National Institute for Health and Care Excellence

Final

Maternal and child nutrition

[H] Evidence reviews for healthy lifestyle interventions for those with gestational diabetes

NICE guideline NG247

Evidence reviews underpinning recommendations 1.2.18 and 1.2.19, and the recommendation for research on dietary interventions during pregnancy for people with gestational diabetes, in the NICE guideline

January 2025

Final

These evidence reviews were developed by NICE

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Healthy lifestyle interventions for those with gestational diabetes

Review question

What are the most effective and cost-effective healthy lifestyle interventions for women with gestational diabetes?

Introduction

During pregnancy, people without pre-existing diabetes can develop gestational diabetes usually because they become less responsive to insulin which controls blood glucose levels. If not managed, gestational diabetes can cause problems such as the baby being large for gestational age, pre-eclampsia and stillbirth. Healthy lifestyle interventions are the first line treatment for gestational diabetes. The aim of this review is to determine what are the most effective and cost-effective healthy lifestyle interventions for those with gestational diabetes.

Summary of the protocol

See Table 1 for a summary of the Population, Intervention, Comparison and Outcome (PICO) characteristics of this review.

Table 1: Summary of the protocol (PICO table)

Population	Pregnant women with gestational diabetes during a single or multiple pregnancy
Intervention	The following interventions will be considered: • diet based interventions (low-/moderate-/high-glycaemic index (GI) diets, low-/high-carbohydrate diet, energy restricted/no energy restricted diet, high/low unsaturated fat diet, probiotics/no probiotics diet, high-fibre/standard-fibre diet, soy protein/no soy protein diet, 'Dietary Approaches to Stop Hypertension (DASH)' diet rich in fruits, vegetables, whole grains and low-fat dairy products and ethnic-specific diet • physical activity-based interventions • management of sedentary behaviour-based interventions (for example, reduce the time sitting) • behaviour-based interventions (counselling, education, coaching, any digital intervention) • monitoring-based interventions (for example, regular weighing, including self-weighing, apps/digital interventions) • multi-component interventions (a combination of the interventions listed above).
Comparison	Standard care as defined by the study Interventions compared with: • each other • a combination of interventions.
Outcome	**Critical** Maternal outcomes: • glycaemic (glucose) control • gestational weight change • mode of delivery: vaginal birth/induction of labour/caesarean birth • hypertensive disorders of pregnancy (pre-eclampsia and gestational hypertension) • need for pharmacological intervention. Fetal/neonatal outcomes: • large for gestational age (LGA) >90th centile • neonatal hypoglycaemia • neonatal mortality and morbidity (include it as a composite outcome if reported).

For further details see the review protocol in appendix A.

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. Methods specific to this review question are described in the review protocol in appendix A and the methods document (supplementary document 1).

Declarations of interest were recorded according to NICE's conflicts of interest policy.

Effectiveness evidence

Included studies

This review included 2 Cochrane systematic reviews (Brown 2017, Han 2017) and 29 studies from 28 randomised controlled trials (RCT) (27 RCTs: Avery 1997, Bo 2014, Borgen 2019, Brankston 2004, Carolan-Olah 2019, Christie 2022, Cypryk 2007, Downs 2017, Durnwald 2016, Ferrara 2011, Garner 1997, Grant 2011, Halse 2014, Jovanovic-Peterson 1989, Lauszus 2001, Louie 2011, Magee 1990, Mendelson 2008, Mijatovic 2020, Moreno-Castilla 2013, Moses 2009, Rae 2000, Reece 1995, Sklempe Kokic 2018, Trout 2016, Valentini 2012, Yew 2021; 1 cluster RCT: Hedderson 2018; 1 secondary paper Halse 2015 to Halse 2014).

The included studies are summarised in Table 2.

The included Cochrane reviews focused on diet based (Han 2017) or physical activity based (Brown 2017) interventions. Eligible studies meeting our protocol criteria from the Cochrane reviews were included. Additional studies covering interventions specified in our protocol which were not considered in the Cochrane reviews were included. Of the 29 studies, 16 RCTs were sourced from the two Cochrane systematic reviews; this included 12 of the 19 studies from Han 2017 (Bo 2014, Cypryk 2007, Garner 1997, Grant 2011, Lauszus 2001, Louie 2011, Magee 1990, Moreno-Castilla 2013, Moses 2009, Rae 2000, Reece 1995, Valentini 2012) and 5 of the 11 studies from Brown 2017 (Avery 1997, Bo 2014, Brankston 2004, Halse 2014, Jovanovic-Peterson 1989). Studies that were not eligible for inclusion based on our protocol were primarily due to not being from high income countries (see excluded studies table in Appendix J for more details). One RCT (Bo 2014) was included in both Cochrane reviews (Han 2017, Brown 2017) interventions as there were four arms (physical activity, mixed interventions, physical activity+mixed interventions and standard care) with different comparison focus in each Cochrane review.

In addition, 12 studies which were either published after the date ranges of the Cochrane reviews or included different interventions to the Cochrane reviews were included in the review. There were no additional eligible studies found in the same date range or prior to inclusions dates covering the same interventions as the Cochrane systematic reviews.

According to the protocol we included studies from high income countries, and they were conducted in Australia, Canada, Croatia, Denmark, Italy, Norway, Poland, Singapore, Spain and USA.

See the literature search strategy in appendix B and study selection flow chart in appendix C.

Population

The study population included pregnant women with a diagnosis of gestational diabetes mellitus. Studies did not report information on prior bariatric surgery status.

Only one study (Rae 2000) included women during multiple pregnancy in their population, with inclusion of 7 sets of twins.

Gestational diabetes diagnostic criteria differed between studies and included:

- The Australasian Diabetes in Pregnancy (ADIPS) criteria (Halse 2014, Moses 2009, Rae 2000) or a modified version (Louie 2011);
- American Diabetes Association (ADA) 2000 criteria (Ferrara 2011);
- Canadian Diabetes Association guidelines (Brankston 2004, Grant 2011);
- Carpenter and Coustan criteria (Hedderson 2018, Magee 1990, Trout 2016);
- Hatem et al 1998 criteria (Garner 1997);
- International Association of the Diabetes and Pregnancy Study Groups (IADPSG) criteria (Christie 2022, Sklempe 2018);
- Metzger et al 1998 criteria (Valentini 2012);
- National Diabetes and Pregnancy clinical 2006 guidelines (Moreno-Castilla 2013);
- O'Sullivan and Mahan criteria (1964) and Metzger 1991 national consensus screening guidelines (Avery 1997);

- World Health Organisation (WHO) criteria (Cypryk 2007, Yew 2021 with the latter study using 2013 criteria).

Two studies used two different criteria: Mijatovic 2020 used ADIPS 1998 or IADPSG criteria depending on hospital, and Durnwald 2016 used Carpenter and Coustan criteria and another method which was not stated. Seven studies did not report the criteria used (Bo 2014, Borgen 2019, Downs 2017, Jovanovic-Peterson 1989, Lauszus 2001, Mendelson 2008, Reece 1995).

Timing of diagnosis of gestational diabetes, where reported, typically occurred during 24-28 gestational weeks, although in some studies this started earlier or spanned a wider time-period (Yew 2021: 12-30 gestational weeks; Downs 2017: 16 gestational weeks, Louie 2011: 20-32 gestational weeks and earlier if high risk; Trout 2016: 24-32 gestational weeks).

Interventions/comparators

Evidence was identified for diet based, physical activity based, behaviour based and monitoring based interventions (the latter as part of multicomponent interventions). No evidence was identified for sedentary based interventions or monitoring based interventions alone, such as self-weighing. Evidence was not found for the following types of diets specified in the protocol: 'Dietary Approaches to Stop Hypertension' (DASH diet), probiotics and soy protein/no soy protein diet.

Diet based interventions were sourced from the Han 2017 Cochrane systematic review and an additional 2 studies outside of the publication date range with diet as an intervention focus were also identified.

Physical activity-based interventions were sourced from the Brown 2017 Cochrane systematic review and an additional 3 studies outside of the publication date range with physical activity as an intervention focus were also identified. The 5 RCTs sourced from the Brown 2017 Cochrane systematic review compared physical activity to standard care or control (Avery 1997, Bo 2014, Brankston 2004, Halse 2014, Jovanovic-Peterson 1989). Where diet was the same for both physical activity intervention and control, the intervention was classified as physical activity. Outside of Brown 2017, two studies comparing physical activity intervention to standard care/control (Christie 2022, Sklempe Kokic 2018) and another study (Downs 2017) with three arms of face-to-face physical activity, home based physical activity and standard care/control were included.

