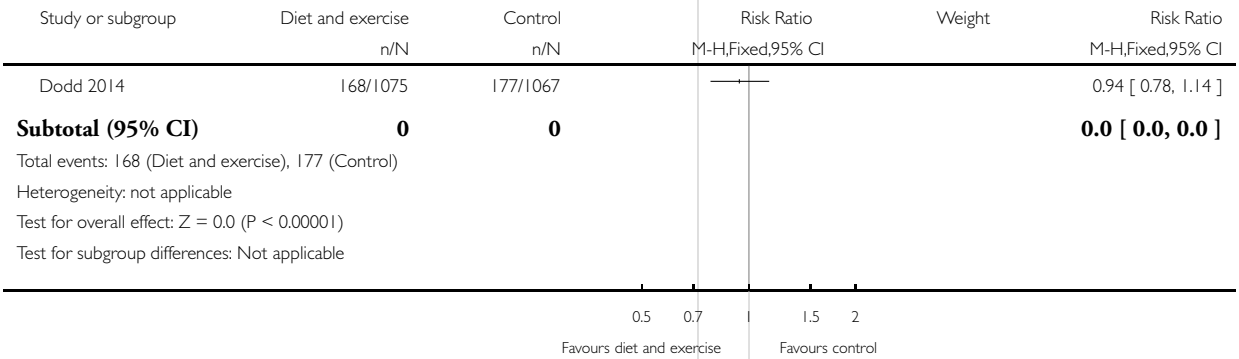



### Analysis 1.18. Comparison 1 Combined diet and exercise versus control, Outcome 18 Postpartum haemorrhage (> 600 mL).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 18 Postpartum haemorrhage (> 600 mL)



### Analysis 1.19. Comparison 1 Combined diet and exercise versus control, Outcome 19 Postpartum infection (wound infection).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 19 Postpartum infection (wound infection)

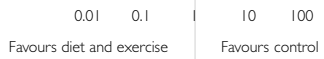
| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 32/1075 | 30/1067 | | | 1.06 [ 0.65, 1.73 ] |
| **Subtotal (95% CI)** | **0** | **0** | | | **0.0 [ 0.0, 0.0 ]** |

Total events: 32 (Diet and exercise), 30 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 0.0 (P < 0.00001)

Test for subgroup differences: Not applicable




### Analysis 1.20. Comparison 1 Combined diet and exercise versus control, Outcome 20 Postpartum infection (endometritis).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 20 Postpartum infection (endometritis)

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 12/1075 | 10/1067 | | | 1.19 [ 0.52, 2.74 ] |
| **Subtotal (95% CI)** | **0** | **0** | | | **0.0 [ 0.0, 0.0 ]** |

Total events: 12 (Diet and exercise), 10 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 0.0 (P < 0.00001)

Test for subgroup differences: Not applicable

### Analysis 1.21. Comparison 1 Combined diet and exercise versus control, Outcome 21 Postpartum infection (postpartum antibiotics).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 21 Postpartum infection (postpartum antibiotics)

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 99/1075 | 98/1067 | | | 1.00 [ 0.77, 1.31 ] |
| **Subtotal (95% CI)** | **0** | **0** | | | **0.0 [ 0.0, 0.0 ]** |
| Total events: 99 (Diet and exercise), 98 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 0.0 (P < 0.00001) | | | | | |
| Test for subgroup differences: Not applicable | | | | | |


### Analysis 1.22. Comparison 1 Combined diet and exercise versus control, Outcome 22 Adherence with the intervention (data on diet).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 22 Adherence with the intervention (data on diet)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Total calorie intake at 2 months after enrolment | | | | | | |
| Hui 2012 | 53 | 1991 (458) | 53 | 2416 (848) | | -425.00 [ -684.47, -165.53 ] |
| 2 Carbohydrate intake (g) at 2 months after enrolment | | | | | | |
| Hui 2012 | 53 | 283 (71) | 53 | 324 (126) | | -41.00 [ -79.94, -2.06 ] |
| 3 Protein intake (g) at 2 months after enrolment | | | | | | |
| Hui 2012 | 53 | 85.5 (21) | 53 | 94.6 (34.4) | | -9.10 [ -19.95, 1.75 ] |
| 4 Fat intake (g) at 2 months after enrolment | | | | | | |
| Hui 2012 | 53 | 62.5 (24.4) | 53 | 86.8 (36.2) | | -24.30 [ -36.05, -12.55 ] |
| 5 Saturated fat intake (g) at 2 months after enrolment | | | | | | |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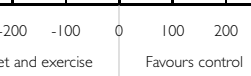
| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| Hui 2012 | 53 | 19.7 (9.2) | 53 | 29.2 (13.2) | | -9.50 [ -13.83, -5.17 ] |
| 6 Cholesterol intake (mg) at 2 months after enrolment | | | | | | |
| Hui 2012 | 53 | 208 (104) | 53 | 323 (220) | | -115.00 [ -180.51, -49.49 ] |
| 7 Fibre intake (g) at 2 months after enrolment | | | | | | |
| Hui 2012 | 53 | 24.3 (9.9) | 53 | 23.3 (11.8) | | 1.00 [ -3.15, 5.15 ] |
| 8 Carbohydrate ratio (%) at 2 months after enrolment | | | | | | |
| Hui 2012 | 53 | 55.8 (5.8) | 53 | 52.6 (7.7) | | 3.20 [ 0.60, 5.80 ] |
| 9 Protein ratio (%) at 2 months after enrolment | | | | | | |
| Hui 2012 | 53 | 17.1 (3.7) | 53 | 15.7 (3.3) | | 1.40 [ 0.07, 2.73 ] |
| 10 Fat ratio (%) at 2 months after enrolment | | | | | | |
| Hui 2012 | 53 | 27 (6.5) | 53 | 31.5 (7.5) | | -4.50 [ -7.17, -1.83 ] |



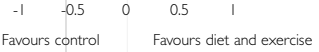

## Analysis 1.23. Comparison 1 Combined diet and exercise versus control, Outcome 23 Adherence with the intervention (data on physical activity).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 23 Adherence with the intervention (data on physical activity)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Physical activity index at 2 months after enrolment | | | | | | |
| Hui 2012 | 95 | 1.85 (0.44) | 85 | 1.45 (0.72) | | 0.40 [ 0.22, 0.58 ] |



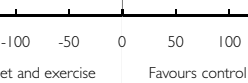
## Analysis 1.24. Comparison 1 Combined diet and exercise versus control, Outcome 24 Adherence with the intervention (data on diet).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 24 Adherence with the intervention (data on diet)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Calorie intake (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 1615 (642) | 133 | 1659 (626) | | -44.00 [ -197.91, 109.91 ] |
| 2 Percentage of calories from fat (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 32.3 (5.8) | 133 | 33.2 (5.2) | | -0.90 [ -2.24, 0.44 ] |
| 3 Percentage of calories from carbohydrates (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 54.6 (7.3) | 133 | 53.4 (6.7) | | 1.20 [ -0.50, 2.90 ] |
| 4 Percentage of calories from protein (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 15.3 (2.8) | 133 | 15.4 (2.7) | | -0.10 [ -0.77, 0.57 ] |
| 5 Percentage of calories from sweets (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 15.6 (9.6) | 133 | 14.4 (7.5) | | 1.20 [ -0.90, 3.30 ] |
| 6 Daily calories from soft drinks (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 25 (50.6) | 133 | 33.1 (70.3) | | -8.10 [ -22.92, 6.72 ] |
| 7 Daily saturated fat (late pregnancy) (g) | | | | | | |
| Phelan 2011 | 128 | 19.4 (9.4) | 133 | 20.3 (8.5) | | -0.90 [ -3.08, 1.28 ] |
| 8 Daily servings of vegetables (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 2.4 (1.7) | 133 | 2.2 (1.3) | | 0.20 [ -0.17, 0.57 ] |
| 9 Daily servings of fruit and fruit juices (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 2 (1) | 133 | 1.9 (1.1) | | 0.10 [ -0.15, 0.35 ] |
| 10 Daily servings of breads, cereals, rice, pasta (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 4.7 (2.3) | 133 | 4.9 (2.1) | | -0.20 [ -0.73, 0.33 ] |
| 11 Daily servings of milk, yoghurt, cheese (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 1.7 (1.1) | 133 | 1.7 (1) | | 0.0 [ -0.26, 0.26 ] |
| 12 Daily frequency of fats, oils, sweets, sodas (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 3.2 (1.8) | 133 | 3.2 (1.4) | | 0.0 [ -0.39, 0.39 ] |
| 13 Weekly fast food (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 1.5 (2.3) | 133 | 2.1 (3.3) | | -0.60 [ -1.29, 0.09 ] |
| 14 Daily iron from food (late pregnancy) (mg) | | | | | | |
| Phelan 2011 | 128 | 12.4 (5) | 133 | 13 (5.5) | | -0.60 [ -1.87, 0.67 ] |
| 15 Daily calcium from food (late pregnancy) (mg) | | | | | | |

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| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| Phelan 2011 | 128 | 988.2 (428.5) | 133 | 973.4 (403.4) | | 14.80 [ -86.25, 115.85 ] |
| 16 Total daily dietary fibre (late pregnancy) (g) | | | | | | |
| Phelan 2011 | 128 | 16.2 (6.4) | 133 | 15.8 (6.9) | | 0.40 [ -1.21, 2.01 ] |
| 17 Daily vitamin D from food (late pregnancy) (IU) | | | | | | |
| Phelan 2011 | 128 | 175.6 (119.4) | 133 | 179.4 (108.1) | | -3.80 [ -31.47, 23.87 ] |
| 18 Daily folate from food (late pregnancy) ( g) | | | | | | |
| Phelan 2011 | 128 | 264.8 (133) | 133 | 248.3 (115.2) | | 16.50 [ -13.74, 46.74 ] |




**Analysis 1.25. Comparison 1 Combined diet and exercise versus control, Outcome 25 Adherence with the intervention (data on physical activity).**

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 25 Adherence with the intervention (data on physical activity)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Physical activity (late pregnancy) (kcal) | | | | | | |
| Phelan 2011 | 128 | 1012 (868) | 133 | 804 (849) | | 208.00 [ -0.40, 416.40 ] |
| 2 Physical activity (6 months postpartum) (kcal) | | | | | | |
| Phelan 2011 | 128 | 1209 (1214) | 133 | 1011 (975) | | 198.00 [ -69.75, 465.75 ] |
| 3 Physical activity (12 months postpartum (kcal) | | | | | | |
| Phelan 2011 | 128 | 1209 (2570) | 133 | 785 (952) | | 424.00 [ -49.71, 897.71 ] |

