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Combined diet and exercise interventions for preventing gestational diabetes mellitus (Review)

Shepherd E, Gomersall JC, Tieu J, Han S, Crowther CA, Middleton P

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[Intervention Review]

Combined 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 infants 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. This is an update of a Cochrane review that was first published in 2015.

Objectives

To assess the effects of diet interventions in combination with exercise interventions for pregnant women for preventing GDM, and associated adverse health consequences for the mother and her infant/child.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (27 November 2016) and reference lists of retrieved studies.

Selection criteria

We included randomised controlled trials (RCTs) and cluster-RCTs, comparing combined diet and exercise interventions with no intervention (i.e. standard care), that reported on GDM diagnosis as an outcome. Quasi-RCTs were excluded. Cross-over trials were not eligible for inclusion. We planned to include RCTs comparing two or more different diet/exercise interventions, however none were identified.

Data collection and analysis

Two review authors independently assessed study eligibility, extracted data, assessed the risk of bias of the included trials and assessed quality of evidence for selected maternal and infant/child outcomes using the GRADE approach. We checked data for accuracy.

Main results

In this update, we included 23 RCTs (involving 8918 women and 8709 infants) that compared combined diet and exercise interventions with no intervention (standard care). The studies varied in the diet and exercise programs evaluated and health outcomes reported. None reported receiving funding from a drug manufacturer or agency with interests in the results. Overall risk of bias was judged to be unclear due to the lack of methodological detail reported. Most studies were undertaken in high-income countries.

For our primary review outcomes, there was a possible reduced risk of **GDM** in the diet and exercise intervention group compared with the standard care group (average risk ratio (RR) 0.85, 95% confidence interval (CI) 0.71 to 1.01; 6633 women; 19 RCTs; $\text{Tau}^2 = 0.05$; $I^2 = 42\%$; $P = 0.07$; *moderate-quality evidence*). There was also a possible reduced risk of **caesarean section** (RR 0.95, 95% CI 0.88 to 1.02; 6089 women; 14 RCTs; *moderate-quality evidence*). No clear differences were seen between groups for **pre-eclampsia** (RR 0.98, 95% CI 0.79 to 1.22; 5366 participants; 8 RCTs; *low-quality evidence*), **pregnancy-induced hypertension and/or hypertension** (average RR 0.78, 95% CI 0.47 to 1.27; 3073 participants; 6 RCTs; $\text{Tau}^2 = 0.19$; $I^2 = 62\%$; *very low-quality evidence*), **perinatal mortality** (RR 0.82, 95% CI 0.42 to 1.63; 3757 participants; 2 RCTs; *low-quality evidence*) or **large-for-gestational age** (RR 0.93, 95% CI 0.81 to 1.07; 5353 participants; 11 RCTs; *low-quality evidence*). No data were reported for **infant mortality or morbidity composite**.

Subgroup analyses (based on trial design, maternal body mass index (BMI) and ethnicity) revealed no clear differential treatment effects. We were unable to assess the impact of maternal age, parity and specific features of the diet and exercise interventions. Findings from sensitivity analyses (based on RCT quality) generally supported those observed in the main analyses. We were not able to perform subgroup analyses based on maternal age, parity or nature of the exercise/dietary interventions due to the paucity of information/data on these characteristics and the inability to meaningfully group intervention characteristics.

For most of the secondary review outcomes assessed using GRADE, there were no clear differences between groups, including for **perineal trauma** (RR 1.27, 95% CI 0.78 to 2.05; 2733 participants; 2 RCTs; *moderate-quality evidence*), **neonatal hypoglycaemia** (average RR 1.42, 95% CI 0.67 to 2.98; 3653 participants; 2 RCTs; $\text{Tau}^2 = 0.23$; $I^2 = 77\%$; *low quality evidence*); and **childhood adiposity** (BMI z score) (MD 0.05, 95% CI -0.29 to 0.40; 794 participants; 2 RCTs; $\text{Tau}^2 = 0.04$; $I^2 = 59\%$; *low-quality evidence*). However, there was evidence of less **gestational weight gain** in the diet and exercise intervention group compared with the control group (mean difference (MD) -0.89 kg, 95% CI -1.39 to -0.40; 5052 women; 16 RCTs; $\text{Tau}^2 = 0.37$; $I^2 = 43\%$; *moderate-quality evidence*). No data were reported for **maternal postnatal depression** or **type 2 diabetes; childhood/adulthood type 2 diabetes, or neurosensory disability**.

Authors' conclusions

Moderate-quality evidence suggests reduced risks of GDM and caesarean section with combined diet and exercise interventions during pregnancy as well as reductions in gestational weight gain, compared with standard care. There were no clear differences in hypertensive disorders of pregnancy, perinatal mortality, large-for-gestational age, perineal trauma, neonatal hypoglycaemia, and childhood adiposity (*moderate- to very low-quality evidence*).

Using GRADE methodology, the evidence was assessed as *moderate to very low quality*. Downgrading decisions were predominantly due to design limitations (risk of bias), and imprecision (uncertain effect estimates, and at times, small sample sizes and low event rates), however two outcomes (pregnancy-induced hypertension/hypertension and neonatal hypoglycaemia), were also downgraded for unexplained inconsistency (statistical heterogeneity).

Due to the variability of the diet and exercise components tested in the included studies, the evidence in this review has limited ability to inform practice. Future studies could describe the interventions used in more detail, if and how these influenced behaviour change and ideally be standardised between studies. Studies could also consider using existing core outcome sets to facilitate more standardised reporting.

PLAIN LANGUAGE SUMMARY

Combined diet and exercise in pregnancy for preventing gestational diabetes mellitus

Review question

What are the effects of combined diet and exercise for preventing gestational diabetes mellitus (GDM), and related health problems for mothers and their babies? This is an update of a Cochrane review that was first published in 2015.

Background

GDM is high blood sugar (hyperglycaemia) during pregnancy. Up to a quarter of pregnant women develop GDM, with some at a higher risk than others (such as overweight or obese women, older women, and those of particular ethnicities). GDM can lead to significant health problems for women and their babies. In the short term, women with GDM may develop pre-eclampsia (high blood pressure (hypertension) and protein in the urine), or give birth by caesarean section. Their babies may grow large for their gestational age, and, as a result, be injured at birth, and/or cause injury to their mothers during birth. Babies of mothers with GDM often have low blood glucose (hypoglycaemia) and are overweight. Later in life, health problems such as neurosensory disabilities and type 2 diabetes can develop in these babies. Eating well and exercising is known to prevent type 2 diabetes and may be effective for preventing GDM.

Study characteristics

We searched for evidence in November 2016 and included 23 randomised controlled trials (RCTs) (involving 8918 women and their 8709 babies). Most studies were undertaken in high-income countries. All of the studies compared women receiving diet and exercise programs with women receiving standard care without diet and exercise programs. The studies varied in the diet and exercise programs evaluated and health outcomes reported. None reported receiving funding from a drug manufacturer or agency with interests in the results.

Combined diet and exercise interventions for preventing gestational diabetes mellitus (Review)

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Key results

Findings from 19 studies (6633 women) showed a possible reduction in GDM in women who received diet and exercise programs compared with women who received standard care. Fourteen studies (6089 women) showed a possible reduction in caesarean birth (14 studies; 6089 women) and 16 studies (5052 women) showed lower weight gain during pregnancy in women who received exercise programs. We found no differences between groups in other health problems for: pre-eclampsia (8 studies; 5366 women); high blood pressure (6 studies; 3073 women); a large for age baby at birth (11 studies; 5353 babies); and perineal trauma (2 studies; 2733 women). Death of babies around birth (2 studies; 3757 babies), the baby having low blood glucose after birth (2 studies; 3653 babies), and infants being overweight (2 studies; 794 infants) did not differ in the two groups. Effects on depression or type 2 diabetes for mothers, a combined outcome of death or ill-health for babies, or type 2 diabetes or neurosensory disability for babies as children were not reported. Participant views of programs were examined.

The evidence suggests combined diet and exercise programs may be effective for preventing GDM though the optimum components of these programs are not yet clear. Future studies could describe the interventions used in more detail, if and how these influenced behaviour change and ideally be standardised between studies. Studies could also consider measuring similar maternal and infant outcomes and report them in a standardised way.

Quality of the evidence

The overall risk of bias was judged unclear due to lack of information on methods. We assessed evidence quality using GRADE considerations for selected key outcomes. Our assessments ranged from moderate to very low.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Combined diet and exercise interventions versus standard care (mother)

Combined diet and exercise interventions for preventing GDM

Population: pregnant women, excluding women already diagnosed with GDM, type 1 or type 2 diabetes

Setting: Australia (2 RCTs), Brazil (1 RCT), Canada (2 RCTs), China (2 RCTs), Denmark (1 RCT), Egypt (1 RCT), Finland (3 RCTs), Germany (1 RCT), Italy (2 RCTs), Norway (1 RCT), UK (2 RCTs), USA (5 RCTs)

Intervention: combined diet and exercise interventions

Comparison: standard care

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (RCTs)	Quality of the evidence (GRADE)	Comments
	Risk with control	Risk with diet and exercise interventions				
GDM	Trial population		average RR 0.85	6633	⊕⊕⊕⊖	
	168 per 1000	143 per 1000 (119 to 170)	(0.71 to 1.01)	(19 RCTs)	MODERATE ^{1,3}	
Hypertensive disorders of pregnancy (pre-eclampsia)	Trial population		RR 0.98	5366	⊕⊕⊖⊖	Eclampsia was not reported by any trials (Sagedal 2017 reports combined severe pre-eclampsia, HELLP and eclampsia)
	57 per 1000	55 per 1000 (45 to 69)	(0.79 to 1.22)	(8 RCTs)	LOW ^{2,4}	
Hypertensive disorders of pregnancy (pregnancy-induced hypertension/hypertension)	Trial population		average RR 0.78	3073	⊕⊖⊖⊖	
	103 per 1000	80 per 1000 (48 to 130)	(0.47 to 1.27)	(6 RCTs)	VERY LOW ^{2,5,6}	
Caesarean section	Trial population		RR 0.95	6089	⊕⊕⊕⊖	
	299 per 1000	284 per 1000 (263 to 305)	(0.88 to 1.02)	(14 RCTs)	MODERATE ⁷	
Perineal trauma	Trial population		RR 1.27	2733	⊕⊕⊕⊖	

	21 per 1000 27 per 1000 (17 to 44)	(0.78 to 2.05)	(2 RCTs)	MODERATE ²
Gestational weight gain (kg)	Trial population The mean gestational weight gain in the intervention group was 0.89 kg less (1.39 kg less to 0.40 kg less)	MD - 0.89 (-1.39 to -0.40)	5052 (16 RCTs)	⊕⊕⊕⊖ MODERATE ^{8,9}
Postnatal depression		Not estimable	(0 RCTs)	No data reported for postnatal depression in any of the included RCTs
Type 2 diabetes mellitus		Not estimable	(0 RCTs)	No data reported for type 2 diabetes mellitus in any of the included RCTs

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI)

CI: confidence interval; **GDM:** gestational diabetes mellitus; **HELLP:** Haemolysis, Elevated Liver enzymes and Low Platelet count; **kg:** kilograms; **MD:** mean difference; **RCT:** randomised controlled trial; **RR:** risk ratio; **UK:** United Kingdom; **USA:** United States of America

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹Trial limitations (-1): 19 RCTs, intervention unable to be blinded (not downgraded for this as outcome is objective); some RCTs with potentially serious design limitations (unclear randomisation, attrition bias)

²Imprecision (-1): confidence interval crossing the line of no effect

³Inconsistency (0): $I^2 = 42\%$, possibly largely due to one trial (Dodd 2014), not downgraded))

⁴Trial limitations (-1): 8 RCTs, intervention unable to be blinded (not downgraded for this as outcome is objective); some RCTs with potentially serious design limitations (unclear randomisation, attrition bias)

⁵Trial limitations (-1): 6 RCTs, intervention unable to be blinded (not downgraded for this as outcome is objective); some RCTs with potentially serious design limitations (unclear randomisation, attrition bias)

⁶Inconsistency (-1): $I^2 = 62\%$

⁷Trial limitations (-1): 14 RCTs, intervention unable to be blinded (not downgraded for this as outcome is objective); some RCTs with potentially serious design limitations (unclear randomisation, attrition bias)

⁸Trial limitations (-1): 16 RCTs, intervention unable to be blinded (not downgraded for this as outcome is objective); some RCTs with potentially serious design limitations

⁹Inconsistency (0): $I^2 = 43\%$ (not downgraded)

Summary of findings 2. Combined diet and exercise interventions versus standard care (child)

Combined diet and exercise interventions for preventing GDM

Population: pregnant women, excluding women already diagnosed with GDM, type 1 or type 2 diabetes

Setting: Australia (2 RCTs), Brazil (1 RCT), Canada (2 RCTs), China (2 RCTs), Denmark (1 RCT), Egypt (1 RCT), Finland (3 RCTs), Germany (1 RCT), Italy (2 RCTs), Norway (1 RCT), UK (2 RCTs), USA (5 RCTs)

Intervention: combined diet and exercise interventions

Comparison: standard care

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (RCTs)	Quality of the evidence (GRADE)	Comments
	Risk with control	Risk with diet and exercise interventions				
Perinatal mortality	Trial population		RR 0.82	3757	⊕⊕⊕⊖	LOW ¹
	10 per 1000	8 per 1000 (4 to 16)	(0.42 to 1.63)	(2 RCTs)		
Large-for-gestational age	Trial population		RR 0.93	5353	⊕⊕⊕⊖	LOW ^{2,3}
	135 per 1000	126 per 1000 (109 to 144)	(0.81 to 1.07)	(11 RCTs)		
Mortality or morbidity composite			Not estimable	(0 RCTs)		No data reported for mortality or morbidity composite in any of the included RCTs
Neonatal hypoglycaemia	Trial population		average RR 1.42	3653	⊕⊕⊕⊖	LOW ^{3,4}
	63 per 1000	90 per 1000 (42 to 189)	(0.67 to 2.98)	(2 RCTs)		
Childhood adiposity (latest time reported) (BMI z score)	Trial population		MD 0.05	794	⊕⊕⊕⊖	LOW ^{3,5,6} Additional meta-analyses presented in review for: abdominal circumference, subscapular skinfold thickness, triceps skinfold thickness and total body fat
	The mean BMI z score in the intervention group was 0.05 higher (0.29 lower to 0.40 higher)		(-0.29 to 0.40)	(2 RCTs)		

Type 2 diabetes mellitus		Not estimable	(0 RCTs)	No data reported for type 2 diabetes mellitus in any of the included RCTs
Neurosensory disability		Not estimable	(0 RCTs)	No data reported for neurosensory disability in any of the included RCTs

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **GDM:** gestational diabetes mellitus; **MD:** mean difference; **RCT:** randomised controlled trial; **RR:** risk ratio; **UK:** United Kingdom; **USA:** United States of America

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹Imprecision (-2): confidence interval crossing the line of no effect and few events

²Trial limitations (-1): 12 RCTs, some with potentially serious or very serious design limitations (> 62% of weight from 1 RCT at low risk of bias overall)

³Imprecision (-1): confidence interval crossing the line of no effect

⁴Inconsistency (-1): $I^2 = 77\%$

⁵Trial limitations (-1): 2 RCTs with potentially serious or very serious design limitations (particularly in relation to attrition bias for long-term follow-up)

⁶Inconsistency (0): $I^2 = 59\%$ (not downgraded)

BACKGROUND

Description of the condition

Introduction and definition

Gestational diabetes mellitus (GDM) 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 potential risk factors for GDM; these include increasing maternal body mass index (BMI), physical inactivity (Chasan-Taber 2008), advancing maternal age (Morisset 2010), increasing parity, and certain ethnicities. Diets low in fibre, with a high glycaemic load have been shown to increase the risk of GDM (Zhang 2006). Women who have had a previous macrosomic baby (birthweight 4000 g or more), have had previous GDM (Petty 2010), have a family history or first-degree relative with diabetes, or have polycystic ovarian syndrome (Reece 2010) are also at an increased risk of GDM. High 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 2 diabetes mellitus and maternal obesity (Bottalico 2007; Dabelea 2005). Depending on the population sampled, screening procedures and diagnostic criteria used, reported prevalences range up to 28% (Jiwani 2012). Screening procedures vary internationally, with inconsistencies between and within countries, ranging from universal or routine screening, to testing on a case-by-case basis (i.e. risk factor screening), according to clinician or patient decisions (Buckley 2012). Diagnostic criteria similarly vary worldwide.

The Hyperglycaemia and Adverse Pregnancy Outcome (HAPO) study was designed to clarify risks of adverse outcomes associated with degrees of maternal glucose intolerance (Coutan 2010). Given the lack of consistency internationally in regards to diagnostic criteria for GDM, 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 - with revised (lower) cut-off values of thresholds representing an odds ratio for adverse pregnancy outcomes of 1.75 for women with GDM, compared with women without GDM (IADPSG Consensus Panel 2010). These criteria diagnose GDM if any of the following three 75 g oral glucose tolerance test (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). While studies have generally revealed a higher GDM prevalence when using the IADPSG compared with other criteria, some (Duran 2014; Hung 2015), but not all (Gerome 2017), have found an improvement in pregnancy outcomes with their use. Debate and controversy surrounding the risks, costs and benefits of use of these diagnostic criteria is ongoing (Farrar 2016; Langer 2013).

Health consequences of GDM

GDM is associated with an increased occurrence of a number of complications during pregnancy including pre-eclampsia, and the requirement for induction of labour or caesarean section (Reece 2010). Fetal consequences may include macrosomia, which in turn may be associated with adverse maternal outcomes such as uterine rupture, and perineal trauma (Reece 2010). Women who develop GDM have a significantly increased risk of developing type 2 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 (Reece 2009; Reece 2010). Large-for-gestational-age infants are at increased risk of birth injury, including shoulder dystocia, bone fractures and nerve palsies (Henriksen 2008; Reece 2010). These infants are at increased risk of developing type 2 diabetes, hypertension, obesity and metabolic syndrome later in life (Reece 2010; Whincup 2008). In addition, babies born to mothers with GDM are at increased risk of neonatal hypoglycaemia, respiratory distress syndrome, polycythaemia (raised red blood cell count), hyperbilirubinaemia, and being born preterm (Reece 2009; Reece 2010). Such health consequences together contribute to a need for enhanced neonatal care.

In randomised controlled trials, the treatment of women with 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 (Crowther 2005; Landon 2009). The importance of management for women with GDM is now widely accepted (Alwan 2009; Crowther 2005; Landon 2009) and is the subject of several Cochrane reviews, assessing different aspects of management, including lifestyle interventions (Brown 2017a), insulin (Brown 2016a), oral anti-diabetic therapies (Brown 2017b), exercise (Ceysens 2016), dietary supplementation with myo-inositol (Brown 2016b), and different intensities of glycaemic control (Martis 2016).

Description of the intervention

Dietary interventions

The aim of dietary advice or related interventions in pregnancy is to optimise health outcomes, which might include controlling excessive gestational weight gain or glycaemic control. While

observational evidence indicates a relationship between GDM and high consumption of processed meats, snacks and fast foods and low consumption of vegetables before or during pregnancy (Lamyian 2017; Schoenaker 2015), evidence from intervention studies about the influence of diet on preventing GDM is sparse.

Exercise interventions

Benefits of exercise during pregnancy are now recognised, and thus women are generally encouraged to engage in 'moderate' exercise in the absence of any known pregnancy or medical complications (ACOG 2015; NICE 2017). 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 2 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 2 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 diet and exercise interventions alone and separately for the prevention of type 2 diabetes and GDM have been widely assessed, more recently there has been a shift towards combining such interventions in what may be regarded as 'lifestyle' interventions.

Several randomised controlled trials have established that the progression to type 2 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 2 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 2 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 2 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 2012; Tieu 2017). The review '*Dietary advice in pregnancy for preventing gestational diabetes mellitus*' (Tieu 2017) included 11 trials, and concluded that while very low-quality evidence suggests a possible reduction in GDM risk for women receiving dietary advice versus standard care, further high-quality evidence is needed to determine the effects of dietary advice interventions in pregnancy (Tieu 2017). The review '*Exercise for pregnant women for preventing gestational diabetes mellitus*' (Han 2012), included five trials, and concluded that there was no clear evidence to support a reduction in GDM risk for women receiving an exercise intervention versus standard care, and highlighted a need for further high-quality evidence (Han 2012).

As it is widely acknowledged that many factors are associated with GDM risk, it is considered plausible that lifestyle interventions, aimed at addressing lifestyle-related risk factors, may be effective in preventing GDM. Such lifestyle interventions may combine diet interventions 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 2017) and '*Exercise for pregnant women for preventing gestational diabetes mellitus*' (Han 2012), and will assess combined diet and exercise interventions for preventing GDM. This is an update of the review which was first published in 2015 (Bain 2015).

OBJECTIVES

To assess the effects of diet interventions in combination with 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 gestational diabetes mellitus (GDM). We included cluster-randomised trials, and trials published as abstracts only. We excluded quasi-randomised controlled trials. Cross-over trials were not eligible for inclusion.

Types of participants

We included trials of pregnant women regardless of age, gestation, parity or plurality. We excluded trials involving women with pre-existing GDM, type 1 or type 2 diabetes.

Types of interventions

We included interventions that incorporated any type of diet intervention with any type of exercise intervention. We included trials where such interventions were compared with no intervention (i.e. standard care), and planned to include where they were compared with a different diet and exercise intervention.

Types of outcome measures

For this update, we used the standard outcomes agreed by consensus between review authors of Cochrane Pregnancy and Childbirth systematic reviews for prevention and treatment of GDM and pre-existing diabetes.

Primary outcomes

Mother

- GDM (diagnostic criteria as defined in individual trials)
- Hypertensive disorders of pregnancy (e.g. pre-eclampsia, pregnancy-induced hypertension, eclampsia)
- Caesarean section

Child

- Perinatal mortality (stillbirth or neonatal mortality)
- Large-for-gestational age
- Mortality or morbidity composite (e.g. death, shoulder dystocia, bone fracture or nerve palsy)

Secondary outcomes

Mother

Perinatal outcomes

- Operative vaginal birth
- Induction of labour
- Perineal trauma
- Placental abruption
- Postpartum haemorrhage
- Postpartum infection
- Gestational weight gain
- Adherence to the intervention
- Behaviour changes associated with the intervention
- Relevant biomarker changes associated with the intervention

- Sense of well-being and quality of life
- Views of intervention
- Breastfeeding (e.g. at discharge, six weeks postpartum)

Long-term maternal outcomes

- Postnatal depression
- Postnatal weight retention or return to pre-pregnancy weight
- Body mass index (BMI)
- GDM in subsequent pregnancy
- Type 1 diabetes mellitus
- Type 2 diabetes mellitus
- Impaired glucose tolerance
- Cardiovascular health (e.g. blood pressure, hypertension, cardiovascular disease, metabolic syndrome)

Child

Fetal/neonatal outcomes

- Stillbirth
- Neonatal mortality
- Gestational age at birth
- Preterm birth (before 37 weeks gestation; before 34 weeks gestation)
- Apgar score less than seven at five minutes
- Macrosomia
- Small-for-gestational age
- Birthweight and z score
- Head circumference and z score
- Length and z score
- Ponderal index
- Adiposity (e.g. as measured by BMI, skinfold thickness)
- Shoulder dystocia
- Nerve palsy
- Bone fracture
- Respiratory distress syndrome
- Hypoglycaemia
- Hyperbilirubinaemia

Childhood/adulthood outcomes

- Weight and z scores
- Height and z scores
- Head circumference and z scores
- Adiposity (e.g. as measured by BMI, skinfold thickness)
- Cardiovascular health (e.g. blood pressure, hypertension, cardiovascular disease, metabolic syndrome)
- Employment, education and social status/achievement
- Type 1 diabetes mellitus
- Type 2 diabetes mellitus
- Impaired glucose tolerance
- Neurosensory disability

Health services

- Number of hospital or health professional visits (e.g. midwife, obstetrician, physician, dietitian, diabetic nurse)
- Number of antenatal visits or admissions

- Length of antenatal stay
- Neonatal intensive care unit admission
- Length of postnatal stay (mother)
- Length of postnatal stay (baby)
- Costs to families associated with the management provided
- Costs associated with the intervention
- Cost of maternal care
- Cost of infant care

To be included, trials had to report on our primary outcome, GDM. Trials that appeared to meet other criteria for inclusion in this review that did not report on GDM have been included as 'Awaiting classification' (pending the availability/reporting of GDM outcome data), and will be re-considered in future updates of this review.

Search methods for identification of studies

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

Electronic searches

We searched Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (27 November 2016).

The Register is a database containing over 22,000 reports of controlled trials in the field of pregnancy and childbirth. For full search methods used to populate Pregnancy and Childbirth's Trials Register including the detailed 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, please follow this link to the editorial information about the [Cochrane Pregnancy and Childbirth](#) in the Cochrane Library and select the '**Specialized Register**' section from the options on the left side of the screen.

Briefly, Cochrane Pregnancy and Childbirth's Trials Register is maintained by their Information Specialist 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.
7. scoping searches of [ClinicalTrials.gov](#) and the WHO International Clinical Trials Registry Platform (ICTRP).

Search results are screened by two people and the full text of all relevant trial reports identified through the searching activities described above is reviewed. Based on the intervention described, each trial report is assigned a number that corresponds to a specific Pregnancy and Childbirth review topic (or topics), and is then added to the Register. The Information Specialist searches the Register for each review using this topic number rather than keywords. This results in a more specific search set which has been fully accounted for in the relevant review sections ([Included](#)

[studies](#); [Excluded studies](#); [Studies awaiting classification](#); [Ongoing studies](#)).

Searching other resources

We searched the reference lists of retrieved trials.

We did not apply any language or date restrictions.

Data collection and analysis

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

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 trials, two review authors extracted the data using the agreed form. We resolved discrepancies through discussion or, if required, we consulted a 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 trial 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 trial 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 trial 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 trial the methods used, if any, to blind trial participants and personnel from knowledge of which intervention a participant received. We considered trials 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 trial 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 trial, 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 trial 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 trial's pre-specified outcomes and all expected outcomes of interest to the review were reported);

- high risk of bias (where not all the trial'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; trial 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 trial any important concerns we had about other possible sources of bias.

We assessed whether each trial 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 trials 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](#).

Assessment of the quality of the evidence using the GRADE approach

For this update, we evaluated the quality of the evidence for the below outcomes using the GRADE approach as outlined in the [GRADE handbook](#). The GRADE approach uses five considerations (trial limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for specific outcomes. The evidence can be downgraded from 'high quality' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, inconsistency, imprecision of effect estimates or publication bias.

Mother

Perinatal outcomes

- GDM
- Hypertensive disorders of pregnancy (e.g. pre-eclampsia, pregnancy-induced hypertension, eclampsia)
- Caesarean section
- Perineal trauma
- Gestational weight gain

Long-term maternal outcomes

- Postnatal depression
- Type 2 diabetes mellitus

Child

Fetal/neonatal outcomes

- Perinatal mortality (stillbirth or neonatal mortality)
- Large-for-gestational age
- Mortality or morbidity composite (e.g. death, shoulder dystocia, bone fracture or nerve palsy)
- Hypoglycaemia

Childhood/adulthood outcomes

- Adiposity (e.g. as measured by BMI, skinfold thickness)
- Type 2 diabetes mellitus
- Neurosensory disability

'Summary of findings' table

We used [GRADEpro](#) Guideline Development Tool to import data from Review Manager 5.3 ([RevMan 2014](#)) in order to create 'Summary of findings' tables for maternal and child outcomes. Summaries of the intervention effect and measures of quality according to the GRADE approach are presented in the 'Summary of findings' tables.

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. In future updates, we plan to use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster-randomised trials

We included 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) of 0.12 derived from an included trial ([Luoto 2011](#)). 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 trial 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 trials

In future updates of this review, if we include multi-arm trials, we plan 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 trials, we noted levels of attrition. In future updates, we plan to explore the impact of including trials with high levels of missing data in the overall assessment of treatment effect by using sensitivity analyses.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we 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 trials in a meta-analysis, we investigated reporting biases (such as publication bias) using funnel plots. We assessed funnel plot asymmetry visually. In future updates of this review, if asymmetry is suggested by a visual assessment, we plan to perform exploratory analyses to investigate it.

Data synthesis

We carried out statistical analysis using Review Manager software ([RevMan 2014](#)). We used fixed-effect meta-analysis for combining data where it was reasonable to assume that trials 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 Tau^2 and I^2 .

Subgroup analysis and investigation of heterogeneity

Had we 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 diet and exercise interventions assessed were considered likely to affect 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 less than 18.5 kg/m² versus BMI of 18.5 to 24.9 kg/m² versus BMI of 25 to 29.9 kg/m² versus BMI of 30 kg/m² to 39.9 kg/m² and versus BMI of 40 kg/m² or more).
- Ethnicity (ethnic groups at high risk for GDM versus ethnic groups for lower risk of 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 versus 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 nature of the exercise/dietary interventions due to the paucity of information/data on these characteristics and the inability to meaningfully group intervention characteristics.

Formation of subgroups for maternal BMI and ethnicity was restricted by reporting in the included trials. Our analyses based

on maternal BMI thus included the following subgroups: BMI less than 25 kg/m² versus BMI of 25 kg/m² or more versus BMI of 30 kg/m² or more versus any BMI; our analyses based on ethnicity included the following subgroups: majority 'low risk' ethnicities versus majority 'high risk' ethnicities versus mixed ethnicities versus unclear ethnicities.

We also performed a subgroup analysis on unit of randomisation - cluster-randomised versus individually-randomised trials.

We used only 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 Chi² statistic and P value, and the interaction test I² value.

Sensitivity analysis

We carried out sensitivity analyses to explore the effects of trial quality assessed by sequence generation and allocation concealment, by omitting trials 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

In the previous version of the review we identified 79 records relating to 41 studies. We included 13 trials, excluded 11, 16 were ongoing, and one was awaiting further classification. See [Figure 1](#).

Figure 1. Study flow diagram for previous version of the review (Bain 2015)

Updated searches of the Cochrane Pregnancy and Childbirth's Trials Register in February 2015 (28 records) and November 2016 (72 records) identified 100 new records; and additional searching identified 23 records. Therefore we assessed 123 new records.

We included 10 new trials (Bruno 2016; Hawkins 2014; Herring 2016; Hoirisch-Clapauch 2016; Hui 2014; Jing 2015; Koivusalo 2016; Poston 2015; Sagedal 2017; Wang 2015), excluded nine studies (Barakat 2006; Bo 2014; Crowther 2012; McGowan 2013; Parat

2015; Peacock 2014; Simmons 2015; Sun 2016; Youngwanichsetha 2014), identified eight ongoing studies (Chasan-Taber 2015; Clements 2016; Farajzadegan 2013; Garmendia 2015; Kennelly 2016; Rauh 2014; Spieker 2015; Vesco 2012), and eight await further classification (Asci 2016; Kieffer 2014; Kim 2015; Marcinkevage 2013; Mujsindi 2014; Santos-Rocha 2015; Skouteris 2016; Torres 2016). We also identified additional records relating to nine of the trials included in the previous version of this review. See Figure 2.

Figure 2. Update study flow diagram.

Figure 2. (Continued)

Where required, we also re-classified some of the studies/records which were listed as excluded, ongoing or awaiting classification in the previous version of the review.

Overall, therefore, we have included 23 trials (Asbee 2009; Bruno 2016; Dodd 2014; El Beltagy 2013; Harrison 2013; Hawkins 2014; Herring 2016; Hoirisch-Clapauch 2016; Hui 2012; Hui 2014; Jing 2015; Koivusalo 2016; Korpi-Hyovalti 2011; Luoto 2011; Petrella 2013; Phelan 2011; Polley 2002; Poston 2013; Poston 2015; Rauh 2013; Sagedal 2017; Vinter 2011; Wang 2015), excluded 15 studies (Barakat 2006; Bo 2014; Clapp 1997; Crowther 2012; Luoto 2010; McGowan 2013; Nascimento 2012; NCT00924599; Parat 2015; Peacock 2014; Quinlivan 2011; Ruchat 2012; Simmons 2015; Sun 2016; Youngwanichsetha 2014), 14 are ongoing (Chasan-Taber 2015; Clements 2016; Farajzadegan 2013; Garmendia 2015; Jelsma 2013; Kennelly 2016; Nagle 2013; NCT01643356; NCT01693510; NCT01719406; NCT01782105; Rauh 2014; Spieker 2015; Vesco 2012), and 10 await further classification, pending the availability of data on GDM (Althuisen 2013; Asci 2016; Kieffer 2014; Kim 2015; Marcinkavage 2013; Mujsindi 2014; Santos-Rocha 2015; Skouteris 2016; Torres 2016; Wilkinson 2012).

Included studies

Following application of eligibility criteria 23 randomised controlled trials were included in this review (Asbee 2009; Bruno 2016; Dodd 2014; El Beltagy 2013; Harrison 2013; Hawkins 2014; Herring 2016; Hoirisch-Clapauch 2016; Hui 2012; Hui 2014; Jing 2015; Koivusalo 2016; Korpi-Hyovalti 2011; Luoto 2011; Petrella 2013; Phelan 2011; Polley 2002; Poston 2013; Poston 2015; Rauh 2013; Sagedal 2017; Vinter 2011; Wang 2015). Two trials (Luoto 2011; Rauh 2013) were cluster-randomised and the other 21 were individually-randomised.

A total of 8918 women and 8709 infants were involved in the included trials. Dodd 2014 was the largest trial, randomising 2212 women, followed by Poston 2015, randomising 1280 women. Korpi-Hyovalti 2011, Petrella 2013, Herring 2016 and Hawkins 2014 were the smallest trials randomising 60, 63, 66 and 68 women, respectively. For the majority of included trials, fewer women were included in the analyses than were randomised, with a maximum of 6633 women and 5763 infants included in review meta-analyses.

Settings

The majority of the trials were conducted in upper-middle and high-income countries. Five trials were conducted in the USA (Asbee 2009; Hawkins 2014; Herring 2016; Phelan 2011; Polley 2002); three in Finland (Koivusalo 2016; Korpi-Hyovalti 2011; Luoto 2011); two in Australia (Dodd 2014; Harrison 2013); two in the UK (Poston 2013; Poston 2015); two in Canada (Hui 2012; Hui 2014); two in Italy (Bruno 2016; Petrella 2013); two in China (Jing 2015; Wang 2015); and one each in Brazil (Hoirisch-Clapauch 2016); Denmark (Vinter

2011); Egypt (El Beltagy 2013); Germany (Rauh 2013); and Norway (Sagedal 2017).

Participants

All participants were pregnant women. Where reported, the mean (standard deviation (SD)) ages of women ranged from 25.5 (4.8) years in Polley 2002 to 32.3 (4.9) (diet and exercise intervention) and 32.6 (4.5) (standard care) years in Koivusalo 2016. In eight of the trials (Bruno 2016; Harrison 2013; Koivusalo 2016; Petrella 2013; Poston 2013; Poston 2015; Rauh 2013; Wang 2015), the mean ages of women in both the diet and exercise intervention and standard care groups were at least 30 years. Maternal age across the trials is further summarised in Table 1.

In regards to body mass index (BMI), 13 of the trials (Asbee 2009; Hoirisch-Clapauch 2016; Hui 2012; Hui 2014; Jing 2015; Koivusalo 2016; Korpi-Hyovalti 2011; Luoto 2011; Phelan 2011; Polley 2002; Rauh 2013; Sagedal 2017; Wang 2015) generally included all women regardless of their BMI, though some had restrictions: four had a specific lower acceptable BMI (ranging from 18 kg/m² to 19.8 kg/m²) (Phelan 2011; Polley 2002; Rauh 2013; Sagedal 2017); and three had a specific upper acceptable BMI (of 25 kg/m²) (Wang 2015), (or 40 kg/m²) (Asbee 2009; Phelan 2011). The remaining 10 trials only included women who were overweight or obese (six trials: Bruno 2016; Dodd 2014; Harrison 2013; Hawkins 2014; Herring 2016; Petrella 2013); or obese (four trials: El Beltagy 2013; Poston 2013; Poston 2015; Vinter 2011). The BMI eligibility criteria are reflected in the mean (SD) or median (interquartile range (IQR)) BMI of women pre-pregnancy or at baseline, which was reported in all except for two trials (El Beltagy 2013; Hoirisch-Clapauch 2016), and is summarised in Table 2.

Considering ethnicity, three trials included women predominately of ethnicities regarded to be at high risk for GDM (Asbee 2009: more than 75% of women were Hispanic or African American; Hawkins 2014: all women were Hispanic; Herring 2016: all women were African American), while five trials included women predominately of ethnicities at lower risk of GDM (Bruno 2016: more than 80% of women were Caucasian; Dodd 2014: more than 90% of women were Caucasian; Petrella 2013: more than 75% were Caucasian; Phelan 2011: more than 68% of women were non-Hispanic white; Vinter 2011: all women were Caucasian). In seven trials ethnicity was considered 'mixed' or there was insufficient information to confidently determine ethnicity (Harrison 2013 reported only on country of birth (Australia, Southeast Asia, Southern/Central Asia, other); Hui 2012 and Hui 2014 reported only that approximately 20% of women were First Nations (Canadian Aboriginal people with First Nations status); Polley 2002, Poston 2013 and Poston 2015 only reported on the proportion of women who were 'Black' or 'White' (or 'Asian', or 'Other'); and Rauh 2013 only reported that over 80% of women were born in Germany). In eight trials, no baseline information related to the ethnicity/race/country of birth of women was reported (El Beltagy 2013; Hoirisch-Clapauch 2016; Jing 2015;

Koivusalo 2016; Korpi-Hyovalti 2011; Luoto 2011; Sagedal 2017; Wang 2015). Information related to ethnicity is further summarised in Table 3.

Only one trial (Sagedal 2017) reported eligibility criteria relating to parity - including only nulliparous women. Both nulliparous and multiparous women were included in the remaining trials (Asbee 2009; Bruno 2016; Dodd 2014; Harrison 2013; Hawkins 2014; Herring 2016; Koivusalo 2016; Korpi-Hyovalti 2011; Luoto 2011; Petrella 2013; Phelan 2011; Polley 2002; Poston 2013; Poston 2015; Rauh 2013; Vinter 2011), though six trials did not report clearly report baseline information related to parity (El Beltagy 2013; Hoirisch-Clapauch 2016; Hui 2012; Hui 2014; Jing 2015; Wang 2015). Detailed information relating to parity is reported in Table 4.

Interventions

Each of the 23 included trials assessed an intervention that included both diet and exercise components compared with standard/routine antenatal care and reported on GDM. However, the primary focus of many of the included trials was on limiting gestational weight gain. The interventions assessed varied greatly, as can be seen below.

- **Asbee 2009:** an intensive-lifestyle intervention consisting of an initial standardised counselling session delivered one-on-one in person by a dietitian in which women were provided with dietary advice, instructed to engage in moderate-intensity exercise at least three times a week and educated about the Institute of Medicine (IOM) guidelines for gestational weight gain, supported by personalised monitoring and feedback at follow-up at routine visits.
- **Bruno 2016:** diet and exercise counselling provided in one one-on-one session by a dietitian at baseline (a hypocaloric, low-glycaemic, low-saturated fat diet and 30 minutes of moderate-intensity exercise at least three times a week were recommended) with monitoring of progress on lifestyle changes and further individually-tailored lifestyle advice by the dietitian and gynaecologist at routine antenatal appointments (16th, 20th, 25th and 36th weeks of pregnancy).
- **Dodd 2014:** a comprehensive individually-tailored lifestyle intervention that included a combination of diet and exercise advice and behavioural change strategies, delivered by a research dietitian and trained research assistants in three one-on-one face-to-face sessions (at entry, 28 and 36 weeks), and three phone sessions (at 22, 24 and 32 weeks).
- **El Beltagy 2013:** a 12-week mild exercise and diet control program (no further details provided in the conference abstract of this trial).
- **Harrison 2013:** a personalised intervention delivered by a health coach (exercise physiologist) in four one-on-one sessions scheduled at the same time as routine visits (in which women were provided with individually-tailored advice about diet and encouraged to increase exercise frequency) plus strategies to support behaviour change including self-monitoring (pedometers provided).
- **Hawkins 2014:** an intensive, personalised intervention tailored for Hispanic women consisting of six one-on-one face-to-face counselling sessions (individually-tailored advice about diet provided and women advised to undertake at least 30 minutes of moderate-intensity activity most days of the week to achieve the American College of Obstetricians and Gynecologists guidelines for gestational weight gain) and strategies to support adherence and behaviour change (including five telephone "booster" counselling sessions, pedometers and a exercise log books).
- **Herring 2016:** a technology-based intervention delivered via Facebook, telephone and text messaging and one one-to-one consultation (at baseline) tailored for African American women living in low-income settings consisting of diet and exercise advice (including the recommendation that women increase activity to walking 5000 steps daily), distribution of digital scales for weighing food at home, strategies to support adherence (pedometers and a DVD walking video), and ongoing support via telephone and other technology platforms.
- **Hoirisch-Clapauch 2016:** diet and exercise advice (women were instructed to walk briskly for at least 40 minutes seven days a week, to avoid high-carbohydrate index meals, e.g. such as snacks, candies, fibre-free juices or sugar-sweetened beverages, and to eat two daily servings of meat, poultry, fish or other protein-rich food, starting when they decided to get pregnant and continuing until birth).
- **Hui 2012 and Hui 2014:** an intensive lifestyle intervention consisting of mild to moderate exercise three to five times a week (group sessions in community centres or if not feasible, at home supported by a DVD) plus one-on-one diet counselling sessions (two, with a registered dietitian, providing individually-tailored diet advice) and self-monitoring of gestational weight gain goals.
- **Jing 2015:** a moderate-intensity intervention consisting of two one-on-one in person counselling sessions (with a trained graduate student) on a healthy diet and exercise regimen to follow during pregnancy, education about the benefits of a healthy lifestyle and harms of GDM (materials written by trial staff provided) as well as ongoing communication and support for behaviour change (provided through telephone or Tencent instant messenger).
- **Koivusalo 2016:** an intensive lifestyle-counselling intervention delivered via an initial two-hour group counselling session (at enrolment) followed by three one-to-one in person counselling sessions delivered by trained trial nurses and dietitians supplemented by various strategies to support adherence to the diet and exercise recommendations and weight gain goals including self-monitoring of behaviour (including via food diaries, activity log books and pedometers) and provision of free access to swimming pools and exercise classes of local municipalities.
- **Korpi-Hyovalti 2011:** an intensive lifestyle-counselling intervention that included six one-to-one sessions with a nurse in which women were provided with personalised diet advice to follow during their pregnancy, as well as six sessions with a physiotherapist (in which women were encouraged to exercise 30 minutes daily if they had previously exercised less than two and a half hours per week, and 45 minutes if they had already engaged in two and a half hours per week).
- **Luoto 2011:** an intensive lifestyle counselling delivered by nurses in five face-to-face, one-on-one counselling sessions (in session one gestational goals were set, women were provided with a notebook for monitoring and exercise recommendations were introduced, including participation in a monthly group exercise class, in the second session the healthy diet was introduced, sessions three reinforced the messages and focused on monitoring).

- [Petrella 2013](#): a Therapeutic Lifestyle Changes (TLC) program including a diet of 1700 kcal/day for overweight women and 1800 kcal/day for obese women and mild exercise (30 min/day, three times/week), introduced at randomisation by both a gynaecologist and a dietitian, and further detailed at a subsequent one-hour appointment, with pedometers to support adherence.
- [Phelan 2011](#): an intensive individually-tailored intervention consisting of one face-to-face visit during the first trimester delivered by a dietitian (focused on appropriate gestational weight gain, what constitutes a healthy diet during pregnancy, the benefits of walking 30 minutes walking most days of the week during pregnancy and the importance of daily self-monitoring of eating, exercise, and weight gain) followed by three phone calls from the dietitian to support adherence and provide further tailored advice (women who were over or under weight gain guidelines during any one month interval received additional phone calls that provided structured meal plans, and specific goals).
- [Polley 2002](#): a lifestyle intervention consisting of education about appropriate gestational weight gain (as per the IOM guidelines), personalised advice about diet and exercise, as well as weight monitoring, delivered at regularly scheduled clinic visits by masters and doctoral level staff with training in nutrition or clinical psychology and bi-weekly provision of written education materials/reminders.
- [Poston 2013](#) and [Poston 2015](#): a comprehensive intensive lifestyle change intervention that delivered via a one-to-one appointment with a "Health Trainer" (no specific health professional qualification, but experience in behaviour modification and conducting group sessions) and weekly group sessions for eight consecutive weeks from 19 weeks gestation (for women unable to attend, the session content was delivered by phone or email) which included diet advice (focus on substituting high- with low-GI foods), exercise advice (women encouraged to undertake frequent walking at moderate intensity) as well as goal setting for diet and exercise and strategies to support achieving them (e.g. self-monitoring through use of a pedometer and log-book and provision of a DVD of a specifically devised pregnancy exercise regimen).
- [Rauh 2013](#): the Feasibility of a Lifestyle Intervention in Pregnancy to Optimise maternal weight development (FeLIPO) intervention consisting of two one-to-one lifestyle-counselling sessions with trained researchers (in which women were educated about healthy gestational weight gain as per IOM guidelines, given diet and exercise advice to follow to achieve weight gain goals, including the recommendation of engaging in at least 30 minutes moderate-intensity exercise most days of the week, and were provided with a list of suitable local prenatal exercise programs to attend) plus strategies to support behaviour change (including self-monitoring through use of charts).
- [Sagedal 2017](#): the Norwegian Fit for Delivery (NFFD) intervention consisting of an intensive exercise program that included participation in group-based exercise classes (moderate-intensity exercise) twice a week and additional moderate-intensity exercise three days of the week, diet advice (delivered via telephone by experienced clinical dietitians or graduate students), education focused on the IOM guidelines for gestational weight gain and strategies to support adherence to the lifestyle recommendations (including written materials

reinforcing the recommendations, an invitation to one cooking class and one evening meeting).