Seven RCTs focused on behaviour-based interventions with or without monitoring based interventions and with a standard care comparator (Borgen 2019, Carolan-Olah 2019, Durnwald 2016, Ferrara 2011, Hedderson 2018, Mendelson 2008, Yew 2021). Behavioural interventions involved counselling, education and apps to support behaviour change.

Outcomes

There was evidence available for all listed outcomes in the protocol.

Glycaemic control outcomes were able to be reported for 18 studies (Bo 2014, Brankston 2004, Christie 2022, Cypryk 2007 Downs 2017, Garner 1997, Halse 2014, Jovanovic-Peterson 1989, Lauszus 2001, Louie 2011, Magee 1990, Mendelson 2008, Mijatovic 2020, Rae 2000, Reece 1995, Sklempe Kokic 2018, Trout 2016; Yew 2021). Other studies either not report these outcomes, only reported postpartum values or were not useful or relevant (for example, average rates of daily blood glucose levels or glycaemic index outcomes).

For glycaemic control outcomes, fasting blood glucose was prioritised. Where this was not reported in a study, other measurements were reported. Where multiple measurements of glycaemic control were reported in studies, only one measurement was included in the analysis. Where glycaemia at different intervals of gestation was reported, the last follow-up in gestation was used in the review.

Need for pharmacological treatment was considered as a surrogate outcome for glycaemic control and where available this outcome was reported in the evidence review. Where data was presented for women that had been on pharmacological treatment since baseline and those that initiated this during the intervention, the latter was reported. Pharmacological treatment included insulin, metformin or glyburide with insulin being commonly reported.

Eighteen studies reported the outcome of gestational weight change, either as absolute difference (Avery 1997, Bo 2014, Brankston 2004, Durnwald 2016, Garner 1997, Halse 2014, Lauszus 2001, Mitjatovic 2020, Moreno-Castilla 2013, Rae 2000, Reece 1995, Trout 2016, Yew 2021) or as dichotomous outcome by met or achieved Institute of Medicine (IOM) recommendations (Hedderson 2018, Louie 2011, Mijatovic 2020).

There was variation amongst studies in the start time of weight measurement whether measured at study baseline reflecting weight change during the intervention period (Durnwald 2016, Halse 2014, Moreno-Castilla 2013, Trout 2016) or using pre-pregnancy weight reflecting weight change during the entire pregnancy (Brankston 2004, Mitjatovic 2020, Rae 2000, Valentini 2012), from 12 gestational weeks earlier (Yew 2021) or were unclear in time length (Louie 2011, Reece 1995). Other studies reported final weight (Avery 1997, Bo 2014, Garner 1997, Lauszus 2001).

For caesarean birth outcome, elective and emergency were not always distinguished and therefore were analysed together unless only one of these outcomes was provided.

Some studies reported macrosomia rather than large for gestational age as an outcome. Studies reporting macrosomia as an outcome instead of large for gestational age were downgraded for indirectness.

Definition of neonatal mortality and morbidity outcomes varied between studies. Where studies reported composite of neonatal morbidity without mortality outcomes, this was separated into a neonatal morbidity composite outcome. Where studies only reported neonatal mortality, this was reported separately as an outcome.

Follow-up and analysis

Where reported, mean gestational age in weeks at intervention ranged from 28.8 to 31.8 while gestational age at screening ranged from 26.0 to 30.5 weeks.

When studies reported multiple follow-ups, the last follow-up in gestation was reported. Some reported exact gestational weeks of age whereas for some it was not clear. For mode of birth and large for gestational age outcomes, unless specified otherwise, follow-up time was labelled as at birth. For pre-eclampsia or gestational hypertension follow-up time was labelled as diagnosed before birth if the study did not specify gestational weeks. Where women were provided a postpartum questionnaire collecting outcomes were labelled as follow-up after birth.

Strata

All studies but one were conducted in women with single pregnancies. The only study including both single and multiple pregnancies (Rae 2000) did not report outcomes separately for multiple pregnancies. Therefore, data was stratified by single pregnancies only.

Subgroup analyses

Subgroup analyses as per protocol was agreed to be conducted when there was heterogeneity. The following subgroups were identified in the protocol: deprived socioeconomic group; women with disabilities, including learning disabilities and other physical and mental health conditions; lesbian, gay, bisexual, transgender and queer (LGBTQ+) people; ethnicity and White/ White British and women who had bariatric surgery.

There was insufficient information on the above subgroups in the papers. Hence subgroup analysis could not be conducted when there was heterogeneity. Random effects analysis was used in such instances.

Excluded studies

Studies not included in this review are listed, and reasons for their exclusion are provided in appendix K.

Summary of included studies

Summaries of the studies that were included in this review are presented in Table 2.

Table 2: Summary of included studies.

Study	Population	Intervention	Comparison	Outcomes	Comments
Avery 1997 Randomised controlled trial (RCT) USA	N=29 Mean age in years (SD) Intervention: 32.2 (4.9) Comparator: 30.4 (5.1) Mean gestational age in weeks [at screening] (SD) NR Mean gestational age in weeks [at intervention] (SD) NR Mean BMI in kg/m^2 [at baseline] (SD) Intervention: 32.2 (5.9) Control: 30.0 (5.1)	Physical activity: Involved physical activity for 30 minutes 3-4 times a week until the end of pregnancy. Physical activity involved 5-minutes of warm up and cool down, 20 minutes cycle with ergometer or walking at 70% of estimated maximal heart rate. An investigator was present for 2 of the sessions and included maternal and fetal monitoring. Unsupervised exercise was undertaken 1-2 times a week and were taught to check and record their heart rate.	Standard care/control: Stayed on dietary therapy and did not change usual physical activity. Investigator weekly call to check on progress and women were asked to note the date, type and amount of exercise undertaken in their blood sugar record book.	• gestational weight change (kg) • mode of birth: caesarean • gestational hypertension • need for pharmacological intervention • large for gestational age > 90 centile • neonatal hypoglycaemia	Sourced from Brown 2017 Cochrane systematic review. Strata in analysis: single pregnancy. Follow-up or gestational age at diagnosis: At birth for mode of birth and large for gestational age; diagnosed before birth for gestational hypertension; until after birth for neonatal hypoglycaemia; otherwise not reported for other outcomes. All women had been educated in home blood glucose monitoring and dietary counselling prior to entering the study. Fasting and 2-hour postprandial blood glucose was monitored three days per week by all women and

Study	Population	Intervention	Comparison	Outcomes	Comments
					read on a reflectance meter at the next clinic appointment. Daily home blood glucose results were recorded in log books. Glycaemic outcomes could not be reported as the study reports average rates of change in daily blood glucose levels, or baseline values. LGA defined in text as >4000g.
Bo 2014 Randomised controlled trial (RCT) Italy	N=200 Mean age in years (SD) PA: 35.9 (4.8) PA+mixed: 35.5 (4.4) Mixed: 35.1 (4.4) Control (diet): 33.9 (5.3) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) Not reported Mean BMI in kg/m^2 [at baseline] (SD)	Physical activity: Advised to briskly walk at least 20 minutes/day (140 min/week; Borg's scale target rating 12–14) and individually-prescribed diet recommendations*. Physical activity and mixed: Advised to walk briskly at least 20 min/day every day (140 min/week; Borg's scale target rating 12–14) plus individually oral/written recommendations for helping with healthy dietary choices (that is, lowering carbohydrate intake, strategies for out-of-home eating, healthy cooking and food shopping and related behavioural suggestions) and debunking false myths about diet in	Control (diet): Individually-prescribed diet recommendations* *All women were given an individually-prescribed diet (carbohydrates 48% to 50%, proteins 18% to 20%, fats 30% to 35%, fibre 20 g to 25 g/day, no alcohol).	• glycaemic control: end of intervention fasting blood glucose concentration • gestational weight change (kg) • mode of birth: caesarean • need for pharmacological therapy • large for gestational age > 90 centile • neonatal morbidity	Sourced from Brown 2017 and Han 2017 Cochrane systematic reviews. Strata in analysis: single pregnancy. Follow-up: end of intervention (no further details) for glycaemic control, at gestational age of 38 weeks or before delivery (if pre-term) for gestational weight change and need for pharmacological therapy, at birth for mode of birth and large for gestational age; otherwise unclear for other outcomes.