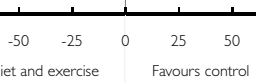
## Analysis 1.26. Comparison 1 Combined diet and exercise versus control, Outcome 26 Adherence with the intervention (data on diet).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 26 Adherence with the intervention (data on diet)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Total energy at 28 weeks (MJ/day) | | | | | | |
| Poston 2013 | 71 | 6.75 (2.57) | 69 | 7.71 (2.3) | | -0.96 [ -1.77, -0.15 ] |
| 2 Dietary glycaemic index at 28 weeks (%) | | | | | | |
| Poston 2013 | 71 | 53 (13) | 69 | 60 (26) | | -7.00 [ -13.84, -0.16 ] |
| 3 Dietary glycaemic load at 28 weeks (g/day) | | | | | | |
| Poston 2013 | 71 | 111 (39) | 69 | 146 (55) | | -35.00 [ -50.83, -19.17 ] |
| 4 Glycaemic load at 28 weeks (% energy) | | | | | | |
| Poston 2013 | 71 | 26.6 (8) | 69 | 31.3 (13.3) | | -4.70 [ -8.35, -1.05 ] |
| 5 Carbohydrate at 28 weeks (% energy) | | | | | | |
| Poston 2013 | 71 | 50 (8.2) | 69 | 48.2 (8) | | 1.80 [ -0.88, 4.48 ] |
| 6 Protein at 28 weeks (% energy) | | | | | | |
| Poston 2013 | 71 | 17.1 (4.9) | 69 | 15.5 (3.2) | | 1.60 [ 0.23, 2.97 ] |
| 7 Protein at 28 weeks (g) | | | | | | |
| Poston 2013 | 71 | 66.5 (23.5) | 69 | 70.6 (24) | | -4.10 [ -11.97, 3.77 ] |
| 8 Total fat at 28 weeks (% energy) | | | | | | |
| Poston 2013 | 71 | 32.5 (7.4) | 69 | 35.9 (7.7) | | -3.40 [ -5.90, -0.90 ] |
| 9 Saturated fatty acid at 28 weeks (% energy) | | | | | | |
| Poston 2013 | 71 | 11.1 (3.8) | 69 | 12.9 (3.9) | | -1.80 [ -3.08, -0.52 ] |
| 10 Monounsaturated fatty acid at 28 weeks (% energy) | | | | | | |
| Poston 2013 | 71 | 10.4 (3.2) | 69 | 11.6 (4) | | -1.20 [ -2.40, 0.00 ] |
| 11 Polyunsaturated acid at 28 weeks (% energy) | | | | | | |
| Poston 2013 | 71 | 6 (2.7) | 69 | 5.9 (2.8) | | 0.10 [ -0.81, 1.01 ] |
| 12 Polyunsaturated fatty acid, saturated fatty acid ratio at 28 weeks | | | | | | |
| Poston 2013 | 71 | 0.64 (0.52) | 69 | 0.51 (0.35) | | 0.13 [ -0.02, 0.28 ] |
| 13 Non-starch polysaccharide at 28 weeks (g) | | | | | | |
| Poston 2013 | 71 | 12 (6) | 69 | 10.5 (4.2) | | 1.50 [ -0.21, 3.21 ] |



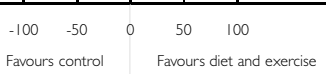
## Analysis 1.27. Comparison 1 Combined diet and exercise versus control, Outcome 27 Adherence with the intervention (data on physical activity).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 27 Adherence with the intervention (data on physical activity)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 By accelerometer: active at 28 weeks (minutes/day) | | | | | | |
| Poston 2013 | 36 | 194 (68) | 39 | 209 (82) | | -15.00 [ -49.00, 19.00 ] |
| 2 By accelerometer: light at 28 weeks (minutes/day) | | | | | | |
| Poston 2013 | 36 | 161 (61) | 39 | 175 (81) | | -14.00 [ -46.30, 18.30 ] |
| 3 By accelerometer: moderate and/or vigorous at 28 weeks (minutes/day) | | | | | | |
| Poston 2013 | 36 | 33 (15) | 39 | 34 (18) | | -1.00 [ -8.48, 6.48 ] |
| 4 By RPAQ questionnaire: active at 28 weeks (minutes/day) | | | | | | |
| Poston 2013 | 56 | 410 (219) | 54 | 367 (175) | | 43.00 [ -30.95, 116.95 ] |
| 5 By RPAQ questionnaire: light at 28 weeks (minutes/day) | | | | | | |
| Poston 2013 | 56 | 340 (204) | 54 | 333 (165) | | 7.00 [ -62.22, 76.22 ] |
| 6 By RPAQ questionnaire: moderate and/or vigorous at 28 weeks (minutes/day) | | | | | | |
| Poston 2013 | 56 | 70 (78) | 54 | 34 (52) | | 36.00 [ 11.31, 60.69 ] |



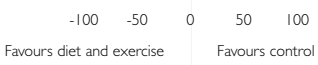
### Analysis 1.28. Comparison 1 Combined diet and exercise versus control, Outcome 28 Adherence with the intervention (data on physical activity).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 28 Adherence with the intervention (data on physical activity)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 By accelerometer: sedentary at 28 weeks (minutes/day) | | | | | | |
| Poston 2013 | 36 | 1197 (77) | 39 | 1175 (86) | | 22.00 [ -14.89, 58.89 ] |
| 2 By RPAQ questionnaire: sedentary at 28 weeks (minutes/day) | | | | | | |
| Poston 2013 | 56 | 1020 (226) | 54 | 1068 (177) | | -48.00 [ -123.71, 27.71 ] |




### Analysis 1.29. Comparison 1 Combined diet and exercise versus control, Outcome 29 Adherence with the intervention.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 29 Adherence with the intervention

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Increase in healthy eating habits (self-reported) | | | | |
| Vinter 2012 | 128/150 | 32/154 | | 4.11 [ 3.00, 5.63 ] |
| 2 Engagement in 'leisure time sporting activities' | | | | |
| Vinter 2012 | 116/150 | 100/154 | | 1.19 [ 1.03, 1.38 ] |

### Analysis 1.30. Comparison 1 Combined diet and exercise versus control, Outcome 30 Adherence with intervention (data on energy intake).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 30 Adherence with intervention (data on energy intake)


### Analysis 1.31. Comparison 1 Combined diet and exercise versus control, Outcome 31 Adherence with the intervention (data on physical activity).

**Adherence with the intervention (data on physical activity)**

| Study | **Outcome** | **Intervention group n = 26** | **Control group n = 12** |
|---|---|---|---|
| Rauh 2013 | Total activity [MET-min/week] baseline | Median: 2473<br>Interquartile range: 1605 to 488 | Median: 3186<br>Interquartile range: 1711 to 4932 |
| Rauh 2013 | Total activity [MET-min/week] 26-28th week | Median: 2529<br>Interquartile range: 1477 to 4282 | Median: 2826<br>Interquartile range: 1480 to 5455 |
| Rauh 2013 | Total activity [MET-min/week] 36-38th week | Median: 1968<br>Interquartile range: 1257 to 3336 | Median: 2232<br>Interquartile range: 1410 to 3685 |
| Rauh 2013 | **Difference within groups (P-value)** | **0.019** | **0.198** |

### Analysis 1.32. Comparison 1 Combined diet and exercise versus control, Outcome 32 Adherence with the intervention (data on physical activity).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 32 Adherence with the intervention (data on physical activity)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Daily step count (28 weeks) | | | | | | |
| Harrison 2013 | 81 | 5203 (3368) | 67 | 4140 (2420) | | 1063.00 [ 128.26, 1997.74 ] |

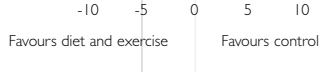

### Analysis 1.33. Comparison 1 Combined diet and exercise versus control, Outcome 33 Well-being and quality of life.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 33 Well-being and quality of life

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Stress (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 8.5 (3) | 133 | 7.8 (2.7) | | 0.70 [ 0.01, 1.39 ] |
| 2 Stress (6 months postpartum) | | | | | | |
| Phelan 2011 | 128 | 8.3 (3) | 133 | 7.8 (2.9) | | 0.50 [ -0.22, 1.22 ] |
| 3 Stress (12 months postpartum) | | | | | | |
| Phelan 2011 | 128 | 8.4 (2.8) | 133 | 8.1 (2.9) | | 0.30 [ -0.39, 0.99 ] |
| 4 Sleep score (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 45.9 (15.7) | 133 | 43.7 (15.9) | | 2.20 [ -1.63, 6.03 ] |
| 5 Sleep score (6 months postpartum) | | | | | | |
| Phelan 2011 | 128 | 40.1 (16.8) | 133 | 37.6 (15.4) | | 2.50 [ -1.41, 6.41 ] |
| 6 Sleep score (12 months postpartum) | | | | | | |




(*Continued* . . . )

(. . . *Continued*)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| Phelan 2011 | 128 | 38.4 (16.5) | 133 | 39 (16.3) | | -0.60 [ -4.58, 3.38 ] |
| 7 Depression scale (late pregnancy) | | | | | | |
| Phelan 2011 | 128 | 4.9 (4.4) | 133 | 5 (4) | | -0.10 [ -1.12, 0.92 ] |
| 8 Depression scale (6 months postpartum) | | | | | | |
| Phelan 2011 | 128 | 5.1 (4.2) | 133 | 4.4 (3.6) | | 0.70 [ -0.25, 1.65 ] |
| 9 Depression scale (12 months postpartum) | | | | | | |
| Phelan 2011 | 128 | 5.6 (4.2) | 133 | 4.9 (4.1) | | 0.70 [ -0.31, 1.71 ] |


### Analysis 1.34. Comparison 1 Combined diet and exercise versus control, Outcome 34 Well-being and quality of life (EQ-5D).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 34 Well-being and quality of life (EQ-5D)

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Mobility problems at 28 weeks | | | | |
| Poston 2013 | 25/80 | 21/75 | | 1.12 [ 0.69, 1.82 ] |
| 2 Self-care problems at 28 weeks | | | | |
| Poston 2013 | 3/80 | 3/75 | | 0.94 [ 0.20, 4.50 ] |
| 3 Usual activity problems at 28 weeks | | | | |
| Poston 2013 | 26/80 | 26/75 | | 0.94 [ 0.60, 1.46 ] |
| 4 Pain and discomfort problems at 28 weeks | | | | |
| Poston 2013 | 54/80 | 45/75 | | 1.13 [ 0.89, 1.43 ] |
| 5 Anxiety and depression problems at 28 weeks | | | | |
| Poston 2013 | 17/80 | 11/75 | | 1.45 [ 0.73, 2.89 ] |

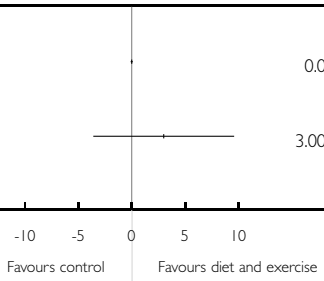
### Analysis 1.35. Comparison 1 Combined diet and exercise versus control, Outcome 35 Well-being and quality of life (EQ-5D).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 35 Well-being and quality of life (EQ-5D)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 'Time Trade-Off' health state rating at 28 weeks | | | | | | |
| Poston 2013 | 80 | 0.79 (0.16) | 75 | 0.79 (0.24) | | 0.0 [ -0.06, 0.06 ] |
| 2 'Visual Analogue Scale' of health related quality of life at 28 weeks | | | | | | |
| Poston 2013 | 80 | 78 (21) | 75 | 75 (21) | | 3.00 [ -3.62, 9.62 ] |



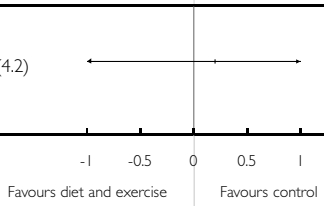

### Analysis 1.36. Comparison 1 Combined diet and exercise versus control, Outcome 36 Well-being and quality of life (EPDS).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 36 Well-being and quality of life (EPDS)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Total at 28 weeks | | | | | | |
| Poston 2013 | 80 | 7.1 (5.2) | 75 | 6.9 (4.2) | | 0.20 [ -1.28, 1.68 ] |



## Analysis 1.37. Comparison 1 Combined diet and exercise versus control, Outcome 37 Well-being and quality of life (EPDS).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 37 Well-being and quality of life (EPDS)