- [Vinter 2011](#): intensive individually-tailored intervention (women in the intervention group received a free six-month gym membership and pedometer, were encouraged to attend exercise classes with a physiotherapist weekly and four to six group coaching sessions, plus individually-tailored diet counselling with trained dietitians on four occasions, at 15, 20, 28, and 35 weeks gestation).
- [Wang 2015](#): a standardised group-based lifestyle intervention that included three education sessions of 40 to 60 minutes on "a balanced diet" during pregnancy, the benefits of proper exercise (women were encouraged to walk at least 30 minutes walking after a meal at least once a day) and appropriate gestational weight gain (defined according to the IOM recommendations).

For additional details on the diet and exercise interventions (and controls) and how they varied across the trials see [Characteristics of included studies](#).

Outcomes

For the primary outcomes for the mother, data in a format suitable for meta-analysis were reported for GDM by 19 trials ([Bruno 2016](#); [Dodd 2014](#); [Harrison 2013](#); [Herring 2016](#); [Hui 2012](#); [Hui 2014](#); [Jing 2015](#); [Koivusalo 2016](#); [Korpi-Hyövalti 2011](#); [Luoto 2011](#); [Petrella 2013](#); [Phelan 2011](#); [Polley 2002](#); [Poston 2013](#); [Poston 2015](#); [Rauh 2013](#); [Sagedal 2017](#); [Vinter 2011](#); [Wang 2015](#)), pre-eclampsia by eight trials ([Dodd 2014](#); [Koivusalo 2016](#); [Luoto 2011](#); [Phelan 2011](#); [Polley 2002](#); [Poston 2015](#); [Sagedal 2017](#); [Vinter 2011](#)), hypertension by six trials ([Bruno 2016](#); [Dodd 2014](#); [Koivusalo 2016](#); [Petrella 2013](#); [Phelan 2011](#); [Polley 2002](#)), and caesarean section by 14 trials ([Asbee 2009](#); [Bruno 2016](#); [Dodd 2014](#); [Herring 2016](#); [Hui 2012](#); [Hui 2014](#); [Koivusalo 2016](#); [Petrella 2013](#); [Phelan 2011](#); [Polley 2002](#); [Poston 2015](#); [Rauh 2013](#); [Sagedal 2017](#); [Vinter 2011](#)). For the primary outcomes for the child, data were reported in a format suitable for meta-analysis by two trials for perinatal mortality ([Dodd 2014](#); [Poston 2015](#)) and 11 trials for large-for-gestational age ([Bruno 2016](#); [Dodd 2014](#); [Herring 2016](#); [Hui 2012](#); [Hui 2014](#); [Luoto 2011](#); [Poston 2013](#); [Poston 2015](#); [Rauh 2013](#); [Sagedal 2017](#); [Vinter 2011](#)); no trial reported on mortality or morbidity composite (e.g. death, shoulder dystocia, bone fracture or nerve palsy).

Some data were reported for all secondary outcomes for the mother in the perinatal period, with between one and 17 included trials reporting data suitable for meta-analyses or other data tables for these outcomes. However in regards to long-term outcomes for the mother, data were only available for postnatal weight retention or return to pre-pregnancy weight, BMI and cardiovascular health (blood pressure); no data were reported by the included trials for postnatal depression; GDM in a subsequent pregnancy; type 1 diabetes mellitus; type 2 diabetes mellitus or impaired glucose tolerance. Similarly, some data were reported for all secondary outcomes for the child in the fetal/neonatal period, with one, up to 13 included trials reporting data suitable for meta-analyses for these outcomes. However in regards to childhood/adulthood outcomes, data were only available for weight, height, head circumference, adiposity and cardiovascular health; no data were reported by the included trials for employment, education and social status/achievement; type 1 diabetes mellitus; type 2 diabetes mellitus; impaired glucose tolerance; or neurosensory disability. Secondary outcomes related to health services were generally

reported by only one to four included trials for included in meta-analyses; no trial reported data for the outcome number of hospital or health professional visits.

Funding

Funding sources were reported by 18 included trials (Asbee 2009; Bruno 2016; Dodd 2014; Harrison 2013; Hawkins 2014; Herring 2016; Hui 2012; Hui 2014; Koivusalo 2016; Korpi-Hyovalti 2011; Luoto 2011; Phelan 2011; Polley 2002; Poston 2013; Poston 2015; Rauh 2013; Sagedal 2017; Vinter 2011); funding bodies listed by the trials were all non-commercial organisations (e.g. government funding bodies, health services, and other not-for-profit foundations). Five trials did not describe sources of funding (if any) (El Beltagy 2013; Hoirsch-Clapauch 2016; Jing 2015; Petrella 2013; Wang 2015).

Declarations of interest

Sixteen of the trials (Asbee 2009; Bruno 2016; Dodd 2014; Harrison 2013; Hawkins 2014; Hui 2012; Hui 2014; Jing 2015; Koivusalo 2016; Korpi-Hyovalti 2011; Luoto 2011; Petrella 2013; Phelan 2011; Poston 2013; Rauh 2013; Vinter 2011) reported that there were no conflicts of interests for any of the authors. Four trials (El Beltagy 2013; Hoirsch-Clapauch 2016; Polley 2002; Wang 2015) did not report any information regarding declarations of interest. The remaining three trials (Herring 2016; Poston 2015; Sagedal 2017) reported information related to potential conflicts of interest

for the trial authors, primarily related to income received from pharmaceutical companies/other commercial organisations. For further detail of these reported declarations, see [Characteristics of included studies](#).

Excluded studies

We excluded 15 studies (Barakat 2006; Bo 2014; Clapp 1997; Crowther 2012; Luoto 2010; McGowan 2013; Nascimento 2012; NCT00924599; Parat 2015; Peacock 2014; Quinlivan 2011; Ruchat 2012; Simmons 2015; Sun 2016; Youngwanichsetha 2014). Seven trials assessed the effects of diet (Clapp 1997; McGowan 2013; Parat 2015; Quinlivan 2011) or exercise (Barakat 2006; Nascimento 2012; Ruchat 2012) interventions (not combined diet and exercise interventions), and one compared a diet and exercise intervention with a diet alone intervention and an exercise alone intervention (Simmons 2015). In five trials, the participants were women preconception (NCT00924599), or women with GDM (Bo 2014; Peacock 2014; Youngwanichsetha 2014) or borderline GDM (Crowther 2012). One trial was non-randomised (Luoto 2011) and one was quasi-randomised (Sun 2016).

Risk of bias in included studies

For a summary of the risk of bias across the included trials, see [Figure 3](#) and [Figure 4](#). Primarily due to lack of reporting, the overall risk of bias was judged to be unclear.

Figure 3. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included trials.

Figure 4. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included trial.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Asbee 2009	+	+	-	?	-	-	+
Bruno 2016	+	+	-	+	-	-	+
Dodd 2014	+	+	-	+	+	+	+
El Beltagy 2013	?	?	-	?	?	?	?
Harrison 2013	+	+	-	+	+	?	+
Hawkins 2014	?	?	-	+	+	-	+
Herring 2016	+	+	-	?	?	?	+
Hoirisch-Clapauch 2016	?	?	-	?	-	?	?
Hui 2012	+	+	-	?	?	?	+
Hui 2014	+	+	-	+	+	?	+
Jing 2015	+	?	-	?	?	?	+
Koivusalo 2016	?	+	-	+	+	?	+
Korpi-Hyovalti 2011	+	?	-	?	?	-	?
Luoto 2011	+	?	-	?	-	?	?
Petrella 2013	+	+	-	?	+	-	+
Phelan 2011	+	+	-	+	+	?	+
Polley 2002	?	?	-	?	+	?	+
Poston 2013	+	+	-	?	+	?	+
Poston 2015	+	+	-	?	?	+	+
Rauh 2013	+	?	-	?	+	?	-

Figure 4. (Continued)

Rauh 2013	+	?	-	?	+	?	-
Sagedal 2017	+	?	-	+	+	+	+
Vinter 2011	+	+	-	?	?	?	?
Wang 2015	?	?	-	?	+	?	?

Allocation

Methods to generate the random sequence were judged to be adequate in 17 of the 23 included trials (Asbee 2009; Bruno 2016; Dodd 2014; Harrison 2013; Herring 2016; Hui 2012; Hui 2014; Jing 2015; Korpi-Hyovalti 2011; Luoto 2011; Petrella 2013; Phelan 2011; Poston 2013; Poston 2015; Rauh 2013; Sagedal 2017; Vinter 2011), all using computer-generated random number lists/tables. In the remaining six trials (El Beltagy 2013; Hawkins 2014; Hoirisch-Clapauch 2016; Koivusalo 2016; Polley 2002; Wang 2015), the risk of selection bias associated with sequence generation was judged to be unclear, with insufficient information provided.

Thirteen trials (Asbee 2009; Bruno 2016; Dodd 2014; Harrison 2013; Herring 2016; Hui 2012; Hui 2014; Koivusalo 2016; Petrella 2013; Phelan 2011; Poston 2013; Poston 2015; Vinter 2011) were judged to have used adequate methods for allocation concealment. Of these, 10 (Asbee 2009; Bruno 2016; Harrison 2013; Herring 2016; Hui 2012; Hui 2014; Koivusalo 2016; Petrella 2013; Phelan 2011; Vinter 2011) reported using sealed envelopes (with varying detail provided regarding these envelopes being consecutively numbered, opaque etc.) and three (Dodd 2014; Poston 2013; Poston 2015) used centralised phone or online randomisation services. For the remaining 10 trials (El Beltagy 2013; Hawkins 2014; Hoirisch-Clapauch 2016; Jing 2015; Korpi-Hyovalti 2011; Luoto 2011; Polley 2002; Rauh 2013; Sagedal 2017; Wang 2015), the risk of selection bias was judged to be unclear, with no methods detailed, or the reported methods lacking sufficient detail.

Blinding

In all 23 trials (Asbee 2009; Bruno 2016; Dodd 2014; El Beltagy 2013; Harrison 2013; Hawkins 2014; Herring 2016; Hoirisch-Clapauch 2016; Hui 2012; Hui 2014; Jing 2015; Koivusalo 2016; Korpi-Hyovalti 2011; Luoto 2011; Petrella 2013; Phelan 2011; Polley 2002; Poston 2013; Poston 2015; Rauh 2013; Sagedal 2017; Vinter 2011; Wang 2015), the risk of performance bias, due to inadequate blinding of women and/or trial personnel, was judged to be high. While for some trials, lack of blinding was specifically stated, for others, no information was provided. While some of the trials suggested that women and/or trial personnel were blinded, in view of the interventions assessed, it was considered unlikely that this would have been successfully achieved.

Considering blinding of outcome assessors, only eight trials (Bruno 2016; Dodd 2014; Harrison 2013; Hawkins 2014; Hui 2014; Koivusalo 2016; Phelan 2011; Sagedal 2017) clearly indicated that blinded trial personnel were involved in outcome assessment or data collection, and were judged to be at low risk of detection bias. For the remaining 15 trials, the risk of detection bias was judged to be unclear (Asbee 2009; El Beltagy 2013; Herring 2016; Hoirisch-Clapauch 2016; Hui 2012; Jing 2015; Korpi-Hyovalti 2011; Luoto

2011; Petrella 2013; Polley 2002; Poston 2013; Poston 2015; Rauh 2013; Vinter 2011; Wang 2015), with many of the trials not clearly detailing whether it was possible to blind outcome assessors.

Incomplete outcome data

Twelve trials (Dodd 2014; Harrison 2013; Hawkins 2014; Hui 2014; Koivusalo 2016; Petrella 2013; Phelan 2011; Polley 2002; Poston 2013; Rauh 2013; Sagedal 2017; Wang 2015) were judged to be at a low risk of attrition bias, with minimal losses to follow-up, and similar numbers/reasons for losses between groups. For four trials (Asbee 2009; Bruno 2016; Hoirisch-Clapauch 2016; Luoto 2011), the risk of bias due to incomplete outcome data was judged to be high. In Asbee 2009, of the 144 women randomised, 100 (69%) were included in the analyses; further, the number of women excluded from each group was not reported; in Bruno 2016, of the 191 women randomised, 131 (69%) were included in the analyses; women lost to follow-up differed from those included in the analyses on a number of characteristics; in Hoirisch-Clapauch 2016, of the 480 women randomised, 319 (66%) completed the trial; and in Luoto 2011, of the 634 women who agreed to participate, 399 (63%) were followed up (and, for a number of outcomes "number missing" is reported in the manuscript tables, however it was not clear from which groups the data were missing).

The remaining seven trials (El Beltagy 2013; Herring 2016; Hui 2012; Jing 2015; Korpi-Hyovalti 2011; Poston 2015; Vinter 2011) were judged to be at an unclear risk of attrition bias. In two of the trials (Herring 2016; Korpi-Hyovalti 2011), losses/exclusions of approximately 10% were considered relatively high in small samples (66 and 60, respectively); in one trial (Vinter 2011), of 360 women randomised, a maximum of 304 (84%) were included in the analyses; in three trials (Hui 2012; Jing 2015; Poston 2015) there was some concern regarding differential losses/exclusions between groups; the final trial (El Beltagy 2013), was reported in abstract form only, with insufficient information to determine losses/exclusions.

Judgements regarding risk of attrition bias were primarily made considering the main trial period and the assessment of perinatal and fetal/neonatal clinical outcomes (not longer-term maternal or child follow-up, where reported).

Selective reporting

Only three trials (Dodd 2014; Poston 2015; Sagedal 2017) were judged to be at low risk of reporting bias, providing data for pre-specified and/or expected outcomes (including from the published protocols). Fifteen trials were judged to be at an unclear risk of reporting bias (El Beltagy 2013; Harrison 2013; Herring 2016; Hoirisch-Clapauch 2016; Hui 2012; Hui 2014; Jing 2015; Koivusalo 2016; Luoto 2011; Phelan 2011; Polley 2002; Poston 2013; Rauh

2013; Vinter 2011; Wang 2015). For the majority of these trials, there was insufficient information to confidently assess selective reporting (i.e. no access to a published trial protocol).

The remaining five trials (Asbee 2009; Bruno 2016; Hawkins 2014; Korpi-Hyovalti 2011; Petrella 2013) were judged to be at a high risk of reporting bias. Outcomes in Asbee 2009 were not clearly pre-specified in the methods; while the results section detailed a number of outcomes, no outcome data were reported: *"no statistically significant differences were noted between the groups"*. In Bruno 2016, for a number of outcomes, it was only reported that there *"were very few and did not differ between groups"*. Hawkins 2014 reported very limited clinical data and reported GDM incompletely in the text, providing only the number of cases across both groups. Korpi-Hyovalti 2011 reported P values for baseline characteristics, and a number of outcomes only as *"NS"*, and for some outcomes, made 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)"*. Petrella 2013 reported a number of outcomes incompletely in the text as *"similar"* or described *"no statistically significant differences"* between groups.

Other potential sources of bias

Sixteen trials (Asbee 2009; Bruno 2016; Dodd 2014; Harrison 2013; Hawkins 2014; Herring 2016; Hui 2012; Hui 2014; Jing 2015; Koivusalo 2016; Petrella 2013; Phelan 2011; Polley 2002; Poston 2013; Poston 2015; Sagedal 2017) were judged to be at a low risk of potential sources of other 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 diet and exercise intervention group than for the standard care group (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 six trials (El Beltagy

2013; Hoirisch-Clapauch 2016; Korpi-Hyovalti 2011; Luoto 2011; Vinter 2011; Wang 2015), the risk of other bias was judged to be unclear, due to, for example, possible baseline imbalances between groups (Korpi-Hyovalti 2011; Luoto 2011; Vinter 2011), or insufficient methodological information available to confidently assess other sources of bias (El Beltagy 2013; Hoirisch-Clapauch 2016; Wang 2015).

Effects of interventions

See: [Summary of findings for the main comparison](#) Combined diet and exercise interventions versus standard care (mother); [Summary of findings 2](#) Combined diet and exercise interventions versus standard care (child)

Combined diet and exercise interventions versus standard care

Primary outcomes

Mother

GDM

There was a possible reduced risk of gestational diabetes mellitus (GDM) in the diet and exercise intervention group compared with the standard care group (average risk ratio (RR) 0.85, 95% confidence interval (CI) 0.71 to 1.01; 6633 participants; 19 trials; $\text{Tau}^2 = 0.05$; $I^2 = 42\%$; $P = 0.07$; *moderate-quality evidence*) (Analysis 1.1). The screening/diagnostic tests and criteria used across the 19 trials are reported in Table 5. Three of the trials (Harrison 2013; Luoto 2011; Vinter 2011) reported data for GDM according to additional diagnostic criteria (see Table 5). While we have included the data from the main/pre-specified criteria reported by the trials in the meta-analysis, when we substituted results for the additional criteria provided into the meta-analysis for this outcome, the overall result remained largely unchanged. No obvious asymmetry was observed on visual assessment of a funnel plot for this outcome (Figure 5).

Figure 5. Funnel plot of comparison: 1 Diet and exercise interventions versus control, outcome: 1.1 Gestational diabetes.

Four trials presented data for GDM that could not be included in the above meta-analysis: [Asbee 2009](#) reported "No statistically significant differences were noted between the groups in... gestational diabetes mellitus"; [El Beltagy 2013](#) reported "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)"; [Hawkins 2014](#) reported "When we repeated the above analyses excluding women with gestational diabetes ($n = 7$), the findings were virtually unchanged"; [Hoirisch-Clapauch 2016](#) reported "Protocol W + D... helped prevent gestational diabetes (OR, 0.1; 95% CI, 0.02-0.57);" and "W&D... reduced the risk of gestational diabetes (2% vs. 11%)".

Hypertensive disorders of pregnancy

There was no evidence of a difference in the risk of pre-eclampsia between the diet and exercise and standard care groups (RR 0.98, 95% CI 0.79 to 1.22; 5366 participants; 8 trials; *low-quality evidence*); nor in the risk of severe pre-eclampsia, eclampsia or HELLP (Haemolysis, Elevated Liver enzymes and Low Platelet count) syndrome (RR 0.72, 95% CI 0.35 to 1.46; 2088 participants; 2 trials) ([Analysis 1.2](#)); pregnancy-induced hypertension and/

or hypertension (average RR 0.78, 95% CI 0.47 to 1.27; 3073 participants; 6 trials; $\text{Tau}^2 = 0.19$; $I^2 = 62\%$; *very low-quality evidence*); pregnancy-induced hypertension (average RR 0.46, 95% CI 0.16 to 1.29; 810 participants; 4 trials; $\text{Tau}^2 = 0.72$; $I^2 = 69\%$) or hypertension (RR 1.07, 95% CI 0.84 to 1.38; 2532 participants; 3 trials) ([Analysis 1.3](#)).

Three trials presented data for pre-eclampsia that could not be included in the above meta-analysis: [Asbee 2009](#) reported that "No statistically significant differences were noted between the groups in... preeclampsia"; [Korpi-Hyovalti 2011](#) reported "There was no statistically significant difference between the randomised groups in terms of pre-eclampsia;" and [Hoirisch-Clapauch 2016](#) reported "W&D... reduced the risk of... preeclampsia (5% vs. 13%)".

Caesarean section

There was a possible reduction in the risk of caesarean birth between the diet and exercise and standard care groups (RR 0.95, 95% CI 0.88 to 1.02; 6089 participants; 14 trials; *moderate-quality evidence*) ([Analysis 1.4](#)). No obvious asymmetry was observed on visual assessment of a funnel plot for this outcome ([Figure 6](#)).

Figure 6. Funnel plot of comparison: 1 Diet and exercise interventions versus control, outcome: 1.4 Caesarean section.

[Korpi-Hyovalti 2011](#) reported "There was no statistically significant difference between the randomised groups in terms of...Caesarean deliveries (data not shown)".

Child

Perinatal mortality

Only [Dodd 2014](#) and [Poston 2015](#) reported on perinatal mortality, and there was no evidence of a difference in the risk observed between the diet and exercise and standard care groups (RR 0.82, 95% CI 0.42 to 1.63; 3757 participants; 2 trials; *low-quality evidence*) ([Analysis 1.5](#)).

[Hoirisch-Clapauch 2016](#) reported "Protocol W + D... increased the rate of take-home (OR, 6.9; 95% CI, 3.93–12.3)... babies;" and "W&D increased the rate of take-home (88% vs. 52%)... babies".

Large-for-gestational age

There was no evidence of a difference in the risk of large-for-gestational age between the diet and exercise and standard care groups (RR 0.93, 95% CI 0.81 to 1.07; 5353 participants; 11 trials; *low-quality evidence*) ([Analysis 1.6](#)). No obvious asymmetry was observed on visual assessment of a funnel plot for this outcome ([Figure 7](#)).

Figure 7. Funnel plot of comparison: 1 Diet and exercise interventions versus control, outcome: 1.6 Large-for-gestational age.

Two trials presented data for large-for-gestational age that could not be included in the above meta-analysis: [Hoirisch-Clapauch 2016](#) reported "Protocol W+D... increased the rate of... appropriate-for gestational-age babies (OR, 7.5, 95% CI, 3.56–15.8);" and "W&D increased the rate of... appropriate-for-gestational-age babies (respectively 90% vs. 63% and 92% vs. 61% of all live-born babies);" and [Petrella 2013](#) reported "Large for gestational age babies were similar among groups".

Mortality or morbidity composite

A mortality or morbidity composite was not reported by any of the included trials.

Secondary outcomes

Mother

Perinatal outcomes

Operative vaginal birth

There was no evidence of a difference in the risk of operative vaginal birth between the diet and exercise intervention and standard care groups (RR 1.07, 95% CI 0.86 to 1.34; 2164 participants; 3 trials) ([Analysis 1.7](#)).

[Asbee 2009](#) reported "No statistically significant differences were noted between the groups....[in] rate of... operative vaginal delivery".

Induction of labour

There was no evidence of a difference in the risk of induction of labour between the diet and exercise intervention and standard care groups (average RR 0.92, 95% CI 0.79 to 1.06; 3907 participants; 5 trials; $\tau^2 = 0.01$; $I^2 = 39\%$) ([Analysis 1.8](#)).

[Korpi-Hyovalti 2011](#) reported "There was no statistically significant difference between the randomised groups in terms of... induction of labor".

Perineal trauma

Only [Dodd 2014](#) and [Sagedal 2017](#) reported on perineal trauma, and there was no evidence of a difference in the risk between the diet and exercise intervention and standard care groups (RR 1.27, 95% CI 0.78 to 2.05; 2733 participants; 2 trials; *moderate-quality evidence*) ([Analysis 1.9](#)).

Three trials presented data for perineal trauma that could be included in the above meta-analysis: [Asbee 2009](#) reported "No statistically significant differences were noted between the groups in...vaginal lacerations;" [Korpi-Hyovalti 2011](#) reported "There was no statistically significant difference between the randomised groups in terms of... lacerations;" and [Petrella 2013](#) reported "No statistically significant differences were found in maternal morbidity (...perineal tears) at delivery".

Placental abruption

Only [Poston 2015](#) reported on placental abruption and observed no evidence of a difference in the risk between the diet and exercise intervention and standard care groups (RR 2.96, 95% CI 0.12 to 72.50; 1555 participants; 1 trial) ([Analysis 1.10](#)).

Postpartum haemorrhage

There was no evidence of a difference in the risk of postpartum haemorrhage between the diet and exercise intervention and standard care groups (RR 1.03, 95% CI 0.89 to 1.18; 4235 participants; 3 trials) ([Analysis 1.11](#)).

[Petrella 2013](#) reported "No statistically significant differences were found in maternal morbidity (post-partum hemorrhage ...) at delivery".

Postpartum infection

[Dodd 2014](#) and [Poston 2015](#) were the only trials to report data on outcomes relating to postpartum infection, and observed no

evidence of a difference in the risk between the diet and exercise intervention and standard care groups for endometritis (RR 1.19, 95% CI 0.52 to 2.74; 2142 participants; 1 trial), wound infection (RR 1.06, 95% CI 0.65 to 1.73; 2142 participants; 1 trial), postpartum antibiotic use (RR 1.00, 95% CI 0.77 to 1.31; 2142 participants; 1 trial), and postpartum sepsis (RR 0.33, 95% CI 0.01 to 8.06; 1555 participants; 1 trial) ([Analysis 1.12](#)).

Gestational weight gain

There was evidence of less total gestational weight gain in the diet and exercise intervention group compared with the standard care group (mean difference (MD) -0.89 kg, 95% CI -1.39 to -0.40; 5052 participants; 16 trials; $\tau^2 = 0.37$; $I^2 = 43\%$; moderate-quality evidence) ([Analysis 1.13](#)). Some asymmetry was observed on visual assessment of a funnel plot for this outcome, possibly indicating a lack of small negative studies ([Figure 8](#)).

Figure 8. Funnel plot of comparison: 1 Diet and exercise interventions versus control, outcome: 1.13 Gestational weight gain (kg).

Four additional trials that did not report on total gestational weight gain, reported on weight gain at various time points during pregnancy; there was no evidence of a difference in gestational weight gain during the first (MD -0.03 kg, 95% CI -0.62 to 0.56; 272 participants; 1 trial), second (MD -0.38 kg, 95% CI -0.77 to 0.02; 541 participants; 2 trials) or third trimesters (MD -0.10 kg, 95% CI -1.17 to 0.97; 269 participants; 1 trial), or specifically at 20 to 24 weeks

gestation (MD -0.45 kg, 95% CI -1.48 to 0.58; 221 participants; 1 trial); however, there was evidence of less weight gain at 26 to 28 weeks (MD -0.90 kg, 95% CI -1.75 to -0.05; 203 participants; 1 trial) ([Analysis 1.14](#)).

Three further trials presented data on gestational weight gain that could not be included in the above meta-analysis: [El Beltagy 2013](#) reported "weight gain per week was significantly lower in the

diet and exercise group than the other group ($p < 0.001$); [Hoirisch-Clapauch 2016](#) reported "Protocol W + D... also helped prevent... excessive weight gain in term pregnancies (10 ± 2 versus 17 ± 9 kg);" and [Poston 2013](#) reported "There was also no significant difference in gestational weight gain between control and intervention arms (secondary outcome)".

There was evidence of less gestational weight gain per week in the diet and exercise intervention group compared with the standard

care group (MD -0.03 kg, 95% CI -0.06 to -0.00 ; 2772 participants; 4 trials; $\text{Tau}^2 = 0.00$; $I^2 = 64\%$) ([Analysis 1.15](#)).

There was also evidence of a reduction in gestational weight gain above IOM recommendations in the diet and exercise intervention group compared with the standard care group (average RR 0.87, 95% CI 0.79 to 0.96; 4556 participants; 11 trials; $\text{Tau}^2 = 0.01$; $I^2 = 50\%$) ([Analysis 1.16](#)). No obvious asymmetry was observed on visual assessment of a funnel plot for this outcome ([Figure 9](#)).

Figure 9. Funnel plot of comparison: 1 Diet and exercise interventions versus control, outcome: 1.16 Gestational weight gain (above IOM recommendations).

[Harrison 2013](#) reported "The proportion of women exceeding Institute of Medicine recommendations for gestational weight gain was significantly reduced in the intervention group compared to controls, with results most marked in overweight women (17% vs 55%)".

There was, however, no evidence of a difference in gestational weight gain **within** (RR 1.02, 95% CI 0.93 to 1.11; 3730 participants; 9 trials) ([Analysis 1.17](#)) or **below** (RR 1.10, 95% CI 0.98 to 1.24; 3499 participants; 7 trials) ([Analysis 1.18](#)) IOM recommendations between the diet and exercise intervention and standard care groups.

Adherence to the intervention

The following trials provided information relating to adherence to the intervention, which was not considered suitable for meta-analysis.

- [Harrison 2013](#): "Of the women allocated to the intervention, 95% attended session two, 89% session three and 93% session four".
- [Hawkins 2014](#): "In the lifestyle intervention group, 100% of the first and 96.9% of the second counselling sessions were completed. Rates were 93.5% for the third session and declined to 76.9% for session 4, 87.5% for session 5 and 85.7% for session 6. Overall, the women completed a mean $\pm$ SD of 4 ± 1.45 sessions".
- [Herring 2016](#): "The mean frequency of self-monitoring response texts per intervention participant was 65.2 ± 29.4 (expected texts = 114), with the majority of participants (70%) responding to $\geq 50\%$ of the self-monitoring text prompts... Intervention participants also completed an average of 4 ± 1.5 coaching calls (expected calls = 7) during the first 12 program weeks and an average of 1 ± 0.5 additional calls until delivery... More than 90% of calls were attempted. While few participants (11%) commented or "liked" posts on Facebook, average number of weekly coach posts was 1.7 ± 0.9 , which waned over time".

- [Hui 2014](#): "All participants in the intervention group met with the dietitian at baseline and at 2 months after. These women attended the group exercise and exercise regularly at home according to the protocol".
- [Luoto 2011](#): "The timing of the counseling sessions was as intended: The mean weeks gestation at the primary session was 9 (range 6 to 13), at the first booster session 17 (range 8-25), at the second booster session 23 (range 19 to 29), at the third booster session 33 (range 30 to 37) and at the final booster session 37 (range 34 to 40). The mean duration of the primary counseling session on PA was 21 min (range 5 to 55) and the duration of subsequent booster sessions 10 (range 0 to 30), 11 (range 2 to 32), 10 (range 0 to 56) and 6 min (range 2 to 20). Two participants missed the second booster session at 22-24 weeks gestation and three participants the last booster at 36-37 weeks gestation. The average attendance at the monthly thematic meetings with group exercise was 33% ranging from 20% to 52% in the municipalities. On average, only 6% (municipality-specific range 0% to 15%) of the participants attended all thematic meetings and 33% (municipality-specific range 10% to 67%) at least 3 of the meetings during their pregnancy".
- [Poston 2013](#): "Of the 94 women randomised to the intervention, 82 (88%) attended at least one group session, and 60 (64%) attended 4 or more. A total of 42 women (45%) received material from all eight sessions, 6 by full attendance (6%) and the remainder when partly/wholly covered by subsequent phone contact. For all women, 6.1 (SD 2.6) sessions were attended or partly/wholly covered".
- [Poston 2015](#): "On average, women who were assigned the intervention attended seven (SD 3) of eight health trainer-led sessions, including four in person, and a further three by telephone or email. For sessions attended in person, 30% of women attended only one session, and 46% attended fewer than four. For sessions delivered by any method, 10% of women received only one session and 17% had fewer than four".
- [Sagedal 2017](#): "Among women in the intervention arm, 259 (87.5%) received both dietary consultations, 28 (9.5%) received one, and nine (3%) received none. All received access to physical fitness classes and 274 (92.6%) attended at least one class. The number of classes attended varied between 0 and 38, with a median of 14," and at 12-month follow-up "Among intervention participants in the present analysis, 115 (56.7%) were defined as compliant and 88 (43.3%) non-compliant with the intervention".
- [Vinter 2011](#): "92% of the women completed all four dietetic counseling sessions and 98% completed at least three sessions... The mean attendance for the 20 aerobic classes was 10.4 h, and 56% of women in the intervention group attended the aerobic classes for at least half of the lessons".

Behaviour changes associated with the intervention

Seventeen of the included trials ([Bruno 2016](#); [Dodd 2014](#); [Harrison 2013](#); [Hawkins 2014](#); [Hui 2012](#); [Hui 2014](#); [Jing 2015](#); [Koivusalo 2016](#); [Luoto 2011](#); [Petrella 2013](#); [Phelan 2011](#); [Polley 2002](#); [Poston 2013](#); [Poston 2015](#); [Rauh 2013](#); [Sagedal 2017](#); [Vinter 2011](#)) provided information relating to diet and/or exercise changes, which (given the substantial variation in reporting) was not considered suitable for meta-analysis. We have summarised the findings from the trials in [Analysis 1.19](#). The majority of these trials ([Bruno 2016](#); [Dodd 2014](#); [Harrison 2013](#); [Hawkins 2014](#); [Hui 2012](#); [Hui 2014](#); [Jing 2015](#); [Koivusalo 2016](#); [Luoto 2011](#); [Poston 2013](#); [Poston 2015](#); [Rauh 2013](#); [Sagedal 2017](#); [Vinter 2011](#)) observed some evidence of benefit(s)

in favour of the diet and exercise interventions; while one trial ([Polley 2002](#)) observed no evidence of difference between the diet and exercise interventions and control, and one trial ([Bruno 2016](#)) observed some evidence of benefit in favour of the control for exercise. [Petrella 2013](#) did not report group differences.

Relevant biomarker changes associated with the intervention

Six of the included trials ([Hawkins 2014](#); [Koivusalo 2016](#); [Korpi-Hyovalti 2011](#); [Luoto 2011](#); [Poston 2015](#); [Vinter 2011](#)) provided information related to biomarker changes, which (given the substantial variation in reporting) was not considered suitable for meta-analysis. We have summarised the findings from the trials in [Analysis 1.20](#). Two of the trials ([Koivusalo 2016](#); [Vinter 2011](#)) reported some evidence of benefit(s) in favour of the diet and exercise interventions for these changes; while the other four trials ([Hawkins 2014](#); [Korpi-Hyovalti 2011](#); [Luoto 2011](#); [Poston 2015](#)) observed no evidence of difference between the diet and exercise interventions and control.

Sense of well-being and quality of life

Four of the included trials ([Dodd 2014](#); [Luoto 2011](#); [Phelan 2011](#); [Poston 2013](#)) provided information related to sense of well-being and/or quality of life, which (given the substantial variation in reporting) was not considered suitable for meta-analysis. We have summarised the findings from the trials in [Analysis 1.21](#). One of the trials ([Dodd 2014](#)) observed some evidence of benefit in favour of the diet and exercise intervention; while two of the trials ([Luoto 2011](#); [Poston 2013](#)) observed no evidence of difference between the diet and exercise interventions and control, and one trial ([Phelan 2011](#)) observed some evidence of benefit in favour of the control.

Views of intervention

The following trials provided information relating to views of the intervention, which was not suitable for meta-analysis.

- [Dodd 2014](#): "Although there were no significant differences in the proportion of women who indicated that they would participate in the study again [Lifestyle Advice 433 (74.4%) vs. Standard Care 467 (74.8%); $p = 0.7222$] or recommend participation to a friend [Lifestyle Advice 484 (82.7%) vs. Standard Care 492 (78.8%); $p = 0.2302$], women who received the intervention were more likely to be satisfied with their group allocation [Lifestyle Advice 506 (87.5%) vs. Standard Care 439 (70.6%); $p < 0.0001$]."
- [Hawkins 2014](#): "The majority of the participants were satisfied with the amount of information received (83.9%) and the amount of time spent on the study (88.7%), and found the written materials sometimes or always useful (80.6%). Finally, 91.9% of the women reported that they would definitely or possibly participate in a similar study in the future".
- [Herring 2016](#): "Among intervention participants who completed the treatment acceptability questionnaire ($n = 22$; 81%), 96% reported that the skills they learned in the program were extremely helpful (at least an 8 on a 10-point scale); 96% found the text messages and 82% found the coach calls extremely useful; and 87% reported the program was extremely successful in changing eating habits. Qualitative feedback included: (i) "I believe without this program my weight gain would have been out of control" and (ii) "I'm [now] watching what I eat and drink as well as monitoring my kids diets so we can stay healthy and fit throughout our lives".

- [Poston 2013](#): "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 judged. Women reported having watched the DVD, but few used it regularly".

Breastfeeding

There was no evidence of a difference in exclusive breastfeeding at three days (RR 1.02, 95% CI 0.91 to 1.15; 695 participants; 1 trial), six weeks (RR 0.93, 95% CI 0.76 to 1.13; 202 participants; 1 trial) or six months (RR 0.91, 95% CI 0.61 to 1.36; 921 participants; 2 trials) postpartum ([Analysis 1.22](#)); or in partial breastfeeding at three days (RR 0.51, 95% CI 0.40 to 0.66; 695 participants; 1 trial), six weeks (RR 1.44, 95% CI 0.80 to 2.60; 202 participants; 1 trial) or six months postpartum (RR 0.98, 95% CI 0.82 to 1.18; 921 participants; 2 trials) ([Analysis 1.23](#)).

Three trials presented data on breastfeeding that could not be included in the above meta-analysis: [Rauh 2013](#) reported only group means, with no measures of variance, and found no difference between groups in exclusive and total breastfeeding durations ([Analysis 1.24](#)); [Phelan 2011](#) reported "The intervention did not target breastfeeding and had no significant effect on breastfeeding rates, which were low in both the intervention and standard-care groups (10.4% and 8.3%, respectively, at 6 mo and 3.4% and 4.6%, respectively, at 12 mo)"; [Sagedal 2017](#) reported "There was no significant difference in duration of breastfeeding between women compliant with the intervention and those in the control group (37.3 versus 34.2 weeks, mean difference 3.0 weeks, 95% CI -1.3, 7.5; $P = 0.294$)".

Long-term maternal outcomes

Postnatal depression

Postnatal depression was not reported by the included trials.

Postnatal weight retention or return to pre-pregnancy weight

There was evidence of less postnatal weight retention at latest time reported (from six weeks to 12 months postpartum) in the diet and exercise intervention group compared with the standard care group (MD -0.94 kg, 95% CI -1.52 to -0.37; 1673 participants; 6 trials) ([Analysis 1.25](#)).

There was also evidence of an increased chance of returning to pre-pregnancy weight at latest time reported (from six to 12 months postpartum) in the diet and exercise intervention group compared with the standard care group (RR 1.25, 95% CI 1.08 to 1.45; 960 participants; 3 trials) ([Analysis 1.26](#)).

Postnatal BMI

[Harrison 2013](#) and [Poston 2015](#) reported on postnatal BMI (at six weeks and six months postpartum respectively), and there was no

evidence of a difference between the diet and exercise intervention and standard care groups (MD -0.15 kg/m², 95% CI -0.85 to 0.55; 902 participants; 2 trials). [Harrison 2013](#), however, observed evidence of a smaller change in BMI from baseline to six weeks postpartum in the diet and exercise group compared with the standard care group (MD -0.56 kg/m², 95% CI -1.12 to -0.00; 202 participants; 1 trial) ([Analysis 1.27](#)).

GDM in subsequent pregnancy

GDM in subsequent pregnancies was not reported by the included trials.

Type 1 diabetes mellitus

Type 1 diabetes mellitus was not reported by the included trials.

Type 2 diabetes mellitus

Type 2 diabetes mellitus was not reported by the included trials.

Impaired glucose tolerance

Impaired glucose tolerance was not reported by the included trials.

Cardiovascular health

[Vinter 2011](#) observed no evidence of a difference in median systolic or diastolic blood pressure between the diet and exercise intervention and standard care groups at six months postpartum ([Analysis 1.28](#)).

Child

Fetal/neonatal outcomes

Stillbirth

There was no evidence of a difference in risk of stillbirth between the diet and exercise intervention and standard care groups (RR 0.69, 95% CI 0.35 to 1.36; 4783 participants; 5 trials) ([Analysis 1.29](#)).

[Vinter 2011](#) presented data related to stillbirth, however it was unclear whether one of the three stillbirths occurred in the intervention or standard care 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".

Neonatal mortality

Only [Dodd 2014](#) and [Poston 2015](#) reported on neonatal mortality, and there was no evidence of a difference in risk between the diet and exercise intervention and standard care groups overall (RR 2.31, 95% CI 0.60 to 8.90; 3756 participants; 2 trials), or in [Dodd 2014](#) when mortality associated with no lethal anomalies (RR 0.99, 95% CI 0.06 to 15.85; 2202 participants; 1 trial) and mortality due to lethal anomalies (RR 6.95, 95% CI 0.36 to 134.38; 2202 participants; 1 trial) were considered separately ([Analysis 1.30](#)).

Gestational age at birth

There was no evidence of a difference in gestational age at birth between the diet and exercise intervention and standard care groups (MD 0.05 weeks, 95% CI -0.05 to 0.15; 5658 participants; 11 trials) ([Analysis 1.31](#)). No obvious asymmetry was observed on visual assessment of a funnel plot for this outcome ([Figure 10](#)).

Figure 10. Funnel plot of comparison: 1 Diet and exercise interventions versus control, outcome: 1.31 Gestational age at birth (weeks).

Four trials presented data on gestational age at birth that could not be included in the above meta-analysis: [Polley 2002](#) reported only the mean values by group, and [Vinter 2011](#) reported median values and interquartile ranges by group; neither trial observed evidence of a difference between groups ([Analysis 1.32](#)); [Hoirisch-Clapauch 2016](#) reported "Protocol W + D... increased the rate of ... full-term (OR, 12.2; 95% CI, 5.96–25.2)... babies"; [Korpi-Hyovalti 2011](#) reported "There was no statistically significant difference between

the randomized groups in terms of gestational age... (data not shown)".

Preterm birth

There was evidence of a reduction in preterm birth in the diet and exercise intervention group compared with the standard care group (RR 0.80, 95% CI 0.65 to 0.98; 5398 participants; 11 trials) ([Analysis 1.33](#)). No obvious asymmetry was observed on visual assessment of a funnel plot for this outcome ([Figure 11](#)).

Figure 11. Funnel plot of comparison: 1 Diet and exercise interventions versus control, outcome: 1.33 Preterm birth.

Apgar score less than seven at five minutes

There was no evidence of a difference in risk of Apgar score less than seven at five minutes between the diet and exercise intervention and standard care groups (RR 0.80, 95% CI 0.48 to 1.32; 2864 participants; 3 trials) ([Analysis 1.34](#)).

[Petrella 2013](#) reported "Low 5-min Apgar... [was] equally distributed among groups".

Macrosomia

There was evidence of a reduction in macrosomia, defined as birthweight less than 4000 g (RR 0.89, 95% CI 0.78 to 1.01; 5368 participants; 9 trials; $P = 0.06$) and evidence of a reduction in macrosomia, defined as birthweight less than 4500 g (RR 0.63, 95% CI 0.42 to 0.94; 3061 participants; 4 trials) in the diet and exercise intervention group compared with the standard care group ([Analysis 1.35](#)). No obvious asymmetry was observed on visual assessment of a funnel plot for this outcome ([Figure 12](#)).

Figure 12. Funnel plot of comparison: 1 Diet and exercise interventions versus control, outcome: 1.35 Macrosomia.

Korpi-Hyovalti 2011 reported "There was no difference in macrosomia ($p = 0.480$, adjusted by the prepregnancy weight of the women) between the groups".

Small-for-gestational age

There was a possible increase in the risk of small-for-gestational age between the diet and exercise intervention and standard care groups (RR 1.20, 95% CI 0.95 to 1.52; 2434 participants; 6 trials) (Analysis 1.36).

Birthweight and z score

There was no evidence of a difference in birthweight (MD -17.67 g, 95% CI -46.28 to 10.94; 5763 participants; 13 trials) (Analysis 1.37), or birthweight z score (MD -0.05, 95% CI -0.13 to 0.03; 2661 participants; 4 trials) (Analysis 1.39) between the diet and exercise intervention and standard care groups. No obvious asymmetry was observed on visual assessment of a funnel plot for this outcome (Figure 13).

Figure 13. Funnel plot of comparison: 1 Diet and exercise interventions versus control, outcome: 1.37 Birthweight (g).

Three trials presented data on birthweight that could not be included in the above meta-analysis: [Herring 2016](#) and [Polley 2002](#) reported only the mean values by group; [Vinter 2011](#) reported median values and interquartile ranges by group. While [Herring 2016](#) and [Polley 2002](#) observed no evidence of a difference in birthweight between the two groups, [Vinter 2011](#) reported a higher birthweight in the diet and exercise intervention group compared with the standard care group ([Analysis 1.38](#)).

Head circumference and z score

There was no evidence of a difference in head circumference (MD -0.01 cm, 95% CI -0.11 to 0.10; 4229 participants; 4 trials) ([Analysis 1.40](#)), or head circumference z score (reported by [Dodd 2014](#) only) (MD -0.05, 95% CI -0.14 to 0.04; 2142 participants; 1 trial) ([Analysis 1.41](#)) between the diet and exercise intervention and standard care groups.

Length and z score

There was no evidence of a difference in length between the diet and exercise intervention and standard care groups (MD -0.09 cm, 95% CI -0.26 to 0.09; 3303 participants; 6 trials) ([Analysis 1.42](#)). There was evidence of a lower length z score in the diet and exercise intervention group compared with the standard care group (reported by [Dodd 2014](#) and [Luoto 2011](#) only) (MD -0.08, 95% CI -0.15 to -0.02; 2235 participants; 2 trials) ([Analysis 1.43](#)).

Ponderal index

There was no evidence of a difference in ponderal index between the diet and exercise intervention and standard care groups (MD 0.04 kg/m³, 95% CI -0.16 to 0.25; 2826 participants; 3 trials) ([Analysis 1.44](#)).

Adiposity

[Dodd 2014](#); and [Poston 2015](#) reported on adiposity at birth, and there was no evidence of a difference in sum of skinfold thickness (MD 0.09 mm, 95% CI -0.33 to 0.50; 1472 participants; 2 trials) ([Analysis 1.45](#)) or abdominal circumference (MD -0.01 cm, 95% CI -0.23 to 0.22; 1566 participants; 2 trials) ([Analysis 1.46](#)) between the diet and exercise intervention and standard care groups.

[Dodd 2014](#) and [Poston 2015](#) provided additional information related to adiposity at birth, which (given the substantial variation in reporting) was not considered suitable for meta-analysis. We have summarised the findings from the trials in [Analysis 1.47](#). Neither trial observed evidence of a difference between the diet and exercise intervention and standard care groups for measures of adiposity.

Shoulder dystocia

Only [Dodd 2014](#) and [Sagedal 2017](#) reported on shoulder dystocia, and there was no evidence of a difference in risk between the diet and exercise intervention and standard care groups (RR 1.20, 95% CI 0.79 to 1.83; 2733 participants; 2 trials) ([Analysis 1.48](#)).

Nerve palsy

Dodd 2014 observed no evidence of a difference in risk of nerve palsy between the diet and exercise intervention and standard care groups (RR 1.99, 95% CI 0.36 to 10.82; 2142 participants; 1 trial) (Analysis 1.49).

Bone fracture

Dodd 2014 observed no evidence of a difference in risk of bone fracture between the diet and exercise intervention and standard care groups (RR 1.99, 95% CI 0.36 to 10.82; 2142 participants; 1 trial) (Analysis 1.50).

Respiratory distress syndrome

Only Dodd 2014 and Koivusalo 2016 reported on respiratory distress syndrome, and there was evidence of a reduction in the risk in the diet and exercise intervention group compared with the standard care group (RR 0.56, 95% CI 0.33 to 0.97; 2411 participants; 2 trials) (Analysis 1.51).