Study	Population	Intervention	Comparison	Outcomes	Comments
	PA: 27.3 (4.1) PA+mixed: 27.0 (3.9) Mixed: 26.9 (4.6) Control (diet): 26.8 (4.1)	pregnancy. In addition to individually-prescribed diet recommendations* Mixed: Individually oral/written recommendations for helping with healthy dietary choices (that is, lowering carbohydrate intake, strategies for out-of-home eating, healthy cooking and food shopping and related behavioural suggestions) and debunking false myths about diet in pregnancy. In addition to individually-prescribed diet recommendations*.			
Borgen 2019 Randomised controlled trial (RCT) Norway	N=238 Age in years (n, %) Intervention: • ≤29: 30 (26.1) • 30-37: 66 (57.4) • ≥38: 19 (16.5) Comparator: • ≤29: 27 (22.0) • 30-37: 62 (50.4) • ≥38: 34 (27.6) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational	Mixed intervention: Pregnant+ app and usual care. Pregnant+ app downloaded by women to their smartphone in hospital or at home. The app aimed to support gestational diabetes management by adapting a healthy diet, being physically active and providing blood glucose level feedback. The app contained four icons: • 'Blood glucose': real-time glucose values from a glucometer displayed in graph or table with simple visual indication of normal or high levels. Blood glucose values were recorded manually or	Standard care: • Usual care provided by midwives or diabetes nurses within consultations every 2 weeks. • Information was provided on healthy diet (reducing sugar-rich products, greater consumption of whole grains and vegetables and frequent small meals) and encouragement of regular physical activity	• mode of birth: vaginal birth • mode of birth: induction of labour • mode of birth: caesarean • need for pharmacological intervention • large for gestational age > 90 centile	Strata in analysis: single pregnancy. Follow-up: At birth for mode of birth and large for gestational age outcomes, otherwise unclear. 76.5% in the intervention arm and 76.4% in the comparator arm were at 25-32 gestational weeks at diagnosis. 71.5% of women in the intervention and 81.3% of women in comparator arm were within BMI range 17-30

Study	Population	Intervention	Comparison	Outcomes	Comments
	age in weeks [at intervention] (SD) Not reported Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD) Not reported	automatically uploaded via the Bluetooth. Women had the option to print blood glucose values to assist discussion with their health professionals. • 'Physical activity': Displayed advantages of performing physical activities with written examples and accompanying images of how to perform different activities such as swimming, stretching and strength training during pregnancy. Women could also record personal goals. • 'Food and beverages': Culturally adapted information provided about healthy diet and recommendations for healthy drinks. Culturally tailored food items were illustrated based on language selection and a link to Norwegian Diabetes Foundation provided which includes recipes and further information. • 'Diabetes information': General information about gestational diabetes. Specific information provided about each woman's follow-up in pregnancy and postpartum.	according to pregnancy stage. • Women taught how to measure and record blood glucose levels either on a sheet of paper or in a diary to be shown at consultations. • If a woman in this arm independently downloaded the app, access was restricted to a link to the Norwegian Directorate of Health with generic gestational diabetes information and a link to the Norwegian Federation of Diabetes.		kg/m^2 at baseline. All women received glucometers and lancets from the study coordinators. Glycaemic outcomes could not be reported as the study only provided these at 3 months postpartum. LGA reported as >4000g.

Study	Population	Intervention	Comparison	Outcomes	Comments
		The app also provided information about advantages of breastfeeding and a frequently asked question section as well as a small glossary.			
Brankston 2004 Randomised controlled trial (RCT) Canada	N=32 Mean age in years (SD) Intervention: 31.3 (5.0) Comparator: 30.5 (4.4) Mean gestational age in weeks [at screening] (SD) Intervention: 29.6 (2.1) Comparator: 29.0 (2.0) Mean gestational age in weeks [at intervention] (SD) Not reported Mean pre-pregnancy BMI in kg/m^2 (SD) Intervention: 28.0 (5.7) Comparator: 25.9 (3.4)	Physical activity: Progressive physical conditioning program. Three introductory sessions with supervision from an experienced instructor with weekly contact to ensure safety and adherence. Women were instructed to perform resistance training circuit-type exercises 3 times per week. The level of physical activity to reach was advised to be "somewhat hard". Women were educated on heart rate self-monitoring in order to avoid exceeding 140 beats/min during exercise and recorded each physical activity session in a log book. The intervention was in addition to standard diabetic diet*.	Standard care/control: Standard diabetic diet* and were asked not to start a structured physical activity program during pregnancy *Standard diabetic diet: 40% carbohydrate, 20% protein, 40% fat, calculated at 24 to 30 kcal/kg per day on the basis of the woman's ideal pre-pregnant body weight.	• glycaemic control: end of intervention fasting blood glucose concentration • gestational weight change • need for pharmacological intervention	Sourced from Brown 2017 Cochrane systematic review. Strata in analysis: single pregnancy. Follow-up: end of intervention (no further details) for glycaemic control, unclear for gestational weight change, otherwise not reported. Both groups performed daily fasting and 1- or 2-hour postprandial measurements home glucose monitoring with portable glucometers that had memory capabilities.
Brown 2017 Systematic review of randomised controlled trials (RCTs) From 5 RCTs in this review: Australia,	N RCTs relevant to this review=5/11; ranging from total sample size N=19 (Jovanovic-Peterson 1989) to N=194 (Bo 2014)	Any type of physical activity program (+/- standard care).	Compared with 1) standard care or 2) another intervention.	• extensive, included all of the maternal and neonatal/infant outcomes relevant for this review	5 RCTs were included from this review (Avery 1997, Bo 2014, Brankston 2004, Halse 2014 (Halse 2015), Jovanovic-Peterson 1989).

Study	Population	Intervention	Comparison	Outcomes	Comments
Canada, Italy, USA					
Carolan-Olah 2019 Randomised controlled trial (RCT) Australia	N=116 Mean age in years (SD) Not reported, but total mean age (range) 31.7 (19-43) years Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) Not reported Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD) Not reported	Mixed intervention: Web-based educational intervention with four modules relating to gestational diabetes and four information resources. The four modules covered healthy food choices, healthy habits/ lifestyle, emotions, family and food, and testing blood glucose levels and the four information resources were based on nutrition recommendations and provided information on what is gestational diabetes, healthy diet and exercise, what to do if still hungry and healthy purchases. After each section, a quiz was displayed.	Standard care: Single clinic-based educational class as part of usual care which was held for 1.5 hours by a hospital dietician and diabetes educators at the beginning of a gestational diabetes diagnosis. 5-8 women would usually attend a class covering blood glucose monitoring instructions, healthy diet information, which foods to avoid/limit as well as physical activity and healthy lifestyle.	• large for gestational age > 90 centile	Strata in analysis: single pregnancy. Follow-up: At birth. The study reported all other potentially relevant outcomes at postpartum. LGA reported as >4000g.
Christie 2022 Randomised controlled trial (RCT) Australia	N=32 Mean age in years (SD) Intervention: 35 (4) Comparator: 34 (4) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at	Physical activity: Three 10-minute rounds of continuous walking, within 60 minutes of breakfast, lunch, and dinner.	Standard care: 30 minutes of moderate intensity daily continuous physical activity, undertaken at any time as per physical activity guidelines provided in standard care.	• glycaemic control: during intervention fasting blood glucose	Strata in analysis: single pregnancy. Follow-up: at time of finishing 3 day intervention. All women: • Walking encouraged as main form of exercise with examples provided of how to integrate into daily routine. • Underwent 3 days of

Study	Population	Intervention	Comparison	Outcomes	Comments
	intervention] (SD) Not reported Mean BMI in kg/m^2 [at baseline] (SD) Not reported				baseline standard care, followed by 3 days of their allocation. • Baseline standard care involved a group education session at local health district diabetes service. This involved guideline based nutrition education (NHMRC 2013) focusing on carbohydrates and with low GI index carbohydrates (around two exchanges 15g each) for all meals and snacks; self-monitoring blood glucose and physical activity as described above for standard care. • Wore a continuous glucose monitor and inclinometer for 6 days under free-living conditions between 28-30 gestational weeks. • Recorded their meal times.
Cypryk 2007 Randomised controlled trial (RCT)	N=30 Mean age in years (SD) Not reported, but total mean (SD)	<u>Low-carbohydrate diet:</u> Daily total energy divided as carbohydrate: 45%, protein: 25%, fat: 30% (based on daily	<u>High-carbohydrate diet:</u> Daily total energy divided as carbohydrate:	• glycaemic control: end of intervention fasting blood	Sourced from Han 2017 Cochrane systematic review.