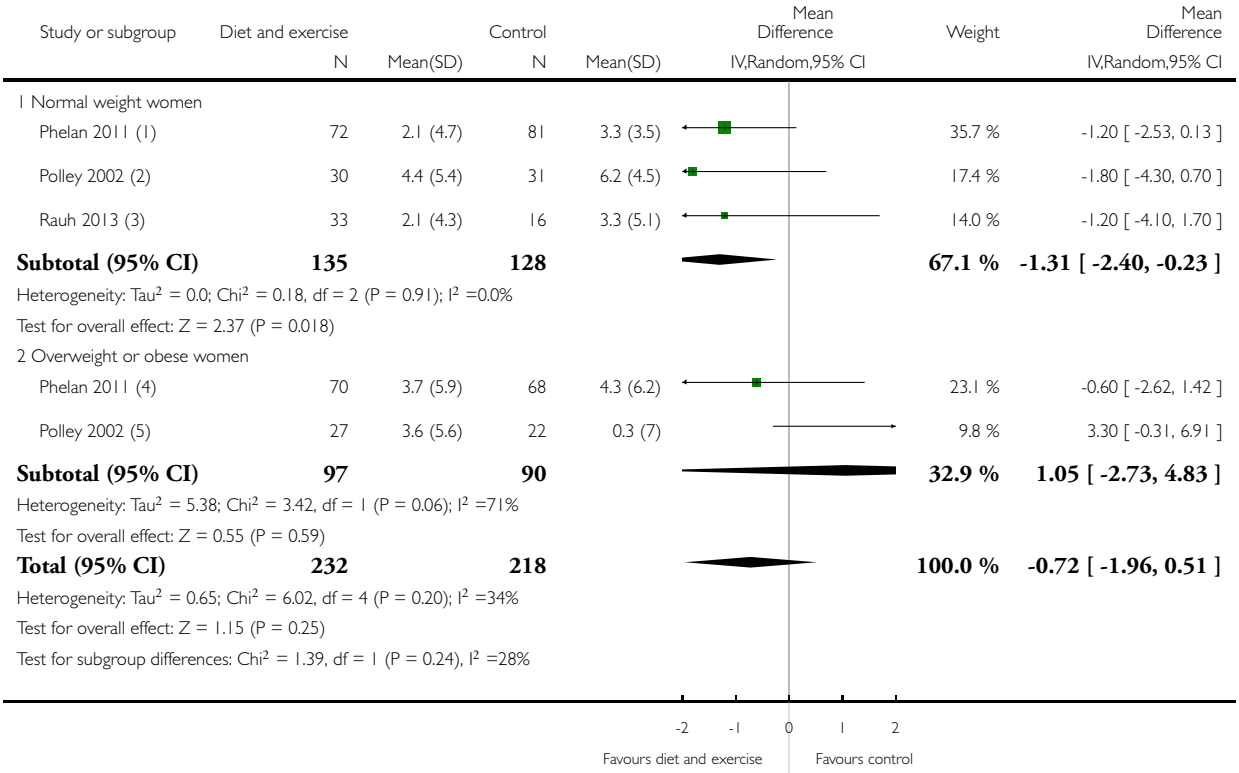
| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Total score > 9 at 28 weeks | | | | |
| Poston 2013 | 21/80 | 17/75 | | 1.16 [ 0.66, 2.02 ] |
| 2 Total score > 12 at 28 weeks | | | | |
| Poston 2013 | 14/80 | 6/75 | | 2.19 [ 0.89, 5.40 ] |

### Analysis 1.38. Comparison 1 Combined diet and exercise versus control, Outcome 38 Postnatal weight retention.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 38 Postnatal weight retention




(1) Women were weighed at 6 months postpartum

(2) Women were weighed at 8 weeks after birth (mean: 8 weeks, standard deviation 7.1 weeks

(3) Women were weighed at 4 months postpartum

(4) Women were weighed at 6 months postpartum

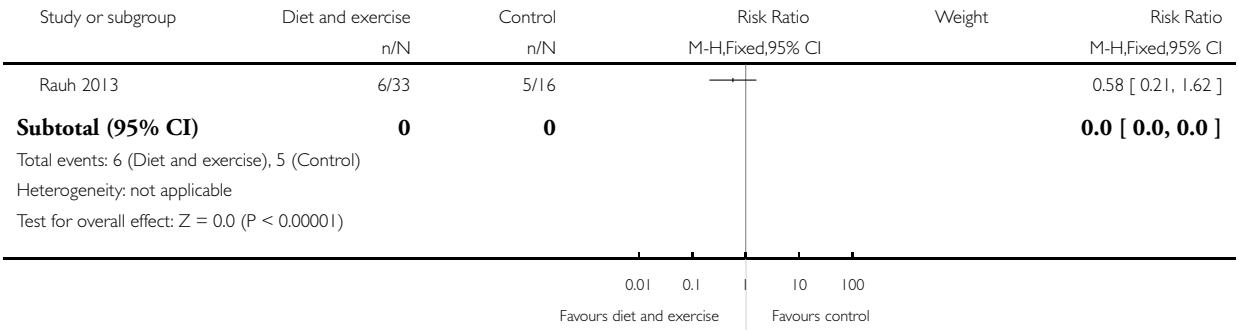
(5) Women were weighed at 8 weeks after birth (mean: 8 weeks, standard deviation 7.1 weeks

### Analysis 1.39. Comparison 1 Combined diet and exercise versus control, Outcome 39 Postnatal weight retention > 5 kg.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 39 Postnatal weight retention > 5 kg

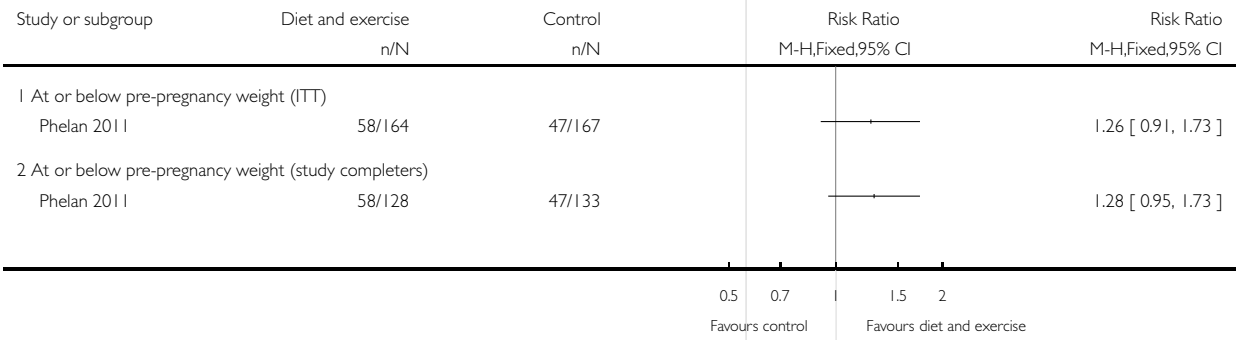



### Analysis 1.40. Comparison 1 Combined diet and exercise versus control, Outcome 40 Weight retention (12 months postpartum).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 40 Weight retention (12 months postpartum)



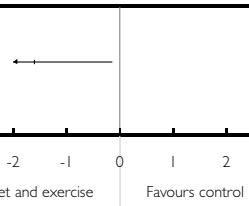
## Analysis 1.41. Comparison 1 Combined diet and exercise versus control, Outcome 41 Weight retention (12 months postpartum).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 41 Weight retention (12 months postpartum)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Net weight retention (study completers) (kg) | | | | | | |
| Phelan 2011 | 128 | 1.4 (6.3) | 133 | 3 (5.7) | | -1.60 [ -3.06, -0.14 ] |



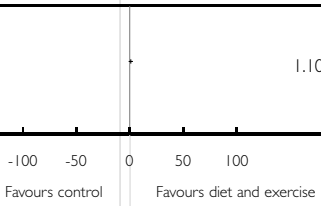

## Analysis 1.42. Comparison 1 Combined diet and exercise versus control, Outcome 42 Weight retention (12 months postpartum).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 42 Weight retention (12 months postpartum)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Weight loss since birth (study completers) (kg) | | | | | | |
| Phelan 2011 | 128 | 13.6 (6.8) | 133 | 12.5 (6.6) | | 1.10 [ -0.53, 2.73 ] |



### Analysis 1.43. Comparison 1 Combined diet and exercise versus control, Outcome 43 Macrosomia.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 43 Macrosomia

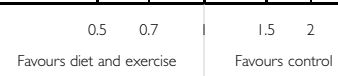
| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 164/1075 | 201/1067 | | 73.2 % | 0.81 [ 0.67, 0.98 ] |
| Luoto 2011 | 9/51 | 8/42 | | 3.2 % | 0.93 [ 0.39, 2.19 ] |
| Phelan 2011 | 20/171 | 17/178 | | 6.0 % | 1.22 [ 0.66, 2.26 ] |
| Polley 2002 | 1/57 | 0/53 | | 0.2 % | 2.79 [ 0.12, 67.10 ] |
| Poston 2013 | 13/86 | 16/84 | | 5.9 % | 0.79 [ 0.41, 1.55 ] |
| Vinter 2012 | 40/150 | 32/154 | | 11.5 % | 1.28 [ 0.85, 1.93 ] |
| **Total (95% CI)** | **1590** | **1578** | | **100.0 %** | **0.90 [ 0.77, 1.05 ]** |

Total events: 247 (Diet and exercise), 274 (Control)

Heterogeneity: $Chi^2 = 5.73$, df = 5 (P = 0.33); $I^2 = 13\%$

Test for overall effect: Z = 1.38 (P = 0.17)

Test for subgroup differences: Not applicable

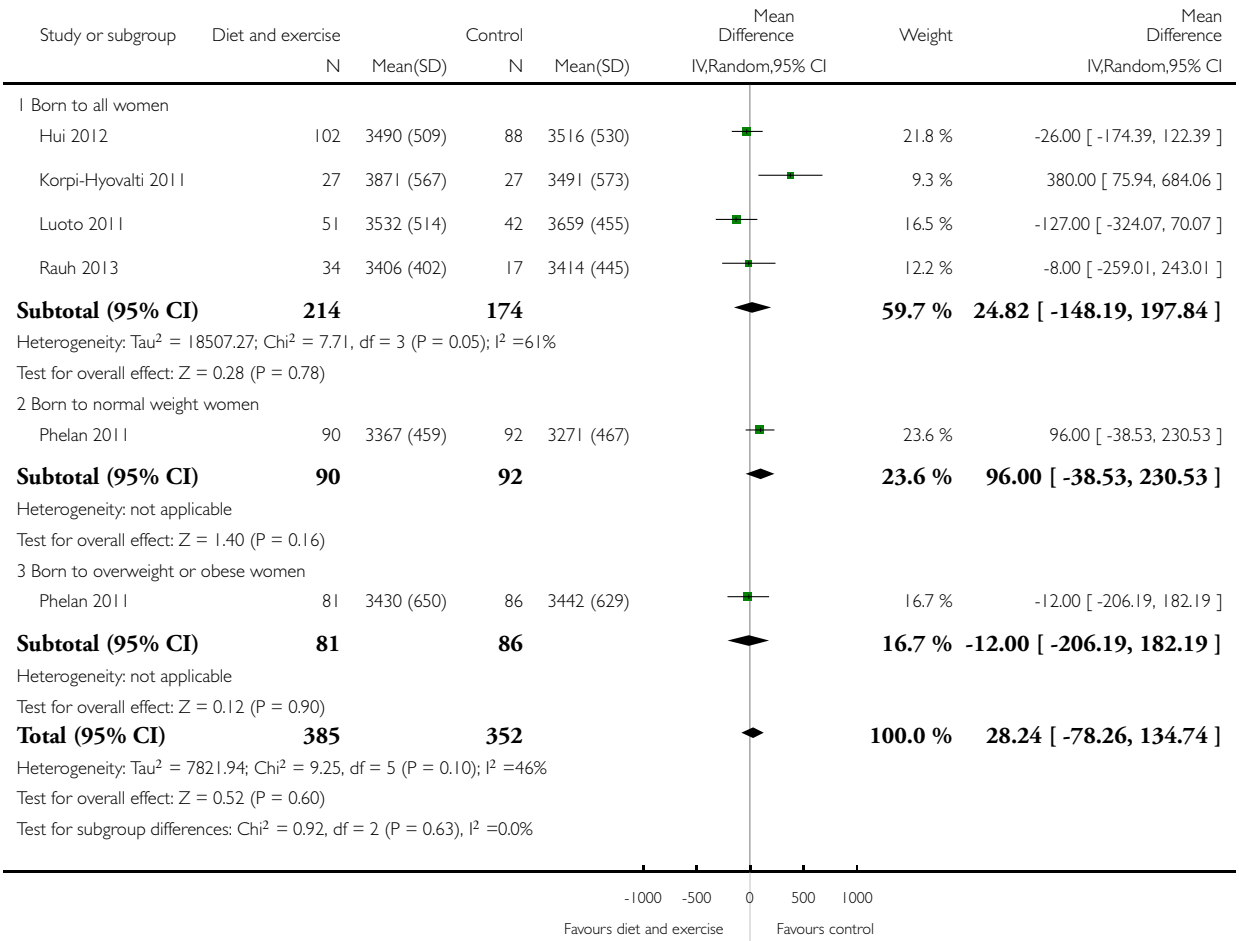


### Analysis 1.44. Comparison 1 Combined diet and exercise versus control, Outcome 44 Birthweight (g).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 44 Birthweight (g)