Korpi-Hyovalti 2011 reported *"There was no statistically significant difference between the randomized groups in terms of... respiratory distress (data not shown)"*.

Hypoglycaemia

Only Dodd 2014 and Poston 2015 reported on neonatal hypoglycaemia, and there was no evidence of a difference in risk between the diet and exercise intervention and standard care groups (average RR 1.42, 95% CI 0.67 to 2.98; 3653 participants; 2 trials; $\text{Tau}^2 = 0.23$; $\text{Chi}^2 = 4.39$, $P = 0.04$; $I^2 = 77\%$; low-quality evidence) (Analysis 1.52).

Hoirisch-Clapauch 2016 reported *"Protocol W + D... also helped prevent... neonatal hypoglycemia (2% versus 17%, OR, 0.1; 95% CI, 0.03–0.46);" and "W&D... reduced the risk of... neonatal hypoglycaemia (2% vs. 16%)"*.

Hyperbilirubinaemia

Dodd 2014 observed no evidence of a difference in risk of neonatal hyperbilirubinaemia between the diet and exercise intervention and standard care groups (RR 0.82, 95% CI 0.61 to 1.11; 2142 participants; 1 trial) (Analysis 1.53).

Korpi-Hyovalti 2011 reported *"There was no statistically significant difference between the randomized groups in terms of... jaundice requiring phototherapy... (data not shown)"*.

Childhood/adulthood outcomes

Weight and z scores

Poston 2015, Rauh 2013 and Vinter 2011 reported on childhood weight (at six months, 10-12 months and 2.8 years respectively), and there was no evidence of a difference between the diet and exercise intervention and standard care groups. (MD -0.05 kg, 95% CI -0.33 to 0.22; 882 participants; 3 trials; $\text{Tau}^2 = 0.03$; $\text{Chi}^2 = 3.20$, $P = 0.20$; $I^2 = 37\%$) (Analysis 1.54). Poston 2015 also observed no difference in childhood weight z score at six months between the diet and exercise intervention and standard care groups (MD -0.09, 95% CI -0.26 to 0.08; 643 participants; 1 trial) (Analysis 1.55).

Height and z scores

Poston 2015 and Vinter 2011 reported on childhood height (at six months, and 2.8 years respectively), and there was no evidence of a difference between the diet and exercise intervention and standard care groups (MD 0.33 cm, 95% CI -0.58 to 1.25; 816 participants; 2 trials) (Analysis 1.56). Poston 2015 also observed no difference in childhood height z score at six months between the diet and exercise intervention and standard care groups (MD -0.02, 95% CI -0.31 to 0.27; 622 participants; 1 trial) (Analysis 1.57).

Head circumference and z scores

Poston 2015 observed no difference in childhood head circumference at six months between the diet and exercise intervention and standard care groups (MD -0.12 cm, 95% CI -0.70 to 0.46; 670 participants; 1 trial) (Analysis 1.58).

Adiposity

Poston 2015 and Vinter 2011 reported on childhood adiposity (at six months, and 2.8 years, respectively), and there was no evidence of a difference between the diet and exercise intervention and standard care groups, as measured by: BMI z score (MD 0.05, 95% CI -0.29 to 0.40; 794 participants; 2 trials; $\text{Tau}^2 = 0.04$; $I^2 = 59\%$; low-quality evidence) (Analysis 1.59), abdominal circumference (MD 0.26 cm, 95% CI -0.37 to 0.90; 833 participants; 2 trials) (Analysis 1.60), subscapular skinfold thickness (MD -0.17 mm, 95% CI -0.66 to 0.32; 705 participants; 2 trials; $\text{Tau}^2 = 0.09$; $I^2 = 70\%$) (Analysis 1.61), triceps skinfold thickness (MD -0.12 mm, 95% CI -0.48 to 0.23; 784 participants; 2 trials) (Analysis 1.62) and total body fat (MD -0.74 %, 95% CI -1.56 to 0.07; 614 participants; 2 trials) (Analysis 1.63).

Poston 2015 and Vinter 2011 provided additional information related to childhood adiposity (at six months, and 2.8 years, respectively), which (given the substantial variation in reporting) was not considered suitable for meta-analysis. We have summarised the findings from the trials in Analysis 1.64. Neither trial observed evidence of a difference between the diet and exercise intervention and standard care groups for measures of adiposity, except for in Poston 2015, who observed evidence of a lower subscapular skinfold thickness z score at six months for the diet and exercise intervention group compared with the standard care group.

Cardiovascular health

Vinter 2011 provided information related to various measures of childhood cardiovascular health at 2.8 years; we have summarised the findings in Analysis 1.65. Vinter 2011 observed no evidence of differences between the diet and exercise intervention and standard care groups for these measures.

Employment, education and social status/achievement

Employment, education and social status/achievement were not reported by the included trials.

Type 1 diabetes mellitus

Type 1 diabetes mellitus was not reported by the included trials.

Type 2 diabetes mellitus

Type 2 diabetes mellitus was not reported by the included trials.

Impaired glucose tolerance

Impaired glucose tolerance was not reported by the included trials.

Neurosensory disability

Neurosensory disability was not reported by the included trials.

Health services

Number of hospital or health professional visits

Numbers of hospital or health professional visits were not reported by the included trials.

Number of antenatal visits or admissions

[Koivusalo 2016](#) observed no evidence of a difference in the number of antenatal clinic visits before the second-trimester oral glucose tolerance test (OGTT) between the diet and exercise intervention and standard care groups (MD 0.00 visits, 95% CI -0.36 to 0.36; 269 participants; 1 trial) ([Analysis 1.66](#)).

[Dodd 2014](#) observed no evidence of a difference in the risk of antenatal hospital admission between the diet and exercise intervention and standard care groups (RR 0.86, 95% CI 0.71 to 1.04; 2153 participants; 1 trial) ([Analysis 1.67](#)).

Length of antenatal stay

[Dodd 2014](#) observed evidence of a reduction in length of antenatal stay for the diet and exercise intervention group compared with the standard care group (MD -0.27 days, 95% CI -0.49 to -0.05; 2153 participants; 1 trial); [Poston 2015](#), however, observed no evidence of a difference in number of antenatal inpatient nights (for those women admitted antenatally) (MD 0.00 nights, 95% CI -1.00 to 1.00; 139 participants; 1 trial) ([Analysis 1.68](#)).

Neonatal intensive care unit admission

There was no evidence of a difference in risk of neonatal intensive care unit admission between the diet and exercise intervention and standard care groups (RR 1.03, 95% CI 0.93 to 1.14; 4549 participants; 4 trials) ([Analysis 1.69](#)).

Three trials presented data on neonatal intensive care unit admission that could not be included in the above meta-analysis: [Bruno 2016](#) reported "Newborns... admitted to the NICU (3) were very few and did not differ between the groups"; [Korpi-Hyovalti 2011](#) reported "There was no statistically significant difference between the randomized groups in terms of... admissions to neonatal intensive care unit... (data not shown);" and [Petrella 2013](#) reported "Neonatal Intensive Care Unit admission [was] equally distributed among groups".

Length of postnatal stay (mother)

[Dodd 2014](#) and [Poston 2015](#) reported on length of postnatal stay (mother) (in [Poston 2015](#) postnatal inpatient nights were reported), and there was no evidence of a difference between the diet and exercise intervention and standard care groups (MD 0.01 days, 95% CI -0.14 to 0.17; 3511 participants; 2 trials; $\tau^2 = 0.01$; $I^2 = 47\%$) ([Analysis 1.70](#)).

Length of postnatal stay (baby)

[Dodd 2014](#) and [Poston 2015](#) reported on length of postnatal stay (baby), and there was no evidence of a difference between the diet

and exercise intervention and standard care groups (MD -0.35 days, 95% CI -0.90 to 0.20; 3618 participants; 2 trials) ([Analysis 1.71](#)).

Costs to families associated with the management provided

[Luoto 2011](#) observed no evidence of a difference in costs to families associated with the management provided between the diet and exercise intervention and standard care groups, as measured by: delivery costs to the patient (MD 3.00 €, 95% CI -10.82 to 16.82; 93 participants; 1 trial) and neonatal care costs to the patient (MD 3.00 €, 95% CI -13.67 to 19.67; 93 participants; 1 trial) ([Analysis 1.72](#)). In [Luoto 2011](#), unit costs were entered at the price level for 2009.

Costs associated with the intervention

[Luoto 2011](#) reported that the supplemental public-health nurse's and physiotherapist's work contributions per person were €118 and €23, respectively for the diet and exercise intervention group. [Luoto 2011](#) observed no evidence of a difference in costs associated with the intervention between the diet and exercise intervention and standard care groups, as measured by: total costs (MD 769.00 €, 95% CI -1032.23 to 2570.23; 93 participants; 1 trial) ([Analysis 1.73](#)). In [Luoto 2011](#) unit costs were entered at the price level for 2009.

[Luoto 2011](#) also reported that "The study indicated that intensive lifestyle counselling among GDM-risk groups was not significantly cost-effective as compared to the usual care for birth weight... quality of life in a 15-dimension questionnaire... or VAS".

Cost of maternal care

[Luoto 2011](#) observed no evidence of a difference in costs of maternal care between the diet and exercise intervention and standard care groups, as measured by: costs of visits for primary health care (MD -43.00 €, 95% CI -127.61 to 41.61; 93 participants; 1 trial), costs of visits for specialist health care (MD -47.00 €, 95% CI -195.33 to 101.33; 93 participants; 1 trial), costs of visits to a diabetes nurse (MD 6.00 €, 95% CI -7.02 to 19.02; 93 participants; 1 trial), costs of visits to a dietitian (not estimable), costs of use of insulin/other diabetes medications (MD -1.00 €, 95% CI -7.83 to 5.83; 93 participants; 1 trial), costs of hospital days before and after delivery (MD 101.00 €, 95% CI -206.71 to 408.71; 93 participants; 1 trial), delivery cost to the municipality (MD 22.00 €, 95% CI -234.43 to 278.43; 93 participants; 1 trial), costs of absence from work (MD 128.00 €, 95% CI -1295.58 to 1551.58; 93 participants; 1 trial) ([Analysis 1.74](#)). In [Luoto 2011](#) unit costs were entered at the price level for 2009.

Cost of infant care

[Luoto 2011](#) observed no evidence of a difference in costs of infant care between the diet and exercise intervention and standard care groups, as measured by: neonatal care cost to municipality (MD 453.00 €, 95% CI -298.20 to 1204.20; 93 participants; 1 trial) ([Analysis 1.75](#)). In [Luoto 2011](#) unit costs were entered at the price level for 2009.

Subgroup analyses

Trial design

Analyses based on trial design used (individually-randomised versus cluster-randomised), revealed no clear subgroup differences for the primary outcomes, GDM ($\text{Chi}^2 = 0.22$; $P = 0.64$; $I^2 = 0\%$) ([Analysis 2.1](#)), pre-eclampsia ($\text{Chi}^2 = 0.07$; $P = 0.79$; $I^2 = 0\%$) ([Analysis 2.2](#)), caesarean birth ($\text{Chi}^2 = 0.52$; $P = 0.47$; $I^2 = 0\%$) ([Analysis 2.3](#)), and

large-for-gestational age ($\text{Chi}^2 = 1.09$; $P = 0.30$; $I^2 = 8.3\%$) (Analysis 2.4), suggesting no clear differences in treatment effect for these outcomes according to the randomisation unit. We did not perform subgroup analyses based on trial design for perinatal mortality and pregnancy-induced hypertension, as only individually-randomised trials reported on these outcomes.

Maternal BMI (at or before trial entry)

Analyses were performed based on maternal BMI at or before trial entry (considering normal weight women ($\text{BMI} < 25 \text{ kg/m}^2$) versus overweight or obese women ($\text{BMI} \geq 25 \text{ kg/m}^2$) versus obese women ($\text{BMI} \geq 30 \text{ kg/m}^2$) versus any women (a mixed subgroup which included normal weight, overweight and obese women)). No clear subgroup differences were revealed for the primary outcomes, GDM ($\text{Chi}^2 = 1.73$, $P = 0.63$, $I^2 = 0\%$) (Analysis 3.1), pre-eclampsia ($\text{Chi}^2 = 3.45$, $P = 0.33$, $I^2 = 13.1\%$) (Analysis 3.2), pregnancy-induced hypertension or hypertension ($\text{Chi}^2 = 2.29$, $P = 0.32$, $I^2 = 12.9\%$) (Analysis 3.3), caesarean section ($\text{Chi}^2 = 0.95$, $P = 0.81$, $I^2 = 0\%$) (Analysis 3.4), perinatal mortality ($\text{Chi}^2 = 0.17$, $P = 0.68$, $I^2 = 0\%$) (Analysis 3.5) or large-for-gestational age ($\text{Chi}^2 = 5.46$, $P = 0.14$, $I^2 = 45.0\%$) (Analysis 3.6), suggesting no clear differences in treatment effect for these outcomes based on maternal BMI. Due to the difficulty in interpreting the results associated with the 'any women' (mixed) subgroup, we also conducted these analyses excluding this subgroup; similarly no clear subgroup differences were observed. Further, when we conducted these analyses combining the 'overweight or obese women' and 'obese women' subgroups, no clear subgroup differences were observed.

Ethnicity

Analyses were performed based on ethnicity (considering majority 'low-risk' ethnicities versus majority 'high-risk' ethnicities versus mixed ethnicities versus unclear). No clear subgroup differences were observed for the primary outcomes, GDM ($\text{Chi}^2 = 0.22$, $P = 0.97$, $I^2 = 0\%$) (Analysis 4.1), pre-eclampsia ($\text{Chi}^2 = 0.04$, $P = 0.98$, $I^2 = 0\%$) (Analysis 4.2), pregnancy-induced hypertension or hypertension ($\text{Chi}^2 = 2.71$, $P = 0.10$, $I^2 = 63.0\%$) (Analysis 4.3), caesarean birth ($\text{Chi}^2 = 1.75$, $P = 0.63$, $I^2 = 0\%$) (Analysis 4.4), perinatal mortality ($\text{Chi}^2 = 0.17$, $P = 0.68$, $I^2 = 0\%$) (Analysis 4.5), or large-for-gestational age ($\text{Chi}^2 = 2.76$, $P = 0.43$, $I^2 = 0\%$) (Analysis 4.6), suggesting no clear differences in treatment effect for these outcomes based on ethnicity. Due to the difficulty in interpreting the results associated with the 'mixed ethnicities' and 'unclear' subgroups, we also conducted these analyses excluding these two subgroups; similarly no clear subgroup differences were observed.

Sensitivity analyses

The 12 trials (Asbee 2009; Bruno 2016; Dodd 2014; Harrison 2013; Herring 2016; Hui 2012; Hui 2014; Petrella 2013; Phelan 2011; Poston 2013; Poston 2015; Vinter 2011) considered to be at low risk of selection bias were included in sensitivity analyses. There was still a possibly reduced risk of GDM between the diet and exercise intervention and standard care groups (though with a widening of the confidence intervals) (average RR 0.86, 95% CI 0.68 to 1.09; 5019 participants; 11 trials; $\text{Tau}^2 = 0.06$; $\text{Chi}^2 = 21.30$, $P = 0.02$; $I^2 = 53\%$) (Analysis 5.1), pre-eclampsia (RR 0.99, 95% CI 0.78 to 1.26; 4311 participants; 4 trials) (Analysis 5.2), pregnancy-induced hypertension or hypertension (average RR 0.58, 95% CI 0.27 to 1.25; 2694 participants; 4 trials; $\text{Tau}^2 = 0.36$; $\text{Chi}^2 = 11.71$, $P = 0.008$; $I^2 = 74\%$) (Analysis 5.3), caesarean birth (RR 0.94, 95% CI 0.87 to 1.02; 4968 participants; 10 trials) (Analysis 5.4), perinatal mortality (RR

0.82, 95% CI 0.42 to 1.63; 3757 participants; 2 trials; identical to main analysis) (Analysis 5.5), or large-for-gestational age (RR 0.95, 95% CI 0.83 to 1.09; 4618 participants; 8 trials) (Analysis 5.6). These findings supported those observed in the main analysis.

DISCUSSION

Summary of main results

in this updated Cochrane review we included 23 randomised controlled trials (involving 8918 women and their 8709 infants) that compared combined diet and exercise interventions with no intervention (standard care).

For our primary review outcomes, there was a possible reduced risk of gestational diabetes mellitus (GDM) and caesarean section for women receiving diet and exercise interventions compared with standard care (both *moderate-quality evidence*). Of the 3353 women receiving diet and exercise interventions, 525 (16%) were diagnosed with GDM, compared with 551 (17%) of the 3280 women receiving standard care (an absolute risk reduction of approximately 1%). These data supported rates of GDM of 168 per 1000 for the standard care group, and 143 per 1000 (95% CI 119 to 170) for the diet and exercise intervention group. There were no clear differences between groups for pre-eclampsia (*low-quality evidence*), pregnancy-induced hypertension/hypertension (*very low-quality evidence*), perinatal mortality (*low-quality evidence*) or large-for-gestational age (*low-quality evidence*). No data were reported from any of the included trials for infant mortality or morbidity composite.

Subgroup analyses (based on trial design, maternal body mass index (BMI) and ethnicity) for our primary outcomes revealed no clear differential treatment effects according to the characteristics assessed. The impact of maternal age, parity and specific features of the diet and exercise interventions could not be assessed, due to the paucity of information/data and the inability to meaningfully group intervention characteristics. Sensitivity analyses (restricted to the trials at low risk of selection bias) supported findings observed in the main analyses.

Similarly, for most of the secondary outcomes assessed using GRADE, there were no clear differences between groups, including for perineal trauma (*moderate-quality evidence*), neonatal hypoglycaemia (*low-quality evidence*), and childhood adiposity (BMI z score) (*low-quality evidence*). However, there was evidence of less gestational weight gain for women receiving diet and exercise interventions compared with standard care (*moderate-quality evidence*). On average, women receiving the diet and exercise interventions gained 0.89 kg less (95% CI 1.39 kg to 0.40 kg less) than women receiving standard care. No data were reported by the included trials for maternal postnatal depression or type 2 diabetes mellitus, or for childhood/adulthood type 2 diabetes mellitus or neurosensory disability.

For the majority of other secondary outcomes (not assessed using GRADE), we did not observe clear differences between groups. However, we did observe additional benefits in relation to gestational weight gain (less gestational weight gain per week; and a lower chance of having gestational weight gain above Institute of Medicine (IOM) recommendations) for women receiving diet and exercise interventions compared with standard care. Further, postnatally, women receiving diet and exercise interventions had

less weight retention and a higher chance of returning to their pre-pregnancy weight compared with those receiving standard care. There were also reductions in preterm birth, macrosomia (defined as birthweight less than 4500 g) and respiratory distress syndrome observed among infants born to mothers receiving diet and exercise interventions, compared with those born to mothers receiving standard care. We did not conduct meta-analyses for secondary outcomes relating to adherence to the intervention, behaviour changes associated with the intervention, relevant biomarker changes associated with the intervention, sense of well-being and quality of life, or views of the intervention, as data were not considered suitable, often due to substantial variation in reporting. Generally, good adherence and positive views were reported among women in the diet and exercise intervention groups. While findings related to biomarker changes and sense of well-being and quality of life were mixed, the majority of trials demonstrated some benefits in regards to diet and/or exercise behaviour changes for women receiving the diet and exercise interventions compared with those receiving standard care.

Overall completeness and applicability of evidence

The evidence for combined diet and exercise interventions during pregnancy for GDM prevention is incomplete. Though we were able to include 23 trials involving almost 9000 women, assessing a wide range of combined diet and exercise interventions, many of these trials reported on few review outcomes. All included trials compared the interventions with standard or routine care, and thus we were not able to consider comparisons of different types of combined diet and exercise interventions.

In regards to review outcomes selected for quality assessment using GRADE, while 19, 16 and 14 trials, respectively provided data for meta-analyses of GDM, gestational weight gain and caesarean section, less than half of the included trials contributed data for meta-analyses for large-for-gestational age (11 trials), pre-eclampsia (eight trials), pregnancy-induced hypertension/hypertension (six trials), perineal trauma (two trials), perinatal mortality (two trials), neonatal hypoglycaemia (two trials), and childhood adiposity (two trials). For the remaining outcomes selected for quality assessment using GRADE (maternal depression and type 2 diabetes; infant mortality or morbidity composite; childhood/adulthood type 2 diabetes and neurosensory disability), no included trials provided data.

For many of our other secondary review outcomes (including outcomes in childhood and those related to the use and costs of healthcare services), evidence was limited to data from one or two trials. Though included trials have now provided some (limited) data on childhood health and maternal health in the postpartum period, for the majority of review outcomes relating to long-term health for the mothers and their infants in childhood and adulthood, there were no data. Thus, there remains a paucity of evidence regarding the effects of these interventions during pregnancy on longer-term health. Further, there were limited data provided from included trials in regards to adherence, women's sense of well-being, quality of life and their views. Reporting of outcomes such as relevant biomarkers and behaviour changes associated with the intervention was not standardised (and varied greatly) in included trials, restricting our ability to combine data.

The ability to draw firm conclusions was further limited, particularly, by notable variations in the characteristics of the

interventions assessed (considering the features of both the diet and exercise components) and women included in the trials. While we chose to combine trials in one comparison, and attempted to explore variation through subgroup analyses, the ability to do this was limited by the difficulty in meaningfully grouping trials according to important characteristics. In regards to applicability, of the 23 included trials, all except one were conducted in upper-middle or high-income countries. This likely limits the generalisability of the findings to other countries, particularly low-resource settings. Further, the included trials used specific and varying screening/diagnostic tests, diagnostic criteria, and subsequent management strategies for GDM, which may limit both the interpretation of data, and also, the applicability of the results for countries/settings using different approaches, and with varying practicability and feasibility considerations.

Quality of the evidence

Risk of bias of the 23 included trials was mixed. [Dodd 2014](#), the largest trial (involving 2212 women and their infants) was considered to be at low risk of bias overall. Across the included trials, there was a general lack of methodological detail provided to assess specific aspects of risk of bias, leading to many 'unclear' judgements. We were able to include 12 of the 23 trials, judged to be at low risk of selection bias, in sensitivity analyses, which largely supported findings from the main analyses (with [Dodd 2014](#) contributing between approximately 20% and 66% of the weight to the meta-analyses).

For outcomes assessed using GRADE, evidence was determined to be *moderate quality* (GDM, caesarean section, gestational weight gain and perineal trauma), *low quality* (pre-eclampsia, perinatal mortality, large-for-gestational age, neonatal hypoglycaemia and childhood adiposity), or *very low quality* (pregnancy-induced hypertension/hypertension). Evidence was predominantly downgraded due to design limitations (risk of bias), and imprecision (uncertain effect estimates, and at times, small sample sizes and low event rates), however two outcomes (pregnancy-induced hypertension/hypertension and neonatal hypoglycaemia), were also downgraded for unexplained inconsistency (statistical heterogeneity).

Potential biases in the review process

The search for trials in this area was performed using Cochrane Pregnancy and Childbirth's Trials Register. It is unlikely that trials that have been conducted have been missed, however unpublished trials, or ongoing trials not registered in clinical trial registries could be missing. Should such trials be identified, we will include them in future updates of the review.

We explored the potential for publication bias using funnel plots for outcomes with 10 or more trials included in meta-analyses (GDM, caesarean section, large-for-gestational age, gestational weight gain, gestational weight gain above the IOM recommendations, gestational age at birth, preterm birth, macrosomia, and birthweight), and there was no clear indication of asymmetry except in the case of gestational weight gain.

We aimed to reduce bias wherever possible by having at least two review authors independently working on trial selection, data extraction, risk of bias judgements, and GRADE assessments.

Agreements and disagreements with other studies or reviews

Two Cochrane reviews have assessed diet interventions (Tieu 2017) and exercise interventions (Han 2012) for GDM prevention. Tieu 2017 included 11 trials involving 2786 women and their infants, six of which compared diet interventions with standard care. Similar to our review, a reduction in GDM was observed for women receiving diet interventions compared with standard care (*very low-quality evidence*), however unlike our review, a subgroup analysis suggested a greater treatment effect for overweight and obese women (Tieu 2017). Tieu 2017 also found less gestational weight gain among women who received diet interventions compared with standard care (*low-quality evidence*). Han 2012 included five trials involving 1115 women and their infants, assessing exercise intervention compared with standard care. Unlike our review, no clear impact of exercise interventions on GDM was shown (quality of evidence not assessed) (Han 2012). Both reviews concluded that additional high-quality evidence is required (Han 2012; Tieu 2017).

A further Cochrane review has assessed diet interventions, exercise interventions, or combined diet and exercise interventions for preventing excessive gestational weight gain in pregnancy (Muktabhant 2015). Muktabhant 2015 included 65 trials, of which 49 involving 11,444 women and their infants contributed data, most of which compared such interventions with standard care. As in our review, diet or exercise, or both, interventions were shown to reduce excessive gestational weight gain (*high-quality evidence*), and lead to lower gestational weight gain compared with standard care (*moderate-quality evidence*) (Muktabhant 2015). Unlike our review, a reduction in maternal hypertension (*low-quality evidence*) was observed, and no clear differences in preterm birth (*moderate-quality evidence*) or macrosomia (*high-quality evidence*) were observed, as were seen in our review. In a subgroup analysis by risk, however, high-risk women who received combined diet and exercise interventions had a lower risk of macrosomia (*moderate-quality evidence*), and their infants had a lower risk of respiratory distress syndrome (*moderate-quality evidence*) (Muktabhant 2015), as we observed. Muktabhant 2015 did not assess the impact of such interventions on GDM (as it is the focus of our review).

Numerous other systematic and non-systematic reviews have assessed diet and/or exercise interventions for reducing adverse pregnancy outcomes, including GDM. The reviews continue to reveal inconsistent findings in regards to benefit, however much of this variation is likely attributable to differences in groups of women and types of interventions (and thus trials) included and assessed. For example, in regards to variations in types of interventions, recently, Song 2016 conducted a systematic review and meta-analysis assessing the effects of diet and/or exercise interventions on the risk of GDM. The review included 29 trials involving 11,487 women and overall showed a reduction in GDM (Song 2016). Song 2016 thus concluded that lifestyle modification during pregnancy can reduce the risk of GDM. However, when combined diet and exercise (14 trials), diet alone (five trials), and exercise alone (10 trials) interventions were considered separately, the observed reductions in GDM were no longer 'statistically significant', although the direction of effect for each type of intervention did suggest benefit (Song 2016). In regards to assessments of interventions in different groups of women, O'Brien 2016, for example, showed no clear impact of diet and/or lifestyle interventions on GDM specifically in women with a normal BMI; while Madhuvrata 2015

showed a reduction in GDM with diet interventions (but not exercise interventions or combined diet and exercise interventions) specifically in women with risk factors for GDM.

A recent individual participant data (IPD) analysis of antenatal diet and exercise interventions (Rogozńska 2017) showed some similarities and some differences with our findings. In the overall IPD, there were 36 studies with 12,343 women (last searched in March 2015), covering diet alone, exercise alone and mixed diet and exercise interventions compared with standard care. The IPD found no overall difference for GDM or preterm birth, in contrast to our finding of a reduction in these two outcomes. However, both our review and the IPD found reductions in gestational weight gain and caesarean section with lifestyle interventions. The IPD included 16 mixed diet and exercise studies but noted that 10 other mixed diet and exercise studies were not included, which may explain differences in findings (our review included 23 studies).

Although evidence appears to be accumulating in favour of diet and combined diet and exercise interventions for the prevention of GDM, uncertainty remains, and further work is required to disentangle specific effects in different groups of women, and with different diet and exercise intervention characteristics.

AUTHORS' CONCLUSIONS

Implications for practice

Moderate-quality evidence suggests reduced risks of GDM and caesarean section with combined diet and exercise interventions during pregnancy as well as reductions in gestational weight gain, compared with standard care. There were no clear differences in hypertensive disorders of pregnancy, perinatal mortality, large-for-gestational age, perineal trauma, neonatal hypoglycaemia, and childhood adiposity (*moderate- to very low-quality evidence*).

Due to the variability of the diet and exercise components tested in the included studies, the evidence in this review has limited ability to inform practice. Future studies need to describe the interventions used in more detail, if and how these influenced behaviour change and ideally be standardised between studies. Studies could consider use existing core outcome sets to facilitate more standardised reporting.

Implications for research

Additional adequately-powered, well-designed randomised controlled trials, addressing the limitations of previous studies, are needed to assess the effects of combined diet and exercise interventions compared with standard care, and further, to assess the effects of different diet and exercise interventions.

It is important for future trials to consider collecting and reporting on important outcomes such as those suggested in this review, including short-term and long-term maternal and infant/child/adult outcomes, and outcomes relating to the use and costs of health services. Improved reporting of maternal characteristics will enable further assessment of variation in intervention effects, such as based on baseline risk for GDM. Enhanced reporting, and exploration of the effects of specific characteristics of the diet and exercise interventions, is required. The data in the current review are complicated by factors such as differing diagnostic criteria for GDM, and varied outcome descriptions and definitions; these are important issues for future trials to consider.

We have identified 14 planned or ongoing studies and 10 are awaiting classification (pending the availability/reporting of data on GDM). We will consider these in the next review update.

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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	<p>144 women were randomised.</p> <p>Setting: The Resident Obstetric Clinic in Charlotte, North Carolina, USA (recruitment from October 2005 to April 2007).</p> <p>Inclusion criteria: women who established antenatal care at 6 to 16 weeks gestation, were aged between 18 and 49 years, who received all antenatal care at the Resident Obstetrics Clinic, were English-speaking, Spanish-speaking or both, and had a singleton pregnancy.</p> <p>Exclusion criteria: women who established antenatal care at > 16 weeks gestation, were non-English or non-Spanish speaking, had a multiple pregnancy, had a BMI > 40 kg/m², had pre-existing diabetes, untreated thyroid disease or hypertension requiring medication, or other medical conditions that might affect body weight, who delivered at an institution other than Carolinas Medical Centre-Main, had a pregnancy ending in preterm birth (< 37 weeks) or who had limited antenatal care (< 4 visits).</p>
Interventions	<p>Intervention group (n = 57)</p> <p>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 dietitian to receive a standardised counselling session including information on pregnancy-specific diet and lifestyle choices.</p> <p>Diet: counselling consisted of recommendations for a patient-focused caloric value divided in a 40% carbohydrate, 30% protein, and 30% fat fashion.</p> <p>Exercise: women were instructed to engage in moderate-intensity exercise > 3 times per week, preferably 5 times. Women also received information on the appropriate GWG using the IOM guidelines. At each routine appointment, women's weight was measured and charted on an IOM GWG Grid in front of them. The healthcare provider informed the women whether their weight was at the appropriate level. If the GWG was appropriate the women were praised and encouraged to continue their diet and exercise regimen. If their GWG was not within the guidelines, their regimen was reviewed, and they were advised on increasing/decreasing intake and exercise.</p> <p>Control group (n = 43)</p> <p>Women received routine antenatal 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 ex-</p>

Asbee 2009 (Continued)

ercise during pregnancy was that included in the standard 'What to do When You're Having a Baby' booklet. At each routine appointment, women's weight was measured and recorded.

Outcomes	<p>Data in meta-analyses for: GWG; caesarean section.</p> <p>Additional narrative text for: GDM; hypertensive disorders of pregnancy: pre-eclampsia; operative vaginal birth; perineal trauma (vaginal lacerations).</p>
Notes	<p>Funding: <i>"Funded by a grant from the Carolina Healthcare Foundation".</i></p> <p>Declarations of interest: <i>"The authors did not report any potential conflicts of interest".</i></p> <p>The trial was terminated early due to time restrictions involved with completing a resident research project.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: <i>"Randomization was performed using computer-generated random allocation".</i>
Allocation concealment (selection bias)	Low risk	Quote: <i>"Study randomization was numbered and sealed in an opaque envelope. Randomization occurred in consecutive order at the time of the new obstetrical visit".</i>
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of women and trial personnel not considered feasible in view of the intervention and control.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	Of 144 women randomised, 44 (31%) were excluded after randomisation; therefore 100 (69%) were included in the analyses. 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 GWG and BMI change from pre-pregnancy to before delivery were discussed in the methods). Whilst the results section details secondary outcomes including operative vaginal birth, neonatal weight, pre-eclampsia, GDM, vaginal/perinatal lacerations and shoulder dystocia, no numeric outcome data were reported; quote: <i>"no statistically significant differences were noted between the groups".</i>
Other bias	Low risk	No obvious sources of other bias identified.

Bruno 2016

Methods	Randomised controlled trial.
Participants	191 women were randomised.

Bruno 2016 (Continued)

Setting: public antenatal clinic at the Obstetric Unit of the Mother-Infant Department of Azienda Ospedaliero-Universitaria, Policlinico di Modena, Modena, Italy (recruitment from February 2013 to June 2014).

Inclusion criteria: pregnant women with a pre-pregnancy BMI ≥ 25 kg/m², aged > 18 years, with a singleton pregnancy, between their 9th and 12th weeks of pregnancy.

Exclusion criteria: chronic diseases including diabetes mellitus (first trimester glycosuria > 100 mg/dL or fasting plasma glucose ≥ 126 mg/dL, or random glycaemia ≥ 200 mg/dL), hypertension, medical conditions or dietary supplements that might affect body weight (e.g. thyroid diseases), previous bariatric surgery, contraindications to exercise, and intent to give birth elsewhere, previous GDM, smoking habits (≥ 5 cigarettes per day).

Interventions

Intervention group (n = 96)

A personalised dietary modification intervention was initiated at enrolment through a 1-hour counselling session with a dietitian. Follow-up visits, scheduled for the 16th, 20th, 25th and 36th weeks of pregnancy, with both the gynaecologist and dietitian, were used to promote adherence to the intervention. At each of the follow-up visits, the women's weight was measured. In addition, women were interviewed by the dietitian about their diet and exercise habits and counselled about possible changes, when necessary. The women who did not attend the 36-week examination received a phone call.

Diet: the primary focus was decreasing the consumption of foods with a high GI and a high saturated fat content by substituting them with healthier alternatives based on the taste and preferences of the women. Personalised dietary advice included prescription of a low GI, low saturated fat diet with a total intake of 1500 kcal/day (in light of the additional physical activity intervention, 200 kcal/day for obese and 300 kcal/day for overweight women were added). The diet plan recommended to women included a wide range of plant foods, cereals, legumes and fish, with olive oil as the main source of fat, and moderate to no consumption of red wine. The diet had a target macronutrient composition of 55% carbohydrates, 20% protein and 25% fat with moderately low fat levels. The recommended intake of carbohydrates was ≥ 225 g/day.

Exercise: the focus was on encouraging women to develop a more active lifestyle. Women were advised to participate in 30 minutes of moderate-intensity activity > 3 times a week. The 'talk test' was recommended to monitor exercise intensity.

Control group (n = 95)

At enrolment, women in the control group attended a 1-hour counselling session with a dietitian, who provided general recommendations on diet during pregnancy, and the same physical activity advice that was given to the women in the intervention group. In accordance with the Italian Guidelines for a healthy diet and physical activity during pregnancy, the women were also provided with a booklet providing nutrition and lifestyle. The dietitian recommended that women avoid food with a high GI, reduce the consumption of food with a high saturated fat content and increase consumption of vegetables and fruit with a low GI. No specific advice about food quantities, caloric intake, meal composition or meal distribution was given. At the follow-up visits, women in the control group were simply asked about their adherence to the suggested lifestyle.

Outcomes

Data in meta-analyses (or other data) for: GDM; caesarean birth; pregnancy-induced hypertension; large-for-gestational age; induction of labour; GWG; behaviour changes associated with the intervention; stillbirth; gestational age at birth; preterm birth; Apgar score < 7 at 5 minutes; macrosomia; small-for-gestational age; birthweight.

Additional narrative text for: NICU admission.

Notes

Funding: "The study was supported by funding from Policlinico University Hospital of Modena. The funders had no role in the study design, data collection or analysis, decision to publish or preparation of the article".

Declarations of interest: "The authors declare that they have no conflicts of interest".

Risk of bias

Bruno 2016 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomization list was obtained by computer-generated random allocation with a 1:1 ratio".
Allocation concealment (selection bias)	Low risk	Quote: "The allocations were sealed in numbered white envelopes, which were kept in the midwifery facility. After eligibility was assessed, a midwife opened the next random envelope".
Blinding of participants and personnel (performance bias) All outcomes	High risk	The trial was described as "open"; quote: "Because of the study design, the gynaecologist and the dietitian knew the group allocation of the patient".
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The obstetrician in charge of the enrolled women was blind to the allocation group. The data regarding the delivery and the newborns were collected from the clinical records by two residents who were blind to the allocation group". Though not clear whether some outcomes (such as GDM and GWG) were able to be assessed blind, we have judged risk of detection bias as low.
Incomplete outcome data (attrition bias) All outcomes	High risk	Of 191 women randomised, 131 (69%) women were included in the analyses. Women lost to follow-up were significantly younger, had a lower educational level and were more frequently overweight.
Selective reporting (reporting bias)	High risk	The protocol, published with ClinicalTrials.gov, was modified before the preliminary analyses; the primary outcome was changed, and additional secondary outcomes were included. The reporting of outcomes is incomplete for outcomes such as NICU admission ("were very few and did not differ between the groups").
Other bias	Low risk	No obvious sources of other bias identified.

Dodd 2014

Methods	Randomised controlled trial.
Participants	<p>2212 women were randomised.</p> <p>Setting: 3 major metropolitan maternity hospitals in Adelaide, South Australia (recruitment from June 2008 to December 2011).</p> <p>Inclusion criteria: women with a BMI ≥ 25 kg/m², with a singleton pregnancy at 10 to 20 weeks gestation.</p> <p>Exclusion criteria: women with a multiple pregnancy, or type 1 or 2 diabetes diagnosed prior to pregnancy.</p>
Interventions	<p>Intervention group (n = 1108 randomised)</p> <p>Women participated in a comprehensive diet and lifestyle intervention that included diet, exercise and behavioural strategies delivered by a research dietitian and trained research assistants. Women attending a planning session with the dietitian 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</p>

Dodd 2014 (Continued)

reinforced during a visit with the dietitian 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.

Diet: 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).

Exercise: advice encouraged women to increase walking and incidental activity.

Control group (n = 1104 randomised)

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	Data in meta-analyses (or other data tables for): GDM; pre-eclampsia; hypertension; caesarean birth; perinatal mortality; large-for-gestational age; induction of labour; perineal trauma; postpartum haemorrhage; postpartum infection; GWG; behaviour changes associated with the intervention; sense of well-being and quality of life; stillbirth; neonatal mortality; gestational age at birth; preterm birth; Apgar score < 7 at 5 minutes; macrosomia; birthweight; birthweight z score; head circumference; head circumference z score; length; length z score; ponderal index; adiposity; shoulder dystocia; bone fracture; nerve palsy; respiratory distress syndrome; neonatal hypoglycaemia; neonatal hyperbilirubinaemia; antenatal admissions; NICU admission; length of antenatal stay; length of postnatal stay (mother); length of postnatal stay (baby). Additional narrative text for: views of the intervention.	
Notes	Funding: <i>"This project was funded by a four year project grant from the National Health and Medical Research Council (NHMRC), Australia (ID 519240). JMD is supported through a NHMRC Practitioner Fellowship (ID 627005). The funder had no role in the study design, data collection, analysis, interpretation, or writing of the report".</i> Declarations of interest: <i>"All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work".</i>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: <i>"The computer generated randomisation schedule used balanced variable blocks in the ratio 1:1 and was prepared by an investigator not involved with recruitment or clinical care".</i>
Allocation concealment (selection bias)	Low risk	Quote: <i>"A research assistant counselled eligible women and then randomised them to receive lifestyle advice or standard care by telephoning the central randomisation service".</i>
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of women and trial personnel not considered feasible in view of the intervention and control.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quotes: <i>"Outcome assessors were blinded to the treatment group allocated."</i> <i>"After birth, a research assistant not involved in providing the intervention and blinded to treatment allocation obtained information relating to antenatal, birth, and infant outcomes from the case notes".</i>
Incomplete outcome data (attrition bias) 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 ma-

Dodd 2014 (Continued)

ternal death, 4 neonatal deaths (3 due to lethal anomalies) and 5 stillbirths. Therefore, there were 1080 women (97%) 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 (97%) women included in the analyses, and 1067 infants (excluding miscarriages, stillbirths and withdrawn consents).

Selective reporting (reporting bias)	Low risk	Data for pre-specified outcomes (according to published trial protocol) were reported.
Other bias	Low risk	No obvious sources of other bias identified.

El Beltagy 2013

Methods	Randomised controlled trial.
Participants	100 women were randomised. Setting: Egypt. Inclusion criteria: obese women at risk of GDM at their first antenatal visit. Exclusion criteria: none detailed.
Interventions	Intervention group (assumed that n = 50 randomised, n = 48 analysed) Women participated in a 12-week mild physical activity program and diet control. Control group (assumed that n = 50 randomised, n = 48 analysed) Not detailed.
Outcomes	Data in meta-analyses for: no outcomes. Additional narrative text for: GDM, GWG, "adverse neonatal outcome".
Notes	Funding: not reported. Declarations of interest: not reported. 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) All outcomes	High risk	Blinding of women and trial personnel not considered feasible in view of the intervention and control.

El Beltagy 2013 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described in abstract.
Incomplete outcome data (attrition bias) 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

Methods	Randomised controlled trial.
Participants	<p>228 women were randomised.</p> <p>Setting: 3 large metropolitan tertiary teaching hospitals in Victoria, Australia (recruited from June 2008 to September 2010).</p> <p>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).</p> <p>Exclusion criteria: women with multiple pregnancies, diagnosed with type 1 or 2 diabetes, BMI > 45 kg/m², pre-existing chronic medical condition, non-English speaking.</p>
Interventions	<p>Intervention group (n = 121 women randomised)</p> <p>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 healthcare providers. The sessions provided pregnancy-specific diet advice, simple healthy eating and physical activity messages. Simple behavioural change strategies were practiced to identify short-term goals, increase self-efficacy and self-monitoring. Goals were determined by women, informed by the lifestyle messages, and included goals such as increasing fruit and vegetable intake, reducing high fat or convenience food, and increasing physical activity frequency. Self-monitoring strategies included use of pedometers and GWG charts based on IOM recommendations. Women received the same written information as controls, in addition to resources promoting optimal health, GWG and lifestyle. On-going contact and support with mobile phone SMS text messages, personalised by name, were provided throughout the trial commencing from the third session, reinforcing simple health messages for diet, physical activity, behaviour change and relapse prevention; 2 healthy lifestyle postcards were also sent at 30 and 34 weeks gestation to maintain engagement and remind women of the simple health messages.</p> <p>Control group (n = 107 women randomised)</p> <p>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 trial support.</p>
Outcomes	Data in meta-analyses (or other data tables) for: GDM; GWG: behaviour changes associated with the intervention; postnatal weight retention; gestational age at birth; preterm birth; birthweight; breastfeeding; postnatal BMI.

Harrison 2013 (Continued)

Additional narrative text for: GWG: adherence to the intervention.

Notes	Funding: <i>"This project is supported by a BRIDGES grant from the International Diabetes Federation. BRIDGES, an International Diabetes Federation project is supported by an educational grant from Lilly Diabetes (Project Number: LT07-121). The Jack Brockhoff Foundation also provided funding for this study. Helena Teede is an NHMRC research fellow. Cheryce Harrison is supported by a Postdoctoral Fellowship (100168) from the National Heart Foundation".</i>	
	Declarations of interest: <i>"The authors declare that they have no competing interests".</i>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: <i>"Participating women were randomly assigned to intervention or control through computer-generated randomized sequencing".</i>
Allocation concealment (selection bias)	Low risk	Quote: <i>"Allocation concealment was achieved by using sealed opaque envelopes".</i>
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the intervention and control, it was not possible to blind women, though <i>"pedometers were sealed to blind participants to their step count"</i> . Blinding of trial personnel is unclear, as although the authors stated: <i>"Care providers, investigators, and outcome data analyzers were blinded to group allocation"</i> 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) All outcomes	Low risk	Quotes: <i>"Care providers, investigators, and outcome data analyzers were blinded to group allocation"; "Anthropometric assessment included weight... and height measured by a registered nurse unaware of participant allocation".</i>
Incomplete outcome data (attrition bias) All outcomes	Low risk	121 women allocated to intervention, 15 (12%) were lost to follow-up, and therefore 106 (88%) were 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 (9%) were lost to follow-up, and therefore 97 (91%) were 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). Follow-up: At 6 weeks postpartum 17 (14%) intervention group women were lost to follow-up, therefore 104 (86%) analysed; 9 (8%) control group women were lost to follow-up, therefore 98 (92%) analysed.
Selective reporting (reporting bias)	Unclear risk	With no access to a trial protocol, it was not possible to confidently assess selective reporting.
Other bias	Low risk	No obvious sources of other bias identified.

Hawkins 2014

Methods	Randomised controlled trial.
Participants	68 women were randomised.
	Setting: Baystate Medical Center and Mercy Medical Center in Western Massachusetts, USA (recruited from April 2010 to August 2011).

Hawkins 2014 (Continued)

Inclusion criteria: Hispanic women aged 18 to 40 years, with a gestational age of < 18 weeks, who were overweight or obese (pre-pregnancy BMI ≥ 25 kg/m²) and who self-reported participating in < 30 minutes of moderate-intensity activity per week.

Exclusion criteria: history of type 2 diabetes, hypertension, heart disease or chronic renal disease; current medications that adversely influence glucose tolerance; not planning to continue the pregnancy to term; contraindications to participating in moderate-intensity physical activity or a low-fat/high-fibre diet; self-reported participation in ≥ 30 minutes of moderate-intensity exercise on ≥ 3 days per week or ≥ 20 minutes of vigorous-intensity exercise on ≥ 1 day per week; or multiple gestation (e.g. twins).