Study	Population	Intervention	Comparison	Outcomes	Comments
Poland	age 28.7 (3.7) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) Not reported Mean BMI in kg/m^2 [at baseline] (SD) Not reported	total energy of 1800 kcal) and advised by a qualified dietician. Women were encouraged to follow the diet until birth.	60%, protein: 25%, fat: 15% (based on daily total energy of 1800 kcal). Women were encouraged to follow the diet until birth.	glucose (mmol/L) • mode of birth: vaginal birth • mode of birth: caesarean • need for pharmacolo gical therapy • large for gestational age > 90 centile	Strata in analysis: single pregnancy. Follow-up: at end of intervention (no further details) for glycaemic control outcome; at birth for mode of birth and large for gestational age outcomes, otherwise not reported Gestational age in weeks at delivery (mean, SD): Low-carbohydrate diet: 38.9 (1.4); High-carbohydrate diet: 38.8 (1.2). All women: • 3-4 days prior to the intervention, blood glucose was recorded from the women's diaries to obtain average 24 hour glycaemia under normal diet conditions. • Educated by a qualified dietician. • For the first 14 days of the intervention, women were instructed to self-monitor their blood glucose at home 4 times a day (fasting and 2 hours

Study	Population	Intervention	Comparison	Outcomes	Comments
					after breakfast, lunch and dinner) and to be recorded in the home blood glucose monitoring diary. • On day 15, nutritional recommendation compliance was checked and diaries were reviewed. • Urine ketones were checked daily. LGA reported as >4000g.
Downs 2017 Randomised controlled trial (RCT) USA	N=65 Mean age in years (SD) Not reported Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) Not reported Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD) Not reported	Physical activity (face-to-face): • Initial in person consultation to explain intervention and receive study materials including education binder, schedules and parking/childcare instructions. • Face to face exercise education, motivational support/self-efficacy enhancement. • Moderate intensity exercise (for example, treadmill walking/jogging, cycle ergometer, low-impact aerobics) on 2 days/week delivered in a 70-min session (for example, 10-min warm-up, 30–40 min exercise, 10-min cooldown, 10–15 min stretching; ACOG, 2002; Padayachee &	Physical activity (home based): • Initial in person consultation to explain intervention and receive study materials including education binder, schedules and parking/childcare instructions. • Same education/motivational support/self-efficacy enhancement as the face to face group but it was delivered every 2 weeks in a 45-min phone session led by a certified	• glycaemic control: during intervention: fasting blood glucose levels • glycaemic control: end of intervention: fasting blood glucose levels • need for pharmacological intervention	Strata in analysis: single pregnancy. Follow-up: at 24 gestational weeks for glycaemic control during intervention, 36 gestational weeks for glycaemic control at end of intervention and until birth for need for pharmacological intervention.

Study	Population	Intervention	Comparison	Outcomes	Comments
		Coombes, 2015) and led by a certified fitness instructor. • Educational curriculum (mailed a week prior to call) was based on the Diabetes Prevention Program (Rubin et al., 2002) and included content on exercise as a way of life, committing to lifestyle change, eating for exercise, managing stress, and staying motivated, The TPB (Ajzen, 1991) content was developed by the first author (for example, benefits/positive attitude characteristics of exercise; sources of and strategies to improve normative/social support, perceived control, and self-regulation; overcoming barriers to exercise such as goal-setting, exercise self-monitoring, and overcoming negative self-talk; motivational tools including positive affirmations/encouraging quotes; and interactive discussions with the instructor on these topics). A registered nurse was present during sessions to monitor negative symptoms and evaluate blood glucose values (that is, women self-checked blood	fitness instructor. • Participants were encouraged to exercise on their own to meet guidelines. Standard care: Standard prenatal care from their healthcare provider which involved diet advice for gestational diabetes and encouragement to exercise based on USDHHS 2008 guidelines.		

Study	Population	Intervention	Comparison	Outcomes	Comments
		glucose before/after exercise sessions; ADA, 2011). • Above in addition to standard care.			
Durnwald 2016 Randomised controlled trial (RCT) USA	N=100 Mean age in years (SD) Intervention: 31.4 (6.3) Comparator: 32.5 (4.8) Mean gestational age in weeks [at screening] (SD) Mixed intervention: 30.8 (2.1) Standard care: 30.6 (2.4) Mean gestational age in weeks [at intervention] (SD) Not reported Mean BMI in kg/m^2 [at baseline] (SD) Not reported	Mixed intervention: Intensive behaviour education program with at least 2 nutrition counselling sessions: • The first session involved standard care nutrition counselling with added motivational messaging. • Second session provided personalized feedback after review of 1 week food diary. Healthy food choices and optimal weight gain were reinforced with focus on healthy attitudes and behaviours in pregnancy. • Women were also provided with a manual (8 pregnancy, 4 postpartum chapters) "The Healthy Gestational Diabetes Pregnancy Program" adapted from a diabetes prevention program which focused on food and inactivity behavioural modification techniques, tips for new healthy attitudes and behaviours and physical activity recommendations focused on increased walking. The manual	Standard care: One off nutrition counselling session with a nutritionist/certified diabetic educator with diet advice based on dietary guidelines consistent with the American Diabetes Association diabetic diet and healthy weight gain advice based on Institute of Medicine guidelines.	• gestational weight change (kg) • mode of birth: induction of labour • mode of birth: caesarean • elective repeat caesarean • hypertensive disorders (pre-eclampsia or gestational hypertension) • need for pharmacological intervention • large for gestational age > 90 centile • Neonatal hypoglycaemia	Strata in analysis: single pregnancy. Follow-up or gestational age at diagnosis: until birth for gestational weight change; at birth for mode of birth and large for gestational age outcomes; diagnosed before birth for hypertensive disorders;otherwise not reported for other outcomes. Glycaemic outcomes could not be reported as these were postpartum values only. LGA reported as >4000g. All women: • Underwent specialised prenatal care for diabetes within a pregnancy program led by maternal fetal medicine specialists. • Used a portable glucometer for daily self blood glucose monitoring involving fasting and 1-

Study	Population	Intervention	Comparison	Outcomes	Comments
		targeted healthy lifestyle choices, motivational messaging and further exercise and nutritional facts. Women reviewed chapters weekly with a research nurse in a 20-30 minute call. Personalised goals were formed for the following week and discussed at the start of the next call. • Received a pedometer.			h postprandial measurement s. • Weekly or biweekly office visit (based on gestational age) for review of blood glucose data by study personnel and insulin or glyburide was initiated if criteria met (see other information).
Ferrara 2011 Randomised controlled trial (RCT) USA	N=197 Age in years (n, %) Intervention: • 21-24: 3 (3.1) • 25-29: 18 (18.8) • 30+: 75 (78.1) Comparator: • 21-24: 4 (4.0) • 25-29: 21 (20.8) • 30+: 76 (75.3) Mean gestational age in weeks [at baseline] (SD) Intervention: 31.8 (5.6) Comparator: 31.0 (6.1) Mean gestational age in weeks [at intervention] (SD)	<u>Mixed intervention:</u> Diet and exercise and breastfeeding intervention (DEBI) provided by two dieticians based on Social Cognitive Theory and Transtheoretical Model. The intervention consisted of three phases - prenantal, postpartum and maintenance (6 months). The prenatal phase involved an individual face to face session (approximately 1 hr) and two individual telephone counselling sessions (each lasting mean (SD) 31.2 (17.7) min). Sessions involved: • Education on increased risk of type 2 diabetes and advised to meet the IOM guidelines. Obese women were told not to exceed a gestational weight gain of 11.4 kg as advised for	<u>Standard care:</u> Printed educational information on gestational diabetes during prenatal period and newsletters on infant safety and general health in postnatal period.	• need for pharmacolo gical intervention • large for gestational age > 90 centile	Strata in analysis: single pregnancy. Follow-up: during pregnancy after gestational diabetes diagnosis for need for pharmacological intervention and at birth for large for gestational age outcome. Other potentially relevant outcomes could not be reported as these were postpartum values only. LGA reported as infant birth weight >4000g.