### Analysis 1.45. Comparison 1 Combined diet and exercise versus control, Outcome 45 Birthweight (g).

**Birthweight (g)**

| Study | Intervention group | Control group | P value |
|---|---|---|---|
| Polley 2002 | Born to normal weight women (n = 30)<br>(Presumed) mean: 3133.0 g<br>Born to overweight women (n = 27)<br>(Presumed) mean: 3282.8 g | Born to normal weight women (n = 31)<br>(Presumed) mean: 3226.4 g<br>Born to overweight women (n = 22)<br>(Presumed) mean: 3349.0 g | Not reported |

**Birthweight (g)** (*Continued*)

| | | | |
|---|---|---|---|
| Vinter 2012 | (n = 150)<br>Median: 3742 g<br>Interquartile range: 3464 to 4070 g | (n = 154)<br>Median: 3593<br>Interquartile range: 3335-3930 | 0.039 |

**Analysis 1.46. Comparison 1 Combined diet and exercise versus control, Outcome 46 Small-for-gestational age.**

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 46 Small-for-gestational age

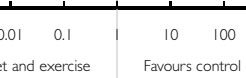
| Study or subgroup | Diet and exercise<br>n/N | Control<br>n/N | Risk Ratio<br>M-H,Fixed,95% CI | Weight | Risk Ratio<br>M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Luoto 2011 | 2/51 | 1/42 | | 45.1 % | 1.65 [ 0.15, 17.54 ] |
| Rauh 2013 | 1/34 | 1/17 | | 54.9 % | 0.50 [ 0.03, 7.51 ] |
| **Total (95% CI)** | **85** | **59** | | **100.0 %** | **1.02 [ 0.18, 5.64 ]** |

Total events: 3 (Diet and exercise), 2 (Control)

Heterogeneity: $Chi^2 = 0.42$, df = 1 (P = 0.52); $I^2 = 0.0\%$

Test for overall effect: Z = 0.02 (P = 0.98)

Test for subgroup differences: Not applicable



### Analysis 1.47. Comparison 1 Combined diet and exercise versus control, Outcome 47 Low birthweight (< 2500 g).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 47 Low birthweight (< 2500 g)

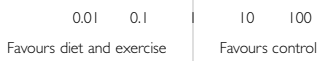
| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Phelan 2011 | 9/171 | 9/178 | | 63.0 % | 1.04 [ 0.42, 2.56 ] |
| Polley 2002 | 5/57 | 5/53 | | 37.0 % | 0.93 [ 0.29, 3.03 ] |
| **Total (95% CI)** | **228** | **231** | | **100.0 %** | **1.00 [ 0.49, 2.05 ]** |

Total events: 14 (Diet and exercise), 14 (Control)

Heterogeneity: $Chi^2 = 0.02$, df = 1 (P = 0.88); $I^2 = 0.0\%$

Test for overall effect: Z = 0.00 (P = 1.0)

Test for subgroup differences: Not applicable




### Analysis 1.48. Comparison 1 Combined diet and exercise versus control, Outcome 48 Neonatal hypoglycaemia requiring treatment.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 48 Neonatal hypoglycaemia requiring treatment

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 107/1075 | 103/1067 | | | 1.03 [ 0.80, 1.33 ] |
| **Subtotal (95% CI)** | **0** | **0** | | | **0.0 [ 0.0, 0.0 ]** |

Total events: 107 (Diet and exercise), 103 (Control)

Heterogeneity: not applicable

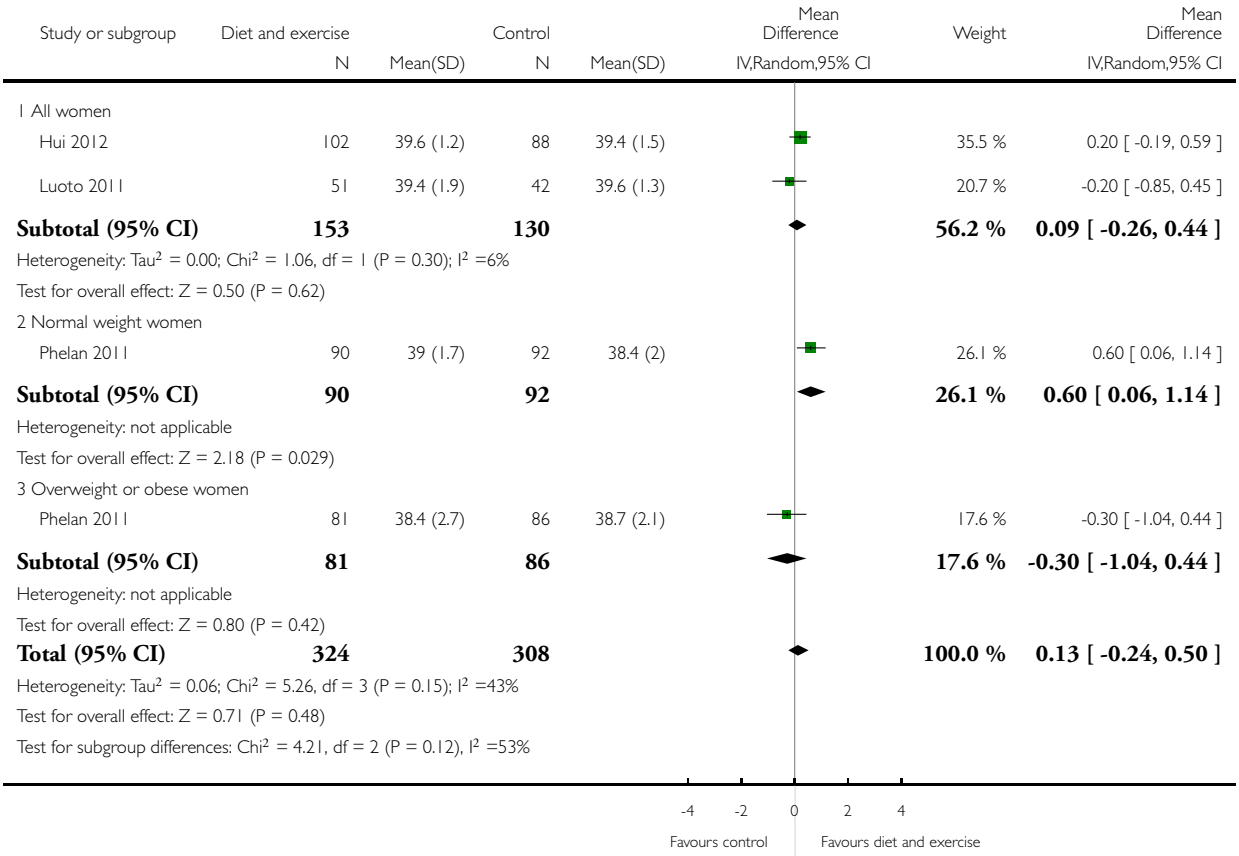
Test for overall effect: Z = 0.0 (P < 0.00001)

### Analysis 1.49. Comparison 1 Combined diet and exercise versus control, Outcome 49 Gestational age at birth (weeks).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 49 Gestational age at birth (weeks)




### Analysis 1.50. Comparison 1 Combined diet and exercise versus control, Outcome 50 Gestational age at birth (days or weeks).

**Gestational age at birth (days or weeks)**

| Study | Intervention group | Control group | P value |
|---|---|---|---|
| Polley 2002 | Normal weight women (n = 30)<br>(Presumed) mean: 39.2 weeks<br>Overweight women (n = 27)<br>(Presumed) mean: 39.4 weeks | Normal weight women (n = 31)<br>(Presumed) mean: 39.5 weeks<br>Overweight women (n = 22)<br>(Presumed) mean: 39.1 weeks | Not reported |

| | | | |
|---|---|---|---|
| Vinter 2012 | (n = 150)<br>Median: 283 days<br>Interquartile range: 273 to 290 days | (n = 154)<br>Median: 283 days<br>Interquartile range: 274 to 289 days | 0.952 |

### Analysis 1.51. Comparison 1 Combined diet and exercise versus control, Outcome 51 Preterm birth.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 51 Preterm birth

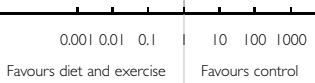
| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 62/1075 | 83/1067 | | 69.0 % | 0.74 [ 0.54, 1.02 ] |
| Petrella 2013 | 0/33 | 10/28 | | 9.4 % | 0.04 [ 0.00, 0.66 ] |
| Phelan 2011 | 16/171 | 20/178 | | 16.2 % | 0.83 [ 0.45, 1.55 ] |
| Polley 2002 | 7/57 | 5/53 | | 4.3 % | 1.30 [ 0.44, 3.85 ] |
| Rauh 2013 | 1/34 | 1/17 | | 1.1 % | 0.50 [ 0.03, 7.51 ] |
| **Total (95% CI)** | **1370** | **1343** | | **100.0 %** | **0.71 [ 0.55, 0.93 ]** |

Total events: 86 (Diet and exercise), 119 (Control)

Heterogeneity: $Chi^2 = 5.60$, df = 4 (P = 0.23); $I^2 = 29\%$

Test for overall effect: Z = 2.51 (P = 0.012)

Test for subgroup differences: Not applicable



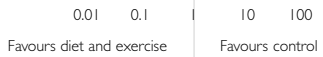
### Analysis 1.52. Comparison 1 Combined diet and exercise versus control, Outcome 52 Shoulder dystocia.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 52 Shoulder dystocia

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 44/1075 | 35/1067 | | | 1.25 [ 0.81, 1.93 ] |
| **Subtotal (95% CI)** | **0** | **0** | | | **0.0 [ 0.0, 0.0 ]** |
| Total events: 44 (Diet and exercise), 35 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 0.0 (P < 0.000001) | | | | | |
| Test for subgroup differences: Not applicable | | | | | |




### Analysis 1.53. Comparison 1 Combined diet and exercise versus control, Outcome 53 Bone fracture.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 53 Bone fracture

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 4/1075 | 2/1067 | | | 1.99 [ 0.36, 10.82 ] |
| **Subtotal (95% CI)** | **0** | **0** | | | **0.0 [ 0.0, 0.0 ]** |
| Total events: 4 (Diet and exercise), 2 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 0.0 (P < 0.000001) | | | | | |

### Analysis 1.54. Comparison 1 Combined diet and exercise versus control, Outcome 54 Nerve palsy.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 54 Nerve palsy

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 4/1075 | 2/1067 | | | 1.99 [ 0.36, 10.82 ] |
| **Subtotal (95% CI)** | **0** | **0** | | | **0.0 [ 0.0, 0.0 ]** |
| Total events: 4 (Diet and exercise), 2 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 0.0 (P < 0.00001) | | | | | |

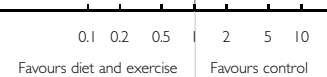

### Analysis 1.55. Comparison 1 Combined diet and exercise versus control, Outcome 55 Hyperbilirubinaemia requiring treatment.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 55 Hyperbilirubinaemia requiring treatment

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 73/1075 | 88/1067 | | | 0.82 [ 0.61, 1.11 ] |
| **Subtotal (95% CI)** | **0** | **0** | | | **0.0 [ 0.0, 0.0 ]** |
| Total events: 73 (Diet and exercise), 88 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 0.0 (P < 0.00001) | | | | | |