Interventions	<p>Intervention group (n = 33 randomised)</p> <p>The intervention consisted of 6 in-person behavioural counselling sessions and 5 telephone booster sessions delivered by bicultural and bilingual health educators, tailored for Hispanic women’s culture and context. All materials were available in Spanish and English and were written at a sixth-grade reading level.</p> <p>Diet: women were encourage to decrease their intake of foods high in saturated fat, and to increase intake of dietary fibre (as recommended by the ADA). Health educators assessed readiness and preferences for change, consistent with the Stage of Change framework, and assisted women in developing dietary change goals. Women were provided with a low-literacy pictured-based food guide by which ethnic and other foods were classified based on GI/fibre content and saturated fat using the ‘traffic light’ colours and self-monitoring logs. Activities in the follow-up in-person and telephone-delivered booster sessions included review of logs, problem-solving of challenges, introduction of new tailored materials and goal setting.</p> <p>Exercise: the physical activity during pregnancy guidelines of the ACOG (≥ 30 minutes of moderate-intensity activity on most days of the week) were discussed. Women were encouraged to achieve the standards set in the guideline through increasing their walking and developing a more active lifestyle. Informed by responses to a 'Stage of Change Questionnaire', women were provided with a stage-matched manual which included motivationally targeted materials combined with tip sheets on building social support for new behavioural patterns and strategies for overcoming barriers to physical activity. The health educators assisted the women in developing personalised physical activity goals. Women were provided with a digital pedometer and a physical activity log to track their progress</p> <p>Control group (n = 35 randomised)</p> <p>Women in the control group received standard care (no further details reported).</p>	
Outcomes	<p>Data in meta-analyses (or other data) for: GWG; behaviour changes associated with the intervention; relevant biomarker changes associated with the intervention; gestational age at birth; birthweight.</p> <p>Additional narrative text for: GDM; adherence to the intervention; views of the intervention.</p>	
Notes	<p>Funding: "This work was supported by CDC/ASPH S3948".</p> <p>Declarations of interest: "None declared".</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "eligible patients were randomized... by the health educators to either a lifestyle intervention or a standard care group. Randomization was stratified by age (< 30 years, ≥ 30 years) and pre-pregnancy BMI (25–30 kg/m², ≥ 30 kg/m² with a block size of four".
Allocation concealment (selection bias)	Unclear risk	As above; no further information provided.

Hawkins 2014 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of women and trial personnel not considered feasible in view of the intervention and control.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Assessments were conducted by telephone, at baseline, mid-pregnancy, and at 6 weeks postpartum by bilingual and bicultural interviewers blinded to the assigned intervention group". Though not clear whether clinical outcomes (such as GDM) were able to be assessed blind, we have judged risk of detection bias as low.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Of the 33 women randomised to the intervention group, 30 (94%), 32 (97%) and 24 (75%) were available for the mid-pregnancy, clinical outcome and postpartum assessments, respectively. Of the 35 women randomised to the control group, 29 (85%), 34 (97%) and 29 (85%) were available for the mid-pregnancy, clinical outcome and postpartum assessments respectively. The losses at mid-pregnancy and postpartum were associated with women being unable to be contacted via telephone; losses for clinical outcomes were associated with women being delivered off-site.
Selective reporting (reporting bias)	High risk	Reporting of GDM is incomplete (only the number of cases across both groups in text) and a very limited number of clinical outcomes are reported.
Other bias	Low risk	No obvious sources of other bias identified.

Herring 2016

Methods	Randomised controlled trial.
Participants	<p>66 women were randomised.</p> <p>Setting: 2 large outpatient obstetric practices at Temple University, Philadelphia, Pennsylvania, USA (recruitment from January 2013 to March 2014).</p> <p>Inclusion criteria: women aged ≥ 18 years, self-identifying as African American, at a gestational age < 20 weeks, with a first trimester BMI of 25 to 45 kg/m², with Medicaid recipient status, and cell phone ownership (including unlimited text messaging) and Facebook membership.</p> <p>Exclusion criteria: women with multiple pregnancies, conditions requiring specialised nutritional care, and endorsed tobacco use.</p>
Interventions	<p>Intervention group (n = 33 randomised)</p> <p>A technology-based behavioural weight control intervention was delivered, via Facebook, telephone and text messaging and 1 in-person consultation (at baseline). The intervention was designed to build women's motivation, support and self-efficacy for weight-related behaviour change, while at the same time remain responsive to low-income African American women's social context. At their baseline visit from the health coach, women were oriented to the program, provided with an overview of behavioural change goals, an explanation of the intervention components, and a review of the schedule. Women were assigned the same scheduled for the first 12 weeks, after which the health coach prioritised the order in which goals were to be repeated until birth. The structure of the intervention implementation was as follows: <u>baseline</u>, in person at Temple; target: self-weighing, behavioural goal: weigh yourself weekly; <u>week 1</u>: telephone; target: energy intake, behavioural goal: limit sugar-sweetened beverages to 1 cup per day; <u>weeks 2 and 4</u>: telephone; target: energy intake; behavioural goal: limit junk and high fat food to no more than 1 per day; <u>weeks 6 and 8</u>: telephone; target: physical activity; behavioural goal: walk 5000 steps daily; <u>weeks 10 and 12</u>: telephone; target: energy intake; behavioural goal: stick to 1 plate of food at each meal. Women were also offered a binder with print versions of the content, if tech-</p>

Herring 2016 (Continued)

nology access was lost. Women were prompted to weigh themselves at home, and were supplied with digital scales.

Diet: in addition to the specific recommendations described above, general recommendations were provided around energy intake. Women were encouraged to limit their sugar-sweetened beverages to 1 cup per day, and stick to 1 plate of food at each meal, with low calorie beverages, and convenient, inexpensive, palatable, nutrient-rich food, compatible with social norms suggested as alternatives (consistent with IOM recommendations).

Exercise: women were encouraged to walk 5000 steps daily (gradually increasing walking by 500 steps each week), and were provided pedometers and a walking DVD.

Control group (n = 33 randomised)

Women received standard obstetric care which included: an initial visit in the first trimester, with comprehensive patient history, physical exam, ultrasound and blood work; follow-up visits monthly until week 24, and every 2 to 3 weeks until week 36, with assessment of weight, blood pressure, urine protein and fetal heart rate; weekly visits from week 36 to birth. Women were also provided with information from the ACOG about optimal GWG.

Outcomes	<p>Data in meta-analyses (or other data) for: GDM; caesarean birth; large-for-gestational age; GWG; preterm birth; small-for-gestational age; birthweight.</p> <p>Additional narrative data for: adherence to intervention; views of intervention.</p>
Notes	<p>Funding: "This study was supported by grants from the National Institutes of Health (NIH K23 HL106231) and the Health Resources and Services Administration (HRSA R40MC26818) of the U.S. Department of Health and Human Services (HHS)".</p> <p>Declarations of interest: "At the time of the study, Dr. Herring served on scientific advisory boards for Novo Nordisk and Johnson and Johnson; Dr. Bennett served on the scientific advisory boards for Nutrisystem and the board of Scale Down; and Dr. Foster served on scientific advisory boards of Con Agra Foods, Tate and Lyle, and United Health Group. Currently, Dr. Foster is a full-time employee of Weight Watchers International. None of these entities have provided financial support for this study nor did they have any influence on the weight control methods in this study. All other authors declare no conflicts of interest".</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was computer-generated (by study statistician) with a 1:1 allocation ratio".
Allocation concealment (selection bias)	Low risk	Quote: "randomization status was concealed in opaque envelopes prepared by the statistician".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Authors reported that "providers and clinic staff were blinded to subject randomisation to prevent contamination". However, blinding of women and trial personnel not considered feasible in view of the intervention and control.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No detail provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of the 33 women randomised to the intervention, 0 were lost to follow-up, 6 were excluded (miscarriage: 3; elective termination: 1; preterm birth: 2); therefore 27 (82%) were analysed. Of the 33 women randomised to usual care, 0 were lost to follow-up, 4 were excluded (miscarriage: 2; preterm birth: 2); and thus 29 (88%) were analysed. Relatively high attrition in small sample.

Herring 2016 (Continued)

Selective reporting (reporting bias)	Unclear risk	Some discrepancies between trial registration and published report (e.g. trial registration reports primary outcome to be: change in maternal weight from early pregnancy (< 20 weeks gestation) to 6 months and 1 year postpartum), whereas main report presents primary outcome as proportion of women with excessive GWG) and additional outcomes noted in trial registration are not presented in published report. No measure of variance reported for birth-weight which thus could not be included in the meta-analysis. With no access to a trial protocol, it was not possible to further assess selective reporting.
Other bias	Low risk	No obvious sources of other bias identified.

Hoirisch-Clapauch 2016

Methods	Randomised controlled trial.
Participants	<p>480 women were randomised.</p> <p>Setting: not specified though authors affiliated to the Hospital Federal dos Servidores do Estado, Rio de Janeiro, Brazil (recruitment from 2011 to 2015).</p> <p>Inclusion criteria: women aged 18 to 40 years, with ≥ 2 consecutive first trimester abortions who conceived spontaneously.</p> <p>Exclusion criteria: antiphospholipid antibodies, second or third trimester losses, multiple pregnancies, physical disabilities such as paraplegia, liver or kidney failure, women assigned to standard care following recommendations given to the intervention group, any condition requiring a priori anticoagulation.</p>
Interventions	<p>Intervention group (n randomised not reported, n = 159 completed the trial)</p> <p>Women were instructed to walk briskly for ≥ 40 minutes 7 days a week, to avoid high carbohydrate index meals (such as snacks, candies, fibre-free juices or sugar-sweetened beverages), and to eat 2 daily servings of meat, poultry, fish or other protein rich food, starting when they decided to get pregnant and continuing until birth.</p> <p>Control group (n randomised not reported, n = 160 completed the trial)</p> <p>Women received standard care (no further detail provided).</p>
Outcomes	<p>Data in meta-analyses for: no outcomes.</p> <p>Additional narrative text for: GDM; pre-eclampsia; large-for-gestational age (appropriate); perinatal mortality; GWG (excessive); preterm birth (full term births); neonatal hypoglycaemia.</p>
Notes	<p>Funding: not reported.</p> <p>Declarations of interest: not reported.</p> <p>Information taken from published abstract only. Correspondence with trial authors provided additional unpublished abstract for manuscript under review.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described in abstract.

Hoirisch-Clapauch 2016 (Continued)

Allocation concealment (selection bias)	Unclear risk	Not described in abstract.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of women and trial personnel not considered feasible in view of the intervention and control.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described in abstract.
Incomplete outcome data (attrition bias) All outcomes	High risk	Of the 480 women randomised, 319 (66%) completed the trial (159 women in the intervention group, and 160 in the control group).
Selective reporting (reporting bias)	Unclear risk	Insufficient information to determine.
Other bias	Unclear risk	Insufficient information to determine.

Hui 2012

Methods	Randomised controlled trial.
Participants	<p>224 women were randomised.</p> <p>Setting: Winnipeg, Manitoba, Canada (recruitment from July 2004 to February 2010).</p> <p>Inclusion criteria: non-diabetic pregnant women (at < 26 weeks gestation), attending antenatal classes or community clinics in Winnipeg.</p> <p>Exclusion criteria: women with medical or obstetric contraindications to exercise during pregnancy.</p>
Interventions	<p>Intervention group (n = 112 randomised, n = 102 analysed)</p> <p>Diet: diet interviews and counselling were provided 2 times to each woman by a registered dietitian – at enrolment, and 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 dietitians 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. Dietitians provided personalised counselling based on the interview results, pregnancy week, GWG and Health Canada Guidelines.</p> <p>Exercise: women were given a community-based exercise program 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 group exercise session and multiple home sessions) of mild-to-moderate exercise for 30 to 45 minutes per session was recommended. It was suggested that the exercise began between 20 to 26 weeks and ended at 36 weeks. The group sessions were held in air-conditioned gymnasiums 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 coordinator from the women.</p> <p>Control group (n = 112 randomised, n = 88 analysed)</p>

Hui 2012 (Continued)

Women received standard antenatal 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	Data in meta-analyses (or other data tables) for: GDM; caesarean birth; large-for-gestational age; GWG: behaviour changes associated with the intervention; gestational age at birth; birthweight.
Notes	<p>Funding: "The study was supported by operating grants from the Lawson Foundation, the Canadian Institutes of Health Research and the Public Health Agency of Canada".</p> <p>Declarations of interest: "The authors do not have any conflict of interest regarding the content of results presented in the text".</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation was performed using a computer-generated randomisation allocation table by a staff member without involvement in the study design".
Allocation concealment (selection bias)	Low risk	Quote: "After randomisation, participants received a sealed envelope labelled with the assigned randomisation number, which contained instructions for participants".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Authors report: "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) All outcomes	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of 112 women randomised to intervention group, 102 (91%) were included in analyses; of 112 women randomised to control group, 88 (79%) were included in analyses. 4 women were excluded from analyses due to miscarriage (1 in the control group, 3 in the intervention group). 23 women discontinued the trial in the control group and 7 in the intervention group (due to relocation, work/study, and loss to follow-up). Suggestion of differential attrition.
Selective reporting (reporting bias)	Unclear risk	With no access to a trial protocol, it was not possible to confidently assess selective reporting.
Other bias	Low risk	No obvious sources of other bias identified.

Hui 2014

Methods	Randomised controlled trial.
Participants	<p>113 women were randomised.</p> <p>Setting: Winnipeg, Manitoba, Canada (recruitment from May 2009 to December 2011).</p> <p>Inclusion criteria: women at < 20 weeks of pregnancy, with no existing diabetes, who signed a consent form.</p>

Hui 2014 (Continued)

Exclusion criteria: none detailed (3 women were excluded because of the existence of medical or obstetric contraindications for exercise during pregnancy).

Interventions	Intervention group (n = 57 women randomised) <p>Women received a community-based lifestyle change intervention.</p> <p>Dietary: women received 1-on-1 dietary counselling at baseline and 2 months later, using Food Choice Map software; women recalled their food intake in a typical week, and women and dietitians placed food stickers on a magnetic board (including food items, portion sizes, frequency of each food) which was scanned into the computer at the end of the session, with daily calorie intake and macronutrients analysed instantly. Nutritional recommendations were then based on the dietary intake analysis and Health Canada guidelines, with consideration of food preferences, beliefs and budgeting. GWG goals were discussed and emphasised. Women received a copy of the Food Choice Map with the agreed changes, which served as the diet plan to promote changes. The follow-up at 2 months reinforced recommendations.</p> <p>Exercise: a group exercise program was delivered, in a group session or via DVD format at home. The program included mild-to-moderate aerobic exercise, stretching and strength exercise. Women were encouraged to exercise 3 to 5 times a week for 30 to 45 minutes, from 20 to 26 weeks to 36 weeks gestation. Women kept a log book as a motivator (attendance < 3 times at the group class, showing no interest to exercise at home or no record of exercise in the log book was considered withdrawal from the trial).</p> <p>Control group (n = 56 women randomised)<p>Women received standard antenatal care, as recommended by the SOGC, and were provided with a package of current information on physical activity and healthy eating during pregnancy from Health Canada.</p></p>	
Outcomes	<p>Data in meta-analyses (or other data tables) for: GDM; caesarean birth; large-for-gestational age; GWG: behaviour changes associated with the intervention; gestational age at birth; birthweight;</p> <p>Additional narrative text for: adherence to the intervention.</p>	
Notes	<p>Funding: "grant support from the Canadian Institutes of Health Research, the Lawson Foundation and the Public Health Agency of Canada".</p> <p>Declarations of interest: "The authors declare that there are no competing interests".</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was performed using a computer-generated randomization allocation table by a staff member without involvement in the study design".
Allocation concealment (selection bias)	Low risk	Quote: "After randomisation participants received a sealed envelope labelled with the assigned randomisation number, which contained instructions for participants".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Authors reported that "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) All outcomes	Low risk	Quote: "Data on delivery route, maternal weight at delivery room, birth weight and birth weight-related obstetric procedures (induction, forceps or caesarean section) were collected from hospital medical charts by student assistants without knowledge in study design". Though not clear whether some outcomes

Hui 2014 (Continued)

		(such as GDM and GWG) were able to be assessed blind, we have judged risk of detection bias as low.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "None of the participants discontinued during the participation". No losses or exclusions.
Selective reporting (reporting bias)	Unclear risk	With no access to a trial protocol, it was not possible to confidently assess selective reporting.
Other bias	Low risk	No obvious sources of other bias identified.

Jing 2015

Methods	Randomised controlled trial.	
Participants	262 women were randomised. Setting: West China Second University Hospital, China (recruitment from September 2012 to February 2013). Inclusion criteria: women with singleton pregnancies, aged ≥ 18 years, who could understand the written Chinese language, and did not have pre-existing diabetes. Exclusion criteria: pregnancy-related complications or general medical disorders not associated with pregnancy.	
Interventions	Intervention group (n = 131 randomised) Women received a lifestyle education intervention informed by the Health Belief Model. The key points of education included harms of GWG and GDM, the benefits of encouraged behaviours, the difficulties involved in change habits, and importance of belief in the efficacy of the intervention. In addition to receiving the standardised health education materials provided by the hospital as part of routine care, women received an education manual on diet and physical activity written by the research team, and had 1-on-1 counselling for ≥ 30 minutes with a trained graduate student, at 16 to 20 weeks gestation and 20 to 24 weeks gestation. The graduate was also available to answer questions about diet and physical activity until 20 to 24 weeks, over the phone or via a group on Tencent instant messenger. Control group (n = 131 randomised) Women received only conventional interventions such as standard health education manuals produced by the hospital.	
Outcomes	Data in meta-analyses (or other data tables) for: GDM: GWG: behaviour changes associated with the intervention.	
Notes	Funding: not reported. Declarations of interest "The authors have no conflicts of interest".	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The participants were divided according to the sequence of time and randomized numbers produced by SAS version 11.0 (SAS Institute Inc, Raleigh, NC, USA)".

Jing 2015 (Continued)

Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Participants and data analysts were masked to group assignment. The investigators were not masked to the assignment so that they could implement the personalized intervention for women in the intervention group". While authors reported women were blinded, blinding of women was not considered feasible in view of the intervention and control.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "Only women who finished the whole study were included in the analysis". In the intervention group, of the 131 women randomised, 115 (88%) were included in the analyses (16 did not complete the trial: 1 had abnormal blood sugar; 2 had spontaneous abortions; 11 relocated; 2 lost to follow-up). In the control group, of the 131 women randomised, 106 (81%) were included in the analyses (25 did not complete the trial: 1 had abnormal blood sugar; 2 had spontaneous abortions; 13 relocated; 9 lost to follow-up). Suggestion of differential attrition.
Selective reporting (reporting bias)	Unclear risk	With no access to a trial protocol, it was not possible to confidently assess selective reporting.
Other bias	Low risk	No obvious sources of other bias identified.

Koivusalo 2016

Methods	Randomised controlled trial.
Participants	<p>293 women were randomised.</p> <p>Setting: multi-centre trial, with 2 rural municipalities: Kauhajoki and Lapua in Finland (from February 2008 to January 2014).</p> <p>Inclusion criteria: women who had 1 or more risk factors for GDM (BMI > 25 kg/m², previous history of GDM, previous child born at > 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 mmol/L, to 5.5 mmol/L, and a 2 hour-OGTT plasma glucose < 7.8 mmol/L.</p> <p>[A 2-hour OGTT was offered to all women at their first contact with maternal healthcare units during gestational weeks 8 to 12].</p> <p>Exclusion criteria: women with GDM (fasting plasma glucose ≥ 5.6 mmol/L or 2-hour plasma glucose ≥ 7.8 mmol/L), and women who did not want to participate in the trial for personal or professional reasons.</p>
Interventions	<p>Intervention group (n = 155 randomised)</p> <p>Women received individualised, structured lifestyle counselling from specifically trained trial nurses (midwives) and dietitians, 3 times during their pregnancy (at medians of 13.3 weeks, 23.1 weeks, and 35.1 weeks). Women also attended a 2-hour group counselling session with a dietitian at the time of enrolment. Women also visited the trial nurses at 6 weeks, 6 months and 12 months postpartum.</p> <p>Diet: for women with a pre-pregnancy BMI ≥ 30 kg/m², the recommendation was no GWG during the first 2 trimesters. Dietary advice was based on Nordic Nutrition Recommendations and focused on optimising women's consumption of vegetables, fruit and berries, whole-grain products rich in fibre, low-</p>

Koivusalo 2016 (Continued)

fat dairy products, vegetable fats high in unsaturated fatty acids, fish, and low-fat meat product, and lowering intakes of sugar-rich foods. 'The plate model' was used during the counselling (filling half a plate with raw or cooked vegetables, one-quarter with starchy carbohydrates (e.g. potato, rice or pasta) and one-quarter with meat, fish, beans, eggs or other sources of protein). The aim was to achieve a total intake of 1600 to 1800 kcal a day, with 40% to 50% energy coming from carbohydrates, 30% to 40% energy from fats and 20% to 25% energy from protein. During the postpartum, breastfeeding and infant nutrition counselling were provided. Women filled out 3-day food diaries every 3 months throughout the trial.

Exercise: women were encouraged to achieve a minimum of 150 minutes (30 minutes 5 times a week, or 50 minutes 3 times a week) of moderate-intensity physical activity per week, and to adopt an overall active lifestyle (moderate-intensity exercise was defined as exercise during which the women became at least slightly out of breath and perspired but were still able to talk or a level equalling 11 to 15 on Borg's visual scale of perceived exertion). Women and trial nurses (midwives) planned, and during the follow-up updated, an individual physical activity program. Women received pedometers, with a recommendation of a minimum of 10,000 steps a day. Women had access, free of charge, to public swimming pools and/or guided exercise groups once a week provided by the municipalities. Where exercise goals were not met, women were instructed to book in with the physical activity advisor. Women completed physical activity log books.

Control group (n = 138 randomised)

Women received general information leaflets on diet and physical activity like those provided by local Primary Health Care centres/antenatal clinics at the time of enrolment. During their pregnancy, women visited the trial nurse 3 times, to make measurements, obtain blood samples, and administer questionnaires, as well as antenatal clinics according to standard practice.

Outcomes	Data in meta-analyses (or other data tables) for: GDM; pre-eclampsia; hypertension (pregnancy-induced hypertension, essential hypertension); caesarean section; GWG; behaviour changes associated with the intervention; relevant biomarker changes associated with the intervention; gestational age at birth; macrosomia; birthweight; birthweight z score; length; respiratory distress syndrome; antenatal visits.	
Notes	Funding: <i>"This study was funded by the Ahokas Foundation, the Finnish Foundation for Cardiovascular Disease, Special State Subsidy for Health Science Research of Helsinki University Central Hospital, Samfundet Folkhalsan, The Finnish Diabetes Research Foundation, the State Provincial Office of Southern Finland, and The Social Insurance Institution of Finland. The funders have not had any role in designing or conducting the study; in the collection, management, analysis, or interpretation of the data; in the preparation, review, or approval of the manuscript; and in the decision to submit the manuscript for publication".</i> Declarations of interest: <i>"No potential conflicts of interest relevant to this article were reported".</i>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: <i>"In the randomization process, we used randomly permuted blocks stratified by risk factors (BMI ≥30 kg/m², history of GDM)".</i> Not stated how randomly permuted blocks were generated; thus judged to be unclear risk of selection bias.
Allocation concealment (selection bias)	Low risk	Quote: <i>"The randomisation was performed by a study nurse and by dispensing the next sequentially numbered subject code and opening the corresponding code envelope, which included the intervention arm to be assigned to the subject".</i>
Blinding of participants and personnel (performance bias)	High risk	Blinding of women and trial personnel not considered feasible in view of the intervention and control.

Koivusalo 2016 (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Blinded-study physicians reviewed participants' obstetric records and confirmed maternal and neonatal diagnosis".
Incomplete outcome data (attrition bias) All outcomes	Low risk	Of 155 women randomised to the intervention group, 11 (7%) were lost; thus 144 (93%) were included in the analyses; of the 138 women randomised to the control group, 13 (9%) were lost; thus 125 (91%) were included in the analyses.
Selective reporting (reporting bias)	Unclear risk	The trial has reported on perinatal outcomes; the trial protocol indicates that 12-month follow-up is also complete (this was not reported on), and that there will be ongoing follow-up to 10 years for mothers, fathers and children. The protocol indicates additional outcomes which have not yet been reported (including maternal quality of life, cost-effectiveness, prevention of maternal type 2 diabetes 1 year after birth, small-for-gestational age and neonatal hypoglycaemia).
Other bias	Low risk	No obvious sources of other bias identified.

Korpi-Hyövalti 2011

Methods	Randomised controlled trial.
Participants	<p>60 women were randomised.</p> <p>Setting: multi-centre trial, with 2 rural municipalities: Kauhajoki and Lapua in Finland (recruitment from April 2005 to May 2006).</p> <p>Inclusion criteria: women who had 1 or more risk factors for GDM (BMI > 25 kg/m², previous history of GDM, previous child born at > 4.5 kg, aged > 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 mmol/L, to 5.5 mmol/L, and a 2 hour OGTT plasma glucose of < 7.8 mmol/L.</p> <p>[a 2-hour OGTT was offered to all women at their first contact with maternal healthcare units during gestational weeks 8 to 12]</p> <p>Exclusion criteria: women with GDM (fasting plasma glucose ≥ 5.6 mmol/L or 2-hour plasma glucose ≥ 7.8 mmol/L), and women who did not want to participate in the trial for personal or professional reasons.</p>
Interventions	<p>Intervention group (n = 30 randomised; n = 27 analysed)</p> <p>Diet: dietary advice tailored to each woman 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 whole grain products (with a goal of carbohydrate 50% to 55% energy, fibre 15 g/1000 kcal, fat 30% energy %, saturated fat < 10% energy, and protein 15% to 20% energy). Recommendation for energy intake was 30 kcal/kg/day for normal weight women and 25 kcal/kg/day for overweight women.</p> <p>Exercise: 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 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 < 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 > 30 kg/m² and the woman had not been active, exercise was started with 15 minutes per day 3 times a week).</p>

Combined diet and exercise interventions for preventing gestational diabetes mellitus (Review)

Korpi-Hyövalti 2011 (Continued)

Control group (n = 30 randomised; n = 27 analysed)

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 antenatal clinical at 1-month intervals according to standard care.

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	<p>Data in meta-analyses (or other tables data) for: GDM; GWG; relevant biomarkers associated with the intervention; birthweight.</p> <p>Additional narrative text for: pre-eclampsia; caesarean birth; induction of labour; perineal trauma (lacerations); gestational age at birth; macrosomia; respiratory distress; hyperbilirubinaemia (jaundice requiring phototherapy); NICU admission.</p>
Notes	<p>Funding: "This study was funded by Seinäjoki Central Hospital and Kuopio University Hospital, University of Eastern Finland and municipalities of Kauhajoki, Lapua i.e. employers of the authors mentioned on the title page. The study was supported by EVO funding from Kuopio University Hospital and South Ostrobothnia Hospital District".</p> <p>Declarations of interest: "The authors declare that they have no competing interests".</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "These high-risk women were randomly assigned to the lifestyle intervention group... or to the close follow-up group... by the study physician in the Central Hospital with the use of a computed randomisation list".
Allocation concealment (selection bias)	Unclear risk	As above, and "The health care nurses who scheduled the study visits did not have access to the randomisation list".
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding, trial described as "open".
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Trial described as "open". No further information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	60 women were randomised; 54 women (90%) 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 ("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 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 tended to have a higher educational status ($P = 0.080$).

Luoto 2011

Methods	Cluster-randomised controlled trial.
Participants	<p>14 municipalities, with 640 women, were randomised.</p> <p>Setting: maternity clinics of primary healthcare centres of 14 municipalities in Pirkanmaa region in south-western Finland. All 14 municipalities with ≥ 70 annual deliveries were recruited to the trial (recruitment from October 2007 to December 2008).</p> <p>Inclusion criteria: pregnant women with ≥ 1 of the following risk factors: BMI ≥ 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 1 or 2 diabetes in first or second degree relatives, aged ≥ 40 years.</p> <p>Exclusion criteria: ≥ 1 of 3 baseline OGTT measurements abnormal (fasting blood glucose ≥ 5.3 mmol/L, ≥ 10.0 mmol/L at 1 hour, and ≥ 8.6 mmol/L at 2 hours), pre-pregnancy type 1 or 2 diabetes, unable to speak Finnish, < 18 years old, multiple pregnancy, a physical restriction preventing physical activity, substance abuse, treatment or clinical history of psychiatric illness.</p>
Interventions	<p>Intervention group (n = 7 municipalities)</p> <p>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 appropriate GWG graph selected to guide the woman in her GWG. 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.</p> <p>Diet: the goal of diet counselling was to help women achieve a healthy diet ($\leq 10\%$ saturated fat, 5% to 10% polyunsaturated fat, 25% to 30% total fat, and $< 10\%$ saccharose of total energy intake, and 25 g/day to 35 g/day fibre). Women were advised to consume vegetables, fruits and berries ≥ 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 $\geq$ 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.</p> <p>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 minutes. Women were offered an opportunity to participate in monthly group exercise sessions.</p> <p>Control group (n = 7 municipalities)</p> <p>Women received no counselling beyond usual care – which included some dietary counselling and follow-up of GWG, but little on physical activity.</p>
Outcomes	<p>Data in meta-analyses (or other data tables) for: GDM; pre-eclampsia; large-for-gestational age; GWG; behaviour changes associated with the intervention; relevant biomarkers associated with the intervention; sense of well-being and quality of life; gestational age at birth; macrosomia; small-for-gestational age; birthweight; birthweight z score; head circumference; length; length z score; ponderal index; costs to families associated with management provided; costs associated with the intervention; costs of maternal care; costs of offspring care.</p> <p>Additional narrative text for: adherence to the intervention; costs associated with the intervention.</p>
Notes	<p>Funding: "The main sources of funding in this study are (Finnish) Diabetes research fund, Competitive research funding from Pirkanmaa hospital district, Academy of Finland, Ministry of Education and Ministry of Social Affairs and Health. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript".</p>

Luoto 2011 (Continued)

Declarations of interest: "The authors have declared that no competing interests exist".

ICC of 0.12 was used in the analyses.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "In the randomization process, participating municipalities were first pairwise matched with regard to annual number of births, size and socio-economic level of the population, estimated incidence of GDM, and urbanity level. Municipalities were then randomized by computer".
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "An inevitable limitation is also that the women and the nurses in the usual care group could not be blinded for the purpose of the study, which may have resulted in changes in their health behavior or counseling practices".
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	14 clusters were randomised and all included in the analyses. Of the 343 women in the intervention group and 297 women in the control group that agreed to participate (after having been screened for eligibility), 81 (24%) in the intervention group and 93 (31%) in the control group were excluded due to abnormal OGTT results at baseline (and 16 and 8 respectively due to miscarriage). The final number of women in the analyses, after further loss to follow-up (27 in the intervention group and 16 in the control group) was 219 in the intervention group and 180 in the control group. Thus, of the women considered preliminarily eligible, who consented to participate, 219 (64%) were followed up in the intervention group, and 180 (60%) in the control group; of the women who received the allocated intervention, 219 (89%) were followed up in the intervention group and 180 (92%) in the control group. For some outcomes "n Missing" is reported in the tables – it is unclear however from which groups the missing data are from (for example, GWG "n Missing" = 31, and it is unclear if these women are from the intervention or control groups).
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 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, 1-year follow-up data are expected; 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

Methods Randomised controlled trial.

Combined diet and exercise interventions for preventing gestational diabetes mellitus (Review)

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Petrella 2013 (Continued)

Participants	63 women were randomised	
	Setting: Obstetric Unit at the Mother-Infant Department of Policlinico Hospital, University of Modena, Modena, Italy (recruitment from April 2011 to October 2011).	
	Inclusion criteria: pregnant women with a pre-pregnancy BMI ≥ 25 kg/m ² , aged > 18 years, with a single pregnancy during their 12th week.	
	Exclusion criteria: twin pregnancy, chronic diseases (e.g. diabetes, chronic hypertension, untreated thyroid diseases), GDM in previous pregnancies, smoking during pregnancy, previous bariatric surgery, engagement in regular physical activity, use of dietary supplements or herbal products known to affect body weight, other medical conditions that might affect body weight, plans to deliver outside the Birth Centre.	
Interventions	Intervention group (n = 33) <p>Women received a "<i>Therapeutic Lifestyle Changes (TLC) Program</i>", with specific follow-up for adherence at the 16th, 20th, 28th and 36th week.</p> <p>Diet: women were prescribed a diet consisting of 1700 kcal/day for overweight women and 1800 kcal/day for obese women, with 3 main meals and 3 snacks. The primary focus of the diet was decreasing high-GI foods and substituting with healthier alternatives; with a second goal being redistribution of the number of meals throughout the day, with the last 2 snacks eaten after dinner to avoid hypoglycaemia at night. The target macronutrient composition was 55% carbohydrate (80% complex with low GI and 20% simple), 20% protein (50% animal and 50% vegetable), 25% fat (12% monounsaturated, 7% polyunsaturated, 6% saturated); the daily intake of carbohydrates was ≥ 225 g/day. The diet was introduced after randomisation by a gynaecologist and dietitian, with a 1-hour counselling session about appropriate GWG at term for preventing unfavourable outcomes. Women completed Food Frequency Questionnaires at baseline and the 36th week.</p> <p>Exercise: the exercise component focused on developing a more active lifestyle, with women advised to participate in 30 minutes of moderate-intensity activity ≥ 3 days a week. Women were provided with a pedometer to wear during each walking session for assessment of adherence, and were told to consider using the 'talk test' (to be able to maintain a conversation during activity).</p> <p>Control group (n = 30)</p> <p>Women received a simple nutritional booklet about lifestyle (in agreement with Italian Guidelines for healthy diet during pregnancy) and attended their regularly scheduled visits with their obstetrician until birth.</p>	
Outcomes	Data in meta-analyses (or other data tables) for: GDM; pregnancy-induced hypertension; caesarean birth; induction of labour; GWG; preterm birth; behaviour changes associated with the intervention.	
	Additional narrative text for: large-for-gestational age; perineal trauma; postpartum haemorrhage; Apgar score < 7 at 5 minutes; NICU admission.	
Notes	Funding: not reported.	
	Declarations of interest: " <i>The authors report no conflicts of interest</i> ".	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: " <i>Randomization list was obtained by using a computer-generated random allocation in blocks of three</i> ".
Allocation concealment (selection bias)	Low risk	Quote: " <i>The numbers were sealed in numbered white envelopes. After eligibility assessment, the midwife open the next envelope</i> ".

Petrella 2013 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of women and trial personnel not considered feasible in view of the intervention and control.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Two women randomized to Controls later withdrew their consent for the study. Therefore, the remnant participants were 33 in the Therapeutic Lifestyle Changes group and 28 in the Controls".
Selective reporting (reporting bias)	High risk	A number of outcomes are reported incompletely as "similar" between groups, or "no statistically significant differences".
Other bias	Low risk	No obvious sources of other bias identified.

Phelan 2011

Methods	Randomised controlled trial.
Participants	<p>401 women were randomised.</p> <p>Setting: 6 obstetric offices in Providence, Rhode Island, USA (recruitment from 2006 to 2008).</p> <p>Inclusion criteria: women with a gestational age between 10 to 16 weeks, with a BMI between 19.8 kg/m² to 40 kg/m², who were non-smoking adults (≥ 18 years), were fluent in English, had access to a telephone, and who had a singleton pregnancy.</p> <p>Exclusion criteria: women with self-reported major health or psychiatric disease, with weight loss during pregnancy, or with a history of ≥ 3 miscarriages.</p>
Interventions	<p>Intervention group (n = 201)</p> <p>Women in the intervention group received all aspects of standard care plus a behavioural lifestyle intervention designed to prevent excessive GWG; no intervention was provided postpartum. The intervention included 1 face-to-face visit with an interventionist at the onset of treatment who discussed appropriate GWG. 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 GWG guidelines during any 1-month interval received additional phone calls (2 calls per month) that provided structured meal plans, and specific goals.</p> <p>Diet: recommendation: calorie goals (20 kcal/kg).</p> <p>Exercise: recommendation: 30 minutes walking most days of the week.</p> <p>Control group (n = 200)</p> <p>Women attended regular scheduled visits to antenatal care providers, occurring monthly until 28 weeks gestation, bi-weekly from 28 to 36 weeks gestation, weekly until birth, and at 6 weeks postpartum. Women received standard nutrition counselling provided 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 trial entry with the trial interventionist and received trial newsletters at 2-month intervals during pregnancy and postpartum, providing information about pregnancy related issues (antenatal vitamins and maternity clothes), to improve retention in the trial.</p>

Phelan 2011 (Continued)

Outcomes

Data in meta-analyses (or other data tables) for: GDM; pre-eclampsia; hypertension; caesarean birth; GWG; behaviour changes associated with the intervention; sense of well-being and quality of life; post-natal weight retention; return to pre-pregnancy weight; gestational age at birth; preterm birth; macrosomia; birthweight.

Additional narrative text for: breastfeeding.

Notes

Funding: "Supported by the National Institutes of Health (grant DK071667)."The National Institutes of Health was not involved in the design and conduct of the study; collection, management, analysis, and interpretation of data; or the preparation, review, or approval of the manuscript".

Declarations of interest: "None of the authors had a conflict of interest".

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was computer-generated (by the study statistician) in randomly varying block sizes and stratified by clinic and BMI category".
Allocation concealment (selection bias)	Low risk	Quote: "allocation was concealed in opaque envelopes prepared by the study statistician".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Authors report "Clinic staff and physicians were blinded to subject randomisation to prevent contamination". However, blinding of women and trial personnel not considered feasible in view of the intervention and control.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quotes: "assessor-blind"; "Postpartum weight, changes in demographics, and breastfeeding status (any breastfeeding compared with formula only) were obtained by a blinded research assistant at the 6-mo postpartum visit. Obstetric records were abstracted after delivery to obtain maternal and fetal complications"; "Assessments were conducted by blind assessors at study entry, 30 wk of gestation, and 6 and 12 mo postpartum". Though not clear whether some outcomes (such as GWG) were able to be assessed blind, we have judged risk of detection bias as low.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Of the 201 women randomised to the intervention group, 188 (94%) attended the 30 week assessment visit, and 159 (79%) attended a 6-month postpartum assessment, though 176 (88%) were included in the 6-month postpartum analyses. Of the 200 women randomised to the control group, 187 (94%) attended the 30-week assessment visit, and 161 (80%) attended a 6-month postpartum assessment, though 182 (91%) were included in the 6-month postpartum analyses. Follow-up: 128 (64%) women in the intervention group attended a 12-month postpartum assessment, though 164 (82%) were included in the 12-month postpartum analyses; 133 (67%) women in the control group attended a 12-month postpartum assessment, though 167 (84%) were included in the 12-month postpartum analyses. [After the exclusion of women with miscarriages, GDM or subsequent pregnancies 320/358 (89% completed the 6-month assessment, and 261/331 (79%) completed the 12-month assessment; "Completers (n = 261) of the 12-mo postpartum assessment were more likely to be married (71.3% compared with 48.6%; P = 0.0004) and white (67.8% compared with 54.2%; P = 0.04) and were marginally older (28.5 compared with 27.3 y; P = 0.08) than the non completers (n = 70)"]
Selective reporting (reporting bias)	Unclear risk	With no access to a trial protocol, it was not possible to confidently assess selective reporting.

Phelan 2011 (Continued)

Other bias	Low risk	No obvious sources of other bias identified. Completers of the 6-month post-partum assessment were older than non-completers, but no other differences were shown (and no differences were shown at baseline between groups).
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Polley 2002

Methods	Randomised controlled trial.	
Participants	<p>120 women were randomised.</p> <p>Setting: Obstetric clinic for low-income women at a hospital in Pittsburgh, Pennsylvania, USA.</p> <p>Inclusion criteria: women < 20 weeks gestation, who gave informed consent.</p> <p>Exclusion criteria: underweight women (BMI < 19.8 kg/m²) based on self-reported height and pre-pregnancy weight, aged < 18 years, whose first antenatal visit was < 12 weeks gestation, with high-risk pregnancies (i.e. drug abuse, chronic health problems, previous complications during pregnancy, or current multiple gestation).</p>	
Interventions	<p>Intervention group (n = 61 randomised; n = 57 followed to birth)</p> <p>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 GWG; 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 weight gain - women whose GWG exceeded the recommended levels were given additional individualised nutrition/behavioural counselling using 6 steps (review of GWG chart; assessment of current eating and exercise based on 24-hour recall or review of self-monitoring records).</p> <p>Diet: the primary focus of the intervention was on decreasing high-fat foods, and substituting healthier alternatives. If these approaches did not help the woman achieve the recommended weight, a more structured meal plan and individualised calorie goals were set.</p> <p>Exercise: the intervention focused on increasing walking and developing a more active lifestyle.</p> <p>Control group (n = 59 randomised; n = 53 followed to birth)</p> <p>Women received standard care, including standard nutrition counselling provided by the physicians, nutritionists and 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.</p>	
Outcomes	<p>Data in meta-analyses (or other data) for: GDM; pre-eclampsia; hypertension; caesarean birth; GWG; behaviour changes associated with the intervention; postnatal weight retention; gestational age at birth; preterm birth; macrosomia; birthweight.</p>	
Notes	<p>Funding: "This work was funded by a grant from Magee-Womens Health Foundation; Magee-Womens Research Institute awarded to Dr Wing".</p> <p>Declarations of interest: not reported.</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Women were randomly assigned"; no further information provided.

Polley 2002 (Continued)

Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of women and trial personnel not considered feasible in view of the intervention and control.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Minimal losses to follow-up during the pregnancy period: of 61 women randomised to the intervention group, 2 women moved out of the area, 1 had a miscarriage, and 1 withdrew; thus 57 (93%) were followed to delivery; in the control group, of 59 women randomised, 4 women moved out of the area and 2 had miscarriages; thus 53 (90%) were followed to delivery. Follow-up: an additional 23 intervention group women were lost to postpartum follow-up, thus 34 (56%) were followed postpartum; an additional 13 control group women were lost postpartum, thus 40 (68%) were followed postpartum.
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 obvious sources of other bias identified.

Poston 2013

Methods	Randomised controlled trial.
Participants	183 women were randomised. Setting: 4 hospitals in the UK (Glasgow, Newcastle, London), in urban settings (recruitment from March 2010 to May 2011). Inclusion criteria: women with a BMI ≥ 30 kg/m ² , singleton pregnancy, a gestational age > 15 weeks and < 17 + 6 weeks. Exclusion criteria: women unable or unwilling to give informed consent, at a gestation < 15 weeks and > 17 + 6 weeks, with pre-existing diabetes, pre-existing essential hypertension (treated), pre-existing renal disease, a multiple pregnancy, systemic lupus erythematosus, antiphospholipid syndrome, sickle cell disease, thalassaemia, coeliac disease, who were prescribed metformin, had a thyroid disease or current psychosis.
Interventions	Intervention group (n = 94 randomised) Women in the intervention group attended a 1-to-1 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 1-to-1 appointment, women received a 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 deliv-

Poston 2013 (Continued)

ered a different element of the dietary and physical activity intervention; goals from the previous week were reviewed and goals set for the following week.

Diet: 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.

Exercise: 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.

Control group (n = 89 randomised)

Women in the control group received standard antenatal care, and returned for data collection appointments with the trial midwife at 27 to 28 + 6 weeks and 34 to 36 + 6 weeks (where possible with coinciding antenatal visits).

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	Data in meta-analyses (or other data tables) for: GDM; large-for-gestational age; behaviour changes associated with the intervention; sense of well-being and quality of life; macrosomia. Additional narrative text for: GWG; adherence to the intervention; views of the intervention.	
Notes	Funding: <i>"This paper presents independent research commissioned by the National Institute for Health Research (NIHR) (UK) under the Programme Grants for Applied Research programme RP-0407-10452. The views expressed in this paper are those of the author(s) and not necessarily those of the National Health Service, the NIHR or the Department of Health. The study was also supported by Guys and St.Thomas' Charity; Reg Charity 251983, UK; Chief Scientist Office, Scottish Government Health Directorates, Edinburgh, UK and Tommy's Charity; Reg Charity 1060508, UK".</i> Declarations of interest: <i>"The authors declare that they have no competing interests".</i>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: <i>"The randomised treatment was allocated automatically, balanced by minimisation for maternal age, centre, ethnicity, parity and BMI".</i>
Allocation concealment (selection bias)	Low risk	Quote: <i>"Randomisation was performed online".</i>
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of women and trial personnel not considered feasible in view of the intervention and control.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) 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

Poston 2013 (Continued)

(84%) women and 85 (90%) neonates were included in the analysis, and 75 (84%) women and 84 neonates (94%) in the control group.

Selective reporting (reporting bias)	Unclear risk	With no access to a trial protocol, it was not possible to confidently assess selective reporting. The methods specify a number of clinical outcomes for which data were "recorded but not reported".
Other bias	Low risk	No obvious sources of other bias identified.

Poston 2015

Methods	Randomised controlled trial.
Participants	<p>1555 women were randomised.</p> <p>Setting: antenatal clinics in 8 inner-city National Health Service Trust Hospitals in the UK: London (3 centres), Bradford, Glasgow, Manchester, Newcastle, and Sutherland (from March 31 2009 to June 2 2014).</p> <p>Inclusion criteria: women > 16 years with a BMI ≥ 30 kg/m², a singleton pregnancy, between 15 weeks and 18 weeks plus 6 days gestation.</p> <p>Exclusion criteria: women who were unable or unwilling to give informed consent, with underlying disorders including pre-pregnancy diagnosis of essential hypertension, diabetes, renal disease, systemic lupus erythematosus, antiphospholipid syndrome, sickle cell disease, thalassaemia, celiac disease, thyroid disease, and current psychosis; and using metformin.</p>
Interventions	<p>Intervention group (n = 783 randomised)</p> <p>The intervention was informed by control theory and elements of social cognitive theory. Within a week of randomisation, women attended an individual interview at their centre, with a health trainer (a person with skills in assisting behavioural change, but not necessarily a health professional). Women had 8 further health trainer-led group or individual sessions of 1 hour, weekly; where women could not attend in person, material was provided by telephone or email. Sessions addressed approaches to achieving SMART (specific, measurable, achievable, relevant and time specific) goals. Women received advice on: self-monitoring, identifying, and problem-solving barriers to behaviour change; enlisting social support; and providing opportunities for social comparison. Women also received a handbook with information about the intervention, with recommended foods and recipes and suggestions for physical activity. In addition, women were provided with a DVD of an exercise regimen safe pregnancy, a pedometer, and a log book for recording their weekly goals.</p> <p>Diet: the diet intervention aimed to promote healthy eating, but not necessarily restrict energy intake; women received tailored recommendations which suggested exchanging foods with medium-to-high GI for those with a lower GI, and restricting intake of saturated fat.</p> <p>Exercise: women were encouraged to incrementally increase walking from a pedometer assessed baseline. The initial goal for walking activity was tailored to each woman's pre-existing activities. The emphasis was walking at moderate intensity, with additional options included, for women who already engaged in some physical activity.</p> <p>Control group (n = 772 randomised)</p> <p>Women in the control group received standard antenatal care, at their trial centre, in accordance with local practice. Typically, women attended 9 appointments. The local practice for women with obesity was informed by the UK NICE guidelines, which stated that women should be advised at first contact with a health professional, and at no other time, about a healthy diet and the benefits of physical activity. The women returned for data collection appointments with the trial midwife at 27 to 28 + 6 weeks and 34 to 36 + 6 weeks (where possible with coinciding antenatal visits). No further information was</p>

Poston 2015 (Continued)

provided to control group women, about benefits of physical activity and diet, beyond that given, as per UK NICE guideline informed practice, in the initial session.