Study	Population	Intervention	Comparison	Outcomes	Comments
	Not reported (soon after GDM diagnosis) Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD) Not reported	overweight women in the IOM guidelines at the time. • Advice to follow the ADA diet and moderate intensity physical activity for 150 minutes per week. • Discussion of written intervention materials about portion size, low GI or fat foods and food label literacy (during telephone counselling sessions). • Lactation consultant also provided advice towards the end of pregnancy until 6 weeks postpartum.			
Garner 1997 Randomised controlled trial (RCT) Canada	N=300 Mean age in years (SD) Intervention 30.7 (4.8) Comparator 30.7 (4.6) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) Not reported Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD) Not reported	<u>Diet (Energy-restricted diet):</u> • Dietary counselling and calorie-restricted diet of 35 kcal/kg ideal body weight per day, with emphasis on spacing of meals and snacks to limit glucose spikes. • Education on home glucose monitoring with semi-quantitative whole blood glucose reagent strips. • Those who required insulin supplementation (see other information for details) had individualised dosing and were carefully monitored. • Women were seen every two weeks for ultrasound, amniotic fluid volume, and	<u>Standard care (No energy-restricted diet):</u> • Women were asked to maintain unrestricted healthy diet for pregnancy based on the Canada Food Guide standards. • For comparison with intervention arm, women performed 2 glucose concentrations per week at home with semi-quantitative whole blood glucose reagent strips. After this, women went back to their primary	• glycaemic control: end of intervention fasting glucose • gestational weight change (kg) • mode of birth: vaginal birth • mode of birth: caesarean • need for pharmacological intervention • large for gestational age > 90 centile (reported as macrosomia, birthweight >4500g) • neonatal hypoglycaemia • neonatal mortality	Sourced from Han 2017 Cochrane systematic review. Strata in analysis: single pregnancy. Follow-up: end of intervention (no further details) for glycaemic control; at birth for mode of birth and large for gestational age outcomes; not reported for all other outcomes.

Study	Population	Intervention	Comparison	Outcomes	Comments
		cardiac size assessment.	obstetric care provider and did not return to the gestational diabetes teaching unit. • The study defined women in this arm who may have had previously undetected type 1 or 2 diabetes as 'failed control' whereby if women had persistent fasting capillary blood glucose > 7.8 mmol/L or 1-hour postprandial concentration > 11.1 mmol/L they were transferred to the treatment arm and placed on diet, insulin, and fetal monitoring.		
Grant 2011 Randomised controlled trial (RCT) Canada	N=29 Mean age in years (SD) Not reported Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational	Low-moderate GI diet: Women selected their choice of starch from a low-GI key food exchange list.	Moderate-high GI diet: Women selected their choice of starch from an intermediate- and high-GI food exchange list, which comprised the standard gestational diabetes diet	• need for pharmacological intervention • large for gestational age > 90 centile	Sourced from Han 2017 Cochrane systematic review. Strata in analysis: single pregnancy. Follow-up: Until birth for need for pharmacological intervention; at birth for large for

Study	Population	Intervention	Comparison	Outcomes	Comments
	age in weeks [at intervention] (SD) Not reported Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD) Not reported		for clinic patients.		gestational age outcome. All women: • Standard medical nutrition therapy: Education on Diabetes Food Guide and Canadian dietary recommendations; dietician recommendation of starch choices/servings intake based on individual gestational energy requirements and Acceptable Macronutrient Distribution Ranges. • Received about $20 per week worth of non-perishable study foods and all blood testing strips. • Performed blood glucose self-monitoring 4 times a day from baseline to week 8 (fasting, 2 hours after breakfast, lunch and dinner). • If lifestyle modification was not made within 2-3 weeks, insulin therapy was initiated. Of excluded women: 3 advised against

Study	Population	Intervention	Comparison	Outcomes	Comments
					exercising due to gestational hypertension; 1 dropped out due to pre-eclampsia (arm not reported). Study reports data for women with impaired glucose tolerance and gestational diabetes. Extraction and analysis based on data for women. diagnosed with gestational diabetes. Data for the gestational diabetes population is taken from Han 2017 as this was based on author correspondence.
Halse 2014, Halse 2015 Randomised controlled trial (RCT) Australia	N=40 Mean age in years (SD) Intervention: 34 (5) Comparator: 32 (3) Mean gestational age in weeks [at screening] (SD) Intervention: 28.8 (0.8) Comparator: 28.8 (1.0) Mean gestational age in weeks [at intervention] (SD)	<u>Physical activity:</u> Home-based exercise program with 5 sessions per week until week 34 of gestation. 3 sessions were supervised by an exercise physiologist and was on an upright stationary cycle ergometer (provided to participants) and on alternate days 2 sessions were not supervised with instruction to perform moderate-intensity aerobic activity of their choosing and record exercise via diary and ratings of perceived exertion scale. Sessions were 25-30 minutes	<u>Standard care:</u> Conventional management of gestational diabetes* and maintained usual physical activity for the period of the intervention. *Conventional management involved an assessment of glycaemic control and counselling by a diabetes educator and dietician.	• glycaemic control: end of intervention HbA1c (%) • gestational weight change (kg) • mode of birth: vaginal birth • mode of birth: induction of labour • mode of birth: caesarean • need for pharmacolo gical intervention	Sourced from Brown 2017 Cochrane systematic review. Strata in analysis: single pregnancy. Follow-up: end of intervention (no further details) for glycaemic control, until mean (SD) 34.6 (0.3) gestational weeks for gestational weight change, at birth for mode of birth outcomes; otherwise not reported.

Study	Population	Intervention	Comparison	Outcomes	Comments
	Intervention: 28.8 (0.8) Comparator: 28.8 (1.0) Mean BMI in kg/m^2 [at baseline] (SD) Intervention: 32.2 (5.9) Comparator: 30.0 (5.1)	in week 1, increasing to 40-45 minutes by week 4. The supervised sessions involved steady state and interval cycling with conditioning ranging from low to moderate intensity cycling and resistance added if needed. There were also brief bouts of vigorous intensity exercise. Intervention was in addition to conventional management* of gestational diabetes.			For all women glucose levels were self-monitored at home via personal glucometers with daily fasting and 120 minutes postprandial glucose levels after breakfast, lunch and dinner which were recorded. Food and drink diaries were provided to participants for the first and last 7 days of the intervention.
Han 2017 Systematic review of randomised controlled trials (RCTs) From 12 RCTs in this review: Australia, Canada, Denmark, Italy, Poland, Spain, USA	Number of RCTs relevant to this review=12/19 ranging from total sample size N=12 (Magee 1990) to N=300 (Garner 1997)	Any type of dietary advice for women with gestational diabetes	Compared with one or more arm including 1) Another type of dietary advice intervention; 2) another form of same type of diet advice 3) different intensity of diet intervention	• extensive, included all of the maternal and neonatal/infant outcomes relevant for this review	12 RCTs across 13 studies were included from this review (Bo 2014, Cypryk 2007, Garner 1997, Grant 2011, Lauszus 2001, Louie 2011, Magee 1990, Moreno-Castilla 2013, Moses 2009, Rae 2000, Reece 1995, Valentini 2012).
Hedderson 2018 Cluster randomised controlled trial (RCT) USA	N cluster=44 N adjusted= 1178 Mean age in years (SD) Not reported Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational	<u>Mixed intervention:</u> Tailored letter • Women received a letter with six tailored messages: 1) weight history information (pre-pregnancy weight/BMI and weight at diagnosis); 2) recommendation for total gestational weight change (GWC) specific to pre-pregnancy BMI (corresponding to	<u>Standard care:</u> In addition to care from their GP, all women with gestational diabetes at the Kaiser Permanente Northern California corresponded with a nurse via telephone from the Regional Perinatal	• gestational weight change - met/achieved IOM guidelines (%) • mode of birth: caesarean • large for gestational age > 90 centile	Strata in analysis: single pregnancy. Follow-up: Until birth for gestational weight change outcome and at birth for mode of birth and large for gestational age outcomes. N mixed (adjusted)=564; N standard care

Study	Population	Intervention	Comparison	Outcomes	Comments
	age in weeks [at intervention] (SD) Not reported Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD) Not reported	the lower limit of the Institute of Medicine range except for those underweight, then not above the midpoint); 3) a corresponding end-of-pregnancy weight goal tailored to pre-pregnancy BMI (4) recommendation for weight management based on gestational weight trajectory; 5) lifestyle advice to meet end-of-pregnancy weight goals; and 6) information on impact of GWC on pregnancy and postpartum health. • Message components 3) to 6) were tailored to the woman's gestational weight trajectory based on end of pregnancy weight goal and divided into categories: gaining too slowly, on track, gaining too quickly and exceeded • All letters included lifestyle advice (for example, ,choose produce, lean protein, low- or non fat dairy, replace sugar-sweetened beverages with water, 30-min daily brisk walks unless advised otherwise) as well as a risk statement (excessive weight gain during a gestational diabetes pregnancy increases risks for	Service Center to facilitate glycaemic control. Women received via mail health education materials from the Perinatal Center just after diagnosis and then 1-2 calls each week to review self-monitored glucose data and receive advice on nutrition and physical activity. Nurses were contactable by phone 7 days a week and dieticians 5 days a week. Health education materials and calls did not cover gestational weight gain content.		(adjusted)=614 Cluster per arm =22. This study did not report glycaemic outcomes.