### Analysis 1.56. Comparison 1 Combined diet and exercise versus control, Outcome 56 Ponderal index (weight, kg/height, m3).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

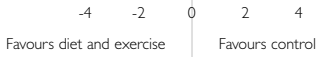
Comparison: 1 Combined diet and exercise versus control

Outcome: 56 Ponderal index (weight, kg/height, m3)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Weight | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|---|
| Luoto 2011 | 51 | 27.6 (2.5) | 42 | 28 (2.2) | | | -0.40 [ -1.36, 0.56 ] |
| **Subtotal (95% CI)** | **0** | | **0** | | | | **0.0 [ 0.0, 0.0 ]** |

Heterogeneity: not applicable

Test for overall effect: Z = 0.0 (P < 0.00001)




### Analysis 1.57. Comparison 1 Combined diet and exercise versus control, Outcome 57 Antenatal admission.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

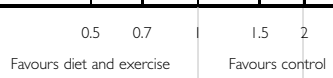
Outcome: 57 Antenatal admission

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 166/1080 | 191/1073 | | | 0.86 [ 0.71, 1.04 ] |
| **Subtotal (95% CI)** | **0** | **0** | | | **0.0 [ 0.0, 0.0 ]** |

Total events: 166 (Diet and exercise), 191 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 0.0 (P < 0.00001)



### Analysis 1.58. Comparison 1 Combined diet and exercise versus control, Outcome 58 Length of antenatal stay (days).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

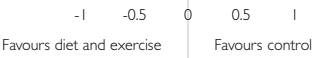
Outcome: 58 Length of antenatal stay (days)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Weight | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|---|
| Dodd 2014 | 1080 | 0.58 (2.11) | 1073 | 0.85 (3.05) | | | -0.27 [ -0.49, -0.05 ] |
| **Subtotal (95% CI)** | **0** | | **0** | | | | **0.0 [ 0.0, 0.0 ]** |

Heterogeneity: not applicable

Test for overall effect: Z = 0.0 (P < 0.00001)

Test for subgroup differences: Not applicable




### Analysis 1.59. Comparison 1 Combined diet and exercise versus control, Outcome 59 Length of postnatal stay (mother) (days).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

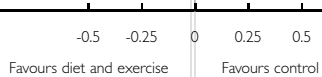
Comparison: 1 Combined diet and exercise versus control

Outcome: 59 Length of postnatal stay (mother) (days)

| Study or subgroup | Diet and exercise N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Weight | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|---|
| Dodd 2014 | 1075 | 2.85 (1.79) | 1067 | 2.91 (1.71) | | | -0.06 [ -0.21, 0.09 ] |
| **Subtotal (95% CI)** | **0** | | **0** | | | | **0.0 [ 0.0, 0.0 ]** |

Heterogeneity: not applicable

Test for overall effect: Z = 0.0 (P < 0.00001)



## Analysis 1.60. Comparison 1 Combined diet and exercise versus control, Outcome 60 Admission to neonatal intensive care unit (or special care).

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 1 Combined diet and exercise versus control

Outcome: 60 Admission to neonatal intensive care unit (or special care)

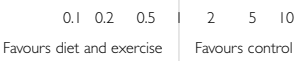
| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 394/1075 | 385/1067 | | 94.7 % | 1.02 [ 0.91, 1.14 ] |
| Vinter 2012 | 21/150 | 22/154 | | 5.3 % | 0.98 [ 0.56, 1.71 ] |
| **Total (95% CI)** | **1225** | **1221** | | **100.0 %** | **1.01 [ 0.91, 1.13 ]** |

Total events: 415 (Diet and exercise), 407 (Control)

Heterogeneity: $Chi^2 = 0.02$, df = 1 (P = 0.90); $I^2 = 0.0\%$

Test for overall effect: Z = 0.25 (P = 0.81)

Test for subgroup differences: Not applicable

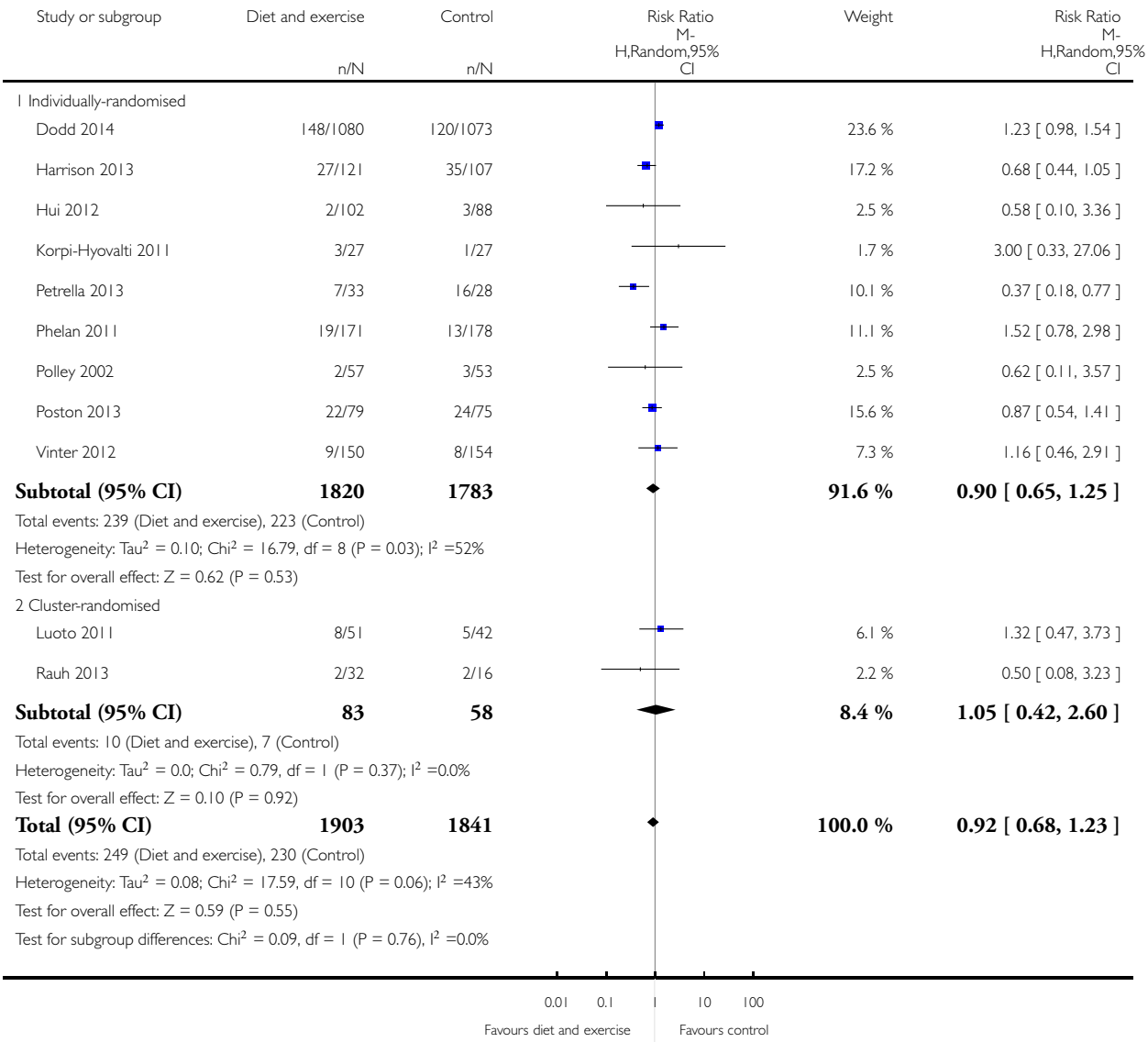


## Analysis 2.1. Comparison 2 Diet and exercise versus control (subgroups based on unit of randomisation), Outcome 1 Gestational diabetes.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 2 Diet and exercise versus control (subgroups based on unit of randomisation)

Outcome: 1 Gestational diabetes

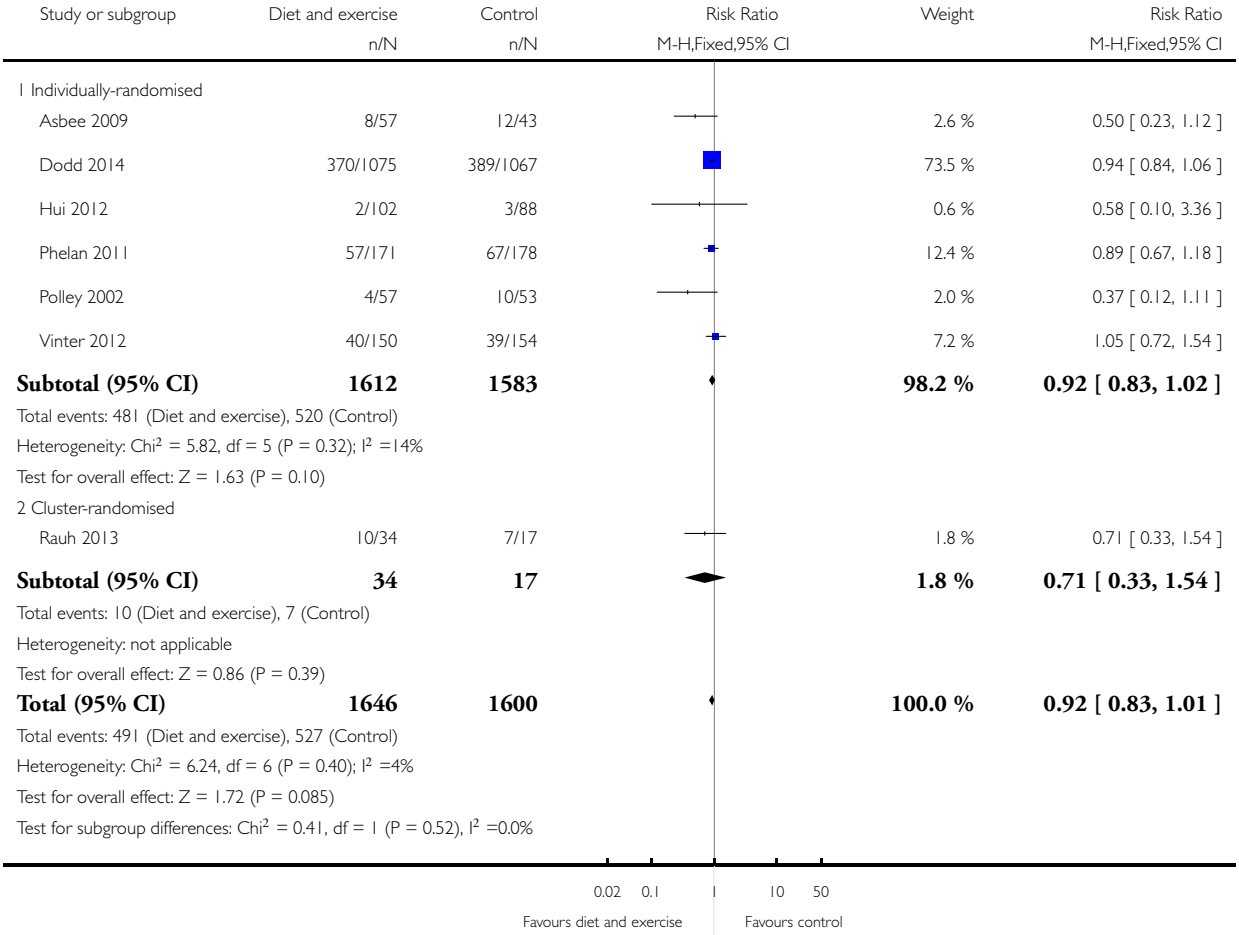


## Analysis 2.2. Comparison 2 Diet and exercise versus control (subgroups based on unit of randomisation), Outcome 2 Caesarean birth.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 2 Diet and exercise versus control (subgroups based on unit of randomisation)