Outcomes	Data in meta-analyses (or other data tables) for: GDM; pre-eclampsia; caesarean birth; perinatal mortality; large-for-gestational age; operative vaginal birth; induction of labour; placental abruption; postpartum haemorrhage; postpartum infection; GWG; behaviour changes associated with the intervention; relevant biomarkers associated with the intervention; breastfeeding; postnatal weight retention; postnatal BMI; stillbirth; neonatal mortality; gestational age at birth; preterm birth; macrosomia; small-for-gestational age; birthweight; head circumference; adiposity; neonatal hypoglycaemia; childhood weight; childhood weight z score; childhood height; childhood height z score; childhood head circumference; childhood adiposity; length of antenatal stay; NICU admission; length of postnatal stay (mother); length of postnatal stay (baby).	
	Additional narrative text for: adherence to the intervention.	
Notes	<p>Funding: "Our research was funded by the UK's National Institute for Health Research (NIHR) under its grants for applied research programme (RP-PG-0407-10452). Support was also received from the NIHR collaboration for leadership in applied health research (to JS, PTS, and ALB). Contributions to funding were also provided by the Chief Scientist Office Scottish Government Health Directorates (Edinburgh) (CZB/A/680), Guys and St Thomas' Charity, Tommy's Charity (to LP, ALB, and NP), and the NIHR Biomedical Research Centre at Guy's and St Thomas' NHS Foundation Trust and King's College London. KMG is supported by the NIHR through the NIHR Southampton Biomedical Research Centre. LP and KMG are supported by the European Union's seventh framework programme (FP7/2007-2013; project EarlyNutrition, grant agreement 289346). The views expressed in this Article are those of the authors and not necessarily those of the UK's National Health Service, the NIHR, or the Department of Health in England".</p> <p>Declarations of interest: "LP reports a research grant from Abbott Nutrition, outside the submitted work. TABS reports personal consultancy fees from the Natural Hydration Council, Heinz Foods, Archer Daniels Midland, the Global Dairy Platform, and GlaxoSmithKline, outside the submitted work; and is a trustee and scientific governor for the British Nutrition Foundation, outside the submitted work. KMG reports reimbursement of travel and accommodation expenses from Nestle Nutrition Institute, outside the submitted work; research grants from Abbott Nutrition and Nestec, outside the submitted work; and patents pending for phenotype prediction, predictive use of CpG methylation, and maternal nutrition composition, outside the submitted work. All other authors declare no competing interests".</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "We used a computer-generated randomisation procedure via a password-protected website".
Allocation concealment (selection bias)	Low risk	Quotes: "We used a computer-generated randomisation procedure via a password-protected website"; "allocation to study groups was done by centre's UP-BEAT trial midwife".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Authors reported: "in view of the nature of the intervention, participants and staff were aware of allocations".
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of the 783 women randomised to the intervention group, primary outcome data were available for 629 (80%) mothers, and 761 (97%) infants; and of the 772 women randomised to the control group primary outcome data were provided for 651 (84%) mothers and 751 (97%) infants. Authors reported that "the main reason for missing outcome data was that participants declined to attend fur-

Poston 2015 (Continued)

ther study visits". More women in the intervention group (129; 16%) compared with the control group (92; 12%) failed to complete the OGTT required for the primary outcome.

Follow-up: 1522 women were approached for 6-month follow-up, 720 (47%) infants, and 707 (47%) women took part. Authors reported that: *"in comparison with those who did not take part, mothers who attended the 6-month visit were on average 1.3 years older, more likely to be Caucasian, nulliparous, to have had gestational diabetes mellitus in the index pregnancy...and were less likely to be current smokers" and "infants who attended the 6-month appointment had a greater gestational age at delivery...were 67g heavier, and more likely to have been breast-fed at birth than those who did not attend"*.

Selective reporting (reporting bias)	Low risk	Outcomes appear to have been measured and reported (though not yet in full) as per published trial protocol.
Other bias	Low risk	No obvious sources of other bias identified.

Rauh 2013

Methods	Cluster-randomised controlled trial.
Participants	<p>250 women from 8 gynaecological practices.</p> <p>Setting: gynaecological practices in Munich, Germany (from February 2010 to August 2011).</p> <p>Inclusion criteria: pregnant women, > 18 years, with a singleton pregnancy, prior to their 18th week of pregnancy, with a BMI ≥ 18 kg/m², with "sufficient" German language.</p> <p>Exclusion criteria: women with any condition preventing physical activity (cervical incompetence, placenta praevia, persistent bleeding), pre-pregnancy diabetes, uncontrolled chronic diseases that could affect weight development (thyroid dysfunction, psychiatric diseases).</p>
Interventions	<p>Intervention group (4 practices: 83 women recruited, 74 analysed)</p> <p>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, GWG); setting behavioural goals.</p> <p>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).</p> <p>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 antenatal physical activity programs and advised to participate in such programs.</p>

Rauh 2013 (Continued)

Each woman received a GWG chart personalised according to her baseline BMI group, which incorporates the IOM's GWG recommendations. Women were asked to use their chart to monitor their weight development, weekly.

Control group (4 practices: 167 women recruited, 152 analysed)

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	Data in meta-analyses (or other data tables) for: GDM: caesarean birth; large-for-gestational age; operative vaginal birth; induction of labour; GWG; behaviour changes associated with the intervention; breastfeeding; postnatal weight retention; preterm birth; small-for-gestational age; birthweight; length; child weight.
Notes	<p>Funding: <i>"The study was partially funded by the Else Kröner-Fresenius Foundation, Bad Homburg. This work was supported by the German Research Foundation (DFG) and the Technische Universität München within the funding programme Open Access Publishing".</i></p> <p>Declarations of interest: <i>"The authors declare that they have no competing interests".</i></p> <p>ICC of 0.12 was used in analyses.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: <i>"were randomly assigned to either an 'intervention' or 'control group' using a computer-generated randomization allocation table".</i>
Allocation concealment (selection bias)	Unclear risk	Quote: <i>"Randomization was performed by a research not involved in the study design thereby preventing allocation bias".</i>
Blinding of participants and personnel (performance bias) All outcomes	High risk	The trial was <i>"open-label"</i> . Quote: <i>"The nature of the study meant that participants and study staff were not blinded to the types of interventions".</i>
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	<p>83 women were recruited to the control group; and 167 to the intervention group. 4 (5%) women from the control group withdrew (relocation, personal reasons, unable to contact) and 8 (5%) women in the intervention group withdrew (personal reasons, complications in pregnancy). A further 3 (7% total) 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.</p> <p><u>Follow-up:</u> 72 (87%) women in the control group and 152 (91%) in the intervention group could be contacted at the 4-month follow-up. 65 (78%) women in the control group and 148 (89%) women in the intervention group were included in the 1-year follow-up.</p>
Selective reporting (reporting bias)	Unclear risk	With no access to a trial protocol, it was not possible to confidently assess selective reporting.
Other bias	High risk	Quote: <i>"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".</i> The authors speculated that this may have been due to unmotivated gy-

Rauh 2013 (Continued)

naecologists/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 influence 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. The sample size calculations did not take into account clustering.

Sagedal 2017

Methods	Randomised controlled trial.
Participants	<p>606 women were randomised.</p> <p>Setting: 8 healthcare clinics in southern Norway, cities of Kristiansand and Mandal, as well as the more rural surrounding areas (recruitment from September 2009 to February 2013).</p> <p>Inclusion criteria: women who were nulliparous, with a singleton pregnancy at ≤ 20 weeks gestation, with a pre-pregnancy BMI ≥ 19 kg/m², who were literate in Norwegian or English, who provided informed signed consent.</p> <p>Exclusion criteria: women with pre-existing diabetes, disabilities precluding participation in a physical fitness program, continued substance abuse or planned relocation outside of the trial area before birth.</p>
Interventions	<p>Intervention group (n = 303 randomised)</p> <p>Women received the Norwegian Fit for Delivery (NFFD) intervention, a lifestyle intervention that included dietary counselling and an exercise program. The NFFD lifestyle counselling and recommendations were reinforced with booklets, access to an Internet site, and with an invitation to 1 cooking class, as well as to an evening meeting (which provided information on the trial and the value of healthy eating and exercise in pregnancy).</p> <p>Diet: focused on 10 recommendations designed to increase awareness of food choices, with specific advice on portion sizes, regular meal patterns, limiting the consumption of snack foods, and increasing the intake of water, fruits and vegetables. The dietary counselling was performed by telephone, with an initial consultation and then a follow-up 4 to 6 weeks later, each of approximately 20 minutes. Counsellors were either experienced clinical dietitians or graduate students in public health, trained and supervised by the NFFD team. Women were informed of the recommended GWG based on pre-pregnancy BMI and current IOM guidelines.</p> <p>Exercise: women were advised to attend twice-weekly exercise classes at a local gym facility, all following the same pattern: 10 minutes of warm-up, 40 minutes of strength training and cardiovascular exercise at moderate intensity (using aerobics, callisthenics, and weight training), and 10 minutes of stretching. The intensity of the exercise was self-monitored using Borg's scale of perceived exertion, with a target intensity of 12 to 14 on the 6 to 20 scale. Classes were led by physical therapists or students in sports science who were trained and quality-controlled by the NFFD team. Although practical and economic considerations limited classes to 2 per week, women were encouraged to be physically active at moderate intensity on 3 additional days per week, and activity was assessed using questionnaire responses in late pregnancy.</p> <p>Control group (n = 303 randomised)</p> <p>Women in the control group received routine antenatal care in accordance with Norwegian standards: 8 antenatal appointments, including 1 second-trimester ultrasound examination, with additional care as needed. The standard care was provided through alternating visits with midwives and doctors, as per standard practice. All women, including those in the control group, received a booklet with advice</p>

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Sagedal 2017 (Continued)

on antenatal nutrition and physical activity, including recommendations for GWG based on the IOM guidelines.

Outcomes	Data in meta-analyses (or other data tables) for: GDM; pre-eclampsia, caesarean birth; large-for-gestational age; operative vaginal birth; perineal trauma; postpartum haemorrhage; GWG; behaviour changes associated with the intervention; postnatal weight retention; return to pre-pregnancy weight; stillbirth; gestational age at birth; Apgar score < 7 at 5 minutes; preterm birth; macrosomia; small-for-gestational age; birthweight; length; head circumference; ponderal index; shoulder dystocia; admission to NICU.	
	Additional narrative text for: breastfeeding; adherence to the intervention.	
Notes	Funding: "The NFFD trial was funded by the Norwegian South-Eastern Regional Health Authority, with additional funding from the municipalities of Aust Agder and Vest Agder. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the article". Declarations of interest: "Full disclosure of interests available to view online as supporting information;" "Dr. Sagedal reports grants from South-Eastern Norway Regional Health Authority and grants from the municipalities of southern Norway, during the conduct of the study;" All other authors "nothing to disclose".	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "using a computer-generated list with 1 : 1 allocation ratio in blocks of 20".
Allocation concealment (selection bias)	Unclear risk	Quote: "A research nurse assigned participants...The research nurse never met the participants, had no role in recruitment or measurements, and had no knowledge of questionnaire responses".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "It was not feasible to blind participants to their group allocation, but they were instructed to refrain from revealing this to assessors".
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote; "All examinations, blood test evaluations, record reviews, and scoring of questionnaire responses were performed by assessors blinded to group allocation".
Incomplete outcome data (attrition bias) All outcomes	Low risk	<p>Of the 303 women randomised to the intervention group, 296 (98%) were included in the main analyses; of the 303 women randomised to the control group, 295 (97%) were included in the main analyses (14 and 15 women respectively withdrew from the participation but consented to data collection).</p> <p>Follow-up: of the 591 women included in the analyses, 32 withdrew consent and 1 had a stillborn, leaving 558 eligible for follow-up; after exclusion of those who were not weighed $\geq$ once postpartum (6 or 12 months) and those who were subsequently pregnant at 12 months postpartum, 201 (66%) of the 303 women in the intervention group and 188 (62%) of the 303 women in the control group were included in the 12-month analyses. Authors reported that compared with measured women at 12 months, missing women at 12 months follow-up were "somewhat younger...had lower educational levels...lower income ...and tended to have a higher pre-pregnancy BMI...Women with missing postpartum data had a similar GWG to those measured".</p>

Sagedal 2017 (Continued)

Selective reporting (reporting bias)	Low risk	Outcomes reported as per the published trial protocol, except for the pre-specified outcomes 'maternal glucose levels, and 'hormones related to glucose metabolism'.
Other bias	Low risk	No obvious sources of other bias identified.

Vinter 2011

Methods	Randomised controlled trial.
Participants	<p>360 women were randomised.</p> <p>Setting: 2 university hospitals in Denmark: Odense and Aarhus University Hospital (recruitment from October 2007 to October 2010).</p> <p>Inclusion criteria: women aged 18 to 40 years at 10 to 14 weeks gestation, with a BMI of 30 to 45 kg/m² as calculated from pre-pregnancy weight or first measured weight in pregnancy.</p> <p>Exclusion criteria: women with prior serious obstetric complications, chronic diseases (e.g. hypertension and diabetes); positive OGTT in early pregnancy, alcohol or drug abuse, who were Non-Danish speaking, with a multiple pregnancy.</p>
Interventions	<p>Intervention group (n = 180 randomised, n = 150 analysed)</p> <p>Dietary counselling was performed by trained dietitians 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.</p> <p>Diet: energy requirements were individually estimated according to weight and level of activity.</p> <p>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.</p> <p>Control group (n = 180 randomised, n = 154 analysed))</p> <p>Women in the control group received the same initial information about the purpose and content of the trial, including access to a website with advice about dietary habits and physical activities in pregnancy, but no additional intervention.</p> <p>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.</p>
Outcomes	<p>Data in meta-analyses (or other data tables) for: GDM; pre-eclampsia; caesarean birth; large-for-gestational age; GWG; behaviour changes associated with the intervention; relevant biomarkers associated with the intervention; breastfeeding; return to pre-pregnancy weight; maternal cardiovascular health; stillbirth; gestational age at birth; preterm birth; macrosomia; birthweight; birthweight z score; length; childhood weight; childhood height; childhood adiposity; childhood cardiovascular health; NICU admission.</p> <p>Additional narrative text for: adherence with the intervention.</p>
Notes	<p>Funding: "The study was supported by Trygfonden, The Health Insurance Foundation (Helsefonden), the Faculty of Health Sciences, University of Southern Denmark, the Danish Diabetes Association, Odense University Hospital, the NoVo Foundation, the Danish Medical Association Research Foundation, Aase og Ejnar Danielsens Fond, CMA Medico, and Ferrosan A/S". Follow-up: "Funding for this study was obtained</p>

Vinter 2011 (Continued)

from Odense University Hospital, The Hede Nielsen Family foundation, The A.P. Møller Foundation for the Advancement of Medical Science and Sister lodge No. 3 Freja I.O.O.F. MT is a recipient of PhD scholarships from The Region of Southern Denmark, The faculty of Health sciences, University of Southern Denmark and The Danish PhD school of Molecular Metabolism. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript".

Declarations of interest: "The authors have declared that no competing interests exist".

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "participants were randomized 1:1 by computer-generated numbers".
Allocation concealment (selection bias)	Low risk	Quote: "in closed, opaque envelopes".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Trial described as "non-blinded"; quotes: "blinding was not possible for pragmatic reasons"; "there was no blinding to patients or healthcare professionals".
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Trial described as "non-blinded". No further information provided. For 2.8-year follow-up: "All children were measured by a medical doctor (M.T.) and a research bioanalyst, both blinded to the LiP intervention".
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of the 180 women randomised to each group (360 total), 56 (16%) women dropped out. 30 women dropped out from the intervention group (GDM: 9, withdrew: 18, missed miscarriage: 1, misclassification: 2) and 26 from the control group (GDM: 3, withdrew: 14, twins: 2, missed miscarriage: 4, abortion: 3); thus 150 (83%) women in the intervention group and 154 (86%) in the control group were included in analyses. <u>Follow-up:</u> at 6-month postpartum follow-up, 238 (66%) women were included (123 (68%) in the intervention group, 115 (64%) in the control group); the 66 women who did not attend, and were excluded had "higher mean pre gestational BMI, higher GWG and more obstetric or neonatal complications, but the differences were not significant compared with those who did not attend". For 2.8-year follow-up: 301 children were eligible; 157 (52%) were analysed (82 (55%) of 148 in the intervention group and 75 (49%) 153 in the control group).
Selective reporting (reporting bias)	Unclear risk	With no access to a trial protocol, it was not possible to confidently assess selective reporting. A protocol for the infant follow-up was supplied as supporting information. The trial registration lists "Metabolic Markers" as secondary outcome measures, however data were not reported for these outcomes. Some data are reported incompletely, e.g. breastfeeding at 5 months, "no differences between the intervention groups", and weight development from 0-5 months and 0-12 months "no difference...between the intervention groups...(data not known)".
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 dropout group was older and had a higher percentage with a BMI ≥ 40 kg/m ² , and a higher percentage of smokers, compared with the completing group (though not statistically significant). For the follow-up trial: "At baseline, there were no differences between those who attended and who were lost to follow-up except for 20-h OGTT plasma glucose values performed at 28 weeks gestation".

Wang 2015

Methods	Randomised controlled trial.
Participants	<p>299 women were randomised.</p> <p>Setting: Department of Obstetrics and Gynecology, Peking University First Hospital, China (recruitment from September 2012 to January 2013).</p> <p>Inclusion criteria: women before the 8th gestational weeks, with ≥ 1 risk factor for GDM including age.</p> <p>Exclusion criteria: pre-existing diabetes, multiple pregnancy, ≥ 35 years, pre-pregnancy BMI ≥ 25 kg/m², family history of diabetes mellitus, history of polycystic ovary syndrome, history of GDM or macrosomia from a previous pregnancy</p>
Interventions	<p>Intervention group (n = 151 randomised)</p> <p>All women in the intervention group received routine antenatal care plus a standardised lifestyle intervention delivered at 6 to 8 weeks gestation, and enforcement interventions informed by maternal anthropometrics at 12 to 13 gestational weeks. The standardised courses were delivered by 1 physician and included 3 courses: 'What is a balanced diet?'; 'Proper physical activity is beneficial during pregnancy'; and 'Standard weight-gain during pregnancy'. Each course was group based (< 6 women per group) and lasted 40 to 60 minutes.</p> <p>Diet: key take-home messages relating to diet provided in the courses were: following a balanced diet, defined according to the dietary pagoda of pregnant women in China; and achieving standard GWG, defined according to the IOM 2009 recommendations.</p> <p>Exercise: a key take-home message of the physical activity course was 'proper physical activity is beneficial during pregnancy'. Women were encouraged to walk engage in 30 minutes of walking after a meal $\geq$ once a day.</p> <p>Control group (n = 150 randomised)</p> <p>All women in the control group received routine antenatal care, and were followed until a 75 OGTT was administered at 24 to 28 weeks gestation.</p>
Outcomes	Data in meta-analyses for: GDM; GWG.
Notes	<p>Funding: not reported.</p> <p>Declarations of interest: not reported.</p> <p>Reported to be cluster-randomised, however no indication in reported methods that 'clusters' were randomised, and rather, appeared to be individually randomised.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Authors reported that the trial was cluster randomised. However, it is not clear how clustering was used. The sequence generation is simply described as: "exponential random numbers produced the intervention group and the control group".
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of participants and personnel (performance bias)	High risk	Blinding of women and trial personnel not considered feasible in view of the intervention and control.

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Wang 2015 (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Of the 151 women randomised to the intervention group, 134 (91%) were followed up and included in the analyses (2 refused, 3 had pre-existing diabetes, 4 did not have singleton pregnancies, 8 had abortions). Of the 150 women randomised to the control group, 138 (92%) were followed up and included in the analyses (7 refused, 1 did not have a singleton pregnancy, 4 had abortions).
Selective reporting (reporting bias)	Unclear risk	With no access to a trial protocol, it was not possible to confidently assess selective reporting.
Other bias	Unclear risk	Limited methodological detail provided; insufficient information to determine risk of other bias.

Abbreviations: ACOG: American College of Obstetricians and Gynecologists; ADA: American Diabetes Association; BMI: body mass index; FeLIPO: Feasibility of a Lifestyle Intervention in Pregnancy to Optimise maternal weight development; FITT: frequency, intensity, time, type; GDM: gestational diabetes mellitus; GCT: glucose challenge test; GI: glycaemic index; GWG: gestational weight gain; IOM: Institute of Medicine; MET: multiples of resting metabolic equivalents; NFFD: Norwegian Fit for Delivery; NICE: National Institute for Health and Care Excellence; NICU: neonatal intensive care unit; NIH: National Institutes for Health; NIHR: National Institute for Health Research; OGTT: oral glucose tolerance test; SOGC: Society of Obstetricians and Gynaecologists Canada; UK: United Kingdom; USA: United States of America.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Barakat 2006	This randomised controlled trial assessed the effects of an exercise intervention.
Bo 2014	This randomised controlled trial included women with GDM.
Clapp 1997	This randomised controlled trial assessed the effects of a dietary intervention.
Crowther 2012	This randomised controlled trial included women with borderline GDM.
Luoto 2010	This was a non-randomised controlled trial.
McGowan 2013	This randomised controlled trial assessed the effects of a dietary intervention.
Nascimento 2012	This randomised controlled trial assessed the effects of an exercise intervention.
NCT00924599	This ongoing randomised controlled trial is recruiting and randomising women pre-conception.
Parat 2015	This randomised controlled trial assessed the effects of a dietary intervention.
Peacock 2014	This randomised controlled trial included women with GDM.
Quinlivan 2011	This randomised controlled trial assessed the effects of a dietary intervention.
Ruchat 2012	This randomised controlled trial assessed the effects of different exercise interventions.
Simmons 2015	This randomised controlled trial assessed the effects of a diet and exercise intervention compared with a diet alone intervention and an exercise alone intervention.

Study	Reason for exclusion
Sun 2016	This was a quasi-randomised controlled trial.
Youngwanichsetha 2014	This randomised controlled trial included women with GDM.

Abbreviations: GDM: gestational diabetes mellitus

Characteristics of studies awaiting assessment [ordered by study ID]

Althuisen 2013

Methods	Randomised controlled trial.
Participants	<p>246 women were randomised.</p> <p>Setting: 8 midwifery practices in the Netherlands, in towns with 23,000 to 735,000 inhabitants (from February 2005 to May 2006).</p> <p>Inclusion criteria: pregnant with first child; in first 14 weeks of gestation; able to read, write and speak Dutch; attended 1 of the participating midwifery practices.</p> <p>Exclusion criteria: not reported.</p>
Interventions	<p>Intervention group (n = 123)</p> <p>The "New Life(style) intervention", a life-style modification program individually tailored to each participant, focused on weight development, physical activity and nutrition habits during pregnancy delivered via 4 face-to face individual counselling modules (of approximately 15 minutes a session except for the first session, which lasted 30 minutes) during pregnancy and 1 telephone session after birth. In the sessions, counsellors discussed how to control weight gain during and after pregnancy, and how to maintain or optimise a healthy lifestyle during pregnancy. The content of the first session was summarised in a brochure that was given to women. The women received counselling from 1 counsellor (a member of the trial team) throughout the intervention. A key focus in the counselling sessions was on the IOM guidelines for weight gain during pregnancy, how women were progressing towards achieving the IOM weight gain goals, and how to implement strategies to achieve set goals. A key message relating to exercise was the relationship between energy intake and expenditure. Exercise levels of women were assessed and feedback and goals relating to increasing activity were discussed.</p> <p>Diet: the guidelines for pregnant women of the Dutch Nutrition Centre constituted the basis of the nutritional part of the counselling sessions.</p> <p>Exercise: the information and feedback that counsellors provided on exercise were based on the recommendations of the American Centers for Disease Control and Prevention, which promote 30 minutes of $\geq$ moderate-intensity activity on 5 or all days of the week.</p> <p>Control group (n = 123)</p> <p>Women in the control group received usual care provided by midwives in the Netherlands, where midwives are independent paramedical practitioners, qualified to provide full maternity care to all women whose pregnancies and childbirths are uncomplicated. As per usual practice, women in the control group had their first appointment with the midwife between the 9th and 12th week of gestation. Subsequently they visited the midwife 11 to 13 times during their pregnancy (for about 15 minutes each time).</p>
Outcomes	To date, data have been reported for outcomes including: GWG, postpartum weight, birthweight, macrosomia, preterm birth, caesarean section.

Althuisen 2013 (Continued)

Notes	In the previous version of this review, this trial was 'excluded'; we have now re-classified this trial as 'awaiting classification', pending the availability/reporting of GDM outcome data.
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Asci 2016

Methods	Randomised controlled trial.
Participants	<p>102 women were randomised.</p> <p>Setting: a family health centre providing services for a population of approximately 21,000 people, mostly families with middle-income level, in Istanbul, Turkey (from June 2011 to July 2012).</p> <p>Inclusion criteria: pregnant at ≤ 12 weeks gestation; aged ≥ 18 years; gravidity ≤ 2; without health problems; <i>"got pregnant in natural ways for two times at most"</i>; were pregnant for ≤ 3 months; did not intend to lose weight in pregnancy.</p> <p>Exclusion criteria: not reported.</p>
Interventions	<p>Intervention group (n = 51)</p> <p>Women received an individualised lifestyle intervention focusing on healthy lifestyle, diet, exercise, and weight monitoring, delivered through 4 sessions, at 12 to 15, 16 to 18, 20 to 24, and 37 weeks gestation. At each session, a card indicating personal height, weight, an appropriate GWG range for BMI was prepared and provided to the woman as a reminder. Weights were measured in every meeting and recorded on the card. In addition, objectives of nutrition and physical activity for optimal GWG were specified for the period until the next meeting. Women reaching their objectives were praised and encouraged. Nutrition and physical activity levels of women who could not reach their objectives were discussed, and a more intensive consultancy (repetition and telephone calls) was provided. Counselling and behavioural skill building interventions were personalised according to the barriers of women. Physical activity advice, focused on during the 16 to 18 weeks interview, included the recommendations that women engage in mild-to-moderate safe exercise, (which increased the heart rate to 140 beats/minute while being easily able to talk, for 30 minutes every other day; e.g. elliptical trainer, swimming, Pilates, yoga and mild level aerobic exercises) and that they maintain a more active lifestyle (taking walks every day, going to work by walking, using stairs instead of elevators, participating in sporting activities in their leisure times).</p> <p>Control group (n = 51)</p> <p>Women received routine antenatal care. This included follow-up ≥ 4 times during pregnancy. At each follow-up, weight was measured; however, women were not informed on what the GWG range appropriate for their BMI was, or their personal weight changes. Consultancies focused on pregnancy complaints, performing tests, provision of information about the birth and postpartum period, and discussion about circumstances that might pose a danger to women during their pregnancy.</p>
Outcomes	To date, data have been reported for outcomes including: health-promoting lifestyle behaviours; dietary intake; physical activity; GWG; postpartum weight retention; gestational age; caesarean section; hospitalisation time; birthweight; birth length.
Notes	Trial 'awaiting classification', pending the availability/reporting of GDM outcome data.

Kieffer 2014

Methods	Randomised controlled trial.
Participants	278 women were randomised.

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Kieffer 2014 (Continued)

Setting: women recruited via a federally qualified health centre, Supplemental Nutrition Program for Women, Infants, and Children clinics, located in a predominantly low-income, Mexican-origin Latino community in southwest Detroit, USA (from 2004 to 2006).

Inclusion criteria: women ≥ 18 years of age; residents of southwest Detroit; pregnant at < 20 weeks gestation.

Exclusion criteria: type 1 or 2 diabetes; an incompetent cervix/cerclage; an active thyroid; multiple gestation; cardiac, vascular or pulmonary disease; drug or alcohol addiction; serious physical or mental illness or condition that would substantially interfere with participation in or completion of the entire intervention.

Interventions	<p>Intervention group (n = 139)</p> <p>Women received the Spanish language Healthy Mothers on the Move (MOMs) intervention, an 11-week, culturally-tailored community-based lifestyle behaviour change intervention offering home visits (2), group classes (9), related activities and social support, delivered by community health workers and peers. Women were provided with general pregnancy education and information, discussion and activities aimed at developing knowledge and skills needed to reduce social and environmental barriers to healthy eating, regular exercise, and management of daily life stressors. Each group meeting concluded with content review and goal setting. While the intervention included an exercise component, and women were encouraged to engage in regular exercise, the focus was on dietary behaviours. Meeting 1, "<i>healthy mom, healthy baby</i>", focused on discussing stress and dietary behaviours. In meeting 2, and the home visits, community health workers encouraged women to develop and review behavioural goals. 4 meetings focused specifically on providing dietary advice: Meeting 3, "<i>plan to eat healthy</i>", focused on discussing the role of nutrition, beliefs about food and eating patterns during pregnancy, and included a home visit. Meetings 5, 6 and 7 were group meetings titled "<i>Eat More Fiber</i>", "<i>Eat More Fruits and Vegetables</i>" and "<i>Eat Less Fat and Sugar</i>" respectively. They offered education and discussion about these topics, and used the US Department of Agriculture Pregnancy Food Guide Pyramid, as well as food label reading, food models and taste test activities. Optional weekly group activities such a healthy cooking demonstrations corresponding to the 3 different dietary topics (meetings 5 to 7), were offered. A key component of the intervention was informational and emotional social support from the community health workers and peers. Community health workers encouraged women to problem solve, share strategies, and recognise each other's efforts.</p> <p>Control group (n = 139)</p> <p>The control group, reported as the "<i>minimal intervention</i>" group, received 3 group pregnancy education meetings, delivered in Spanish by professional staff from a partner organisation, in a separate community setting. The sessions used MOMs curriculum materials related to pregnancy, child-birth, fetal, newborn, and postpartum development and care. The women also received March of Dimes and ACOG materials about eating and exercise during pregnancy. Similar to women in the intervention group, the control group women received transportation and child care required for participation in all trial activities, monthly newsletters, attendance reminder cards and phone calls, small mother and baby care gift incentives after each intervention meeting, and \$50 grocery store gift certificates after baseline and follow-up data collection.</p>
Outcomes	To date, data have been reported for outcomes including: depressive symptoms (CES-D scores); dietary intake.
Notes	Trial 'awaiting classification', pending the availability/reporting of GDM outcome data.

Kim 2015

Methods	Randomised controlled trial
Participants	1664 women were randomised

Kim 2015 (Continued)

Setting: 4 hospitals serving a large and racially diverse population in a metropolitan area within the northeastern USA (dates not reported).

Inclusion criteria: pregnant women aged 18 to 35 years; planned to deliver in 1 of the 4 participating hospitals; consented ≤ 20 weeks gestation, available for a 24-month intervention; planned to carry pregnancy to term and keep the baby; read and understood English; had a valid e-mail address.

Exclusion criteria: BMI $< 18.5 \text{ kg/m}^2$ or $\geq 35.0 \text{ kg/m}^2$; multiple gestation; 3 or more consecutive miscarriages; presence of pre-pregnancy medical conditions that could influence weight loss or gain.

Interventions	<p>Intervention group 1 (n= 554)</p> <p>Women received an online <i>"healthy weight intervention during pregnancy and postpartum"</i> program. Women were also provided with access to online goal-setting and self-monitoring tools throughout their pregnancy, designed to encourage them to achieve several behavioural targets for appropriate GWG. 3 features and related activities in the web-based program were used to promote the desired change: (1) A weight tracking feature requested women to enter their weight regularly; (2) A physical activity feature first reviewed information on physical activity during pregnancy and then encouraged women to reflect and report on this and options for increasing their activity; based on this, the website offered women feedback, named appropriate goal areas, outlined barriers that could be encountered in the pursuit of those goals, and described strategies to overcome those barriers; women were promoted to set personal goals by specifying types of activities that they hoped to participate in, and timeline for accomplishing these goals; they were encouraged to come back to the website to monitor progress on (or simply remind themselves of) their physical activity goals. (3) A feature related to diet provided women with recommendations about healthy eating behaviours during pregnancy based on their responses to questions assessing common dietary problem areas; women were encouraged to indicate which issue area they would like to focus on at the time, to set timelines for achieving goals, and to monitor progress towards achieving the goals. Women also received a postpartum program (not described in detail).</p> <p>Intervention group 2 (n = 556)</p> <p>Women received an online <i>"healthy weight during pregnancy only"</i> program. During pregnancy, women received the same intervention as those in intervention group 1 (see above).</p> <p>Control group (n = 554)</p> <p>Women were provided with a standardised basic version of the web-based program. This included access to pregnancy-related information and a variety of features, including informational and interactive features that women could use to gather information and advice about pregnancy, maintain calendars for their appointments with antenatal care providers, and share experiences with other women who had access to the website through a blog feature.</p>
Outcomes	To date, data have been reported for outcomes including: goal-setting and self-monitoring behaviour; beliefs about weight control; motivation and intention.
Notes	Trial 'awaiting classification', pending the availability/reporting of GDM outcome data.

Marcinkevage 2013

Methods	Randomised controlled trial.
Participants	57 women were randomised.
	Setting: Grady Memorial Hospital, a large metropolitan hospital in the USA.

Marcinkevage 2013 (Continued)

Inclusion criteria: women (Black or Hispanic) aged 18 to 45 years; overweight or obese (BMI > 25 kg/m²); a sedentary lifestyle (< 30 minutes/day of moderate physical activity); established antenatal care established at < 20 weeks of gestation; singleton pregnancy.

Exclusion criteria: a history of diagnosis of type 2 diabetes, hypertension, cardiovascular disease, chronic renal disease, active liver disease, or anaemia; receipt of medications which adversely influence glucose tolerance; multiple pregnancies; not planning to continue pregnancy to term; contraindications to participate in regular physical activity; mental conditions - unable to understand nature, scope and possible consequences of the trial.

Interventions	<p>Intervention group (n = 28)</p> <p>Women received a lifestyle intervention consisting of monthly visits focused on increasing fruit and vegetable intakes, reducing intakes of fats and sugars, and increasing levels of moderate physical activity.</p> <p>Control group (n = 29)</p> <p>Women received regular care. This was comprised of counselling routinely provided to all women as recommended by the IOM for appropriate nutrition and weight gain, and ACOG guidelines for appropriate physical activity during pregnancy.</p>
Outcomes	To date, data have been reported for outcomes including: glucose and insulin indices; activity (total, sedentary behaviour); GWG.
Notes	Trial 'awaiting classification', pending the availability/reporting of GDM outcome data.

Mujsindi 2014

Methods	Randomised controlled trial.
Participants	<p>79 women were randomised.</p> <p>Setting: not reported.</p> <p>Inclusion criteria: obese women; singleton pregnancies.</p> <p>Exclusion criteria: not reported.</p>
Interventions	<p>Intervention group</p> <p>Women received a "pregnancy, exercise and nutrition (PEN) program". Women received 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).</p> <p>Control group</p> <p>Women received standard care.</p>
Outcomes	To date, data have been reported for outcomes including: GWG: postpartum weight retention.
Notes	Trial 'awaiting classification', pending the availability/reporting of GDM outcome data.

Santos-Rocha 2015

Methods	Randomised controlled trial.
Participants	<p>86 women were randomised.</p> <p>Setting: Portugal.</p> <p>Inclusion criteria: pregnant women; further details not reported.</p> <p>Exclusion criteria: not reported.</p>
Interventions	<p>Intervention group (n = 24)</p> <p>Women received a lifestyle change intervention with a group based physical exercise and nutritional counselling component.</p> <p>Diet: described in the conference abstract as "<i>a monthly 30-minute lecture; supervised by a certified dietitian</i>".</p> <p>Exercise: women received a group-based physical exercise program involving moderate-intensity exercise; they were encouraged to attend 2 sessions per week of 45 minutes, between 14 and 38 weeks' gestation. Each session included: warm up, group-based low impact aerobics, general strength training (including pelvic floor muscle, balance and stabilisation exercises), and cool down (stretching and relaxation). The exercise classes were supervised by graduate fitness instructors.</p> <p>Control group (n = 62).</p> <p>Women received standard care.</p>
Outcomes	To date, data have been reported for outcomes including: physical activity; GWG; postpartum weight retention; gestational age at birth; mode of birth; birthweight; birth length; Apgar score.
Notes	Trial 'awaiting classification', pending the availability/reporting of GDM outcome data.

Skouteris 2016

Methods	Randomised controlled trial.
Participants	<p>261 women were randomised.</p> <p>Setting: Birralee Maternity Service, located in the Eastern Heath Region of Melbourne, Australia (from August 2011 to August 2013).</p> <p>Inclusion criteria: women aged ≥ 18 years; provided informed consent; BMI > 18.5; English speaking; < 18 weeks gestation.</p> <p>Exclusion criteria: history of disordered eating or diabetes.</p>
Interventions	<p>Intervention group (n = 130)</p> <p>In addition to usual care offered to pregnant women by their obstetrician, midwife or GP, women assigned to the "<i>Healthy Coaching Intervention group</i>", received a tailored intervention (with individual and group components) designed to prevent excessive GWG, and promote positive psychosocial and motivational outcomes, delivered by a Health Coach. The individual component included a 1-hour individualised session (either in person or via phone) with a trained Health Coach (an allied health professional) who (1) promoted adoption of healthy lifestyle behaviours for the purpose of weight management and (2) addressed mood management and body image issues that commonly arise during pregnancy. Women had a second session (half hour) via telephone, at 27 weeks gestation and an additional follow-up 15-minute phone consultation at 30 weeks gestation.</p>

Skouteris 2016 (Continued)

In addition, women were offered a fourth optional 15-minute follow-up telephone consultation just prior to reaching 32 weeks gestation. The group component consisted of 2 2-hour sessions, which provided women with additional information related to healthy behaviours and mood, stress control and coping strategies, and supported and assisted them in initiating, maintaining, and achieving their goals for healthy behaviour change both before and after the birth of the child. During the group sessions, women completed activities such as writing a personalised letter to themselves to read 6 weeks post birth.

Control group (n = 131).

Women in the "education alone" group, received usual care, and 2 2 hour education sessions, that offered factual information only. A qualified workplace trainer and assessor ran the sessions.

Outcomes	To date, data have been reported for outcomes including: GWG: motivation, psychosocial, and GWG knowledge and expectations; birthweight; mode of birth; preterm birth.
Notes	Trial 'awaiting classification', pending the availability/reporting of GDM outcome data.

Torres 2016

Methods	Randomised controlled trial.
Participants	<p>Setting: women were from predominantly Hispanic low-income underserved communities, with economic, time, cultural and social barriers for engaging in lifestyle intervention. They were recruited through the Puerto Rico Hospital, located in Puerto Rico, USA.</p> <p>Inclusion criteria: women aged ≥ 18 years; singleton viable pregnancy; willing to receive care at the University Hospital in San Juan Puerto Rico; could be randomised between 9 weeks and 15 weeks 6 days; BMI ≥ 25 kg/m².</p> <p>Exclusion criteria: diagnosis of diabetes prior to pregnancy or HBA1c $\geq 6.5\%$ or another test result suggestive of pre-pregnancy diabetes; IV drug use; HIV infection; non-Spanish speaking; known fetal anomalies; planned termination of pregnancy; history of 3 or more consecutive first-trimester miscarriages; past history of anorexia or bulimia by medical history or self-report; a current eating disorder; actively suicidal; prior or planned bariatric surgery; current use of metformin; unable to participate in group sessions.</p>
Interventions	<p>Intervention group</p> <p>Women received the "Pregnancy and EARLY Life (PEARLS)" lifestyle improvement program. The intervention used an empowerment theoretical framework and was delivered through individual and group-based counselling and communication. Antenatal counselling sessions included: 2 individual and 7 group sessions plus monthly calls. The focus was on improving/modifying total calorie consumption and improving diet quality (by reducing the intake of refined carbohydrates and sugar sweetened beverages), reducing sitting time and increasing physical activity (through promotion of non-structured physical activity). Postpartum counselling sessions included: 2 individual and 2 group sessions plus monthly calls during which women received education on breastfeeding, physical and cognitive activation of the infant, infant feeding patterns, sleep, and diet choices for the infant. Women were provided with brown rice, omega-3 rich vegetable oil and spread, and water monthly. Women set their own goals, which were monitored. To reinforce intervention messages, women were provided with a culturally-tailored physical activity video. The video provided ways to support engagement in physical activity at home by including 5 sessions of 5 to 10 minutes each with low impact, easy to do exercises, such as stretching, aerobics with resistance training, belly dance, Latin dances, and basic yoga poses and respiration techniques.</p> <p>Control group</p> <p>Women received routine antenatal care. In addition, they received regular phone calls and mailings, token gifts and some information related to data gathered during the trial, such as on physical</p>

Torres 2016 (Continued)

	activity, and feedback on behaviour through the trial. Women received 2 antenatal and 1 postpartum group session which provided general pregnancy related information not related to the intervention.
Outcomes	To date, information reported has related to " <i>Development, implementation, lessons learned and future applications</i> ".
Notes	Trial 'awaiting classification', pending the availability/reporting of GDM outcome data.

Wilkinson 2012

Methods	Randomised controlled trial.
Participants	<p>360 women were randomised.</p> <p>Setting: tertiary maternity hospital in South East Queensland, Australia, with approximately 5000 births a year (from 31 August 2010 to 7 March 2011).</p> <p>Inclusion criteria: women ≥ 18 years (or under 18 years with the consent of a parent or guardian); pregnant; attending the Mater Mothers' Hospital antenatal clinic for pregnancy care; able to provide informed consent.</p> <p>Exclusion criteria: unable to read and speak English at a level to allow completion of pen and paper surveys.</p>
Interventions	<p>Intervention group (n = 178)</p> <p>Women received the "<i>healthy start to pregnancy</i>" program, a low-intensity early antenatal health promotion program aimed at improving maternal health behaviours. In addition to participating in the 1-hour early (before 20 weeks gestation if possible) antenatal lifestyle behaviour change workshop, women received written health education material (a booklet) designed to facilitate behaviour change. The education provided during the workshop covered diet, physical activity, healthy GWG, smoking cessation, breastfeeding, goal setting and self-monitoring techniques. Women were provided with contact for ongoing support.</p> <p>Control group (n = 182)</p> <p>Women received usual care. This included receipt of written health education material designed to facilitate behaviour change (the same booklet distributed at the workshop to intervention group women). The booklet was informed by best practice for health education print material and contained evidence-based literature regarding behaviours that influence maternal and infant health outcomes (fruit and vegetable intake; healthy weight gain; physical activity). The booklet included self-monitoring and goal setting activities.</p>
Outcomes	To date, data have been reported for outcomes including: dietary intake; diet quality index; GWG awareness; physical activity; cigarette smoking; intention to breast feed.
Notes	Trial 'awaiting classification', pending the availability/reporting of GDM outcome data.

Abbreviations: ACOG: American College of Obstetricians and Gynecologists; BMI: body mass index; GDM; gestational diabetes mellitus; GWG: gestational weight gain; HbA1c: glycated haemoglobin; HIV: human immunodeficiency virus; IOM: Institute of Medicine; IV: intravenous; MOMs: Healthy Mothers on the Move; PEARLS: Pregnancy and EARLY Life lifestyle improvement program; PEN: pregnancy, exercise and nutrition; USA: United States of America.

Characteristics of ongoing studies [ordered by study ID]

Chasan-Taber 2015

Trial name or title	Proyeto Mamã: a lifestyle intervention in overweight and obese Hispanic women: a randomised controlled trial
Methods	Randomised controlled trial.
Participants	<p>Setting: ambulatory obstetrical practices of Baystate Medical Center in Western Massachusetts, USA.</p> <p>Inclusion criteria: pregnant Hispanic women who are overweight or obese ($\text{BMI} \geq 25 \text{ kg/m}^2$) and 18 to 45 years of age.</p> <p>Exclusion criteria: pre-pregnancy $\text{BMI} < 25 \text{ kg/m}^2$; history of type 2 diabetes; heart disease or chronic renal disease; contraindications to participate in moderate physical activity or a low-fat/high-fibre diet (e.g. Crohn's disease, ulcerative colitis); inability to read English or Spanish at 6th grade level; < 16 or > 45 years of age; > 16 weeks gestation; current medications which adversely influence glucose tolerance; not planning to continue to term or deliver at the trial site; non-singleton pregnancy (e.g., twins, triplets, etc.).</p>
Interventions	<p>Intervention group</p> <p>Women will receive the "<i>Poyeto Mama lifestyle intervention</i>" consisting of exercise and dietary intervention materials culturally-adapted for Hispanics, and shown to be efficacious in previous controlled trials in Hispanic women. The intervention draws from Social Cognitive Theory and the Transtheoretical Model, and includes strategies for partner and/or family support to address specific social, cultural, and economic challenges faced by underserved Hispanic women. To support compliance, actigraphs and the Hispanic food frequency questionnaires will be used. Multimodel contacts (i.e., in person, telephone counselling, and mailed print-based materials) will be used, starting from 12 weeks gestation and continuing to 6 months postpartum. Follow-up will continue for 1-year postpartum. The main focus of the intervention is on encouraging women to meet: (1) IOM guidelines for GWG and postpartum weight loss; (2) ACOG guidelines for physical activity (through increasing walking and developing a more active lifestyle); and (3) ADA guidelines for following a balanced diet (reducing calory intake).</p> <p>Control group</p> <p>Women will receive the "<i>comparison health and wellness</i>" intervention. This will include receipt of mailed health materials and telephone booster calls at the same frequency as the intervention group; however the materials will not focus on exercise and dietary topics, and will include booklets from the ACOG and the American Academy of Pediatrics in English or Spanish. These booklets represent high-quality, standard, low-cost, self-help material currently available to the public.</p>
Outcomes	<p>Primary outcomes: insulin resistance.</p> <p>Other outcomes: mother: GWG, postpartum weight loss; pregnancy and postpartum biomarkers of insulin resistance (i.e. glucose; insulin; HbA1c; HOMA; leptin; adiponectin); postpartum biomarkers of cardiovascular risk (i.e. blood lipids; blood pressure); child: markers of insulin resistance; anthropometric measures.</p>
Starting date	January 2014. Estimated completion date April 2018 (final data collection date for primary outcome measure).
Contact information	Lisa Chasan-Taber, Professor of Epidemiology, University of Massachusetts, Amherst, USA. E-mail: LCT@schoolph.umass.edu
Notes	Recruitment target: 333 women.