Study	Population	Intervention	Comparison	Outcomes	Comments
		poor glucose control during pregnancy and postpartum weight retention). • Letters were at eighth grade reading level and sent in English or Spanish whichever preferred. • In addition to standard care.			
Jovanovic-Peterson 1989 Randomised controlled trial (RCT) USA	N=19 Mean age in years (SD) Intervention: 29.5 (2.5) Comparator: 31.1 (2.8) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) Not reported Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD) Not reported	Physical activity: Supervised aerobic physical activity using an arm ergometer for 20 minutes, 3 times a week for 6 weeks. Intervention was in addition to standard care gestational diabetes diet*. For physical activity, the target heart rate was (220-age in years) x 70% unless > 140 bpm after which the target was 140 bpm. The physical exercise session never went over 50% maximal oxygen consumption.	Standard care/control: Standard care diet* divided into 3 meals and 3 snacks without any structured exercise program for 6 weeks. *Standard gestational diabetes diet: 24-30 kcal/kg/24 hours; 20% protein, 40% carbohydrate, 40% fat	• glycaemic control: end of intervention fasting blood glucose • pre-eclampsia • need for pharmacological therapy • large for gestational age > 90 centile • neonatal morbidity • neonatal mortality and morbidity composite	Sourced from Brown 2017 Cochrane systematic review. Strata in analysis: single pregnancy. Follow-up or gestational age at diagnosis: glycaemic control at end of intervention (no further details); at birth for large for gestational age; before birth for pre-eclampsia; otherwise not reported for other outcomes. All women performed glucose self-monitoring 4 times per day (before breakfast and 1 hour postprandial). LGA reported as >4500g.
Lauszus 2001	N=27	High unsaturated fat diet:	Low unsaturated fat diet:	• glycaemic control: during	Sourced from Han 2017 Cochrane

Study	Population	Intervention	Comparison	Outcomes	Comments
Randomised controlled trial (RCT) Denmark	Mean age in years (SD) High unsaturated fat diet: 31 (1.0) Low unsaturated fat diet: 29 (1.0) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) Not reported Mean BMI in kg/m^2 [at baseline] (SD) High unsaturated fat diet: 35.3 (2.4) Low unsaturated fat diet: 32.2 (1.5)	• High-monounsaturated fat diet from 34 gestational weeks. • Primary source of monounsaturated fatty acid was a hybrid sunflower oil with a high content of oleic acid (80%) and provided to the women. • Snacks were given as almonds and hazelnuts.	• High-carbohydrate diet from 34 gestational weeks. Bread, potato and rice enriched the diet.	intervention (38 week) fasting blood glucose • gestational weight change (kg) • mode of birth: caesarean • preeclampsia • hypertensive disorders (gestational hypertension) • need for pharmacological intervention • large for gestational age > 90 centile	systematic review. Strata in analysis: single pregnancy. Follow-up or gestational age at diagnosis: at 38 gestational weeks for glycaemic control and gestational weight change; at birth for mode of birth outcome and large for gestational age; diagnosed before birth for hypertensive disorders otherwise unclear for other outcomes. All women: • All women were asked to consume a high-carbohydrate diet from gestational diabetes diagnosis until the 34th gestational week. • Apart from diet, women continued their normal eating pattern and activities of daily living. • Women visited the dietitian weekly and weighed with diet reviewed and energy intake adjustments if body weight differed by

Study	Population	Intervention	Comparison	Outcomes	Comments
					>500 g from the planned weight. • Intravenous glucose tolerance test undertaken at baseline, 33rd, 36th and 38th gestational weeks with blood samples for measurements of plasma glucose and insulin concentrations taken at time 0, 2, 3, 4, 5, 6, 8, 10, 14, 19, 30, 40, 60, 90, 120 and 180 min. LGA reported as >4500g. Partially industry funded.
Louie 2011 Randomised controlled trial (RCT) Australia	N=99 Mean age in years (SD) Intervention: 34.0 (4.1) Comparator: 32.4 (4.5) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) Intervention: 29.0 (4.0) Comparator: 29.7 (3.5)	Low-GI diet: Diet glycaemic index target of ≤ 50 with all other nutrients identical to the comparator group.	High-fibre moderate-GI diet: Diet glycaemic index target of about 60 which was similar to the Australian population average glycaemic index.	• glycaemic control: end of intervention blood glucose • gestational weight change kg) • gestational weight change - Met/achieved IOM guidelines (%) • mode of birth: caesarean • need for pharmacological therapy • large for gestational age > 90 centile	Sourced from Han 2017 Cochrane systematic review. Strata in analysis: single pregnancy. Follow-up: end of intervention (no further detail) for glycaemic control outcome, until last weight recorded before birth for gestational weight change, at birth (mean 39 gestational weeks) for caesarean (emergency) and large for gestational age

Study	Population	Intervention	Comparison	Outcomes	Comments
	Mean BMI in kg/m² [at baseline] (SD) Not reported				outcomes, or 36-37 gestational weeks for need for pharmacological therapy outcome. All women: • Had similar healthy diets consisting of protein (15%-25% total daily energy intake), fat (25%-30% total daily energy intake), and carbohydrate (40%-5% total daily energy intake). • Recorded food 3-day food intake for 2 weekdays and 1 weekend day at baseline and 36-37 gestational weeks. • Were provided 2 booklets on food models to help with estimation of portion sizes. • At least 3 face-to-face visits with the study dietician, coinciding with antenatal. appointments. • Food sample baskets provided with primary foods for the allocated diet. • Received routine gestational

Study	Population	Intervention	Comparison	Outcomes	Comments
					diabetes care including instructions to self-monitor blood glucose before breakfast and 1 h after meals. The treating endocrinologist reviewed women every 2–4 weeks prior to 36 weeks and then every week until birth. • Blood samples taken at baseline and around 36 gestational weeks. Emergency caesarean only reported.
Magee 1990 Randomised controlled trial (RCT) USA	N=12 Mean age in years (SD) Intervention: 30 (4) Comparator: 36 (5) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) Intervention: 31 (7) Comparator: 30 (3)	<u>Diet (energy-restricted diet):</u> Energy-restricted diet of 1200 kcal/day with serving size reduction of the first week diet without changes to any other aspects of the diet.	<u>Standard care: (no energy-restricted diet):</u> Remained on the standard diet that was started in the first week which was about 2400 kcal/day.	• glycaemic control: end of intervention fasting blood glucose	Sourced from Han 2017 Cochrane systematic review. Strata in analysis: single pregnancy. Follow-up: At end of 2-week hospital stay. Women were hospitalised for 2 weeks, all receiving the same standard care diet during the first week and started their allocated diet during the 2nd week. During the first week:

Study	Population	Intervention	Comparison	Outcomes	Comments
	Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD) Not reported				• 25% total energy for breakfast, lunch and dinner; 12.5% total energy for afternoon tea and supper consisting of 50% carbohydrate, 30% fat, 20% protein, with 11 g of total dietary fibre per 500 kcal. Inclusion criteria was obese women
Mendelson 2008 Randomised controlled trial (RCT) USA	N=100 Mean age in years (SD) Intervention: 30.6 (5.6) Comparator: 31.5 (5.2) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) Not reported Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD) Not reported	<u>Mixed intervention group:</u> A Parish nurse intervention program with enhanced education and support delivered by nurses fluent in Spanish. A supplemental 1-hour discussion led by Parish nurses on: • Medical recommendations to control gestational diabetes and addressing participant concerns or misunderstanding. • Spiritual principles such as encouragement of prayer and spiritual connection within the participant's belief system. • Education addressing diabetes mechanisms, types and risk factors; how to control diabetes with diet, exercise and medical treatment as well	<u>Standard care:</u> Standard education program on diet, exercise, blood glucose testing as well as insulin administration if needed in one on one 1-hour sessions delivered through handouts, demonstration and discussion.	• glycaemic control: end of intervention fasting glucose • large for gestational age > 90 centile (reported as macrosomia, no further information)	Strata in analysis: single pregnancy. Follow-up: End of intervention (no further details) for glycaemic control outcome and at birth for large for gestational age. Mean (SD) gestational age in weeks at screening was 28.7 (7.6) for total sample.