Outcome: 2 Caesarean birth

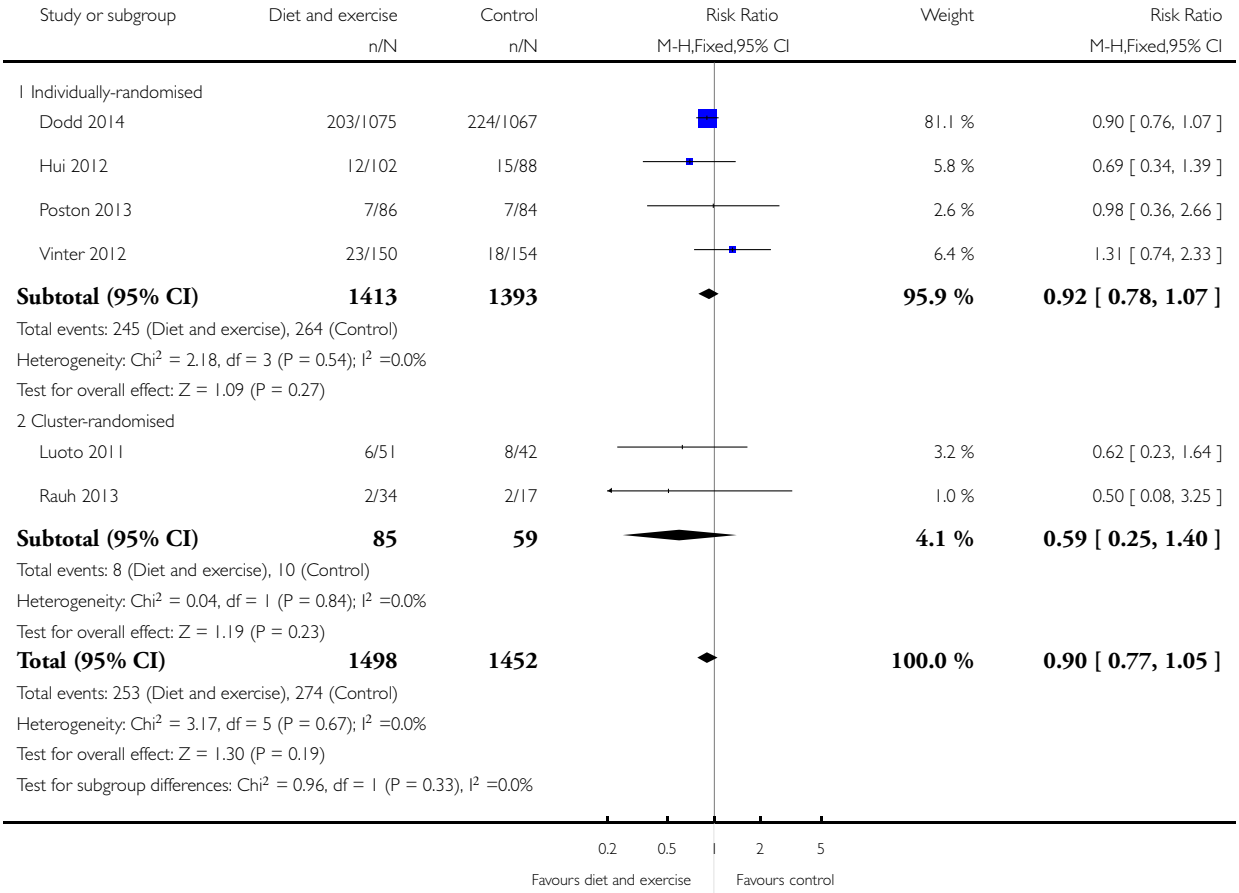


## Analysis 2.3. Comparison 2 Diet and exercise versus control (subgroups based on unit of randomisation), Outcome 3 Large-for-gestational age.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 2 Diet and exercise versus control (subgroups based on unit of randomisation)

Outcome: 3 Large-for-gestational age

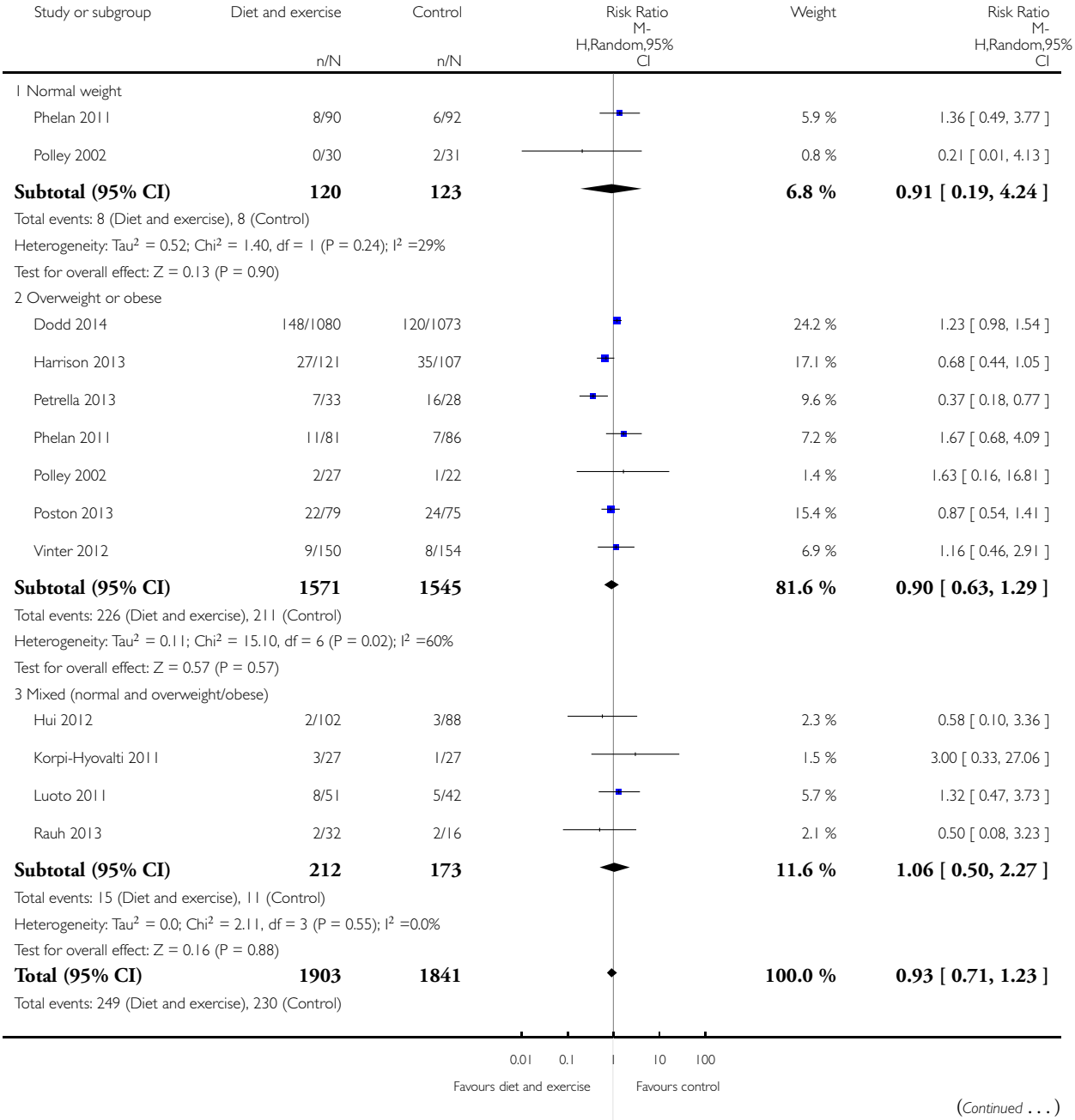


## Analysis 3.1. Comparison 3 Diet and exercise versus control (subgroups based on baseline BMI), Outcome 1 Gestational diabetes.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 3 Diet and exercise versus control (subgroups based on baseline BMI)

Outcome: 1 Gestational diabetes

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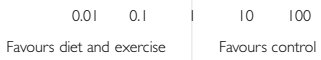
| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| Heterogeneity: $Tau^2$ = 0.07; $Chi^2$ = 18.62, df = 12 (P = 0.10); $I^2$ =36% | | | | | |
| Test for overall effect: Z = 0.48 (P = 0.63) | | | | | |
| Test for subgroup differences: $Chi^2$ = 0.15, df = 2 (P = 0.93), $I^2$ =0.0% | | | | | |




**Analysis 3.2. Comparison 3 Diet and exercise versus control (subgroups based on baseline BMI), Outcome 2 Caesarean birth.**

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 3 Diet and exercise versus control (subgroups based on baseline BMI)

Outcome: 2 Caesarean birth

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| 1 Normal weight | | | | | |
| Phelan 2011 | 24/90 | 25/92 | | 4.7 % | 0.98 [ 0.61, 1.58 ] |
| Polley 2002 | 2/30 | 4/31 | | 0.7 % | 0.52 [ 0.10, 2.61 ] |
| **Subtotal (95% CI)** | **120** | **123** | | **5.4 %** | **0.92 [ 0.58, 1.45 ]** |
| Total events: 26 (Diet and exercise), 29 (Control) | | | | | |
| Heterogeneity: $Chi^2$ = 0.56, df = 1 (P = 0.46); $I^2$ =0.0% | | | | | |
| Test for overall effect: Z = 0.37 (P = 0.71) | | | | | |
| 2 Overweight or obese | | | | | |
| Dodd 2014 | 370/1075 | 389/1067 | | 73.5 % | 0.94 [ 0.84, 1.06 ] |
| Phelan 2011 | 33/81 | 42/86 | | 7.7 % | 0.83 [ 0.59, 1.17 ] |
| Polley 2002 | 2/27 | 6/22 | | 1.2 % | 0.27 [ 0.06, 1.21 ] |
| Vinter 2012 | 40/150 | 39/154 | | 7.2 % | 1.05 [ 0.72, 1.54 ] |
| **Subtotal (95% CI)** | **1333** | **1329** | | **89.7 %** | **0.93 [ 0.84, 1.04 ]** |
| Total events: 445 (Diet and exercise), 476 (Control) | | | | | |
| Heterogeneity: $Chi^2$ = 3.45, df = 3 (P = 0.33); $I^2$ =13% | | | | | |
| Test for overall effect: Z = 1.28 (P = 0.20) | | | | | |
| 3 Mixed (normal and overweight/obese) | | | | | |


(*Continued* . . . )

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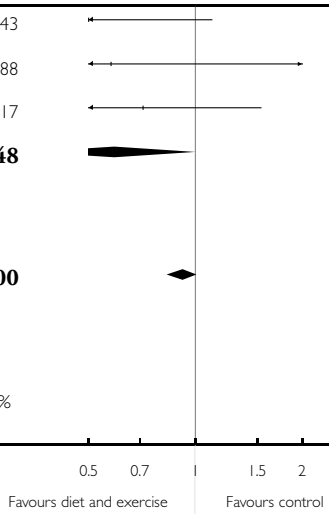
| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Asbee 2009 | 8/57 | 12/43 | | 2.6 % | 0.50 [ 0.23, 1.12 ] |
| Hui 2012 | 2/102 | 3/88 | | 0.6 % | 0.58 [ 0.10, 3.36 ] |
| Rauh 2013 | 10/34 | 7/17 | | 1.8 % | 0.71 [ 0.33, 1.54 ] |
| **Subtotal (95% CI)** | **193** | **148** | | **4.9 %** | **0.59 [ 0.34, 1.00 ]** |
| Total events: 20 (Diet and exercise), 22 (Control) | | | | | |
| Heterogeneity: $Chi^2$ = 0.39, df = 2 (P = 0.82); $I^2$ =0.0% | | | | | |
| Test for overall effect: Z = 1.95 (P = 0.051) | | | | | |
| **Total (95% CI)** | **1646** | **1600** | | **100.0 %** | **0.92 [ 0.83, 1.01 ]** |
| Total events: 491 (Diet and exercise), 527 (Control) | | | | | |
| Heterogeneity: $Chi^2$ = 6.98, df = 8 (P = 0.54); $I^2$ =0.0% | | | | | |
| Test for overall effect: Z = 1.72 (P = 0.085) | | | | | |
| Test for subgroup differences: $Chi^2$ = 2.78, df = 2 (P = 0.25), $I^2$ =28% | | | | | |