Clements 2016

Trial name or title	The "Get Healthy in Pregnancy" Trial.
Methods	Randomised controlled trial.
Participants	<p>Setting: antenatal clinics at 5 hospitals, including Orange Base, Lismore Base and Dubbo Base (located in rural community settings) and (metropolitan settings) in New South Wales, Australia.</p> <p>Inclusion criteria: ≥ 18 years, singleton pregnancy, English speaking, gestation of ≤ 18 weeks, agreed to participate (signed consent forms and verbal consent provided at first coaching call) and attending of the 5 trial hospitals during the recruitment period. Aim is to include 177 and 532 women with a pre-pregnancy BMI of 18.5-24.9 kg/m² (healthy range) and ≥ 25.0 kg/m² (overweight or obese range) respectively. Further, to recruit 248 women across the 3 rural hospitals, and 462 from the metropolitan hospitals (to reflect the larger populations in these areas),</p> <p>Exclusion criteria: key criteria (i) pre-pregnancy BMI, 18.5 kg/m²; (2) gestation over 18 weeks; (3) non English speaking; (4) multiple pregnancy; and (5) women with complex medical conditions. In addition, various pre-existing conditions at screening including: cardiovascular disease; endocrine disease; respiratory disease; and severe lung disorder.</p>
Interventions	<p>Intervention group</p> <p>Women will receive information and telephone-based health coaching designed to support them to achieve appropriate GWG. This is a program run by the "Get Healthy Service (GHS)" that has been adapted specifically for pregnant women. The program comprises up to 10 calls, of between 15 to 40 minutes duration by university qualified coaches (8 during pregnancy and 2 after birth). The length of calls is determined by women. Similar to the standard GHS, the calls are aimed at healthy eating, physical activity and achieving healthy GWG. Calls are based on behaviour change principles designed to help with goal setting, maintaining motivation, overcoming barriers and making sustainable life changes. The timing of calls is designed to be flexible based on women's preferences. Generally, the schedule for calls pre-delivery is: 3 calls in the first 3 weeks, followed by a call every 2 to 3 weeks; unless requested otherwise. For post-pregnancy: 1 call at 10 weeks, 1 call at 14 weeks; unless requested otherwise. Women in the intervention group will also be provided with the following information materials: evidence-based pregnancy specific fact sheets, the "Having a Baby Book" published by New South Wales health, and the "Get Healthy" information booklet, which includes generic advice on healthy eating, physical activity as well as achieving and maintaining a healthy weight. All materials are based on nationally and internationally endorsed guidelines such as the Australian Dietary Guidelines and US IOM GWG guidelines.</p> <p>Control group</p> <p>Women will receive a one-off information and coaching session from a health coach and will receive the information materials described directly above (with the exception of the diary). They will also receive usual care from their maternity clinicians during the trial with the exception of setting their GWG range target and general advice about GWG at their first antenatal visit with their midwife.</p>
Outcomes	<p>Primary outcome: weight of mother (at 36 weeks of pregnancy and 12 months postpartum).</p> <p>Other outcomes: diet of mother (fruit and vegetable intake, at 36 weeks and 12 months postpartum); views of the intervention (mothers/clients and service providers);</p>
Starting date	2 September 2014 (anticipated).
Contact information	Primary investigator: Ms Michelle Maxwell. E-mail: michelle.maxwell@sswahs.nsw.gov.au. Scientific queries: Dr Santosh Khanal. Liverpool Hospital, Don Everett Building, New South Wales, Australia. E-mail: santosh.khanal@sswahs.nsw.gov.au
Notes	Recruitment target: 640 women.

Farajzadegan 2013

Trial name or title	Not reported.
Methods	Randomised controlled trial.
Participants	<p>Setting: 4 urban public health centres and 4 private obstetric offices located in Isfahan, the capital of Isfahan Province, Iran.</p> <p>Inclusion criteria: able to read and write and speak Persian; gestational age 6 to 10 weeks; no disease or condition that requires special medical care or drug counselling.</p> <p>Exclusion criteria: not interested in continuing participation in the trial; taking weight control medication; having any disease or condition requiring special medical care or hospitalisation; multiple pregnancy.</p>
Interventions	<p>Intervention group</p> <p>A "maternal centred life-style modification program" for pregnant women consisting of: (1) provision of an educational package of antenatal care for the women (PCPW); (2) a log book for recording goals and progress; and (3) 10 counselling sessions (appointments at 6 to 10, 11 to 15, 16 to 20, 21 to 25, 26 to 30, 31 to 34, 35 to 37, 38, 39 and 40 weeks gestation. The counselling will be delivered throughout the program by 1 counsellor, who is a midwife. The PCPW educational package consists of 14 chapters: GWG during pregnancy; GWG charting; principles of nutrition in pregnancy; nutritional guidance for low and normal and high BMI; food calories; principles of personal hygiene; mental health; stress management; suitable positions in pregnancy; stretching exercises; respiratory exercises; relaxation; massage in pregnancy; and physical activity principles and guidelines. The log book contains 5 sessions including on planning for delivery and timing of counselling sessions; monitoring GWG (chart); diet and nutrition recording; physical activity goal setting and recording; and stress management goals/records. Each counselling session will be approximately 20 minutes, excepting for the first session, which is 30 minutes. In the first session, the midwife will provide general information about the trial and provide the educational materials and log book. The women's BMI will be calculated and the IOM guidelines for GWG during pregnancy will be discussed and personalised goals set. The counsellor will explain how to monitor/record GWG. At the end of the session the women will be provided with the package and log book and reminded about the date of the next session. During subsequent sessions, the woman and counsellor will review achievements against the goals set. If the GWG trend is above normal, the counsellor will help the woman to find a solution to overcoming difficulties.</p> <p>Control group</p> <p>Women in the control group will attend the clinics at the same pregnancy time points as above. During each visit, the midwife will measure the weight of the women and plot the GWG curve. Aside from this activity related to the trial data collection, women in the control group will receive standard antenatal care.</p>
Outcomes	Primary outcome: GWG.
Starting date	October 2012.
Contact information	Dr Zahra Amini Pozveh, Department of Community Medicine, Isfahan University of Medical Sciences, Hezer Jerib St., Isfahan, Iran. E-mail: aminizahra2005@yahoo.com
Notes	Recruitment target: 160 women.

Garmendia 2015

Trial name or title	The Chilean maternal and infant nutrition cohort study (CHiMINCs).
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Garmendia 2015 (Continued)

Methods	Cluster-randomised controlled trial.
Participants	<p>Setting: 12 primary healthcare centres (> 400 births annually) in 2 counties (La Florida = 5, Puente Alto = 7) in the south east of Santiago, Chile.</p> <p>Inclusion criteria: ≤ 15 weeks gestation; residing within a catchment area of included health centres; expressing that they are not planning to change residence within the next 2 years.</p> <p>Exclusion criteria: women classified as high risk according to Chilean norms (i.e. age < 16 or > 40 years; multiple pregnancies; pre-gestational medical conditions; previous pregnancy-related issues) and/or underweight (BMI < 18.5 kg/m²).</p>
Interventions	<p>Intervention group</p> <p>Women will receive the "CHIMINC" intervention, a low-intensity intervention designed to support the implementation of evidence-based guidelines by enhancing the uptake of existing programs. Women will receive GWG monitoring, diet and physical activity counselling support, and breast-feeding promotion, from the first antenatal visit (< 15 weeks) to 12 months postpartum. The intervention has 2 main components: (1) training for professionals (midwives, dietitians, nurses) including on maternal GWG assessment, use of charts, referral to dietitian criteria, dietary and physical activity recommendations, and how to communicate nutrition messages effectively. (2) actions, including advice about diet and physical activity, provided during antenatal visits.</p> <p>Diet: women will, at the first antenatal visit receive education about optimal GWG, and at each routine midwife visit, computer-based weight assessment and feedback about how to achieve GWG goals. At each subsequent midwife visit women will receive advice about ≥ 2 of the following key nutrition during pregnancy messages ("<i>avoid the consumption of sugar-sweetened beverages</i>"; "<i>restrict the consumption of white bread to two pieces/day</i>"; "<i>replace fatty meats with lean meat and fish</i>"; "<i>eat a variety of vegetables and fruits each day in place of foods higher in fat and calories</i>"). Women will be referred to a dietitian if necessary according to pre-defined criteria.</p> <p>Exercise: women will be invited to physical activity classes. They will be encouraged to attend a program for pregnant women of moderate-intensity exercise (60 minutes, 3 times a week). The program will be delivered at each of the participating sites, and supervised by licensed physical activity instructors. Each session will consist of 10 minutes of strength exercises and 10 minutes of stretching and elongating exercises.</p> <p>Control group</p> <p>Women will receive routine care according to national guidelines.</p>
Outcomes	<p>Primary outcomes: GWG (36 to 40 weeks gestation); maternal diet; postpartum weight retention (12 months postpartum); maternal glycaemic control (at 20 to 24 weeks gestation); breastfeeding (birth to 12 months); lactation rates (at 12 months postpartum); infant weight, length and BMI (during the first year of life); psychomotor development (during first year of life).</p> <p>Secondary outcomes: adherence to the intervention; intervention implementation (including resource use).</p>
Starting date	September 2013 (estimated completion date March 2017).
Contact information	Dr Maria L Garmendia, Institute of Nutrition and Food Technology, University of Chile, Chile. E-mail:mgarmendia@inta.uchile.cl
Notes	Recruitment target: 2400 women.

Jelsma 2013

Trial name or title	DALI: Vitamin D and lifestyle intervention for GDM prevention: an European multi-centre, randomised trial.
Methods	Randomised controlled trial.
Participants	<p>Setting: 9 European countries: UK, Ireland, the Netherlands, Belgium, Poland, Italy, Spain, Austria, Denmark.</p> <p>Inclusion criteria: pregnant women with a pre-pregnancy BMI ≥ 29 kg/m²; before 19 + 6 weeks gestation; with a singleton pregnancy; aged ≥ 18 years.</p> <p>Exclusion criteria: diagnosed with GDM on OGTT before randomisation using IADPSG criteria (fasting venous plasma glucose ≥ 5.1 mmol/L and/or 1-hour glucose ≥ 10 mmol/L and/or 2-hour glucose ≥ 8.5 mmol/L); pre-existing diabetes; not able to walk ≥ 100 metres safely; requiring complex diets; chronic medical conditions (e.g. valvular heart disease); significant psychiatric disease; unable to speak major language of the country of recruitment fluently or unable to converse with the lifestyle coach in another language for which translated materials exist.</p> <p>For the vitamin D arm, 2 additional exclusion criteria apply: current or past abnormal calcium metabolism, e.g. hypo/hyperparathyroidism, nephrolithiasis, hypercalciuria; hypercalciuria (> 0.6 mmol/mmol creatinine in spot morning urine) or hypercalcaemia (> 10.6 mg/dL, 2.65 mmol/L) detected at baseline measurement.</p>
Interventions	<p>This trial will have intervention arms using a 2×(2×2) factorial design:</p> <p>Healthy eating:</p> <ul style="list-style-type: none"> 7 dietary objectives for each woman to achieve or to maintain: 1) <i>"Replace sugary drinks"</i>: To reduce intake of sugary drinks (e.g. replace with water); 2) <i>"Eat more non-starchy vegetables"</i>: To eat more non-starchy vegetables; 3) <i>"Increase fibre consumption"</i>: To choose high-fibre, over low fibre products (≥ 5 g fibre/100 g); 4) <i>"Watch portion size"</i>: To be conscious about the amount of food eaten each meal; 5) <i>"Eat protein"</i>: To increase intake of proteins (e.g. meat, fish, beans); 6) <i>"Reduce fat intake"</i>: To reduce fat intake (e.g. snack, fast food, fried foods); 7) <i>"Eat less carbohydrates"</i>: To reduce intake of carbohydrates (e.g. potatoes, pasta, rice, snacks, candy). Women will receive a 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. Women will receive an action plan for improving dietary behaviour: will be made during the first intervention session and evaluated in subsequent sessions. Intervention sessions will be delivered by 5 1-to-1, face-to-face sessions of approximately 30 to 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. <p>Physical activity:</p> <ul style="list-style-type: none"> Each woman will be advised to: 1) <i>"Be active every day"</i>: 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) <i>"Sit less"</i>: Reduce sedentary time. 3) <i>"Build your strength"</i>: Incorporate upper and/or lower limb resistance exercise. 4) <i>"Take more steps"</i>: To increase the number of steps taken per day. 5) <i>"Be more active at weekends"</i>: To be more active during the weekends. Women will receive a 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 based on ACOG guidelines and information about the above mentioned physical activity advice. Women will receive an action plan for increasing physical activity: will be made during the first intervention session and evaluated in subsequent sessions. Women will receive a pedometer to provide feedback on behaviour and progress. Women will receive an additional (training) video on upper and/or lower limb resistance exercises.

Jelsma 2013 (Continued)

- Women will receive flexible elastic dynabands to encourage upper and/or lower limb resistance exercises at home.
- Intervention sessions will be delivered by 5 1-to-1, face-to-face sessions of approximately 30 to 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.

Vitamin D alone: each vitamin D tablet contains 400 IU, and women will be asked to take 4 tablets/day until birth.

Placebo alone: placebo tablets, identical to the vitamin D tablets in appearance, will be packed in identical bottles with identical labels as the vitamin D bottles. The women will be asked to take 4 tablets daily.

Control: no lifestyle intervention or vitamin D/placebo. Women will receive usual care from their midwife or obstetrician during pregnancy.

Healthy eating and physical activity.

Healthy eating and physical activity and vitamin D.

Healthy eating and physical activity and placebo.

Outcomes	<p>Primary outcome: GWG; fasting glucose; insulin sensitivity.</p> <p>Other outcomes: cost-effectiveness.</p>
Starting date	February 2013.
Contact information	Mireille NM van Poppel, 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. E-mail: mnm.vanpoppel@vumc.nl
Notes	Recruitment target: 880 women.

Kennelly 2016

Trial name or title	Pregnancy, exercise and nutrition research study with app support: a randomized controlled trial.
Methods	Randomised controlled trial.
Participants	<p>Setting: Ireland.</p> <p>Inclusion criteria: singleton pregnancies with a live fetus; smart phone; between the ages of 18 and 45 at 10 to 15 weeks gestation with an early pregnancy BMI ≥ 25 kg/m²; with adequate understanding of the English language and an understanding of the trial to enable them to give informed consent to participate.</p> <p>Exclusion criteria: multiple pregnancy; < 18 or > 45 years of age; with pre-GDM or early onset GDM or past history of GDM; fetal anomaly; previous stillbirth or perinatal death; English inadequate or unable to understand the trial adequately to participate; medical disorder requiring medication.</p>
Interventions	<p>Intervention group</p> <p>Women will receive a "Healthy lifestyle package" consisting 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. Women will have individual and group education sessions on the healthy lifestyle package at randomisation. The re-</p>

Kennelly 2016 (Continued)

search team will contact women every 2 weeks to support adherence to exercise goals and low GI diet.

Control group: women will receive routine antenatal care which does not include specific nutritional advice nor specific advice on GWG.

Outcomes	<p>Primary outcome: GDM.</p> <p>Other outcomes: GWG; GI; activity levels during the third trimester.</p>
Starting date	January 2013.
Contact information	Prof Fionnuala McAuliffe, National Maternity Hospital, Holles St, Dublin, Ireland. E-mail: fionnuala.mcauliffe@ucd.ie
Notes	Recruitment target: 500 women.

Nagle 2013

Trial name or title	Primary prevention of GDM for women who are overweight and obese: a randomised controlled trial.
Methods	Randomised controlled trial.
Participants	<p>Setting: Australia.</p> <p>Inclusion criteria: pregnant women at < 14 weeks gestation; singleton pregnancy; BMI ≥ 25 kg/m²; able to give informed consent in English.</p> <p>Exclusion criteria: diabetes or a history of GDM.</p>
Interventions	<p>Intervention group:</p> <p>From recruitment in the first trimester until birth, women 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.</p> <p>Control group</p> <p>Women will receive usual pregnancy care</p>
Outcomes	<p>Primary outcome: GDM.</p> <p>Other outcomes: large-for-gestational age; self-efficacy related to healthy lifestyle changes in diet and exercise; anxiety; depression.</p>
Starting date	February 2013.
Contact information	Dr Cate Nagle, Deakin University School of Nursing and Midwifery Waterfont Campus 1 Gheringhap St Geelong Victoria 3220, Australia. E-mail: cate.nagle@deakin.edu.au
Notes	Recruitment target: 370.

NCT01643356

Trial name or title	Interventions to reduce excess weight gain in pregnancy in overweight and obese mothers.
Methods	Randomised controlled trial.
Participants	<p>Setting: USA.</p> <p>Inclusion criteria: aged 15 to 46 years; in first trimester; willing not to join any other weight control program while in the trial; BMI 25 to 40 kg/m²; willingness and ability to attend support group meetings either in person or via web; able to read, speak, and understand English.</p> <p>Exclusion criteria: carrying multiple fetuses; GDM at trial entry; type 2 diabetes or blood glucose > 125 mg/dL at screening; self-reported current substance abuse; current smoking; alcohol consumption of > 1 drink per day; pre-existing medical conditions (including bariatric surgery) or use of medications that would impact trial involvement or outcomes testing; eating disorder in the past 2 years; depression or diagnosis of bipolar disorder; concurrent participation in any other research trial that would impact participation in this investigation.</p>
Interventions	<p>Intervention group</p> <p>Women will attend 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 GWG management will be discussed.</p> <p>Control group</p> <p>Women will attend routine clinical care and receive no additional interventions.</p>
Outcomes	<p>Primary outcome: maternal weight change from first trimester to 1-year postpartum; infant weight change from birth to 1-year old.</p> <p>Other outcomes: infant: body composition changes through the first year; characteristics at birth including Apgar score and gestational age; dietary intake and food preferences at 1 year; maternal outcomes: caesarean section; gestational hypertension/pre-eclampsia; preterm birth; birth complications; fasting blood glucose and insulin throughout pregnancy; body composition and energy requirements at baseline and 24 to 28 weeks of pregnancy; total energy expenditure at 24 to 28 weeks of pregnancy; rate of breastfeeding and breastfeeding practices at 1, 3, 6, and 12 months postpartum.</p>
Starting date	July 2012.
Contact information	Dr Susan B Roberts, Tufts University Human Nutrition Research Center on Aging, Boston, Massachusetts, USA, 02111. E-mail: susan.robbers@tufts.edu
Notes	Recruitment target: 75 women.

NCT01693510

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	<p>Setting: Canada.</p> <p>Inclusion criteria: healthy pregnant women > 18 years of age with singleton pregnancies (either nulliparous or multiparous); < 20 weeks gestation; pre-pregnancy BMI > 25 and < 40 kg/m²; plan to deliver at a Hamilton Health Sciences, St Joseph's Healthcare Hamilton, Joseph Brant Hospital or</p>

NCT01693510 (Continued)

by home birth but willing to attend research visits at the McMaster University Medical Centre site; approval of primary care provider; able to provide signed informed consent.

Exclusion criteria: unable to understand some English; currently breastfeeding previous child; pregnancy from in vitro fertilisation; 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; a depression score above 10 on the validated Edinburgh Depression scale as that is indicative of severe depression and should be referred for treatment; smoking.

Interventions	<p>Intervention group:</p> <p>Women will receive a high-protein (25% energy) diet providing low-fat dairy foods, individualised to energy needs and aerobic exercise (walking).</p> <p>Control group</p> <p>Women will receive usual antenatal care.</p>
Outcomes	<p>Primary outcome: GWG within IOM guidelines.</p> <p>Other outcomes: mother and infant bone outcomes at 6 months postpartum.</p>
Starting date	July 2012.
Contact information	Dr Stephanie A Atkinson, McMaster University Medical Centre, Hamilton, Ontario, Canada, L8S 4K1. E-mail: satkins@mcmaster.ca
Notes	Recruitment target: 110 women.

NCT01719406

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	<p>Setting: USA.</p> <p>Inclusion criteria: healthy first-trimester pregnant women.</p> <p>Exclusion criteria: hypertension; diabetes; known cardiopulmonary disease; orthopedic problems or other conditions that would prevent regular physical activity.</p>
Interventions	<p>Intervention group</p> <p>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 wholegrains.</p> <p>Control group</p> <p>Women will receive standard medical care.</p>
Outcomes	<p>Primary outcome: achieving 30 minutes of daily exercise, 4 or more times each week.</p> <p>Other outcomes: eating 5 or more servings of vegetables and/or fruits each day; pregnancy weight gain; HbA1c.</p>

NCT01719406 (Continued)

Starting date	November 2012.
Contact information	Dr Linn Goldberg, Oregon Health and Science University, Portland, Oregon, USA, 97239. E-mail: goldberl@ohsu.edu
Notes	Recruitment target: 30 women.

NCT01782105

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	<p>Setting: Canada</p> <p>Inclusion criteria: women aged ≥ 18 years; with 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).</p> <p>Exclusion criteria: pre-pregnancy diabetes detected in the first trimester (HbA1c $> 6.5\%$; 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.</p>
Interventions	<p>Intervention group</p> <p>Women will receive 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).</p> <p>Control group:</p> <p>In addition to the standard antenatal care for pregnancy, women will receive information about recommended GWG and an evaluation of their nutritional and physical activity habits.</p>
Outcomes	<p>Primary outcome: GWG.</p> <p>Other outcomes: maternal and fetal adipokines; maternal and fetal glycaemic control.</p>
Starting date	December 2011.
Contact information	Dr Marie-France Hivert, Centre Hospitalier Universitaire de Sherbrooke, Sherbrooke, Quebec, Canada, J1H5N4.
Notes	Recruitment target: 16 women.

Rauh 2014

Trial name or title	The Healthy Living in Pregnancy (GeLiS) study.
Methods	Cluster-randomised controlled trial.
Participants	Setting: 10 regions of Bavaria, a federal state of Germany.

Rauh 2014 (Continued)

Inclusion criteria: women aged 18 to 43 years; < 12 weeks gestation; a singleton pregnancy; pre-pregnancy BMI ≥ 18.5 and ≤ 40 kg/m²; sufficient German skills; written informed consent.

Exclusion criteria: multiple pregnancy; high-risk pregnancy prohibiting trial participation (contraindications to exercise e.g. placenta previa, persistent bleeding, cervical incompetence etc.); pre-pregnancy diabetes mellitus or early GDM; uncontrolled chronic diseases (e.g. thyroid dysfunction); psychiatric or psychosomatic diseases; any other diseases which could interfere with compliance according to the trial protocol.

Interventions	<p>Intervention group</p> <p>Women will receive a lifestyle intervention program consisting of 4 structured and partially individualised counselling sessions emphasising optimal diet, physical activity and weight monitoring, delivered by specifically trained and certified professionals (midwives, gynaecologists or medical staff) during the pregnancy period (12 to 16, 16 to 20, 30 to 34 weeks of gestation), and the postpartum period (6 to 8 weeks after birth). The sessions will be delivered alongside routine antenatal visits and will follow a defined curriculum. Women will receive a pedometer as well as brochures that provide: i) examples of adequate exercise; ii) a list of local antenatal physical exercise programs; and iii) recommendations for a balanced diet in pregnancy according to the "Healthy Start - Young Family Network". In the initial counselling session (30 to 45 minutes), women will receive detailed information about a healthy diet and physical activity during pregnancy. The principles of healthy eating and the risks of alcohol, smoking and food borne infections during pregnancy will be discussed. They will also receive advice relating to GWG goals, weight monitoring and critical nutrients during pregnancy. The brochure including the list of suitable exercises and group-based physical exercise programs that are easily accessible will be provided during this session. During visit 2, women will receive specific and detailed individual counselling targeting dietary habits and physical activity, informed by the first counselling session. In the third counselling session, the focus will be on repetition and consolidation of the messages delivered during the earlier sessions. In the final counselling session, women will receive advice about diet during breastfeeding and as in all the sessions, women will have their weight measured and documented.</p> <p>Control group</p> <p>Women in the control group will receive standard antenatal care, including a leaflet about a healthy lifestyle in pregnancy. They will receive no specific advice on diet, physical activity or GWG.</p>
Outcomes	<p>Primary outcome: GWG (proportion of women with excessive GWG as defined by the IOM).</p> <p>Secondary outcomes: GDM; HbA1c; pre-eclampsia; infant anthropometric measures and health status (birthweight, height, head circumference, large-for-gestational age, small-for-gestational age, Apgar scores, pH); mode of birth and obstetric complications; maternal diet and physical activity behaviour; maternal weight after birth (6 to 8 weeks postpartum), maternal well-being (mental health and postnatal depression).</p>
Starting date	September 2013.
Contact information	Hans Hanuer and Kathrin Rach, Research Centre for Nutrition and Food Sciences, Technische Universität München, Freising-Weihenstephan, Germany. E-mail: hans.hauner@tum.de or kathrin.rauh@KERN.bayern.de
Notes	Recruitment target: 2500 women.

Spieker 2015

Trial name or title	Pregnancy and early infancy (POMC-Mother-Baby)
Methods	Randomised controlled trial.

Spieker 2015 (Continued)

Participants	<p>Setting: the Naval Hospital, Camp Lejeune, North Carolina, USA.</p> <p>Inclusion criteria: women aged 18 to 35 years with low risk pregnancies; receiving their care within the Military Health System; planning to reside in the trial area for ≥ 18 months; not at elevated risk of complications due to BMI on determination of pregnancy; BMI > 18 and < 30 kg/m²; not actively involved in another weight management program; able to speak English.</p> <p>Exclusion criteria: current involvement in a structured weight loss program; multiple pregnancies; a medical-risk pregnancy based on VA/DoD Management of Pregnancy Guidelines (e.g., hypertension, thyroid disease).</p>
Interventions	<p>Intervention group</p> <p>Women will receive "positive gains counselling", once each trimester and at 2-week, 2-month, 4-month and 6-month well-child visits (7 sessions in total), focused on the benefits of being physically fit, eating healthy foods, and regular exercise, and the costs of obesity, a high-fat/high-sugar diet, and sedentary behavior. Specific counselling (where possible provided by the same counsellor throughout pregnancy and early infancy) will focus on positive-gain-based cognitive strategies to promote breastfeeding, recognise infant satiety cues, and promote healthy food choices. Each counselling session will have a different topic related to issues specific to each stage of pregnancy/infancy (e.g. preparing for birth, initiating and maintaining breastfeeding, introducing solid foods). By incorporating counselling sessions with pre-existing clinic visits, women will receive additional social and emotional support during pregnancy and after they give birth.</p> <p>Control group</p> <p>Women will receive routine antenatal care in accordance with accepted guidelines. Primary care providers will deliver the anticipatory guidance in their usual fashion with no external cues or counselling by the research team.</p>
Outcomes	Outcomes: GWG; well-being (anxiety and depression, during pregnancy and 2 months postpartum); behaviour (physical activity and diet, mid pregnancy and 6 months postpartum); BMI; child anthropometric measures (during pregnancy and at 2 months, 4 months and 6 months postpartum).
Starting date	Not reported.
Contact information	Tracy Sbrocco. E-mail: tracy.sbrocco@usuhs.edu
Notes	Recruitment target: 120 women.

Vesco 2012

Trial name or title	Healthy Moms Study.
Methods	Randomised controlled trial.
Participants	<p>Setting: 8 obstetrics and gynaecology clinics belonging to the not for profit health maintenance organisation, Kaiser Permanente North West (KPNW), located in Portland, Oregon, USA.</p> <p>Inclusion criteria: obese at the start of pregnancy (BMI ≥ 30 kg/m²); < 20 weeks gestation; singleton pregnancy; member of KPNW; receiving pre-natal care at KPNW; $\geq 18 \leq 50$ years.</p> <p>Exclusion criteria: current treatment for cancer; bariatric surgery; current renal disease; multiple birth anticipated; hyperemesis requiring hospitalisation; diabetes (type 1 or 2); non-English speaking.</p>
Interventions	Intervention group

Vesco 2012 (Continued)

Women will receive a weekly group-based diet and lifestyle intervention focused on achieving the goal of containing their weight during pregnancy to within 3% of their weight at randomisation (at between 10 to 20 weeks gestation). The dietary and physical activity interventions will be tailored to each women's weight and lifestyle.

Diet: women will receive 2 individual counselling sessions on nutrition and once-weekly group sessions and will be supplied with food diaries. To help women stay within their weight goals, intervention staff will monitor women's weight and food records weekly, and adjust calorie targets as needed. Nutrition goals to be focused on will include: *"staying within individual calorie guidelines"*; *"limiting portion sizes: reducing fat intake to 25% of calories"*; *"reducing sweets and sweetened beverages"*; and *"consuming more whole grains and complex carbohydrates"*. Women will be encouraged to follow the DASH diet (without limiting sodium intake) combined with, 1) eating 8 to 12 servings of fruit and vegetables per day; and 2) consuming 2 to 3 servings of low fat dairy products per day.

Exercise: women will be encouraged to engage in ≥ 30 minutes of moderate physical activity per day unless restrictions are advised by their primary obstetric care provider. They will be provided with pedometers to encourage physical activity. They will be asked to record their daily step totals or minutes of physical activity and report on their physical activity at each group session. Physical activity recommendations will emphasise safe activity during pregnancy.

Control group

In addition to routine antenatal care, women will receive information only consisting of a single dietary advice session. Pedometers will not be provided to women in the control group until they have completed the 1-year follow-up visit.

Outcomes	<p>Primary outcomes: maternal weight change (baseline to 2 weeks postpartum).</p> <p>Secondary outcomes: GWG (baseline to 34 weeks gestation); large-for-gestational age; views of the intervention; feasibility of the intervention; behaviour (diet and physical activity); birthweight; feeding patterns; infant growth during the first year of life.</p>
Starting date	October 2009 (planned completion date March 2013).
Contact information	Kimberly Vesco. Center for Health Research, 3800 N.Interstate Avenue, Portland, USA. E-mail: kimberly.k.vesco@kpchr.org
Notes	Recruitment target: 118 women.

Abbreviations: ACOG: American College of Obstetricians and Gynecologists; ADA: American Diabetes Association; BMI: body mass index; CHiMNCs: Chilean maternal and infant nutrition cohort study; DALI: Vitamin D and lifestyle intervention for GDM prevention randomised trial; DASH: Dietary Approaches to Stop Hypertension; FITT: frequency, intensity, time, type; g: gram; GDM: gestational diabetes mellitus; GELiS: Healthy Living in Pregnancy study; GI: glycaemic index; GHW: Get Healthy Service; GWG: gestational weight gain; HbA1c: glycated haemoglobin; HOMA: Homeostasis Model Assessment; IADPSG: International Association of the Diabetes and Pregnancy Study Group; IOM: Institute of Medicine; IU: international units; KPNW: Kaiser Permanente North West; OGTT: oral glucose tolerance test; PCPW: package of antenatal care for the pregnant women; POMC-Mother-Baby: Pregnancy and early infancy study; UK: United Kingdom; USA: United States of America.

DATA AND ANALYSES

Comparison 1. Combined diet and exercise interventions versus standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Gestational diabetes	19	6633	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.71, 1.01]
2 Pre-eclampsia	8		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Pre-eclampsia	8	5366	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.79, 1.22]
2.2 Severe pre-eclampsia/HELLP/eclampsia	2	2088	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.35, 1.46]
3 Pregnancy-induced hypertension and/or hypertension	6		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 Pregnancy-induced hypertension and/or hypertension	6	3073	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.47, 1.27]
3.2 Pregnancy-induced hypertension	4	810	Risk Ratio (M-H, Random, 95% CI)	0.46 [0.16, 1.29]
3.3 Hypertension	3	2532	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.84, 1.38]
4 Caesarean section	14	6089	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.88, 1.02]
5 Perinatal mortality	2	3757	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.42, 1.63]
6 Large-for-gestational age	11	5353	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.81, 1.07]
7 Operative vaginal birth	3	2164	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.86, 1.34]
8 Induction of labour	5	3907	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.79, 1.06]
9 Perineal trauma	2	2733	Risk Ratio (M-H, Fixed, 95% CI)	1.27 [0.78, 2.05]
10 Placental abruption	1	1555	Risk Ratio (M-H, Fixed, 95% CI)	2.96 [0.12, 72.50]
11 Postpartum haemorrhage	3	4235	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.89, 1.18]
12 Postpartum infection	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
12.1 Endometritis	1	2142	Risk Ratio (M-H, Fixed, 95% CI)	1.19 [0.52, 2.74]
12.2 Wound infection	1	2142	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.65, 1.73]
12.3 Postpartum antibiotics	1	2142	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.77, 1.31]
12.4 Postpartum sepsis	1	1555	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 8.06]
13 Gestational weight gain (kg)	16	5052	Mean Difference (IV, Random, 95% CI)	-0.89 [-1.39, -0.40]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
14 Gestational weight gain (various times reported) (kg)	4		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
14.1 First trimester	1	272	Mean Difference (IV, Fixed, 95% CI)	-0.03 [-0.62, 0.56]
14.2 Second trimester	2	541	Mean Difference (IV, Fixed, 95% CI)	-0.38 [-0.77, 0.02]
14.3 Third trimester	1	269	Mean Difference (IV, Fixed, 95% CI)	-0.10 [-1.17, 0.97]
14.4 At 20-24 weeks gestation	1	221	Mean Difference (IV, Fixed, 95% CI)	-0.45 [-1.48, 0.58]
14.5 At 26-28 weeks gestation	1	203	Mean Difference (IV, Fixed, 95% CI)	-0.90 [-1.75, -0.05]
15 Gestational weight gain (kg/week)	4	2772	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.06, -0.00]
16 Gestational weight gain (above IOM recommendations)	11	4556	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.79, 0.96]
17 Gestational weight gain (within IOM recommendations)	9	3730	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.93, 1.11]
18 Gestational weight gain (below IOM recommendations)	7	3499	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.98, 1.24]
19 Behaviour changes associated with the intervention			Other data	No numeric data
20 Relevant biomarker changes associated with the intervention			Other data	No numeric data
21 Sense of well-being and quality of life			Other data	No numeric data
22 Breastfeeding (exclusive)	3		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
22.1 3 days postpartum	1	695	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.91, 1.15]
22.2 6 weeks postpartum	1	202	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.76, 1.13]
22.3 6 months postpartum	2	921	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.61, 1.36]
23 Breastfeeding (partial)	3		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
23.1 3 days postpartum	1	695	Risk Ratio (M-H, Fixed, 95% CI)	0.51 [0.40, 0.66]
23.2 6 weeks postpartum	1	202	Risk Ratio (M-H, Fixed, 95% CI)	1.44 [0.80, 2.60]
23.3 6 months postpartum	2	921	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.82, 1.18]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
24 Breastfeeding			Other data	No numeric data
25 Postnatal weight retention (latest time reported) (kg)	6	1673	Mean Difference (IV, Fixed, 95% CI)	-0.94 [-1.52, -0.37]
26 Return to pre-pregnancy weight (latest time reported)	3	960	Risk Ratio (M-H, Fixed, 95% CI)	1.25 [1.08, 1.45]
27 Postnatal BMI (latest time reported)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
27.1 BMI	2	902	Mean Difference (IV, Fixed, 95% CI)	-0.15 [-0.85, 0.55]
27.2 BMI change from baseline to 6 weeks postpartum	1	202	Mean Difference (IV, Fixed, 95% CI)	-0.56 [-1.12, -0.00]
28 Maternal cardiovascular health (latest time reported)			Other data	No numeric data
29 Stillbirth	5	4783	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.35, 1.36]
30 Neonatal mortality	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
30.1 Total	2	3756	Risk Ratio (M-H, Fixed, 95% CI)	2.31 [0.60, 8.90]
30.2 No lethal anomalies	1	2202	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.06, 15.85]
30.3 Lethal anomalies	1	2202	Risk Ratio (M-H, Fixed, 95% CI)	6.95 [0.36, 134.38]
31 Gestational age at birth (weeks)	11	5658	Mean Difference (IV, Fixed, 95% CI)	0.05 [-0.05, 0.15]
32 Gestational age at birth (days or weeks)			Other data	No numeric data
33 Preterm birth	11	5398	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.65, 0.98]
34 Apgar score less than seven at five minutes	3	2864	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.48, 1.32]
35 Macrosomia	10		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
35.1 > 4000 g	9	5368	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.78, 1.01]
35.2 > 4500 g	4	3061	Risk Ratio (M-H, Fixed, 95% CI)	0.63 [0.42, 0.94]
36 Small-for-gestational age	6	2434	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [0.95, 1.52]
37 Birthweight (g)	13	5763	Mean Difference (IV, Fixed, 95% CI)	-17.67 [-46.28, 10.94]
38 Birthweight (g)			Other data	No numeric data

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
39 Birthweight z score	4	2661	Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.13, 0.03]
40 Head circumference (cm)	4	4229	Mean Difference (IV, Fixed, 95% CI)	-0.01 [-0.11, 0.10]
41 Head circumference z score	1	2142	Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.14, 0.04]
42 Length (cm)	6	3303	Mean Difference (IV, Fixed, 95% CI)	-0.09 [-0.26, 0.09]
43 Length z score	2	2235	Mean Difference (IV, Fixed, 95% CI)	-0.08 [-0.15, -0.02]
44 Ponderal index (kg/m ³)	3	2826	Mean Difference (IV, Fixed, 95% CI)	0.04 [-0.16, 0.25]
45 Adiposity (sum of skinfold thickness) (mm)	2	1472	Mean Difference (IV, Fixed, 95% CI)	0.09 [-0.33, 0.50]
45.1 Sum of biceps, triceps, subscapular, suprailiac, abdominal and thigh skinfold thickness	1	970	Mean Difference (IV, Fixed, 95% CI)	0.03 [-0.86, 0.92]
45.2 Sum of triceps and subscapular skinfold thickness (mm)	1	502	Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.36, 0.56]
46 Adiposity (abdominal circumference) (cm)	2	1566	Mean Difference (IV, Fixed, 95% CI)	-0.01 [-0.23, 0.22]
47 Adiposity			Other data	No numeric data
48 Shoulder dystocia	2	2733	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [0.79, 1.83]
49 Nerve palsy	1	2142	Risk Ratio (M-H, Fixed, 95% CI)	1.99 [0.36, 10.82]
50 Bone fracture	1	2142	Risk Ratio (M-H, Fixed, 95% CI)	1.99 [0.36, 10.82]
51 Respiratory distress syndrome	2	2411	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.33, 0.97]
52 Hypoglycaemia	2	3653	Risk Ratio (M-H, Random, 95% CI)	1.42 [0.67, 2.98]
53 Hyperbilirubinaemia	1	2142	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.61, 1.11]
54 Childhood weight (latest time reported) (kg)	3	882	Mean Difference (IV, Random, 95% CI)	-0.05 [-0.33, 0.22]
54.1 6 months	1	677	Mean Difference (IV, Random, 95% CI)	-0.10 [-0.26, 0.06]
54.2 10-12 months	1	48	Mean Difference (IV, Random, 95% CI)	-0.36 [-0.96, 0.24]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
54.3 2.8 years	1	157	Mean Difference (IV, Random, 95% CI)	0.30 [-0.19, 0.79]
55 Childhood weight z score (latest time reported)	1	643	Mean Difference (IV, Fixed, 95% CI)	-0.09 [-0.26, 0.08]
56 Childhood height (latest time reported) (cm)	2	816	Mean Difference (IV, Fixed, 95% CI)	0.33 [-0.58, 1.25]
56.1 6 months	1	659	Mean Difference (IV, Fixed, 95% CI)	1.04 [-0.58, 2.66]
56.2 2.8 years	1	157	Mean Difference (IV, Fixed, 95% CI)	0.0 [-1.11, 1.11]
57 Childhood height z score (latest time reported)	1	622	Mean Difference (IV, Fixed, 95% CI)	-0.02 [-0.31, 0.27]
58 Childhood head circumference (latest time reported) (cm)	1	670	Mean Difference (IV, Fixed, 95% CI)	-0.12 [-0.70, 0.46]
59 Childhood adiposity (latest time reported) (BMI z score)	2	794	Mean Difference (IV, Random, 95% CI)	0.05 [-0.29, 0.40]
59.1 6 months	1	637	Mean Difference (IV, Random, 95% CI)	-0.11 [-0.39, 0.17]
59.2 2.8 years	1	157	Mean Difference (IV, Random, 95% CI)	0.24 [-0.10, 0.58]
60 Childhood adiposity (latest time reported) (abdominal circumference) (cm)	2	833	Mean Difference (IV, Fixed, 95% CI)	0.26 [-0.37, 0.90]
60.1 6 months	1	676	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.81, 0.85]
60.2 2.8 years	1	157	Mean Difference (IV, Fixed, 95% CI)	0.60 [-0.38, 1.58]
61 Childhood adiposity (latest time reported) (subscapular skinfold thickness) (mm)	2	705	Mean Difference (IV, Random, 95% CI)	-0.17 [-0.66, 0.32]
61.1 6 months	1	548	Mean Difference (IV, Random, 95% CI)	-0.40 [-0.73, -0.07]
61.2 2.8 years	1	157	Mean Difference (IV, Random, 95% CI)	0.10 [-0.33, 0.53]
62 Childhood adiposity (latest time reported) (triceps skinfold thickness) (mm)	2	784	Mean Difference (IV, Fixed, 95% CI)	-0.12 [-0.48, 0.23]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
62.1 6 months	1	627	Mean Difference (IV, Fixed, 95% CI)	-0.18 [-0.61, 0.25]
62.2 2.8 years	1	157	Mean Difference (IV, Fixed, 95% CI)	0.0 [-0.63, 0.63]
63 Childhood adiposity (latest time reported) (total body fat (%))	2	614	Mean Difference (IV, Fixed, 95% CI)	-0.74 [-1.56, 0.07]
63.1 6 months	1	547	Mean Difference (IV, Fixed, 95% CI)	-0.80 [-1.64, 0.04]
63.2 2.8 years	1	67	Mean Difference (IV, Fixed, 95% CI)	0.0 [-3.03, 3.03]
64 Childhood adiposity (latest time reported)			Other data	No numeric data
65 Childhood cardiovascular health (latest time reported)			Other data	No numeric data
66 Antenatal visits	1	269	Mean Difference (IV, Fixed, 95% CI)	0.0 [-0.36, 0.36]
67 Antenatal admissions	1	2153	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.71, 1.04]
68 Length of antenatal stay (days)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
68.1 Antenatal stay (days)	1	2153	Mean Difference (IV, Fixed, 95% CI)	-0.27 [-0.49, -0.05]
68.2 Antenatal inpatient stay (nights), if admitted	1	139	Mean Difference (IV, Fixed, 95% CI)	0.0 [-1.00, 1.00]
69 Neonatal intensive care unit admission	4	4549	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.93, 1.14]
70 Length of postnatal stay (mother) (days)	2	3511	Mean Difference (IV, Random, 95% CI)	0.01 [-0.14, 0.17]
71 Length of postnatal stay (baby) (days)	2	3618	Mean Difference (IV, Fixed, 95% CI)	-0.35 [-0.90, 0.20]
72 Costs to families associated with the management provided (unit cost, €)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
72.1 Delivery cost to the patient	1	93	Mean Difference (IV, Fixed, 95% CI)	3.0 [-10.82, 16.82]
72.2 Neonatal care cost to the patient	1	93	Mean Difference (IV, Fixed, 95% CI)	3.00 [-13.67, 19.67]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
73 Costs associated with the intervention (unit cost, €)	1	93	Mean Difference (IV, Fixed, 95% CI)	769.0 [-1032.23, 2570.23]
73.1 Total costs	1	93	Mean Difference (IV, Fixed, 95% CI)	769.0 [-1032.23, 2570.23]
74 Cost of maternal care (unit cost, €)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
74.1 Visits for primary health care	1	93	Mean Difference (IV, Fixed, 95% CI)	-43.0 [-127.61, 41.61]
74.2 Visits for specialist health care	1	93	Mean Difference (IV, Fixed, 95% CI)	-47.0 [-195.33, 101.33]
74.3 Visits to a diabetes nurse	1	93	Mean Difference (IV, Fixed, 95% CI)	6.00 [-7.02, 19.02]
74.4 Visits to a dietitian	1	93	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
74.5 Use of insulin/other diabetes medication	1	93	Mean Difference (IV, Fixed, 95% CI)	-1.0 [-7.83, 5.83]
74.6 Hospital days before and after delivery	1	93	Mean Difference (IV, Fixed, 95% CI)	101.00 [-206.71, 408.71]
74.7 Delivery cost to the municipality	1	93	Mean Difference (IV, Fixed, 95% CI)	22.0 [-234.43, 278.43]
74.8 Absence from work	1	93	Mean Difference (IV, Fixed, 95% CI)	128.0 [-1295.58, 1551.58]
75 Cost of infant care (unit cost, €)	1	93	Mean Difference (IV, Fixed, 95% CI)	453.0 [-298.20, 1204.20]
75.1 Neonatal care cost to municipality	1	93	Mean Difference (IV, Fixed, 95% CI)	453.0 [-298.20, 1204.20]

Analysis 1.1. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 1 Gestational diabetes.

Analysis 1.2. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 2 Pre-eclampsia.

Analysis 1.3. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 3 Pregnancy-induced hypertension and/or hypertension.

Analysis 1.4. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 4 Caesarean section.

Analysis 1.5. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 5 Perinatal mortality.

Analysis 1.6. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 6 Large-for-gestational age.

Analysis 1.7. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 7 Operative vaginal birth.

Analysis 1.8. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 8 Induction of labour.

Analysis 1.9. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 9 Perineal trauma.

Analysis 1.10. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 10 Placental abruption.