Study	Population	Intervention	Comparison	Outcomes	Comments
		as nutrition therapy (food groups and measurements).			
Mijatovic 2020 Randomised controlled trial (RCT) Australia	N=46 Mean age in years (SD) Low-carbohydrate diet: 32.5 (0.9) High-carbohydrate diet: 34.2 (0.9) Mean gestational age in weeks [at screening] (SD) Low-carbohydrate diet: 28.4 (0.5) High-carbohydrate diet: 28.6 (0.6) Mean gestational age in weeks [at intervention] (SD) Not reported Mean BMI in kg/m^2 [at baseline] (SD) Not reported, but mean (SD) pre-pregnancy BMI kg/m^2: Low-carbohydrate diet: 25.8 (1.0); High-carbohydrate diet 27.8 (1.5)	Low-carbohydrate diet: Absolute carbohydrate target of 135 g/d without energy restriction, based on the estimated average requirement for carbohydrate intake during pregnancy.	High-carbohydrate diet: Absolute carbohydrate target of 180–200 g/d.	• glycaemic control: end of intervention fasting blood glucose • gestational weight change kg) • gestational weight change - met/achieved IOM guidelines (%) • mode of birth: vaginal birth • mode of birth: induction of labour • mode of birth: caesarean • need for pharmacological therapy • large for gestational age > 90 centile	Strata in analysis: single pregnancy. Follow-up: at end of intervention (no further detail) for glycaemic control, at last weight before birth (no further details) for gestational weight change outcomes; at birth for mode of birth and large for gestational age outcomes or until birth for need for pharmacological therapy outcome (Mean (SD) gestational age: Low-carbohydrate diet: 38.7 ± 0.2; High-carbohydrate diet: 38.6 ± 0.2). All women: • Were provided a pictorial booklet displaying carbohydrate content, target portion number, and glycaemic index. • Women who had lower carbohydrate consumption at baseline were encouraged to at more high-fibre, low-GI foods, and this particularly applied to

Study	Population	Intervention	Comparison	Outcomes	Comments
					those allocated to the high carbohydrate diet. • Blood glucose monitoring was part of standard care with 4 finger prick tests per day, the first in the morning following an overnight fast, and remainder at 1-or 2-h after each of the 3 main meals • Study visits every 2 weeks at same time as antenatal appointment. • At baseline and end of 6 week intervention, women recorded three 24-hour food diary entries (including 2 weekdays and 1 weekend day) and a 2 day blood ketone diary. Trial name: MAMI 1 (Macronutrient Adjustments in Mothers with gestational diabetes study 1).
Moreno-Castilla 2013 Randomised controlled trial (RCT) Spain	N=150 Mean age in years (SD) Intervention: 33.5 (3.7) Comparator: 32.1 (4.4)	<u>Low-carbohydrate diet:</u> Diet consisting of carbohydrate with 40% of total daily calorie amount; fat with 40% of total daily calorie amount and mainly by higher olive oil consumption;	<u>High-carbohydrate diet:</u> Diet consisting of carbohydrate with 55% of total daily calorie amount; Fat with 25% of	• gestational weight change kg) • mode of birth: caesarean • gestational hypertension	Sourced from Han 2017 Cochrane systematic review. Strata in analysis: single pregnancy.

Study	Population	Intervention	Comparison	Outcomes	Comments
	Mean gestational age in weeks [at screening] (SD) Intervention: 30.4 (3.0) Comparator: 30.1 (3.5) Mean gestational age in weeks [at intervention] (SD) Not reported Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD) Not reported	Protein with 20% of total daily calorie amount.	total daily calorie amount; protein with 20% of total daily calorie amount.	• need for pharmacological intervention • large for gestational age > 90 centile • neonatal hypoglycaemia • neonatal mortality	Follow-up or gestational age at diagnosis: to last recorded predelivery weight within 4 weeks preceding delivery from medical records birth for gestational weight change, unclear for need for pharmacological intervention; until birth forgestational hypertension; otherwise at birth for all other outcomes (Gestational age mean (SD): low-carbohydrate diet 39.0 (2.1); high-carbohydrate diet 38.9 (1.8)). This study did not report glycaemic outcomes. All women: Calculation of the energy content for each woman's diet was based on pre-gestational weight with a minimum of 1800 kcal/day.
Moses 2009 Randomised controlled trial (RCT) Australia	N=63 Mean age in years (SEM) Intervention: 30.8 (0.7) Comparator: 31.3 (0.8) Mean gestational age in weeks	<u>Low-moderate GI diet:</u> Diet based on previously verified low–GI food, including pasta, grain breads, and unprocessed breakfast cereals with a high-fibre content. Women were told to avoid white bread,	<u>Moderate-high GI diet:</u> Diet with a high-fibre and low-sugar content and no specific advice around GI index. Advised to eat potatoes, whole wheat bread, and	• mode of birth: caesarean • mode of birth: vaginal birth • mode of birth: induction of labour • need for pharmacolo	Sourced from Han 2017 Cochrane systematic review. Strata in analysis: single pregnancy Follow-up: at birth (35-37

Study	Population	Intervention	Comparison	Outcomes	Comments
	[at screening] (SEM) Intervention: 30.3 (0.2) Comparator: 29.9 (0.2) Mean gestational age in weeks [at intervention] (SD) Not reported Mean BMI in kg/m^2 [at baseline] (SD) Intervention: 32.0 (1.2) Comparator: 32.8 (1.4)	processed commercial breakfast cereals, potatoes, and some rice types.	specific high-fibre, moderate-to-high GI breakfast cereals.	gical intervention • large for gestational age > 90 centile	gestational weeks) for all outcomes. All women: • Given a home glucose meter and instructed to measure after fasting and 1 hour after beginning each of their 3 major meals at least every second day. • Had a minimum of 4 diabetes centre visits with a dietitian providing dietary assessment; if insulin was required, visited as necessary for adjustments. • Given a booklet explaining carbohydrate choices and the amount of carbohydrate food in 1 serving (based on 15 g portions). • Were advised to have 3 small meals and 2-3 snacks with a specified number of carbohydrate servings. This study only reported glycaemic index outcomes. 9/19 women in the high–

Study	Population	Intervention	Comparison	Outcomes	Comments
					glycaemic index group who met the treatment target criteria and then started the low GI diet no longer met the criteria for insulin initiation.
Rae 2000 Randomised controlled trial (RCT) Australia	N=125 Mean age in years (SD) Intervention: 30.2 (NR) Comparator: 30.6 (NR) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) Not reported Mean BMI in kg/m^2 [at baseline] (SD) Not reported, at diagnosis reported for intervention: 37.9 (0.7); comparator: 38.0 (0.7)	Energy-restricted diet: Diabetic diet of 6800-7600 kJ energy per day and represented 70% of the Recommended Dietary Intake for pregnant women (30% energy restriction).	No energy-restricted diet: Diabetic diet without energy restriction of 8600-9500 kJ energy per day.	• glycaemic control: during/at end of intervention fasting glucose • gestational weight change (kg) • mode of birth: vaginal birth • mode of birth: induction of labour • mode of birth: caesarean • preeclampsia • need for pharmacological intervention • large for gestational age > 90 centile	Sourced from Han 2017 Cochrane systematic review. Strata in analysis: single pregnancy (note study includes 7 sets of twins 3 sets in the energy-restricted diet group and 4 sets in the no energy-restricted diet group but outcomes were not reported separately for these women). Follow-up or gestational age at diagnosis: during/at end of intervention (no further details) for fasting glucose, until birth for gestational weight change, at birth for mode of birth outcomes; before birth for pre-eclampsia outcome need for pharmacological intervention neonatal mortality and unclear for neonatal hypoglycaemia, and large for