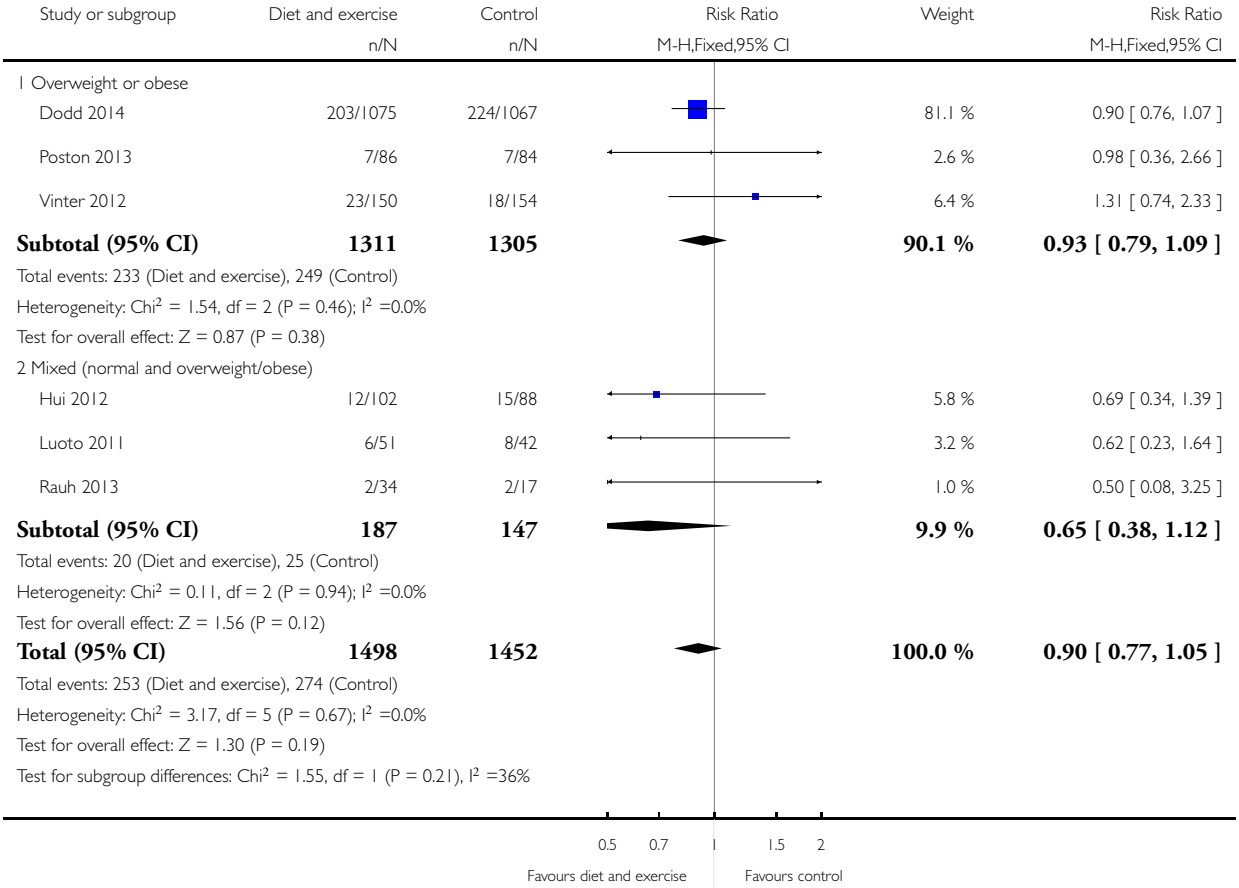


## Analysis 3.3. Comparison 3 Diet and exercise versus control (subgroups based on baseline BMI), Outcome 3 Large-for-gestational age.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 3 Diet and exercise versus control (subgroups based on baseline BMI)

Outcome: 3 Large-for-gestational age

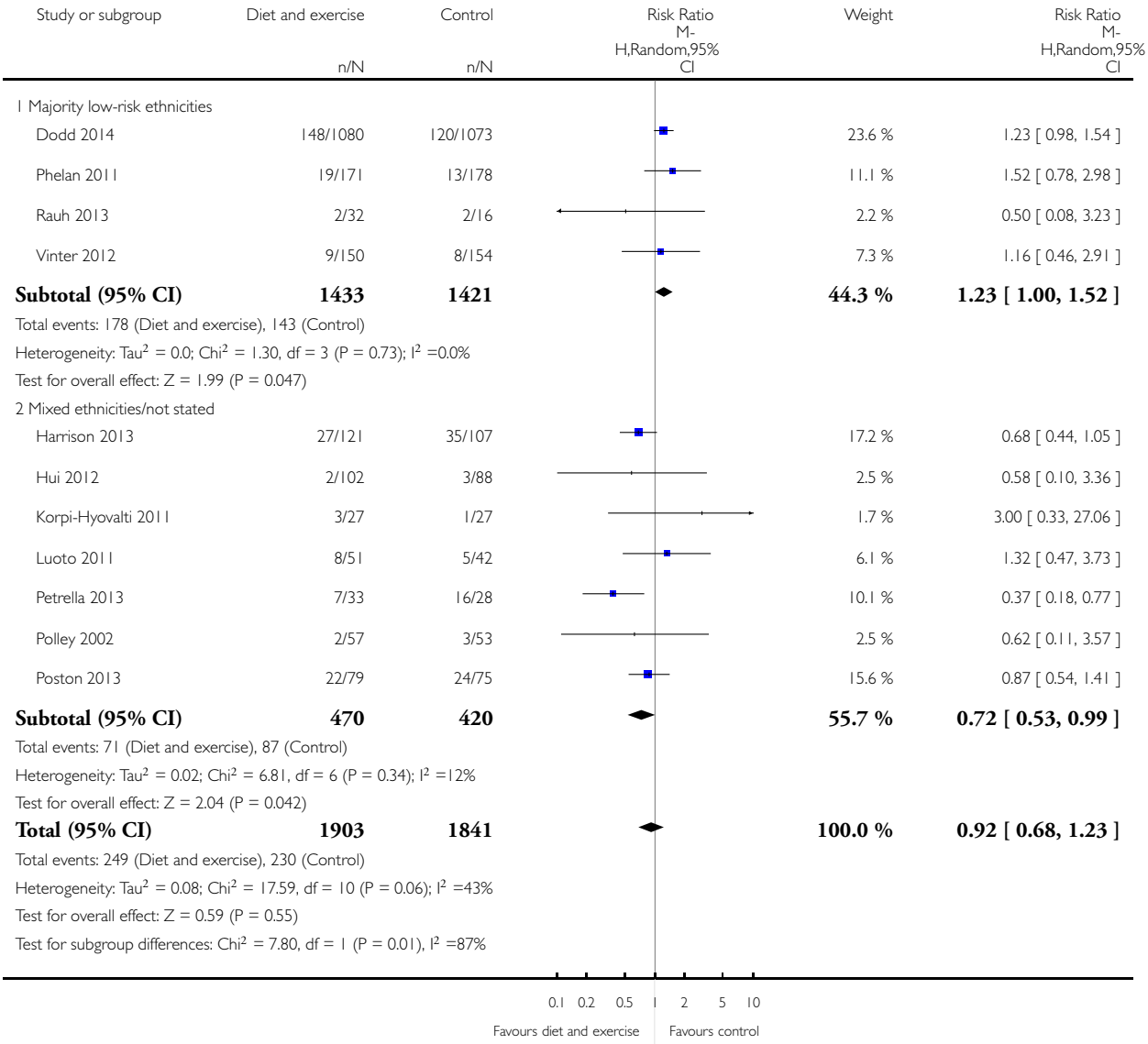


## Analysis 4.1. Comparison 4 Diet and exercise versus control (subgroups based on ethnicity), Outcome 1 Gestational diabetes.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 4 Diet and exercise versus control (subgroups based on ethnicity)

Outcome: 1 Gestational diabetes

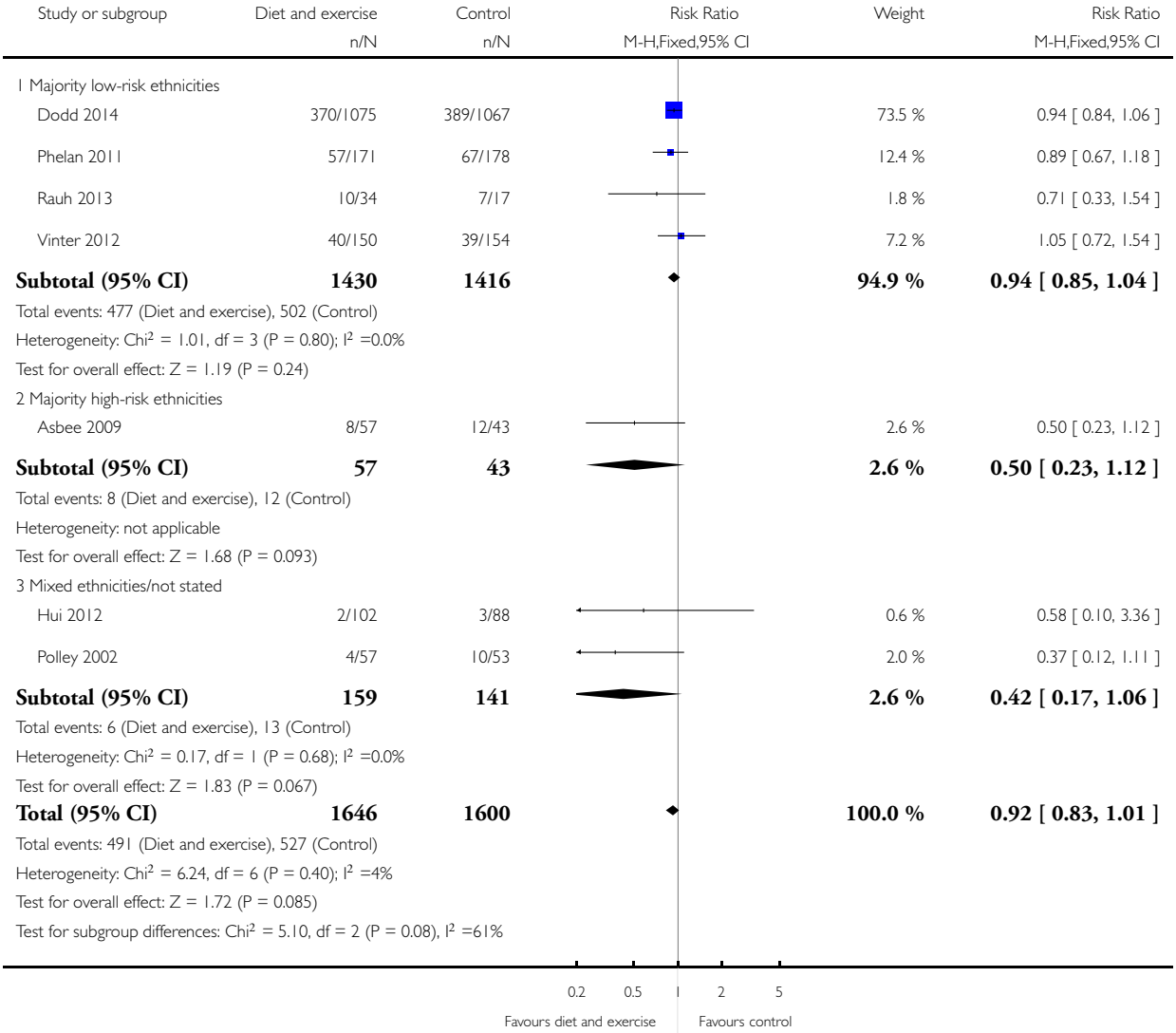


## Analysis 4.2. Comparison 4 Diet and exercise versus control (subgroups based on ethnicity), Outcome 2 Caesarean birth.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 4 Diet and exercise versus control (subgroups based on ethnicity)