Analysis 1.11. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 11 Postpartum haemorrhage.

Analysis 1.12. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 12 Postpartum infection.

Analysis 1.13. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 13 Gestational weight gain (kg).

Analysis 1.14. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 14 Gestational weight gain (various times reported) (kg).

Analysis 1.15. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 15 Gestational weight gain (kg/week).

Analysis 1.16. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 16 Gestational weight gain (above IOM recommendations).

Analysis 1.17. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 17 Gestational weight gain (within IOM recommendations).

Analysis 1.18. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 18 Gestational weight gain (below IOM recommendations).

Analysis 1.19. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 19 Behaviour changes associated with the intervention.

Study	Behaviour changes associated with the intervention			
	Diet	Exercise	Benefit in favour of intervention	Benefit in favour of control
Bruno 2016	Higher proportion of women in intervention group, compared with the control group, with Food Frequency Questionnaire score ≥ 2 at 36th week ($P = 0.028$). No clear difference between groups in ≥ 2 servings of vegetables/day ($P = 0.400$) or ≤ 3 times/week of food rich in saturated fat; higher proportion of women in intervention group, compared with the con-	No clear difference between groups in number of steps/day or duration of physical activity in minutes at the 20th week. Women in the intervention group, compared with the control group, were less active at the 36th week (fewer steps/day ($P = 0.016$) and had a shorter duration of physical activity ($P = 0.039$)).	Some (diet)	Some (exercise)

Study	Behaviour changes associated with the intervention			
	Diet	Exercise	Benefit in favour of intervention	Benefit in favour of control
	trol group, having ≤ 30 g sugar/day ($P = 0.026$).			
Dodd 2014	<p>Macronutrient consumption and food groups</p> <p>No clear differences between groups (from trial entry, to 28 weeks, 36 weeks, 4 months) for total energy (kJ) ($P = 0.09$), bread and cereals (servings/day) ($P = 0.27$), dairy (servings/day) ($P > 0.09$ after trial entry), meat and legumes (servings/day) ($P = 0.14$), non-core group foods (servings/day) ($P > 0.10$), alcohol (g) ($P = 0.20$), carbohydrates (g) ($P = 0.06$), percentage energy from carbohydrates ($P = 0.39$), protein (g) ($P = 0.14$), percentage energy from protein ($P > 0.11$ after trial entry), total fat (g) ($P = 0.48$), percentage energy from total fat ($P = 0.06$), saturated fat (g) ($P = 0.71$), monounsaturated fat (g) ($P = 0.62$), polyunsaturated fat (g) ($P = 0.23$). Women in the intervention group, compared with women in the control group, increased their consumption of fruit (servings/day) ($P = 0.002$), vegetables (servings/day) after trial entry ($P < 0.003$), dietary fibre ($P = 0.002$) and percentage energy from saturated fats ($P = 0.04$) overall.</p> <p>Micronutrient consumption</p> <p>No clear differences between groups (from trial entry, to 28 weeks, 36 weeks, 4 months) for caffeine (mg) ($P = 0.57$), sodium (mg) ($P = 0.10$), iron (mg) ($P = 0.08$), zinc (mg) ($P = 0.11$), magnesium (mg) ($P = 0.06$), phosphorus (mg) ($P = 0.16$), iodine (μg) ($P = 0.38$), retinol (μg) ($P = 0.33$), vitamin B1 (mg) ($P = 0.07$), niacin (mg) ($P = 0.09$) or vitamin E (mg) ($P = 0.17$). Women in the intervention group had greater intake of calcium (mg) (28 week P value = 0.04), potassium (mg) (28 week P value = 0.004; 36 week P value = 0.01), vitamin B2 (mg) (28 week P value = 0.05) (not maintained at 4 months postpartum); and increased consumption of vitamin A active equivalent (μg) ($P = 0.003$), vitamin C (mg) ($P = 0.02$), folate (μg) ($P = 0.03$) and folate food (μg) ($P = 0.02$) overall.</p> <p>Healthy Eating Index (HEI)</p> <p>Women in the intervention group, compared with the control group, had improvements in diet quality (HEI) at 28 and 36 weeks (both $P < 0.0001$); not sustained at 4 months postpartum ($P = 0.41$). Specifically, women in the intervention group, compared with the control group, increased</p>	<p>Physical activity</p> <p>Women in the intervention group, compared with the control group (from trial entry, to 28 weeks, 36 weeks, 4 months) had an increase in total activity ($P = 0.01$); and specifically an increase in household activity ($P = 0.01$). No clear differences between groups for commuting activity ($P = 0.55$), leisure activity ($P = 0.06$) or work activity ($P = 0.52$).</p> <p>Changes in lifestyle and knowledge of healthy exercise during pregnancy</p> <p><i>"women receiving lifestyle advice were more likely to indicate that the approach to participate in the trial prompted changes to... their lifestyle [...]$p < 0.0001$. Women who received the intervention indicated greater knowledge about... exercise during pregnancy [...]$p < 0.0001$] compared with women who received Standard Care."</i></p>	Some (diet and exercise)	No

Study	Behaviour changes associated with the intervention			
	Diet	Exercise	Benefit in favour of intervention	Benefit in favour of control
	<p>consumption of total fruit (28 week P value = 0.0001; 36 week P value < 0.0001; 4 month P value = 0.07), whole fruit (28 week P value = 0.0003; 36 week P value < 0.0001; 4 month P value = 0.30), milk (28 week P value = 0.04; 36 week P value = 0.45; 4 month P value = 0.28) and dark-green and orange vegetables and legumes (overall P value = 0.0006). No clear differences between groups in consumption of total vegetables (P = 0.12), total grains (P = 0.55), whole grains (P = 0.14), meat and beans (P = 0.67), oils (P = 0.15), saturated fat (P = 0.07), sodium (P = 0.34), or calories from solid fat, alcohol and added sugar (P = 0.56).</p> <p>Glycaemic index and glycaemic load</p> <p>No clear difference between groups (from trial entry to 28 weeks, 36 weeks, 4 months) in glycaemic load (P = 0.15) or glycaemic index (P = 0.10).</p> <p>Changes in diet and knowledge of healthy food choices</p> <p><i>"women receiving lifestyle advice were more likely to indicate that the approach to participate in the trial prompted changes to... their diet [... p < 0.0001]... Women who received the intervention indicated greater knowledge about healthy food choices [... p < 0.0001]... compared with women who received Standard Care."</i></p>			
Harrison 2013	Not reported	The intervention group had higher steps/day at 28 weeks gestation compared with the control group (P < 0.05); no clear difference between groups in MET minutes-1/day estimated by the The International Physical Activity Questionnaire (P value not reported). No clear difference between groups at 6 weeks postpartum in physical activity (steps/day) (P = 0.6).	Some (exercise)	No
Hawkins 2014	No clear differences between groups in change from baseline to mid-pregnancy and baseline to postpartum for total caloric intake (P = 0.78; P = 0.44), calories from fat (%) (P = 0.66; P = 0.14), and fibre (g) (P = 0.20; P = 0.23).	No clear differences between groups in change from baseline to mid-pregnancy and baseline to postpartum for moderate-intensity (P = 0.17; P = 0.78), moderate and vigorous-intensity (P = 0.80; P = 0.82), or sports/exercise (P = 0.72; P = 0.63) physical activity; though significant increase in vigorous-intensity physical activity in the intervention compared with control group (P = 0.04; P = 0.046) (MET hours/week).	No (diet) Some (exercise)	No
Hui 2012	At 2 months after enrolment, the intervention group, compared with the control group, had lower daily intakes of total	At 2 months after enrolment, the physical activity index was higher in the intervention	Some (diet) Yes (exercise)	No

Study	Behaviour changes associated with the intervention			
	Diet	Exercise	Benefit in favour of intervention	Benefit in favour of control
	calories ($P = 0.002^*$), carbohydrate (g) ($P = 0.04$), fat (g) ($P = 0.0001^*$), saturated fat (g) ($P = 0.00004^*$), cholesterol (mg) ($P = 0.001^*$) and fat ratio (%) ($P = 0.001^*$); and higher carbohydrate ratio (%) ($P = 0.02$) and protein ratio (%) ($P = 0.04$); no clear differences between groups for intakes of protein (g) ($P = 0.11$), and fibre (g) ($P = 0.63$). At 2 months after enrolment, the intervention group, compared with the control group, had lower daily servings of medium-fat meat ($P = 0.01$), 1-2% fat milk ($P = 0.02$) and oil and fats ($P = 0.02$), and higher daily servings of skim milk ($P = 0.02$); no clear differences between groups for starch ($P = 0.66$), very lean meat ($P = 0.66$), lean meat ($P = 0.17$), high-fat meat ($P = 0.50$), vegetables ($P = 0.43$), fruits ($P = 0.39$), or whole fat milk ($P = 0.15$). *P values with statistical significance after Bonferroni correction.	group compared with the control group ($P = 0.00002$).		
Hui 2014	<u>Pre-pregnancy BMI < 25</u> At 2 months after the onset of the intervention, women in the intervention group compared with the control group had lower intakes of total calorie ($P = 0.01$), carbohydrate (g) ($P = 0.03$), total fat (g) ($P = 0.008$), saturated fat (g) ($P = 0.008$), and cholesterol (mg) ($P = 0.02$); no clear difference between groups for intake of protein (g) ($P = 0.36$). <u>Pre-pregnancy BMI ≥ 25</u> At 2 months after the onset of the intervention, women in the intervention group compared with the control group had lower intakes of total calorie ($P = 0.05$), total fat (g) ($P = 0.02$), saturated fat (g) ($P = 0.01$), and cholesterol (mg) ($P = 0.03$); no clear differences between groups for intakes of carbohydrate (g) ($P = 0.44$) or protein (g) ($P = 0.17$).	<u>Pre-pregnancy BMI < 25</u> At 2 months after the onset of the intervention, women in the intervention group compared with the control group had higher physical activity index (units) ($P < 0.01$). <u>Pre-pregnancy BMI ≥ 25</u> At 2 months after the onset of the intervention, no clear difference between groups for physical activity index (units) (P value not reported)	Some (diet and exercise)	No
Jing 2015	No clear differences between groups at 20-24 weeks gestation for intake of carbohydrate (g) ($P = 0.058$), fat (g) ($P = 0.216$), meat (g) ($P = 0.235$), vegetables (g) ($P = 0.637$), eggs (g) ($P = 0.962$), milk (g) ($P = 0.060$), beans (g) ($P = 0.982$). Higher intake of energy (kcal) ($P = 0.024$), protein (g) ($P = 0.003$), grain (g) ($P = 0.013$), fruit (g) ($P = 0.048$), seafood ($P = 0.031$), and nuts ($P = 0.036$) for women in intervention group compared with control group.	No clear difference between groups at 20-24 weeks for time spent (hours/day) doing moderate activity ($P = 0.824$) [and no clear difference between groups for time spent (hours/day) on intensities A, B, C, E, F, G, H]. Less time spent resting ($P = 0.033$) and more time doing mild activity ($P = 0.016$) among women in the intervention group compared with control group [and more time spent (hours/day) on intensity D].	Some (diet and exercise)	No
Koivusalo 2016	The dietary index score improved more among women in the intervention group, compared with the control group	Women in the intervention group increased their median weekly leisure time physical activity while the physical ac-	Some (diet and exercise)	No

Study	Behaviour changes associated with the intervention			
	Diet	Exercise	Benefit in favour of intervention	Benefit in favour of control
	<p>($P = 0.16$ unadjusted, $P = 0.037$ adjusted). No clear differences between groups in changes in food intake from the first to second trimester for low-fat milk (times/day) ($P = 0.726$), whole-grain cereal (times/day) ($P = 0.182$), fruits and berries (times/day) ($P = 0.865$), vegetables and legumes (times/day) ($P = 0.419$), animal protein (times/day) ($P = 0.658$), snacks (times/week) ($P = 0.112$), sugar sweetened beverages (times/week) ($P = 0.750$), fast food (times/week) ($P = 0.731$), spread fat (score) ($P = 0.103$), cooking fat (score) ($P = 0.937$). Intakes of low-fat cheese ($P = 0.040$) and fish ($P = 0.011$) increased in the intervention group compared with the control group.</p>	<p>tivities of women in the control group remained unchanged ($P = 0.17$ unadjusted, $P = 0.029$ adjusted). No clear difference between groups in proportion of women meeting the physical activity goal (150 minutes/week in the second trimester).</p>		
Luoto 2011	<p>Dietary changes Compared with the control group, from baseline to 26-28 weeks, the intervention group reduced their intake of saccharose (E%) ($P = 0.04$), and saturated fatty acids (E%) ($P = 0.005$); no clear differences between groups seen for intakes of total energy (MJ/day) ($P = 0.97$), total energy (kcal/day) ($P = 0.97$), protein (E%) ($P = 0.094$), carbohydrates (E%) ($P = 0.76$), dietary fibre (g/day) ($P = 0.44$), total fat (E%) ($P = 0.15$), trans fatty acids (E%) ($P = 0.65$), mono saturated fatty acids (E%) ($P = 0.99$), or polyunsaturated fatty acids (E%) ($P = 0.21$). Compared with the control group, from baseline to 36-37 weeks, the intervention group reduced their intake of saccharose (E%) ($P = 0.023$) and saturated fatty acids (E%) ($P = 0.01$) and increased their intake of dietary fibre (g/day) ($P = 0.019$) and polyunsaturated fatty acids (E%) ($P < 0.001$); no clear differences between groups seen for intakes of total energy (MJ/day) ($P = 0.90$), total energy (kcal/day) ($P = 0.90$), protein (E%) ($P = 0.29$), carbohydrates (E%) ($P = 0.60$), total fat (E%) ($P = 0.86$), trans fatty acids (E%) ($P = 0.30$), or mono saturated fatty acids (E%) ($P = 0.51$).</p> <p>Food habits related to the objectives of dietary counselling From baseline to 26-28 weeks, the intervention group, compared with the control group, increased their proportion of high-fibre bread (% of all bread) ($P = 0.001$) and vegetable fats (% of all dietary fat) ($P = 0.001$), while the control group decreased their proportion of low-fat cheeses (% of</p>	<p>Physical activity changes No clear differences between baseline to 26-28 weeks or baseline to 36-37 weeks for total MET minutes/week ($P = 0.36$; $P = 0.63$), MET minutes/week for at least moderate activity ($P = 0.17$; $P = 0.82$), MET minutes/week for light activity ($P = 0.57$; $P = 0.17$), or ≥ 800 MET minutes/week (%) ($P = 0.27$; $P = 0.51$). At 26-28 weeks, the decreases in total leisure-time physical activity (LTPA) (days/week) and moderate-to-vigorous LTPA (days/week) were smaller in the intervention group compared with the control group ($P = 0.040$; $P = 0.016$); though no clear differences between group/days in total LTPA (minutes/week) ($P = 0.58$), moderate-to-vigorous LTPA (minutes/week) ($P = 0.11$), light LTPA (days/week) ($P = 0.80$), light LTPA (minutes/week) ($P = 0.65$), or meeting physical activity recommendations for health (%) ($P = 0.060$) were observed.</p> <p>No clear differences between groups from baseline to 36-37 weeks in total LTPA (days/week: $P = 0.80$; minutes/week: $P = 0.60$), moderate-to-vigorous LTPA (days/week: $P = 0.16$; minutes/week: $P = 0.96$), or light LTPA (days/week: $P = 0.21$; minutes/week: $P = 0.75$), or meeting physical activity recommendations for health (%: $P = 0.70$).</p> <p><i>"From 26-28 weeks' gestation to 36-37 weeks' gestation the number of weekly days with light-intensity LTPA decreased significantly less in INT than in UC (0.1 vs. 0.6 days, $p = 0.05$, not shown in Table 4)."</i></p>	Some (diet and exercise)	No

Study	Behaviour changes associated with the intervention			
	Diet	Exercise	Benefit in favour of intervention	Benefit in favour of control
	<p>all cheese) ($P = 0.001$), and increased intake of snacks high in sugar and/or fat (g/day) ($P = 0.022$); no clear differences between groups in intake of vegetables, fruits and berries (g/day) ($P = 0.117$), fat-free or low-fat milk (% of all milk) ($P = 0.093$), frequency of eating fish (per week) ($P = 0.120$), or high-fat foods (g/day) (0.664). From baseline to 36-37 weeks, the intervention group, compared with the control group, increased their intake of vegetables, fruits and berries (g/day) ($P = 0.001$), proportion of high-fibre bread (% of all bread) ($P = 0.003$) and vegetable fats (% of all dietary fat) ($P = 0.003$), while the control group decreased their proportion of low-fat cheeses (% of all cheese) ($P = 0.009$); no clear differences between groups in proportion of fat-free or low-fat milk (% of all milk) ($P = 0.630$), frequency of eating fish (per week) ($P = 0.068$), intake of high-fat foods (g/day) (0.108), or snacks high in sugar and/or fat (g/day) ($P = 0.551$).</p> <p>Consumption of the main food groups and foods</p> <p>From baseline to 26-28 weeks gestation, the intervention group, compared with the control group, increased total intake of milk ($P = 0.025$), fish ($P = 0.041$), vegetable oils ($P = 0.002$) and oil based salad dressings ($P = 0.002$); while the control group, compared with the intervention group, increased consumption of porridge and breakfast cereals ($P = 0.003$) and candies and chocolates ($P = 0.008$) (all g/day); no clear differences between groups for intake of fruits and berries ($P = 0.575$), cooked potato or in dishes ($P = 0.686$), french fries, chips and other fatty potato products ($P = 0.995$), total bread ($P = 0.459$), rice and pasta ($P = 0.118$), total cheese ($P = 0.318$), red meat and game ($P = 0.851$), poultry ($P = 0.252$), sausages ($P = 0.896$), vegetable spreads ($P = 0.071$), butter and butter mixtures ($P = 0.128$), solid baking margarines ($P = 0.194$), sweet pastries and other sugary food items ($P = 0.055$), pizza and hamburgers ($P = 0.703$), tea ($P = 0.464$), coffee ($P = 0.976$), sugary soft drinks ($P = 0.088$) or juice ($P = 0.096$) (all g/day).</p> <p>From baseline to 36-37 weeks gestation, the intervention group, compared with the control group, increased total intake of fish ($P = 0.044$), vegetable oils ($P = 0.002$) and oil based salad dressings (P</p>			

Study	Behaviour changes associated with the intervention			
	Diet	Exercise	Benefit in favour of intervention	Benefit in favour of control
	<p>= 0.010); while the control group, compared with the intervention group, decreased consumption of vegetables (P = 0.005); no clear differences between groups for intake of fruits and berries (P = 0.134), cooked potato or in dishes (P = 0.157), french fries, chips and other fatty potato products (P = 0.388), total bread (P = 0.175), porridge and breakfast cereals (P = 0.811), rice and pasta (P = 0.187), total milk (P = 0.878), total cheese (P = 0.364), red meat and game (P = 0.806), poultry (P = 0.482), sausages (P = 0.444), vegetable spreads (P = 0.215), butter and butter mixtures (P = 0.417), solid baking margarines (P = 0.208), candies and chocolates (P = 0.133), sweet pastries and other sugary food items (P = 0.104), pizza and hamburgers (P = 0.755), tea (P = 0.235), coffee (P = 0.481), sugary soft drinks (P = 0.730) or juice (P = 0.094) (all g/day).</p>			
Petrella 2013	<p>"Significant changes in eating habits occurred in the Therapeutic Lifestyle Changes group, increasing the number of snacks/day, the consumption of vegetables and fruits. Moreover, intervention also decreased the consumption of sugar. No differences in the number of daily spoons of oil, red meat and complex carbohydrates intake were found."</p>	<p>"The step numbers for each walking session was constant during pregnancy (3267 ± 1683 at 36th week and 3755 ± 1816 at 28th week)."</p>	Not applicable (only reported for intervention group)	Not applicable (only reported for intervention group)
Phelan 2011	<p>"No significant treatment... interaction effects over time were observed... for dietary factors." Repeated-measures ANOVA of time (early pregnancy, late pregnancy, 6 months postpartum, 12 months postpartum) x treatment group interactions for dietary changes in calorie intake, percentage of calories from fat, percentage of calories from carbohydrate, percentage of calories from protein, percentage of calories from sweets, daily calories from soft drinks, daily saturated fat (g), daily servings of vegetables, daily servings of fruit and fruit juices, daily servings of bread, cereals, rice, pasta, daily servings of milk, yogurt, cheese, daily frequency of fats and oils, sweets, sodas, weekly fast food, daily iron from food (mg), daily calcium from food (mg), total daily dietary fibre (g), daily vitamin D from food (IU), daily folate from food (µg): P values all "NS."</p>	<p>"A trend was observed for an effect of the intervention on physical activity... which suggested a small intervention-related increase in calories expended in physical activity during the postpartum period." Repeated-measures ANOVA of time (early pregnancy, late pregnancy, 6 months postpartum, 12 months postpartum) x treatment group interaction for kcal (F = 2.5, P = 0.06, hp2 = 0.02).</p>	No (diet) Yes (exercise)	No
Polley 2002	<p>"All groups decreased their fat consumption from these foods from baseline to 30 weeks, except normal-weight women in the control condition. There</p>	<p>"Changes in exercise level from recruitment to 30 weeks (P>0.8) were not related to treatment condition."</p>	No	No

Study	Behaviour changes associated with the intervention			
	Diet	Exercise	Benefit in favour of intervention	Benefit in favour of control
	<i>was no effect of treatment on changes in fat intake from these foods from recruitment to 30 weeks (P>0.2)."</i>			
Poston 2013	At 28 weeks gestation, the intervention group had lower intakes of total energy (MJ/day) (P = 0.016), dietary glycaemic load (g/day) (P = < 0.001), glycaemic load (%E) (P = 0.013), total fat (%E) (P = 0.010) and saturated fatty acids (%E) (P = 0.015), and higher protein (%E) (P = 0.034), and fibre (non-starch polysaccharides) (g) (P = 0.040) compared with the control group; no clear differences between groups for dietary glycaemic index (%) (P = 0.054), carbohydrate (%E) (P = 0.207), protein (g) (P = 0.204), monounsaturated fatty acids (%E) (P = 0.088), polyunsaturated fatty acids (%E) (P = 0.075), or polyunsaturated fatty acid, saturated fatty acid ratio (P = 0.075). <i>"A principal component analysis (PCA) of Food Frequency Questionnaire (FFQ) data from the UPBEAT pilot study database was performed to derive three diet patterns: two with high coefficients for high-sugar and/or highfat food groups defined as 'Western' and 'Healthy-unhealthy choices' and a 'traditional' African or African-Caribbean diet pattern.... The 'Western' and 'Healthy-unhealthy choices' patterns scores were reduced in those who received the intervention."</i>	At 28 weeks gestation, no clear differences between groups for physical activity, as measured by accelerometer (minutes/day of sedentary, active, light, moderate to vigorous activity) (P values not reported; mean differences with 95% confidence intervals indicate no clear differences), and Recent Physical Activity Questionnaire (minutes/day of sedentary, activity, light activity); self-reported moderate to vigorous activity (minutes/day) was higher in the intervention group compared with the control group (P value not reported; mean difference with 95% confidence interval indicates difference), and women in the intervention group self-reported walking (minutes/day) for leisure more than those in the control group (P = 0.003).	Some (diet and exercise)	No
Poston 2015	At 27-28 weeks and 6 days, women in the intervention group, compared with the control group, had lower mean total energy (MJ/day) (P < 0.0001), glycaemic index (0-100) (P < 0.0001), glycaemic load per day (P < 0.0001), and intake carbohydrate (% energy) (P = 0.0011), total fat (% energy) (P = 0.0011), saturated fat (g/day) (P < 0.0001) and saturated fat (% energy) (P < 0.0001); and higher intake of protein (% energy) (P < 0.0001), and fibre (g/day) (P = 0.013). At 6 months postpartum, women in the intervention group, compared with the control group, had lower glycaemic load per day (P < 0.001), glycaemic index (0-100) (P < 0.001), intakes of total energy (kcal per day) (P < 0.001), saturated fat (% energy) (P < 0.001), and total fat (% energy) (P < 0.001), and higher intake of protein (% energy) (P < 0.001); no clear differences between groups for intakes of carbohydrates (% energy) (P	At 27-28 weeks and 6 days, women in the intervention group, compared with the control group, were more physically active: MET (minutes/week) (P = 0.0015); attributed to more time spent walking (minutes/week) (P = 0.0018), with no clear difference seen between groups for moderate or vigorous activity (minutes/week) (P > 0.99). At 6 months postpartum, no clear differences between groups for measures of physical activity: MET (minutes/week) (P = 0.607), moderate or vigorous activity (minutes/week) (P = 0.681), or walking (minutes/week) (P = 1.00).	Some (diet and exercise)	No

Study	Behaviour changes associated with the intervention			
	Diet	Exercise	Benefit in favour of intervention	Benefit in favour of control
	= 0.835) and fibre (g/day) (P = 0.873).			
Rauh 2013	The intervention group had a lower change from baseline to 36-38th week gestation energy intake compared with the control group (kcal/day) (P = 0.035).	No clear difference between groups in change from baseline to 36-38th week gestation total activity (MET-min/week) (P = 0.425).	Yes (diet) No (exercise)	No
Sagedal 2017	At 36 weeks gestation the intervention group had a higher (more favourable) diet score compared with the control group (P = 0.013); dietary differences favouring the intervention group were identified in 7 domains: 'drinking water when thirsty' (P = 0.002), 'vegetables with dinner' (P = 0.027), 'fruits and vegetables for between-meal snacks' (P = 0.023), 'package size of unhealthy foods' (P = 0.010), 'added sugar' (P = 0.005), 'eating beyond satiety' (P = 0.009) and 'food labels' (P = 0.011); no clear differences between groups for 'meal regularity' (P = 0.176), 'eating sweets or snacks without appreciation' (P = 0.446), 'added salt' (P = 0.680).	At 36 weeks gestation the intervention group compared with the control group had higher weekly energy expenditure (MET-minutes/week) (P = 0.009), and according to the International Physical Activity Questionnaire, fewer had 'low activity', and more had 'moderate activity' and 'high activity' (P = 0.013).	Some (diet) Yes (exercise)	No
Vinter 2011	<i>"When asked at 35 weeks' gestation whether participation in the LiP study had resulted in more healthy eating habits, 85% of women in the intervention group responded affirmatively. In addition, 21% of women in the control group thought that their dietary habits in pregnancy were positively influenced by their participation."</i> At 35 weeks' gestation, women in the intervention group had higher self-reported physical activity levels compared with those in the control group (physical activity $\geq$ 2 hours/week (P = 0.001); physical activity making them sweaty or short of breath $\geq$ 2 hours/week (P < 0.001)); no clear differences between groups at 6 months postpartum (physical activity $\geq$ 2 hours/week (P = 0.620); physical activity making them sweaty or short of breath $\geq$ 2 hours/week (P = 0.961)).	<i>"Among women in the intervention group, 77.5% undertook leisure time sporting activities in addition to the aerobic classes. In addition, 65% of women in the control group engaged in some type of leisure time sporting activities during pregnancy (P = 0.016)."</i> At 35 weeks' gestation, women in the intervention group had improved eating habits compared with those in the control group (considered themselves as in the most healthy eating habit groups (P = 0.003)); no clear differences between groups at 6 months postpartum (considered themselves as in the most healthy eating habit groups (P = 0.609)).	Some (diet and exercise)	No

Analysis 1.20. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 20 Relevant biomarker changes associated with the intervention.

Study	Relevant biomarker changes associated with the intervention		
	Results	Benefit in favour of intervention	Benefit in favour of control
Hawkins 2014	No clear differences between groups in change in biomarkers of insulin resistance from baseline to mid-pregnancy: glucose (mmol/L) (P = 0.63); in-	No	No

Relevant biomarker changes associated with the intervention			
Study	Results	Benefit in favour of intervention	Benefit in favour of control
	sulin (pmol/L) (P = 0.39); leptin (pmol/L) (P = 0.73); adiponectin (nmol/L) (P = 0.51); resistin (nmol/L) (P = 0.19); tumour necrosis factor-alpha (pmol/L) (P = 0.11); c-reactive protein (nmol/L) (P = 0.19).		
Koivusalo 2016	Women in the intervention group compared with the control group had a greater change (reduction) in fasting plasma glucose from baseline to the third trimester (P = 0.026 unadjusted; P = 0.011 adjusted). No clear difference between groups in change (increase) in 2-hour glucose from baseline to second trimester (P = 0.92 unadjusted, P = 0.42 adjusted).	Some	No
Korpi-Hyovalti 2011	No clear difference between groups in fasting glucose (mmol/L), OGTT 1-hour glucose (mmol/L), OGTT 2-hour glucose (mmol/L), or area under the curve (mmol/L/2 hour) (all reported to be P = NS) at weeks 26-28.	No	No
Luoto 2011	There were no clear differences between groups in glucose intolerance measurements at 26-28 weeks (glucose concentrations in 2-hour OGTT (mg/L): fasting (P = 0.44), 1-hour (P = 0.23), 2-hour (P = 0.99); insulin (P = 0.10), or HOMA-IR (P = 0.13)); or in the change from baseline (8-12 weeks) to 26-28 week values for insulin (P = 0.23), or HOMA-IR (P = 0.24).	No	No
Poston 2015	At 27-28 weeks and 6 days gestation, no clear differences between groups in fasting blood glucose (mmol/L) (P = 0.49), 1-hour blood glucose (mmol/L) (P = 0.43), 2-hour blood glucose (mmol/L) (P = 0.81), plasma fasting insulin (mU/L) (P = 0.57), HOMA-IR (units) (P = 0.60), plasma triglycerides (mmol/L) (P = 0.39), plasma LDL cholesterol (mmol/L) (P = 0.27), plasma HDL cholesterol (mmol/L) (0.93), plasma VLDL (mmol/L) (P = 0.39).	No	No
Vinter 2011	<i>Glucose metabolism and insulin sensitivity</i> No clear differences between groups in fasting plasma glucose (mmol/L) at 28-30 weeks (P = 0.060) or 34-36 weeks (P = 0.431). No clear differences between groups in 2-hour oral glucose tolerance test (mmol/L) at 28-30 weeks (P = 0.459) or 34-36 weeks (P = 0.723). No clear differences between groups in fasting insulin (mU/L) at 34-36 weeks (P = 0.065) or change from baseline to 34-36 weeks fasting insulin (P = 0.063); women in the intervention group had lower fasting insulin at 28-30 weeks (P = 0.040), and lower change from baseline to 28-30 weeks fasting insulin (P = 0.015). No clear differences between groups in HOMA-IR at 34-36 weeks (P = 0.062) or change from baseline to 34-36 weeks fasting insulin (P = 0.079); women in the intervention group had lower fasting insulin at 28-30 weeks (P = 0.032), and lower change from baseline to 28-30 weeks fasting insulin (P = 0.022). <i>Lipid metabolism</i> No clear differences between groups at 28-30 weeks or 34-36 weeks for fasting cholesterol (mmol/L) (P = 0.332; P = 0.484), fasting HDL (mmol/L) (P = 0.781;	Some	No

Relevant biomarker changes associated with the intervention			
Study	Results	Benefit in favour of intervention	Benefit in favour of control
	P = 0.871), fasting LDL (mmol/L) (P = 0.148; P = 0.183), or fasting triglycerides (mmol/L) (P = 0.385; P = 0.399).		

Analysis 1.21. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 21 Sense of well-being and quality of life.

Sense of well-being and quality of life			
Study	Results	Benefits in favour of intervention	Benefits in favour of control
Dodd 2014	<p>There were no clear differences between groups (from trial entry, to 28 weeks, 36 weeks and 4 months postpartum) in mean depressive scores (Edinburgh Postnatal Depression Scale (EPDS) mean scores) (adjusted P = 0.25), risk of depression (EPDS score > 12, %) (adjusted P = 0.95), symptoms of anxiety (Spielberger State-Trait Anxiety Inventory (STAI) mean scores) (adjusted P = 0.51), or risk of high level anxiety (STAI score ≥ 15, %) (adjusted P = 0.31). There were no clear differences between groups for any of the domains assessing health related quality of life (from trial entry, to 28 weeks, 36 weeks and 4 months postpartum) (mean scores: physical functioning adjusted P = 0.53; physical role adjusted P = 0.59; bodily pain adjusted P = 0.27; general health adjusted P = 1.00; vitality adjusted P = 0.48; social functioning adjusted P = 0.52; emotional role adjusted P > 0.11; mental health adjusted P = 0.07; physical component adjusted P = 0.47; mental component adjusted P = 0.36). For emotional role and mental health domains there were significant interactions between treatment group and time point (P = 0.03; P = 0.007); although there were no significant differences between treatment groups at any individual time point, the pattern of change over pregnancy differed according to treatment group.</p> <p><i>"All women reported a high degree of satisfaction with their pregnancy... p = 0.8722... and with birth... p = 0.9235... Most women agreed or strongly agreed that they felt in control during their pregnancy... p = 0.9945... and birth... p = 0.4510... and they liked their care providers... p = 0.1530... There were no differences with regard to the proportion of women who felt healthy during pregnancy... p = 0.3517... women who received the intervention were more likely to feel reassured about their own health... p = 0.0112... and that of their baby... p = 0.0143... In the postpartum period, most women felt healthy... p = 0.5942... and were not concerned about their future health... p = 0.9444... or the future health of their baby or child... p = 0.9467"</i></p>	Some (reassurance about own health and health of baby)	No
Luoto 2011	No clear difference between groups from 8-13 weeks to 36-37 weeks in change in health related quality of life (15D questionnaire) (P = 0.24), or perceived health (VAS scale of 0-10 cm) (P = 0.061).	No	No

Sense of well-being and quality of life			
Study	Results	Benefits in favour of intervention	Benefits in favour of control
Phelan 2011	<p>"The intervention group... had a significantly greater increase in scores on the Edinburgh Depression Scale during the postpartum period than did the standard-care group ($F = 23.2$, $P = 0.0001$, $hp2 = 0.094$); however, multiple logistic regression analyses indicated no significant effects of the intervention compared with standard care on the prevalence of depression (defined as a score ≥ 13) at 30 wk of gestation (6.4% compared with 7.2%, respectively), 6 mo (3.4% compared with 3.6%, respectively), or 12 mo (5.2% compared with 6.3%, respectively) postpartum. Both groups reported very low depression scores overall... No significant treatment... interaction effects over time were observed for dietary disinhibition, stress or sleep."</p> <p>Repeated-measures ANOVA of time (early pregnancy, late pregnancy, 6 months postpartum, 12 months postpartum) x treatment group interactions for disinhibition, stress, and sleep score: P values all reported to be "NS."</p>	No	Some (Edinburgh Depression Scale scores)
Poston 2013	<p>At 28 weeks gestation, there was no clear difference between groups in the numbers of women reporting problems in each of the EuroQol quality of life (EQ-5D) questionnaire domains: mobility, self-care, usual activities, pain and discomfort, anxiety and depression; or in the time trade-off health state rating and visual analogue scale of health related quality of life (0 to 100) (P values not reported, however treatment effects indicate no clear differences). At 28 weeks gestation there were also no clear differences between groups in Edinburgh Postnatal Depression Score total, total score > 9, and total score > 12 (P values not reported, however treatment effects indicate no clear differences).</p>	No	No

Analysis 1.22. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 22 Breastfeeding (exclusive).

Analysis 1.23. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 23 Breastfeeding (partial).

Analysis 1.24. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 24 Breastfeeding.

Study	Breastfeeding		P value
	Diet and exercise	Control	
Rauh 2013	Mean (SD not reported) (N = 148, unadjusted)	Mean (SD not reported) (N = 65, unadjusted)	P = 0.180 P = 0.465

Study	Breastfeeding		P value
	Diet and exercise	Control	
	Exclusive breastfeeding duration (days): 130.7 Total breastfeeding duration (days): 232.1	Exclusive breastfeeding duration (days): 116.3 Total breastfeeding duration (days): 219.4	

Analysis 1.25. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 25 Postnatal weight retention (latest time reported) (kg).

Analysis 1.26. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 26 Return to pre-pregnancy weight (latest time reported).

Analysis 1.27. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 27 Postnatal BMI (latest time reported).

Analysis 1.28. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 28 Maternal cardiovascular health (latest time reported).

Maternal cardiovascular health (latest time reported)				
Study	Intervention	Control	P value	
Vinter 2011	6 months postpartum (median (IQR)) (N = 123) Systolic blood pressure (mm Hg): 122 (116–129) Diastolic blood pressure (mm Hg): 83.5 (78–88)	6 months postpartum (median (IQR)) (N = 115) Systolic blood pressure (mm Hg): 122 (115–128) Diastolic blood pressure (mm Hg): 82 (78–88)	0.770 0.733	

Analysis 1.29. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 29 Stillbirth.

Analysis 1.30. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 30 Neonatal mortality.

Analysis 1.31. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 31 Gestational age at birth (weeks).

Analysis 1.32. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 32 Gestational age at birth (days or weeks).

Study	Gestational age at birth (days or weeks)		P value
	Intervention group	Control group	
Polley 2002	Mean (SD not reported) Normal weight women (N = 30) 39.1 weeks Overweight women (N = 27) 39.4 weeks	Mean (SD not reported) Normal weight women (N = 31) 39.5 weeks Overweight women (N = 22) 39.1 weeks	Not reported
Vinter 2011	Median (IQR) (N = 150) 283 days (273-290)	Median (IQR) (n = 154) 283 days (274-289)	0.952

Analysis 1.33. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 33 Preterm birth.

Analysis 1.34. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 34 Apgar score less than seven at five minutes.

Analysis 1.35. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 35 Macrosomia.

Analysis 1.36. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 36 Small-for-gestational age.

Analysis 1.37. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 37 Birthweight (g).

Analysis 1.38. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 38 Birthweight (g).

Study	Birthweight (g)		P value
	Intervention group	Control group	
Herring 2016	Mean (SD not reported) (N = 27) 3147	Mean (SD not reported) (N = 29) 3361	Mean difference: -213 (95% CI: -431 to 3.7)
Polley 2002	Mean (SD not reported) Born to normal weight women (N = 30) 3133.0 Born to overweight women (N = 27) 3282.8	Mean (SD not reported) Born to normal weight women (N = 31) 3226.4 Born to overweight women (N = 22) 3349.0	Not reported
Vinter 2011	Median (IQR) (N = 150) 3742 (3464-4070)	Median (IQR) (N = 154) 3593 (3335-3930)	0.039

Analysis 1.39. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 39 Birthweight z score.

Analysis 1.40. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 40 Head circumference (cm).

Analysis 1.41. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 41 Head circumference z score.

Analysis 1.42. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 42 Length (cm).

Analysis 1.43. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 43 Length z score.

Analysis 1.44. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 44 Ponderal index (kg/m3).

Analysis 1.45. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 45 Adiposity (sum of skinfold thickness) (mm).

Analysis 1.46. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 46 Adiposity (abdominal circumference) (cm).

Analysis 1.47. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 47 Adiposity.

Adiposity			
Study	Intervention	Control	P value
Dodd 2014	Neonatal anthropometric measures Mean (SD) (N = 488) Chest circumference (cm): 34.24 (1.92) Arm circumference (cm): 11.23 (1.01) Biceps SFTM (mm): 4.37 (1.12) Triceps SFTM (mm): 5.45 (1.30) Subscapular SFTM (mm): 5.15 (1.30) Suprailiac SFTM (mm): 5.76 (1.83) Abdominal SFTM (mm): 3.85 (1.02) Thigh SFTM (mm): 6.99 (1.85) Abdominal circumference to length ratio: 0.65 (0.04) Fat mass (g): 522.72 (180.70) Fat-free mass (g): 3026.64 (339.96) Percentage body fat: 14.41 (3.39) Percentage fat-free mass: 85.59 (3.39)	Neonatal anthropometric measures Mean (SD) (N = 482) Chest circumference (cm): 34.27 (2.08) Arm circumference (cm): 11.18 (1.12) Biceps SFTM (mm): 4.31 (1.13) Triceps SFTM (mm): 5.41 (1.44) Subscapular SFTM (mm): 5.11 (1.21) Suprailiac SFTM (mm): 5.75 (1.92) Abdominal SFTM (mm): 3.82 (1.06) Thigh SFTM (mm): 7.02 (1.90) Abdominal circumference to length ratio: 0.65 (0.04) Fat mass (g): 523.48 (189.05) Fat-free mass (g): 3030.07 (362.54) Percentage body fat: 14.37 (3.44) Percentage fat-free mass: 85.63 (3.44)	<i>"Average body circumferences, SFTM and calculated body fat measures were similar between the treatment groups, with no statistically significant differences identified... There were also no statistically significant differences identified between the two groups, with regard to fat-free mass (R0) and percentage fat-free mass (R0) obtained using bio-impedance analysis"</i> (P value: 0.94; 0.60; 0.45; 0.85; 0.90; 0.97; 0.85; 0.74; 0.90; 0.94; 0.97; 0.91; 0.91; 0.56; 0.79)
Poston 2015	Mean (SD) (N = 249) Triceps SFTM (mm): 5.3 (1.4) (N = 244) Subscapular SFTM (mm): 5.7 (1.4)	Mean (SD) (N = 268) Triceps SFTM (mm): 5.3 (1.6) (N = 258) Subscapular SFTM (mm): 5.6 (1.4)	<i>"Neonatal anthropometric measures were evaluated in a subgroup of infants and did not differ between groups"</i> (P values: 0.72; 0.66)

Analysis 1.48. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 48 Shoulder dystocia.

Analysis 1.49. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 49 Nerve palsy.

Analysis 1.50. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 50 Bone fracture.

Analysis 1.51. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 51 Respiratory distress syndrome.

Analysis 1.52. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 52 Hypoglycaemia.

Analysis 1.53. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 53 Hyperbilirubinaemia.

Analysis 1.54. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 54 Childhood weight (latest time reported) (kg).

Analysis 1.55. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 55 Childhood weight z score (latest time reported).

Analysis 1.56. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 56 Childhood height (latest time reported) (cm).

Analysis 1.57. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 57 Childhood height z score (latest time reported).

Analysis 1.58. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 58 Childhood head circumference (latest time reported) (cm).

Analysis 1.59. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 59 Childhood adiposity (latest time reported) (BMI z score).

Analysis 1.60. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 60 Childhood adiposity (latest time reported) (abdominal circumference) (cm).

Analysis 1.61. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 61 Childhood adiposity (latest time reported) (subscapular skinfold thickness) (mm).

Analysis 1.62. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 62 Childhood adiposity (latest time reported) (triceps skinfold thickness) (mm).

Analysis 1.63. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 63 Childhood adiposity (latest time reported) (total body fat) (%).

Analysis 1.64. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 64 Childhood adiposity (latest time reported).

Childhood adiposity (latest time reported)			
Study	Intervention	Control	P value
Poston 2015	Anthropometric measures at 6 months Mean (SD) (N = 267) Subscapular SFTM z score: 0.08 (1.37) (N = 296) Triceps SFTM z score: 0.10 (1.56) (N = 267) Sum of SFTM (mm): 17.08 (3.93) (N = 267) Subscapular triceps ratio: 0.83 (0.22) (N = 315) Waist length ratio: 0.64 (0.08) (N = 314) Weight for length z score: -0.08 (1.79) (N = 329) Mid upper arm circumference (cm): 15.30 (1.49)	Anthropometric measures at 6 months Mean (SD) (N = 280) Subscapular SFTM z score: 0.36 (1.37) (N = 298) Triceps SFTM z score: 0.24 (1.43) (N = 280) Sum of SFTM (mm): 17.71 (3.97) (N = 280) Subscapular triceps ratio: 0.85 (0.23) (N = 328) Waist length ratio: 0.64 (0.10) (N = 324) Weight for length z score: 0.08 (1.63) (N = 347) Mid upper arm circumference (cm): 15.39 (2.08)	<p>"There was no statistical difference in triceps skinfold thickness... but subscapular skinfold thickness z-score was... lower in the intervention arm... The infant sum of skinfold thickness... did not reach statistical significance... There were no differences... in other anthropometric measures between the two arms" (P values: 0.021; 0.246; 0.058; 0.423; 0.928; 0.184; 0.511)</p>
Vinter 2011	Anthropometric measures at 2.8 years Mean (95% CI) or N (%) (N = 82) Overweight or obese: 9 (10.9%) BMI (kg/m ²): 16.4 (16.1; 16.7) Hip (cm): 50.8 (50.1; 51.5) Abdominal circumference/hip ratio: 0.97 (0.95; 0.97) Dual Energy X-ray scan results at 2.8 years Mean (95% CI) (N = 37) Total fat (g): 2463 (2147; 2779) Lean body mass (g): 11,336 (10,942; 11,730)	Anthropometric measures at 2.8 years Mean (95% CI) or N (%) (N = 75) Overweight or obese: 5 (6.7%) BMI (kg/m ²): 16.1 (15.8; 16.4) Hip (cm): 50.2 (49.4; 51.0) Abdominal circumference/hip ratio: 0.96 (0.95; 0.97) Dual Energy X-ray scan results at 2.8 years Mean (95% CI) (N = 30) Total fat (g): 2442 (2189; 2696) Lean body mass (g): 11,236 (10,797; 11,675)	<p>"At a significance level of 0.05 (two-sided), there were no statistically significant differences in any variables between the LiP intervention and control groups." (Individual P values not reported)</p>

Analysis 1.65. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 65 Childhood cardiovascular health (latest time reported).

Study	Childhood cardiovascular health (latest time reported)		P value
	Intervention	Control	
Vinter 2011	Metabolic risk factors at 2.8 years Mean (95% CI) or N (%) (N = 63) Systolic blood pressure (mm Hg): 98.3 (93.7–105.3) Systolic blood pressure $\geq$ 90th percentile: 16 (25.4) Diastolic blood pressure (mm Hg): 64.3 (61.0–67.3) Diastolic blood pressure $\geq$ 90th percentile: 16 (25.4) (N = 59) Fasting plasma glucose (mmol/L): 5.2 (4.6–5.6) Fasting plasma glucose $\geq$ 5.6 mmol/L: 16 (20.8) (N = 39) Fasting insulin (pmol/L): 16 (8–33) Fasting insulin $\geq$ 55 pmol/L: 3 (7.7) Fasting HDL (mmol/L): 1.2 (1.1–1.4) Fasting HDL $\geq$ 1.03 mmol/L: 6 (17.1) Fasting triglycerides (mmol/L): 0.7 (0.6–1.1) Fasting triglycerides $\geq$ 1.7 mmol/L: 1 (2.9) Metabolic syndrome (a high abdominal circumference plus 2 or more of the following: low HDL, high triglycerides, high fasting glucose, and high systolic and/or diastolic blood pressure): 0 (0)	Metabolic risk factors at 2.8 years Mean (95% CI) or N (%) (N = 54) Systolic blood pressure (mm Hg): 97.3 (94.3–101.3) Systolic blood pressure $\geq$ 90th percentile: 12 (22.0) Diastolic blood pressure (mm Hg): 62.0 (60.3–65.3) Diastolic blood pressure $\geq$ 90th percentile: 12 (22.0) (N = 59) Fasting plasma glucose (mmol/L): 5.1 (4.7–5.5) Fasting plasma glucose $\geq$ 5.6 mmol/L: 13 (18.1) (N = 51) Fasting insulin (pmol/L): 12 (8–18) Fasting insulin $\geq$ 55 pmol/L: 3 (5.9) Fasting HDL (mmol/L): 1.3 (1.1–1.5) Fasting HDL $\geq$ 1.03 mmol/L: 6 (12.2) Fasting triglycerides (mmol/L): 0.9 (0.6–1.0) Fasting triglycerides $\geq$ 1.7 mmol/L: 3 (6.1) Metabolic syndrome (a high abdominal circumference plus 2 or more of the following: low HDL, high triglycerides, high fasting glucose, and high systolic and/or diastolic blood pressure): 0 (0)	<i>"At a significance level of .05 (two-sided), there were no statistically significant differences in any variables between the LiPi and LiPc groups."</i>

Analysis 1.66. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 66 Antenatal visits.

Analysis 1.67. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 67 Antenatal admissions.

Study or subgroup	Diet and exercise	Control	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Fixed, 95% CI		M-H, Fixed, 95% CI
Test for overall effect: $Z=1.51(P=0.13)$					
Favours diet and exercise 0.2 0.5 1 2 5 Favours control					

Analysis 1.68. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 68 Length of antenatal stay (days).

Study or subgroup	Diet and exercise		Control		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
1.68.1 Antenatal stay (days)							
Dodd 2014	1080	0.6 (2.1)	1073	0.9 (3.1)		100%	-0.27[-0.49,-0.05]
Subtotal ***	1080		1073			100%	-0.27[-0.49,-0.05]
Heterogeneity: Not applicable							
Test for overall effect: $Z=2.39(P=0.02)$							
1.68.2 Antenatal inpatient stay (nights), if admitted							
Poston 2015	74	2.9 (3.5)	65	2.9 (2.5)		100%	0[-1,1]
Subtotal ***	74		65			100%	0[-1,1]
Heterogeneity: Not applicable							
Test for overall effect: Not applicable							
Favours diet and exercise -1 -0.5 0 0.5 1 Favours control							

Analysis 1.69. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 69 Neonatal intensive care unit admission.

Study or subgroup	Diet and exercise	Control	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Fixed, 95% CI		M-H, Fixed, 95% CI
Dodd 2014	394/1075	385/1067		76.74%	1.02[0.91,1.14]
Poston 2015	65/761	57/751		11.39%	1.13[0.8,1.58]
Sagedal 2017	38/296	38/295		7.56%	1[0.65,1.52]
Vinter 2011	21/150	22/154		4.31%	0.98[0.56,1.71]
Total (95% CI)	2282	2267		100%	1.03[0.93,1.14]
Total events: 518 (Diet and exercise), 502 (Control)					
Heterogeneity: $\tau^2=0$; $\chi^2=0.36$, $df=3(P=0.95)$; $I^2=0\%$					
Test for overall effect: $Z=0.48(P=0.63)$					
Favours diet and exercise 0.5 0.7 1 1.5 2 Favours control					

Analysis 1.70. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 70 Length of postnatal stay (mother) (days).

Study or subgroup	Diet and exercise		Control		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Dodd 2014	1075	2.9 (1.8)	1067	2.9 (1.7)		54.38%	-0.06[-0.21,0.09]
Favours diet and exercise -0.5 -0.25 0 0.25 0.5 Favours control

Analysis 1.71. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 71 Length of postnatal stay (baby) (days).

Analysis 1.72. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 72 Costs to families associated with the management provided (unit cost, €).

Analysis 1.73. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 73 Costs associated with the intervention (unit cost, €).

Analysis 1.74. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 74 Cost of maternal care (unit cost, €).

Analysis 1.75. Comparison 1 Combined diet and exercise interventions versus standard care, Outcome 75 Cost of infant care (unit cost, €).

Comparison 2. Combined diet and exercise interventions versus standard care: subgroups based on study design

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Gestational diabetes	19	6633	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.71, 1.01]
1.1 Individually-randomised	17	6492	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.70, 1.01]
1.2 Cluster-randomised	2	141	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.42, 2.60]
2 Pre-eclampsia	8	5366	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.79, 1.22]
2.1 Individually-randomised	7	5273	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.78, 1.21]
2.2 Cluster-randomised	1	93	Risk Ratio (M-H, Fixed, 95% CI)	1.24 [0.22, 7.05]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 Caesarean section	14	6089	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.88, 1.02]
3.1 Individually-randomised	13	6038	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.88, 1.02]
3.2 Cluster-randomised	1	51	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.33, 1.54]
4 Large-for-gestational age	11	5353	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.81, 1.07]
4.1 Individually-randomised	9	5209	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.82, 1.08]
4.2 Cluster-randomised	2	144	Risk Ratio (M-H, Fixed, 95% CI)	0.59 [0.25, 1.40]

Analysis 2.1. Comparison 2 Combined diet and exercise interventions versus standard care: subgroups based on study design, Outcome 1 Gestational diabetes.

Analysis 2.2. Comparison 2 Combined diet and exercise interventions versus standard care: subgroups based on study design, Outcome 2 Pre-eclampsia.

Analysis 2.3. Comparison 2 Combined diet and exercise interventions versus standard care: subgroups based on study design, Outcome 3 Caesarean section.

Analysis 2.4. Comparison 2 Combined diet and exercise interventions versus standard care: subgroups based on study design, Outcome 4 Large-for-gestational age.

Comparison 3. Combined diet and exercise interventions versus standard care: subgroups based on maternal BMI

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Gestational diabetes	19	6633	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.72, 1.02]
1.1 Normal weight women (BMI < 25 kg/m ²)	3	300	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.19, 4.24]
1.2 Overweight or obese women (BMI ≥ 25kg/m ²)	8	2901	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.50, 1.20]
1.3 Obese women (BMI ≥ 30kg/m ²)	3	1738	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.81, 1.13]
1.4 Any women	8	1694	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.63, 1.03]
2 Pre-eclampsia	8	5366	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.79, 1.21]
2.1 Normal weight women (BMI < 25 kg/m ²)	2	243	Risk Ratio (M-H, Fixed, 95% CI)	0.34 [0.10, 1.22]
2.2 Overweight or obese women (BMI ≥ 25kg/m ²)	3	2369	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.82, 1.54]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.3 Obese women (BMI $\geq 30\text{kg/m}^2$)	2	1809	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.64, 1.32]
2.4 Any women	3	945	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.51, 1.73]
3 Pregnancy-induced hypertension or hypertension	6	3073	Risk Ratio (M-H, Random, 95% CI)	0.71 [0.41, 1.25]
3.1 Underweight women	1	110	Risk Ratio (M-H, Random, 95% CI)	0.70 [0.26, 1.88]
3.2 Normal weight women (BMI $< 25\text{ kg/m}^2$)	1	182	Risk Ratio (M-H, Random, 95% CI)	0.28 [0.08, 0.97]
3.3 Overweight or obese women (BMI $\geq 25\text{kg/m}^2$)	5	2781	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.43, 1.58]
4 Caesarean section	14	6089	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.88, 1.02]
4.1 Normal weight women (BMI $< 25\text{ kg/m}^2$)	3	300	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.58, 1.45]
4.2 Overweight or obese women (BMI $\geq 25\text{kg/m}^2$)	7	2662	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.83, 1.01]
4.3 Obese women (BMI $\geq 30\text{kg/m}^2$)	2	1826	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.87, 1.12]
4.4 Any women	5	1301	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.75, 1.28]
5 Perinatal mortality	2	3757	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.42, 1.63]
5.1 Overweight or obese women (BMI $\geq 25\text{kg/m}^2$)	1	2202	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.32, 3.07]
5.2 Obese women (BMI $\geq 30\text{ kg/m}^2$)	1	1555	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.31, 1.74]
6 Large-for-gestational age	11	5353	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.81, 1.07]
6.1 Normal weight women (BMI $< 25\text{ kg/m}^2$)	1	57	Risk Ratio (M-H, Fixed, 95% CI)	0.6 [0.11, 3.32]
6.2 Overweight or obese women (BMI $\geq 25\text{kg/m}^2$)	4	2385	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.76, 1.06]
6.3 Obese women (BMI $\geq 30\text{kg/m}^2$)	3	1986	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.89, 1.54]
6.4 Any women	4	925	Risk Ratio (M-H, Fixed, 95% CI)	0.64 [0.40, 1.03]

Analysis 3.1. Comparison 3 Combined diet and exercise interventions versus standard care: subgroups based on maternal BMI, Outcome 1 Gestational diabetes.

Analysis 3.2. Comparison 3 Combined diet and exercise interventions versus standard care: subgroups based on maternal BMI, Outcome 2 Pre-eclampsia.

Study or subgroup	Diet and exercise	Control	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Fixed, 95% CI		M-H, Fixed, 95% CI
Test for subgroup differences: $\chi^2=3.45$, $df=1$ ($P=0.33$), $I^2=13.07\%$					
			0.05 0.2 1 5 20		
			Favours diet and exercise		Favours control

Analysis 3.3. Comparison 3 Combined diet and exercise interventions versus standard care: subgroups based on maternal BMI, Outcome 3 Pregnancy-induced hypertension or hypertension.

Study or subgroup	Diet and exercise	Control	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
3.3.1 Underweight women					
Polley 2002	6/57	8/53		13.98%	0.7[0.26,1.88]
Subtotal (95% CI)	57	53		13.98%	0.7[0.26,1.88]
Total events: 6 (Diet and exercise), 8 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: $Z=0.71$ ($P=0.48$)					
3.3.2 Normal weight women (BMI < 25 kg/m²)					
Phelan 2011	3/90	11/92		11.16%	0.28[0.08,0.97]
Subtotal (95% CI)	90	92		11.16%	0.28[0.08,0.97]
Total events: 3 (Diet and exercise), 11 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: $Z=2.01$ ($P=0.04$)					
3.3.3 Overweight or obese women (BMI ≥ 25 kg/m²)					
Bruno 2016	2/69	13/62		9.32%	0.14[0.03,0.59]
Dodd 2014	101/1080	94/1073		23.57%	1.07[0.82,1.4]
Koivusalo 2016	19/144	12/125		18.18%	1.37[0.7,2.72]
Petrella 2013	1/33	7/28		5.8%	0.12[0.02,0.93]
Phelan 2011	17/81	11/86		17.99%	1.64[0.82,3.29]
Subtotal (95% CI)	1407	1374		74.85%	0.82[0.43,1.58]
Total events: 140 (Diet and exercise), 137 (Control)					
Heterogeneity: $\tau^2=0.33$; $\chi^2=14.35$, $df=4$ ($P=0.01$); $I^2=72.12\%$					
Test for overall effect: $Z=0.59$ ($P=0.55$)					
Total (95% CI)	1554	1519		100%	0.71[0.41,1.25]
Total events: 149 (Diet and exercise), 156 (Control)					
Heterogeneity: $\tau^2=0.33$; $\chi^2=19.26$, $df=6$ ($P=0$); $I^2=68.85\%$					
Test for overall effect: $Z=1.18$ ($P=0.24$)					
Test for subgroup differences: $\chi^2=2.29$, $df=1$ ($P=0.32$), $I^2=12.85\%$					
			0.1 0.2 0.5 1 2 5 10		
			Favours diet and exercise		Favours control

Analysis 3.4. Comparison 3 Combined diet and exercise interventions versus standard care: subgroups based on maternal BMI, Outcome 4 Caesarean section.

Analysis 3.5. Comparison 3 Combined diet and exercise interventions versus standard care: subgroups based on maternal BMI, Outcome 5 Perinatal mortality.

Analysis 3.6. Comparison 3 Combined diet and exercise interventions versus standard care: subgroups based on maternal BMI, Outcome 6 Large-for-gestational age.

Comparison 4. Combined diet and exercise interventions versus standard care: subgroups based on ethnicity

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Gestational diabetes	19	6633	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.71, 1.01]
1.1 Majority 'low risk' ethnicities	5	2998	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.50, 1.43]
1.2 Majority 'high risk' ethnicities	1	56	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.07, 16.33]
1.3 Mixed ethnicities	7	2123	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.76, 1.05]
1.4 Unclear	6	1456	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.61, 1.12]
2 Pre-eclampsia	8	5366	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.79, 1.22]
2.1 Majority 'low risk' ethnicities	3	2806	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.76, 1.29]
2.2 Mixed ethnicities	2	1615	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.58, 1.58]
2.3 Unclear	3	945	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.51, 1.73]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 Pregnancy-induced hypertension or hypertension	6	3073	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.47, 1.27]
3.1 Majority 'low risk' ethnicities	5	2804	Risk Ratio (M-H, Random, 95% CI)	0.64 [0.34, 1.17]
3.2 Unclear	1	269	Risk Ratio (M-H, Random, 95% CI)	1.37 [0.70, 2.72]
4 Caesarean section	14	6089	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.88, 1.02]
4.1 Majority 'low risk' ethnicities	5	2987	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.84, 1.03]
4.2 Majority 'high risk' ethnicities	2	156	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.54, 1.42]
4.3 Mixed ethnicities	5	1986	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.82, 1.07]
4.4 Unclear	2	960	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [0.84, 1.56]
5 Perinatal mortality	2	3757	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.42, 1.63]
5.1 Majority 'low risk' ethnicities	1	2202	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.32, 3.07]
5.2 Mixed ethnicities	1	1555	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.31, 1.74]
6 Large-for-gestational age	11	5353	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.81, 1.07]
6.1 Majority 'low risk' ethnicities	3	2577	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.77, 1.07]
6.2 Majority 'high risk' ethnicities	1	56	Risk Ratio (M-H, Fixed, 95% CI)	3.21 [0.14, 75.68]
6.3 Mixed ethnicities	5	2036	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.80, 1.38]
6.4 Unclear	2	684	Risk Ratio (M-H, Fixed, 95% CI)	0.63 [0.32, 1.23]

Analysis 4.1. Comparison 4 Combined diet and exercise interventions versus standard care: subgroups based on ethnicity, Outcome 1 Gestational diabetes.

Analysis 4.2. Comparison 4 Combined diet and exercise interventions versus standard care: subgroups based on ethnicity, Outcome 2 Pre-eclampsia.

Analysis 4.3. Comparison 4 Combined diet and exercise interventions versus standard care: subgroups based on ethnicity, Outcome 3 Pregnancy-induced hypertension or hypertension.

Analysis 4.4. Comparison 4 Combined diet and exercise interventions versus standard care: subgroups based on ethnicity, Outcome 4 Caesarean section.

Analysis 4.5. Comparison 4 Combined diet and exercise interventions versus standard care: subgroups based on ethnicity, Outcome 5 Perinatal mortality.

Analysis 4.6. Comparison 4 Combined diet and exercise interventions versus standard care: subgroups based on ethnicity, Outcome 6 Large-for-gestational age.

Comparison 5. Combined diet and exercise interventions versus standard care: sensitivity analyses

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Gestational diabetes	11	5019	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.68, 1.09]
2 Pre-eclampsia	4	4311	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.78, 1.26]
3 Pregnancy-induced hypertension	4	2694	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.27, 1.25]
4 Caesarean section	10	4968	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.87, 1.02]
5 Perinatal mortality	2	3757	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.42, 1.63]
6 Large-for-gestational age	8	4618	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.83, 1.09]

Analysis 5.1. Comparison 5 Combined diet and exercise interventions versus standard care: sensitivity analyses, Outcome 1 Gestational diabetes.

Analysis 5.2. Comparison 5 Combined diet and exercise interventions versus standard care: sensitivity analyses, Outcome 2 Pre-eclampsia.

Analysis 5.3. Comparison 5 Combined diet and exercise interventions versus standard care: sensitivity analyses, Outcome 3 Pregnancy-induced hypertension.

Analysis 5.4. Comparison 5 Combined diet and exercise interventions versus standard care: sensitivity analyses, Outcome 4 Caesarean section.

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
Test for overall effect: $Z=1.52(P=0.13)$					
Favours diet and exercise			1	Favours control	

Analysis 5.5. Comparison 5 Combined diet and exercise interventions versus standard care: sensitivity analyses, Outcome 5 Perinatal mortality.

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	6/1105	6/1097		33.26%	0.99[0.32,3.07]
Poston 2015	9/783	12/772		66.74%	0.74[0.31,1.74]
Total (95% CI)	1888	1869		100%	0.82[0.42,1.63]
Total events: 15 (Diet and exercise), 18 (Control)					
Heterogeneity: $\tau^2=0$; $\chi^2=0.17$, $df=1(P=0.68)$; $I^2=0\%$					
Test for overall effect: $Z=0.56(P=0.58)$					
Favours diet and exercise			0.001 0.1 1 10 1000	Favours control	

Analysis 5.6. Comparison 5 Combined diet and exercise interventions versus standard care: sensitivity analyses, Outcome 6 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
Bruno 2016	1/69	7/62		2.17%	0.13[0.02,1.01]
Dodd 2014	203/1075	224/1067		66.31%	0.9[0.76,1.07]
Herring 2016	1/27	0/29		0.14%	3.21[0.14,75.68]
Hui 2012	12/102	15/88		4.75%	0.69[0.34,1.39]
Hui 2014	6/57	4/56		1.19%	1.47[0.44,4.94]
Poston 2013	7/86	7/84		2.09%	0.98[0.36,2.66]
Poston 2015	71/761	61/751		18.11%	1.15[0.83,1.59]
Vinter 2011	23/150	18/154		5.24%	1.31[0.74,2.33]
Total (95% CI)	2327	2291		100%	0.95[0.83,1.09]
Total events: 324 (Diet and exercise), 336 (Control)					
Heterogeneity: $\tau^2=0$; $\chi^2=8.38$, $df=7(P=0.3)$; $I^2=16.45\%$					
Test for overall effect: $Z=0.7(P=0.48)$					
Favours diet and exercise			0.5 0.7 1 1.5 2	Favours control	

ADDITIONAL TABLES

Table 1. Maternal age (years)

Study ID	Diet and exercise intervention	Control
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Table 1. Maternal age (years) *(Continued)*

Asbee 2009	Mean (SD): 26.7 (6.0)	Mean (SD): 26.4 (5.0)
Bruno 2016	Mean (SD): 31.5 (5)	Mean (SD): 30.8 (5.5)
Dodd 2014	Mean (SD): 29.3 (5.4)	Mean (SD): 29.6 (5.6)
El Beltagy 2013	Not reported	Not reported
Harrison 2013	Mean (SD): 32.4 (4.6)	Mean (SD): 31.7 (4.5)
Hawkins 2014	N (%) ≤ 20 years: 6 (18.2) 21–24 years: 14 (42.4) 25–28 years: 5 (15.2) ≥ 29 years: 8 (24.2)	N (%) ≤ 20 years: 3 (8.6) 21–24 years: 14 (40.0) 25–28 years: 8 (22.9) ≥ 29 years: 10 (28.6)
Herring 2016	Mean (SD): 25.9 (4.9)	Mean (SD): 25.0 (5.7)
Hoirisch-Clapauch 2016	Not reported	Not reported
Hui 2012	Mean (SD): 30.1 (5.2)	Mean (SD): 28.7 (5.9)
Hui 2014	Mean (SD) BMI ≤ 24.9 kg/m ² : 31 (3) BMI ≥ 25 kg/m ² : 31 (4)	Mean (SD) BMI ≤ 24.9 kg/m ² : 29 (6) BMI ≥ 25 kg/m ² : 32 (5)
Jing 2015	Mean (SD): 29.57 (4.13)	Mean (SD): 29.89 (3.86)
Koivusalo 2016	Mean (SD): 32.3 (4.9)	Mean (SD): 32.6 (4.5)
Korpi-Hyovalti 2011	Mean (SD): 29.1 (5.4)	Mean (SD): 29.8 (5.4)
Luoto 2011	Mean (SD): 29.5 (4.8)	Mean (SD): 30.0 (4.7)
Petrella 2013	Mean (SD): 31.5 (4.2)	Mean (SD): 32.4 (5.9)
Phelan 2011	Mean (SD): 28.6 (5.2)	Mean (SD): 28.8 (5.2)
Polley 2002	Mean (SD): 25.5 (4.8)	
Poston 2013	Mean (SD): 30.4 (5.7)	Mean (SD): 30.7 (4.9)
Poston 2015	Mean (SD): 30.5 (5.5)	Mean (SD): 30.4 (5.6)
Rauh 2013	Mean (SD): 32.2 (4.4)	Mean (SD): 30.8 (4.9)
Sagedal 2017	Mean (SD): 27.9 (4.2)	Mean (SD): 28.1 (4.5)
Vinter 2011	Median (IQR): 29 (27 - 32)	Median (IQR): 29 (26 - 31)
Wang 2015	Mean (SD): 31.0 (3.8)	Mean (SD): 30.27 (3.64)

Abbreviations: BMI: body mass index; IQR: interquartile range; N: number; SD: standard deviation

Table 2. Maternal BMI (kg/m²)

Study ID	Diet and exercise intervention	Control
Asbee 2009	Mean (SD): 25.5 (6.0) [pre-pregnancy]	Mean (SD): 25.6 (5.1) [pre-pregnancy]
Bruno 2016	Mean (SD): 33.3 (6) [pre-pregnancy]	Mean (SD): 33.4 (5.5) [pre-pregnancy]
	Mean (SD): 34.5 (6.8) [baseline]	Mean (SD): 33.9 (5.7) [baseline]
Dodd 2014	Median (IQR): 31.0 (28.1-35.9) [baseline]	Median (IQR): 31.1 (27.7-35.6) [baseline]
El Beltagy 2013	Not reported (all women were obese)	Not reported (all women were obese)
Harrison 2013	Mean (SD): 30.4 (5.6) [baseline]	Mean (SD): 30.3 (5.9) [baseline]
Hawkins 2014	N (%) [pre-pregnancy] 25–30 kg/m ² : 15 (45.5) ≥ 30 kg/m ² : 18 (54.5)	N (%) [pre-pregnancy] 25–30 kg/m ² : 18 (51.4) ≥ 30 kg/m ² : 17 (48.6)
Herring 2016	Mean (SD): 33.5 (5.8) [early pregnancy]	Mean (SD): 32.2 (5.4) [early pregnancy]
Hoirisch-Clapauch 2016	Not reported	Not reported
Hui 2012	Mean (SD): 25.7 (5.1) [pre-pregnancy]	Mean (SD): 24.9 (5.4) [pre-pregnancy]
Hui 2014	Mean (SD) [pre-pregnancy]	Mean (SD) [pre-pregnancy]
	BMI ≤ 24.9 kg/m ² : 21.6 (2.2)	BMI ≤ 24.9 kg/m ² : 22.6 (1.9)
	BMI ≥ 25 kg/m ² : 29.5 (5.1)	BMI ≥ 25 kg/m ² : 29.7 (1.3)
Jing 2015	Mean (SD): 20.44 (2.54) [pre-pregnancy]	Mean (SD): 20.44 (2.54); 20.74 (2.43) [pre-pregnancy]
Koivusalo 2016	Mean (SD): 31.5 (6.0) [pre-pregnancy]	Mean (SD): 32.0 (5.5) [pre-pregnancy]
	Mean (SD): 32.2 (5.9) [baseline]	Mean (SD): 32.3 (5.4) [baseline]
Korpi-Hyovalti 2011	Mean (SD): 27.3 (6.0) [baseline]	Mean (SD): 25.5 (3.4) [baseline]
Luoto 2011	Mean (SD): 26.3 (4.9) [pre-pregnancy]	Mean (SD): 26.4 (4.3) [pre-pregnancy]
Petrella 2013	Mean (SD): 32.1 (5) [baseline]	Mean (SD): 32.9 (6.2) [baseline]
Phelan 2011	Mean (SD): 26.32 (5.6) [baseline]	Mean (SD): 26.48 (5.9) [baseline]
Polley 2002	Mean (SD) [pre-pregnancy]	Mean (SD) [pre-pregnancy]
	Normal weight: 22.8 (1.9)	Normal weight: 22.5 (2.0)
	Overweight: 31.4 (6.0)	Overweight: 34.1 (7.2)
Poston 2013	Mean (SD): 36.5 (4.7) [baseline]	Mean (SD): 36.1 (4.8) [baseline]
Poston 2015	Mean (SD): 36.3 (5.0) [baseline]	Mean (SD): 36.3 (4.6) [baseline]
Rauh 2013	Median (IQR): 21.7 (19.9 - 23.7) [pre-pregnancy]	Median (IQR): 22.8 (20.6 - 26.6) [pre-pregnancy]
	Median (IQR): 22.2 (20.7 - 24.3) [booking]	Median (IQR): 23.3 (21.2 - 26.8) [booking]

Table 2. Maternal BMI (kg/m²) (Continued)

Sagedal 2017	Mean (SD): 23.8 (4.1) [pre-pregnancy]	Mean (SD): 23.5 (3.7) [pre-pregnancy]
Vinter 2011	Median (IQR): 33.4 (31.7 - 36.5)	Median (IQR): 33.3 (31.7 - 36.9)
Wang 2015	Mean (SD): 22.95 (3.65) [pre-pregnancy]	Mean (SD): 23.06 (3.63) [pre-pregnancy]

Abbreviations: BMI: body mass index; IQR: interquartile range; N: number; SD: standard deviation

Table 3. Maternal ethnicity

Study ID	Diet and exercise intervention	Control
Asbee 2009	N (%) African American: 15 (26.3) Asian: 3 (5.3) White: 5 (8.8) Hispanic: 33 (57.9) Other: 1 (1.8)	N (%) African American: 9 (21.4) Asian: 1 (2.4) White: 8 (19.0) Hispanic: 23 (54.8) Other: 1 (2.4)
Bruno 2016	N (%) Caucasian: 79 (82.3) African: 12 (12.6) Others: 5 (5.2)	N (%) Caucasian: 78 (82.1) African: 13 (13.7) Others: 4 (4.3)
Dodd 2014	N (%) White: 995 (90.0) Asian: 26 (2.4) Indian: 40 (3.6) Other: 44 (4.0)	N (%) White: 998 (91.0) Asian: 34 (3.1) Indian: 35 (3.2) Other: 30 (2.7)
El Beltagy 2013	Not reported (conducted in Egypt)	Not reported (conducted in Egypt)
Harrison 2013	Country of birth, N (%) Australia: 36 (44) Southeast Asia: 14 (16) Southern/Central Asia: 36 (43) Other: 14 (18)	Country of birth, N (%) Australia: 38 (41) Southeast Asia: 12 (13) Southern/Central Asia: 36 (38) Other: 14 (15)
Hawkins 2014	N (%) Hispanic: 33 (100)	N (%) Hispanic: 35 (100)
Herring 2016	N (%) African American: 33 (100)	N (%) African American: 33 (100)
Hoirisch-Clapauch 2016	Not reported	Not reported
Hui 2012	N (%) First Nations (Canadian Aboriginals with First Nations status): 19 (17.4)	N (%) First Nations (Canadian Aboriginals with First Nations status): 22 (25.0)
Hui 2014	First Nations (Canadian Aboriginals with First Nations status), N (%) BMI ≤ 24.9 kg/m ² : 2 (6.7)	First Nations (Canadian Aboriginals with First Nations status), N (%) BMI ≤ 24.9 kg/m ² : 1 (3.7)

Table 3. Maternal ethnicity (Continued)

	BMI ≥ 25 kg/m ² : 3 (11.1)	BMI ≥ 25 kg/m ² : 4 (13.8)
Jing 2015	Not reported (conducted in China)	Not reported (conducted in China)
Koivusalo 2016	Not reported (conducted in Finland)	Not reported (conducted in Finland)
Korpi-Hyovalti 2011	Not reported (conducted in Norway)	Not reported (conducted in Norway)
Luoto 2011	Not reported (conducted in Finland)	Not reported (conducted in Finland)
Petrella 2013	N (%) Caucasian: 28 (84.9) Maghreb: 4 (12.1) Other: 1 (3.0)	Caucasian: 20 (66.7) Maghreb: 6 (20) Other: 4 (13.3)
Phelan 2011	N (%) Non-Hispanic White: 138 (68.7) Latina and Hispanic: 39 (19.6) Non-Hispanic African American: 14 (7.1) Other: 9 (4.6)	N (%) Non-Hispanic White: 135 (67.5) Latina and Hispanic: 39 (19.6) Non-Hispanic African American: 19 (9.6) Other: 7 (3.3)
Polley 2002	N (%) Black: 47 (39) White 73 (61)	
Poston 2013	N (%) White: 52 (55) Black: 38 (40) Asian: 2 (2) Other: 2 (2)	N (%) White: 51 (57) Black: 32 (26) Asian: 1 (1) Other: 5 (6)
Poston 2015	N (%) White: 490 (63) Black: 202 (26) Asian: 47 (6) Other: 44 (6)	N (%) White: 483 (63) Black: 200 (26) Asian: 48 (6) Other: 41 (5)
Rauh 2013	Country of birth, N (%) Germany: 140 (83.8) Others: 27 (16.2)	Country of birth, N (%) Germany: 68 (81.9) Others: 15 (18.1)
Sagedal 2017	Not reported (conducted in Norway)	Not reported (conducted in Norway)
Vinter 2011	N (%)	N (%)

Table 3. Maternal ethnicity (Continued)

Caucasian: 150 (100)

Caucasian: 154 (100)

Wang 2015	Not reported (conducted in China)	Not reported (conducted in China)
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Abbreviations: N: number

Table 4. Maternal parity

Study ID	Diet and exercise intervention	Control
Asbee 2009	N (%) 0: 26 (45.6) 1 or more: 31 (54.4)	N (%) 0: 19 (44.2) 1 or more: 24 (55.8)
Bruno 2016	N (%) 0: 53 (55.2)	N (%) 0: 59 (62.1)
Dodd 2014	N (%) 0: 441 (40.2)	N (%) 0: 441 (40.2)
El Beltagy 2013	Not reported	Not reported
Harrison 2013	N (%) First pregnancy: 42 (51) Second pregnancy: 36 (43) Third pregnancy or higher: 22 (27)	N (%) First pregnancy: 43 (46) Second pregnancy: 37 (40) Third pregnancy or higher: 20 (21)
Hawkins 2014	N (%) 0: 6 (19.4) 1: 10 (32.3) 2: 7 (22.6) ≥ 3: 8 (25.8)	N (%) 0: 11 (31.4) 1: 10 (28.6) 2: 3 (8.6) ≥ 3: 11 (31.4)
Herring 2016	N (%): 0: 9 (27)	N (%): 0: 10 (30)
Hoirisch-Clapauch 2016	Not reported	Not reported
Hui 2012	Not reported	Not reported
Hui 2014	Not reported	Not reported
Jing 2015	Not reported	Not reported
Koivusalo 2016	Previous deliveries, N (%) 0: 61 (42) 1: 42 (29) 2: 29 (20) ≥ 3: 12 (8)	Previous deliveries, N (%) 0: 52 (42) 1: 38 (30) 2: 24 (19) ≥ 3: 11 (9)
Korpi-Hyovalti 2011	N (%) 0: 13 (50)	N (%) 0: 17 (63)
Luoto 2011	N (%)	N (%)

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Table 4. Maternal parity *(Continued)*

	0: 103 (47.0)	0: 73 (40.6)
Petrella 2013	N (%) 0: 13 (39.4)	N (%) 0: 13 (43.3)
Phelan 2011	N (%) 0: 153 (76.3) ≥ 1: 48 (23.7)	N (%) 0: 153 (76.6) ≥ 1: 47 (23.4)
Polley 2002	N (%) First pregnancy: 56 (47) Second pregnancy: 36 (30) Third pregnancy: 20 (17) > third pregnancy: 7 (6)	
Poston 2013	N (%) 0: 42 (45) 1: 29 (31) ≥ 2: 23 (24)	N (%) 0: 38 (43) 1: 36 (40) ≥ 2: 15 (17)
Poston 2015	N (%) 0: 336 (43) ≥ 1: 447 (57)	N (%) 0: 338 (44) ≥ 1: 434 (56)
Rauh 2013	N (%) 0: 110 (65.9) 1: 50 (29.9) ≥ 2: 7 (4.2)	N (%) 0: 53 (63.9) 1: 23 (27.7) ≥ 2: 7 (8.4)
Sagedal 2017	N (%) 0: 303 (100)	N (%) 0: 303 (100)
Vinter 2011	N (%) 0: 79 (52.7)	N (%) 0: 84 (54.6)
Wang 2015	Not reported	Not reported

Abbreviations: N: number

Table 5. GDM diagnosis

Study ID	Timing	Screening/diagnosis test(s) and glucose	Reference(s)	Notes
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Table 5. GDM diagnosis (Continued)

		threshold(s) used for diagnosis			
Asbee 2009	Not reported	Not reported	Not provided		Data not provided in format suitable for meta-analysis
Bruno 2016	16th to 18th weeks; repeated in 24th to 28th weeks for women negative at first test	75 g 2-hour OGTT Thresholds: fasting ≥ 5.1 mmol/L and/or 1-hour ≥ 10.0 mmol/L and/or 2-hour ≥ 8.5 mmol/L	<i>"IADPSG criteria"</i> (no reference provided)		
Dodd 2014	Not reported	<i>"all women were encouraged to undergo screening"</i> 75 g 2-hour OGTT Thresholds: fasting ≥ 5.5 mmol/L or 2-hour ≥ 7.8 mmol/L	South Australian Perinatal Practice Guidelines 2013 (South Australian Perinatal Practice Guidelines: diabetes mellitus and abnormal glucose tolerance Government of Australia, SA Health, 2013. www.health.sa.gov.au/ppg/Default.aspx?PageContentID=2118&tabid=100 .)		
El Beltagy 2013	24 to 28 weeks	<i>"All women underwent routine GDM screening"</i>	Not provided		Data not provided in format suitable for meta-analysis
Harrison 2013	28 weeks	2-hour OGTT Thresholds: fasting ≥ 5.5 mmol/L and/or 2-hour ≥ 8.0 mmol/L <u>OR</u> Thresholds: fasting ≥ 5.1 mmol/L and/or 1-hour ≥ 10.0 mmol/L and/or 2-hour ≥ 8.5 mmol/L	ADIPS 1998 (Hoffmann L, Nolan C, Wilson JD, Oats JJN, Simmons D. Gestational diabetes mellitus: management guidelines. MJA 1998;169:93–7.) <u>OR</u> IADPSG 2010 (Metzger BE, Gabbe SG, Persson B, et al. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycaemia in pregnancy. Diabetes Care 2010;33:676–82.)		
Hawkins 2014	24 to 28 weeks gestation	50 g 1-hour OGTT Thresholds: 1-hour > 7.493 mmol/L 100 g 3-hour OGTT Thresholds: not reported	American Diabetes Association 2012 (American Diabetes Association. Standards of medical care in diabetes–2012. Diabetes Care 2012; 35(Suppl. 1): S11–63.)		
Herring 2016	Not reported	Not reported	Not provided		
Hoirisch-Cla- pauch 2016	Not reported	Not reported	Not provided		Data not provided in format suitable for meta-analysis

Table 5. GDM diagnosis (Continued)

Hui 2012	Not reported	Not reported	Canadian Diabetes Association 2008 (Canadian Diabetes Association. 2008 Clinical practice guidelines for the prevention and management of diabetes in Canada. Can J Diabetes 2008;32:S168–80.)	
Hui 2014	Not reported	Not reported	Canadian Diabetes Association 2008 (Canadian Diabetes Association, Clinical Practice Guidelines Committee, Canadian Diabetes Association: 2008 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Can J Diabetes Care 2008, 32:S1:171.)	
Jing 2015	Not reported	Not reported	Not provided	
Koivusalo 2016	24 to 28 weeks	75 g 2-hour OGTT Thresholds: fasting ≥ 5.3 mmol/L and/or 1-hour ≥ 10.0 mmol/L and/or 2-hour ≥ 8.6 mmol/L	American Diabetes Association 2008 (Holcomb SS; American Diabetes Association. Update: standards of medical care in diabetes. Nurse Pract 2008;33:12–5.)	
Korpi-Hyovalti 2011	26 to 28 weeks	75 g 2-hour OGTT Thresholds: fasting ≥ 5.6 mmol/L or 2-hour ≥ 7.8 mmol/L	Modified from the World Health Organization 1998 (Alberti KG, Zimmet PZ: Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: diagnosis and classification of diabetes mellitus: provisional report of WHO consultation. Diabet Med 1998, 15:539–53.)	All women also underwent 75 g 2 hour OGTT at 8 to 12 weeks; those diagnosed with GDM were excluded from the trial
Luoto 2011	26 to 28 weeks	2-hour OGTT Thresholds: fasting ≥ 5.3 mmol/L and/or 1-hour > 10.0 mmol/L and/or 2-hour > 8.6 mmol/L <u>OR</u> 1) Any of the above thresholds or newborn birthweight ≥ 4500 g or use of insulin or other diabetic medication 2) Any of the above thresholds or newborn birthweight ≥ 4000 g or use of insulin or other diabetic medication 3) Any of the above thresholds or use of	American Diabetes Association 2010 ((2010) Diagnosis and classification of diabetes mellitus. Diabetes Care 33: S62–9.)	Data in meta-analysis according to American Diabetes Association 2010 criteria [use of data according to other criteria did not change results]

Table 5. GDM diagnosis (Continued)

		insulin or other diabetic medication		
Petrella 2013	16th to 18th week or 24th to 28th week "as recommend"	75 g 2-hour OGTT Thresholds: not reported	American Diabetes Association 2011 (American Diabetes Association. Standards of medical care in diabetes-2011. Diabetes Care 2011;34:S11–61.)	
Phelan 2011	Not reported	Not reported	Not provided	
Polley 2002	Not reported	Not reported	Not provided	
Poston 2013	27 + 0 to 28 + 6 weeks	75 g 2-hour OGTT Thresholds: fasting ≥ 5.1 mmol/L and/or 1-hour ≥ 10.0 mmol/L and/or 2-hour ≥ 8.5 mmol/L	IADPSG 2010 (Metzger B, Gabbe SG, Persson B, Buchanan TA, Catalano PA, Damm P, Dyer AR, Leiva A, Hod M, Kitzmiller JL, Lowe LP, McIntyre HD, Oats JJ, Omori Y, Schmidt MI: International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycaemia in pregnancy. Diabetes Care 2010, 33:676–82.)	
Poston 2015	27 + 0 to 28 + 6 weeks	75 g 2-hour OGTT Thresholds: fasting ≥ 5.1 mmol/L and/or 1-hour ≥ 10.0 mmol/L and/or 2-hour ≥ 8.5 mmol/L	IADPSG 2010 (Metzger BE, Gabbe SG, Persson B, et al. International Association of Diabetes and Pregnancy Study Groups recommendations on the diagnosis and classification of hyperglycaemia in pregnancy. Diabetes Care 2010; 33: 676–82.)	
Rauh 2013	24th to 28th week	2-hour OGTT Thresholds: not reported	German Society of Gynecology and Obstetrics 2010 (Deutsche Gesellschaft für Gynäkologie und Geburtshilfe e.V.: Diagnostik und Therapie des Gestationsdiabetes. [http://www.dgkg.de/leitlinien/].)	
Sagedal 2017	30 weeks	75 g 2-hour OGTT Thresholds: 2-hour ≥ 7.8 mmol/L	Norway national criteria 2008 (Tore HH, Torun C. Veileder i Fødselshjelp 2008 In) NGFNSf-GaO, editor. Veileder i Fødselshjelp 2008; 2008. p. 112.); World Health Organization 2006 (World Health Organization. Definition and Diagnosis of Diabetes Mellitus and Intermediate Hyperglycaemia: Report of a WHO/IDF Consultation. Geneva, Switzerland: World Health Organization, 2006.)	
Vinter 2011	28 to 30 weeks and 34 to 36 weeks	75 g 2-hour OGTT Thresholds: 2-hour ≥ 9 mmol/L <u>OR</u> Thresholds: 2-hour ≥ 8.5 mmol/L	"Danish national recommendations" (no reference provided) <u>OR</u> IADPSG 2010 (Metzger BE, Gabbe SG, Persson B, Buchanan TA, Catalano PA, Damm P et al. International Association of Diabetes and Pregnancy Study Group's recommendations on the diagnosis and classification of hyperglycaemia in pregnancy. Diabetes Care 2010; 33: 676–82.)	All women also underwent an OGTT at baseline (12 to 15 weeks); those diagnosed with GDM were excluded from the trial Data in meta-analysis according to Danish national recommendations [use

Table 5. GDM diagnosis (Continued)

				of data according to IADPSG 2010 criteria did not change results]
Wang 2015	24 to 28 weeks	75 g OGTT	<i>"The International Association of Diabetes and Pregnancy Study Groups (IADPSG) criterion was used"</i> (no reference provided)	

Abbreviations: ADIPS: Australasian Diabetes in Pregnancy Society; g: gram; GDM: gestational diabetes mellitus; IADPSG: International Association of the Diabetes and Pregnancy Study Group; OGTT: oral glucose tolerance test;

WHAT'S NEW

Date	Event	Description
27 November 2016	New citation required and conclusions have changed	Ten new trials have been included (Bruno 2016 ; Hawkins 2014 ; Herring 2016 ; Hoirisch-Clapauch 2016 ; Hui 2014 ; Jing 2015 ; Koivusalo 2016 ; Poston 2015 ; Sagedal 2017 ; Wang 2015), and additional data included for some previously included trials. In regards to our primary and secondary review outcomes, new/ altered findings include: a possible reduction in gestational diabetes mellitus and in caesarean section, and reductions in gestational weight gain, postnatal weight retention, macrosomia and respiratory distress syndrome with diet and exercise interventions compared with standard care.
27 November 2016	New search has been performed	Search and methods updated. One new author (Judith Gomersall) joined the review team for this update.

HISTORY

Protocol first published: Issue 3, 2013

Review first published: Issue 4, 2015

Date	Event	Description
11 June 2015	Amended	Added Acknowledgements statement.

CONTRIBUTIONS OF AUTHORS

For this update of the review, Emily Shepherd and Judith Gomersall assessed the citations and studies found for inclusion, extracted data, assessed risk of bias and quality of evidence using the GRADE approach, conducted analyses and wrote the first draft of the review. All review authors (Joanna Tieu, Shanshan Han, Caroline Crowther and Philippa Middleton) assisted with data interpretation and edited and commented on the review.

For the first version of the review, Emily Shepherd (nee Bain) and Morven Crane assessed the citations and studies found for inclusion, extracted data, assessed risk of bias and conducted data analyses. Emily Shepherd, Morven Crane and Shanshan Han 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.

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

DECLARATIONS OF INTEREST

Emily Shepherd: none known.

Judith Gomersall: none known.

Joanna Tieu has received funding for work outside of the scope of this review- NHMRC postgraduate scholarship, Ken Muirden fellowship (administered by Arthritis Australia; jointly funded by Australian Rheumatology Association and Roche).

Shanshan Han: Shanshan Han was an investigator on one of the excluded trials ([Crowther 2012](#)). Assessment of eligibility for inclusion was carried out by other members of the review team who were not directly involved in the trial.

Caroline Crowther: Caroline Crowther was an investigator on one of the included trials ([Dodd 2014](#)), and one of the excluded trials ([Crowther 2012](#)). All tasks relating to these trials (assessment of eligibility for inclusion, and if applicable, data extraction and assessment of risk of bias) were carried out by other members of the review team who were not directly involved in the trials.

Philippa Middleton: Philippa Middleton was an investigator on one of the excluded trials ([Crowther 2012](#)). Assessment of eligibility for inclusion was carried out by other members of the review team who were not directly involved in the trial.

SOURCES OF SUPPORT

Internal sources

- ARCH: Australian Research Centre for Health of Women and Babies, Robinson Research Institute, The University of Adelaide, Australia.
- Healthy Mothers, Babies and Children, SAHMRI: South Australian Health and Medical Research Institute, Adelaide, Australia.
- Liggins Institute, The University of Auckland, Auckland, New Zealand.

External sources

- NHMRC: National Health and Medical Research Council, Australia.
Funding for the Australian and New Zealand Pregnancy and Childbirth Satellite
- NIHR: National Institute for Health Research, UK.
Cochrane Review Incentive Scheme Award: 16/72/02

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

For this update, we have updated the methods to be in line with those in the standard template used by Cochrane Pregnancy and Childbirth, specifically we included use of the GRADE approach to assess the quality of the body of evidence and the use of 'Summary of findings' tables. Judith Gomersall has joined the review team for this update.

We have revised the review outcomes, using the standardised outcome set agreed by consensus between review authors of Cochrane Pregnancy and Childbirth systematic reviews for prevention and treatment of GDM and pre-existing diabetes.

We have clarified that in order to be eligible, trials had to report on our primary outcome, GDM. Trials that appeared to meet other eligibility criteria, that did not report on GDM have been included as 'Awaiting classification' (pending the availability/reporting of data on GDM), and will be re-considered in future updates of this review. We have also clarified that in order to be eligible, trials had to compare a combined diet and exercise intervention with no intervention (i.e. standard care) or with a different diet and exercise intervention. Our review title has been edited accordingly. Trials comparing a diet and exercise intervention with a diet only intervention, or an exercise only intervention, were not eligible, as such trials assess the effects of the addition of an exercise or diet intervention, and thus are of relevance to the [Han 2012](#) and [Tieu 2017](#) reviews, respectively.

INDEX TERMS

Medical Subject Headings (MeSH)

*Diet; *Exercise; Cesarean Section [statistics & numerical data]; Combined Modality Therapy [methods]; Diabetes, Gestational [*prevention & control]; Hypertension [epidemiology]; Perinatal Mortality; Perineum [injuries]; Pregnancy Complications, Cardiovascular [epidemiology]; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Infant, Newborn; Pregnancy