Outcome: 2 Caesarean birth

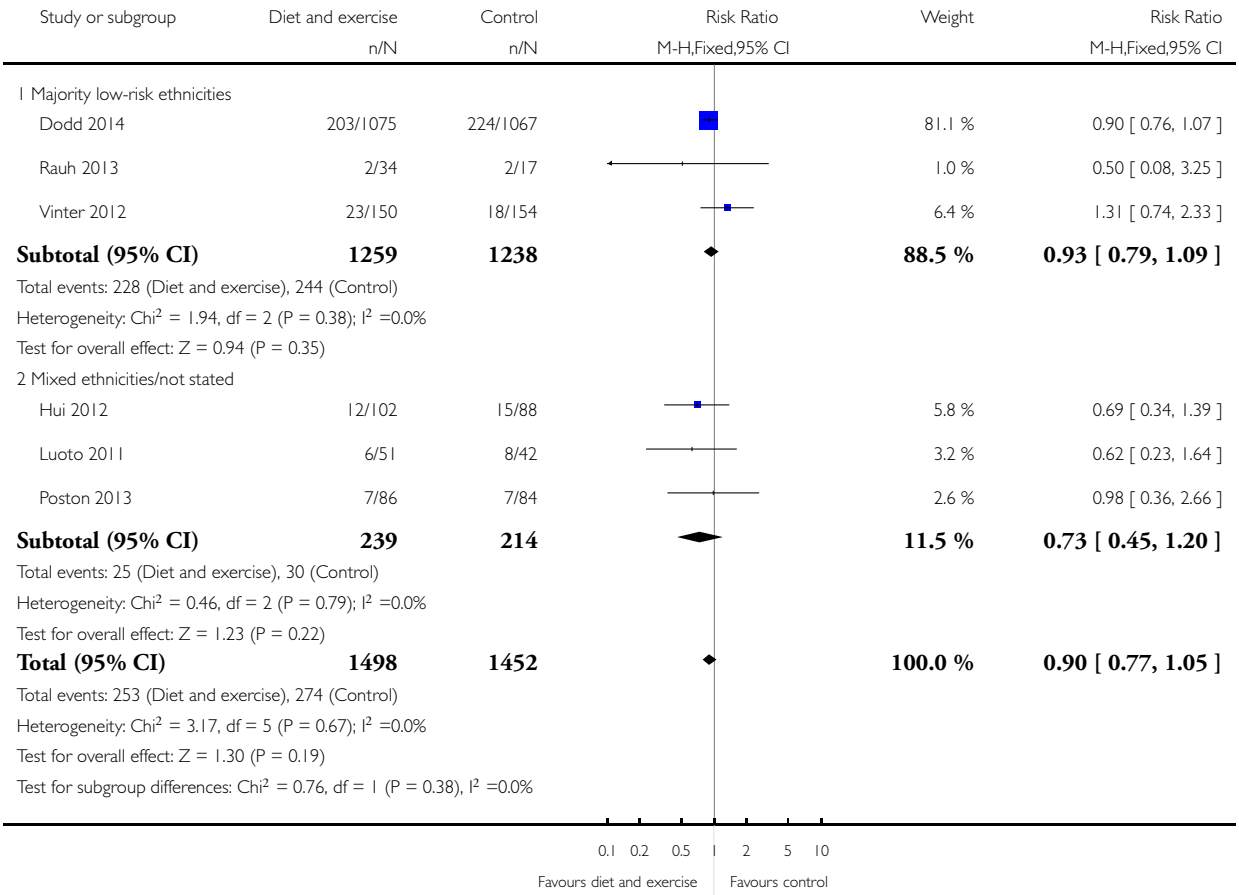


## Analysis 4.3. Comparison 4 Diet and exercise versus control (subgroups based on ethnicity), Outcome 3 Large-for-gestational age.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 4 Diet and exercise versus control (subgroups based on ethnicity)

Outcome: 3 Large-for-gestational age

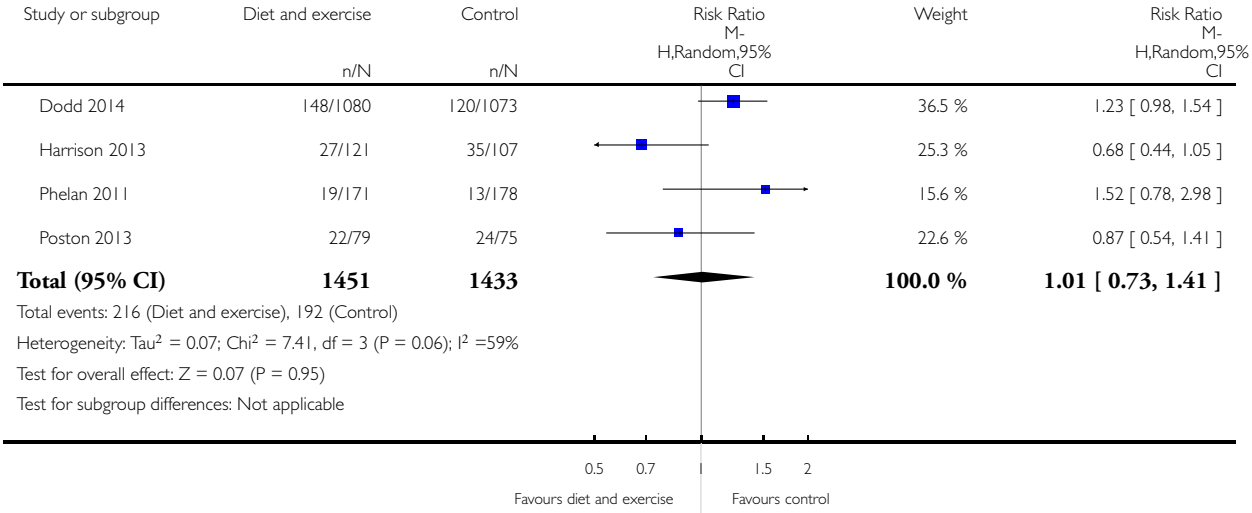


## Analysis 5.1. Comparison 5 Diet and exercise versus control (sensitivity analysis), Outcome 1 Gestational diabetes.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 5 Diet and exercise versus control (sensitivity analysis)

Outcome: 1 Gestational diabetes



### Analysis 5.2. Comparison 5 Diet and exercise versus control (sensitivity analysis), Outcome 2 Caesarean birth.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 5 Diet and exercise versus control (sensitivity analysis)

Outcome: 2 Caesarean birth

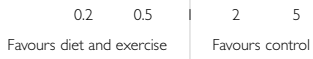
| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Asbee 2009 | 8/57 | 12/43 | | 2.9 % | 0.50 [ 0.23, 1.12 ] |
| Dodd 2014 | 370/1075 | 389/1067 | | 83.1 % | 0.94 [ 0.84, 1.06 ] |
| Phelan 2011 | 57/171 | 67/178 | | 14.0 % | 0.89 [ 0.67, 1.18 ] |
| **Total (95% CI)** | **1303** | **1288** | | **100.0 %** | **0.92 [ 0.83, 1.03 ]** |

Total events: 435 (Diet and exercise), 468 (Control)

Heterogeneity: $Chi^2$ = 2.43, df = 2 (P = 0.30); $I^2$ =18%

Test for overall effect: Z = 1.49 (P = 0.14)

Test for subgroup differences: Not applicable




### Analysis 5.3. Comparison 5 Diet and exercise versus control (sensitivity analysis), Outcome 3 Large-for-gestational age.

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 5 Diet and exercise versus control (sensitivity analysis)

Outcome: 3 Large-for-gestational age

| Study or subgroup | Diet and exercise n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Dodd 2014 | 203/1075 | 224/1067 | | 96.9 % | 0.90 [ 0.76, 1.07 ] |
| Poston 2013 | 7/86 | 7/84 | | 3.1 % | 0.98 [ 0.36, 2.66 ] |
| **Total (95% CI)** | **1161** | **1151** | | **100.0 %** | **0.90 [ 0.76, 1.07 ]** |

Total events: 210 (Diet and exercise), 231 (Control)

Heterogeneity: $Chi^2$ = 0.03, df = 1 (P = 0.87); $I^2$ =0.0%

Test for overall effect: Z = 1.21 (P = 0.23)

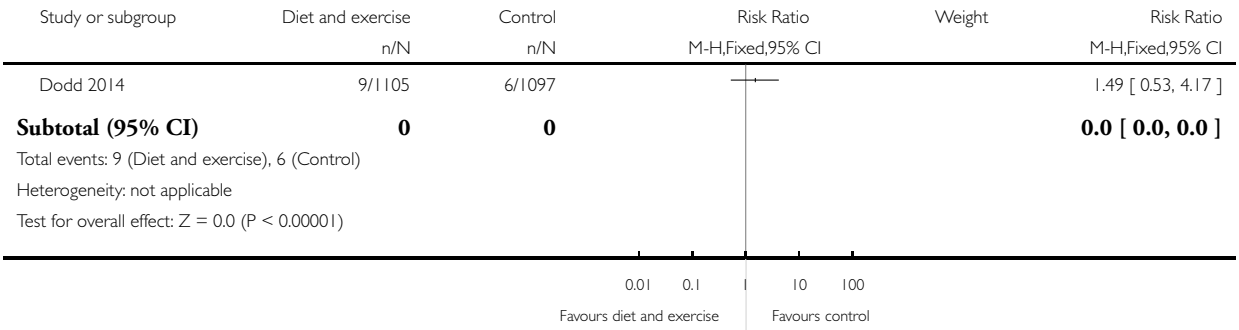
Test for subgroup differences: Not applicable

**Analysis 5.4. Comparison 5 Diet and exercise versus control (sensitivity analysis), Outcome 4 Perinatal mortality.**

Review: Diet and exercise interventions for preventing gestational diabetes mellitus

Comparison: 5 Diet and exercise versus control (sensitivity analysis)

Outcome: 4 Perinatal mortality




## WHAT'S NEW

Last assessed as up-to-date: 11 February 2014.

| Date | Event | Description |
|---|---|---|
| 11 June 2015 | Amended | Added Acknowledgements statement. |

## CONTRIBUTIONS OF AUTHORS

Morven Crane wrote the rst draft of the protocol, with all review authors (Emily Bain, Joanna Tieu, Shanshan Han, Philippa Middleton, Caroline Crowther) making comments and contributing to subsequent drafts.

For the review, Morven Crane and Emily Bain assessed the citations and studies found for inclusion, assessed risk of bias and conducted data analyses. Emily Bain, Shanshan Han and Morven Crane wrote the first draft of the review, and all review authors (Joanna Tieu, Caroline Crowther, Philippa Middleton) assisted with data interpretation and edited and commented on the review.

## DECLARATIONS OF INTEREST

Emily Bain: none known.

Morven Crane: none known.

Joanna Tieu: none known.

Caroline Crowther was an investigator on the LIMIT Trial (Dodd 2014). All tasks relating to this study (assessment of eligibility for inclusion, assessment of risk of bias, data extraction) were carried out by other members of the review team who were not directly involved in the trial.

Caroline Crowther, Philippa Middleton and Shanshan Han are also investigators on one of the ongoing trials (Crowther 2012). Therefore, in future updates of this review, all tasks relating to this study (assessment of eligibility for inclusion; and if included, assessment of risk of bias, data extraction etc.) will be carried out by other members of the review team who are not directly involved in this trial.

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