Study	Population	Intervention	Comparison	Outcomes	Comments
					gestational age outcomes. All women: • Research dietitian gave diabetes education at each antenatal visit. • Hyperglycaemia control, blood glucose capillary self-monitoring: pre- and 2 hours post every meal 6 times daily, for a minimum of 2 days per week. • Medical staff judged insulin initiation (see criteria in other information). • Metabolic monitoring for HbA1c, serum beta-hydroxybutyrate, urinary ketone. • 3-day food intake diaries to assess diet adherence.
Reece 1995 Randomised controlled trial (RCT) USA	N=22 Mean age in years (SD) Not reported Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at	<u>Diet (high-fibre diet):</u> Diet of 80 g fibre per day with fat comprising 20% daily energy intake, and carbohydrate comprising 60% of daily energy intake.	<u>Standard care (standard-fibre diet)</u>: American Diabetes Association (ADA) diet comprising 20 g fibre per day; with fat comprising 30% daily energy intake and carbohydrate comprising 50% of daily energy intake.	• gestational weight change (kg) • glycaemic control during/at end of intervention: mean blood glucose (mmol/L • need for pharmacological intervention	Sourced from Han 2017 Cochrane systematic review. Strata in analysis: single pregnancy Follow-up: unclear for all outcomes. All women: Self-monitoring of capillary blood glucose 6 times

Study	Population	Intervention	Comparison	Outcomes	Comments
	intervention] (SD) Not reported Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD) Not reported				a day (before and after each meal), two times a week with women asked to record these as much as possible.
Sklempe Kokic 2018 Randomised controlled trial (RCT) Croatia	N=42 Mean age in years (SD) Intervention: 32.78 (3.83) Comparator: 31.95 (4.91) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) Not reported Mean BMI in kg/m^2 [at baseline] (SD) Not reported, but pre-pregnancy BMI in (kg/m^2; mean SD): Intervention: 24.39 (4.89); Comparator 25.29 (4.65)	Physical activity: • Supervised moderate aerobic and resistance physical activity program held two times a week for 50-55 minutes. The program was which was structured and personalised. The aerobic component was performed on a treadmill with heart rate monitoring (target heart rate within aerobic zone of 65–75% of maximum heart rate). The program continued throughout pregnancy with minimum duration of 6 weeks. • Also asked to undertake 30 minutes of brisk walking per day and record this activity in a diary. • In addition to standard care.	Standard care: Standard prenatal care for gestational diabetes and allowed to carry out their own exercise.	• glycaemic control: end of intervention fasting blood glucose • mode of birth: induction of labour • mode of birth: caesarean • need for pharmacological therapy • neonatal hypoglycaemia	Strata in analysis: single pregnancy. Follow-up: end of intervention (no further detail) for glycaemic control; at birth for mode of birth outcomes; after birth for neonatal hypoglycaemia, and unclear for need for pharmacological therapy. All women: • Consumed recommended diet for gestational diabetes: 1800 kcal per day with 20% proteins (90 g), 30% fat (60 g) and 50% carbohydrates (225 g) over three main meals and three snacks.
Trout 2016 Randomised controlled trial (RCT) USA	N=68 Mean age in years (SD) Baseline values not reported; at	Low-carbohydrate diet: • Women were placed on a lower-carbohydrate diet of 35–40% of total calories.	High-carbohydrate diet: • Women followed the usual pregnancy	• glycaemic control: end of intervention fasting blood glucose	Strata in analysis: single pregnancy. Follow-up: at end of intervention (no

Study	Population	Intervention	Comparison	Outcomes	Comments
	birth reported: Low-carbohydrate diet: 30.09 (6.15) High-carbohydrate diet: 29.63 (5.19) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) "At study entry" Low-carbohydrate diet: 29.17 (2.78) High-carbohydrate diet: 30.50 (2.85) Mean BMI in kg/m^2 [at baseline] (SD) Timepoint of measurement undefined: Low-carbohydrate diet: 33.84 (8.84) High-carbohydrate diet: 31.80 (8.68)		diet of 50–55% carbohydrates.	• gestational weight change kg) • mode of birth: Induction of labour • mode of birth: caesarean • need for pharmacological intervention • large for gestational age > 90 centile • neonatal hypoglycaemia • neonatal mortality and morbidity	further detail) for glycaemic control, until birth for gestational weight change (Mean (SD) gestational weeks at delivery: Low-carbohydrate diet 37.78 (1.66); High-carbohydrate diet: 37.76 (1.74)), at birth for mode of birth and large for gestational age outcomes; otherwise not reported. All women: • Received standard care by their obstetric provider. • Diabetes education self-management training by a certified diabetes educator (CDE) and training on carbohydrate gram counting by CDE or research team. Women practiced weighing/measuring foods and carbohydrate content calculations via pocket sized book provided. • After CDE consultation, total maximum daily carbohydrate gram count in

Study	Population	Intervention	Comparison	Outcomes	Comments
					relation to total daily caloric intake was tailored. • Were provided instructional sheet with written examples of healthy foods and sample food menu plans. • Encouraged to distribute the total carbohydrate allocation over 3 meals and snacks per day. • Taught how to use a portable self-monitoring blood glucometer and asked to perform self-monitoring of blood glucose 4 times a day (fasting and 2 hours after meals). • Self-monitored urine ketones every morning, checked by staff at prenatal visits. • Were asked to bring their blood glucose and food logs or meter records to their prenatal care. Appointments to discuss with their CDE, perinatal nurses, or providers. • Were clinically evaluated every 2 weeks until 36 weeks'

Study	Population	Intervention	Comparison	Outcomes	Comments
					gestation, and then weekly. LGA reported as ≥4000g.
Valentini 2012 Randomised controlled trial (RCT) Italy	N=20 Mean age in years (SD) Intervention: 28.9 (3.3) Comparator: 30.2 (4.7) Mean gestational age in weeks [at screening] (SD) Not reported Mean gestational age in weeks [at intervention] (SD) Not reported Mean BMI in kg/m^2 [at baseline] (SD) Not reported	Diet (ethnic-specific diet) • Photographic atlas was used to prescribe a diet including common foods from the women's home countries. • Dishes broken down into the ingredient components, displayed as raw and cooked with measures such as cups, or spoonfuls handfuls or pinches preferred over kitchen scales. • Food pyramids of the home country were employed.	Standard care (standard healthy diet): • Meal plan based on the American diabetes associations (ADA) guidelines for gestational diabetes.	• gestational weight change kg) • mode of birth: caesarean • gestational hypertension • need for pharmacological intervention • large for gestational age > 90 centile • neonatal hypoglycaemia • neonatal morbidity	Sourced from Han 2017 Cochrane systematic review. Strata in analysis: single pregnancy Follow-up: until birth or otherwise at birth for mode of birth and large for gestational age outcomes. All women: • Both diets had the same nutrient components: ethnic-specific diet comprising carbohydrate: 55%, fat: 28%, protein: 17%, fibre: 21 g and standard care diet comprising carbohydrate: 53%, fat: 28%, protein: 18%, fibre: 26 g; and energy intake was from 1800 to 2200 Kcal, depending on pre-pregnancy BMI. • Prior to meal plan creation, women underwent a dietary assessment to assess essential nutrient intake

Study	Population	Intervention	Comparison	Outcomes	Comments
					adequacy, excessive eating, identify avoided foods and allergies/intolerances. • Taught about target serving sizes via food models, using measures in cups, glasses, and bowls. • Nurses taught women how to self-monitor blood glucose levels with targets of fasting plasma glucose < 5.3 mmol/ L and 1-h postprandial plasma glucose < 7.2 mmol/L. Those on diet without initiated insulin therapy undertook 2 measurements per day (fasting and 1-h postprandial glucose on alternate meals over the course of a week) and those on diet with insulin therapy initiated undertook 4 measurements per day (fasting and 1 h after breakfast, lunch, and dinner). • Women saw a specialist every 2 weeks.

Study	Population	Intervention	Comparison	Outcomes	Comments
					This study did not report glycaemic outcomes. Neonatal morbidity composite outcome includes hypoglycaemia, neonatal asphyxia, respiratory distress syndrome, and hyperbilirubinemia, hypocalcaemia.
Yew 2021 Randomised controlled trial (RCT) Singapore	N=340 Mean age in years (SD) Intervention: 31.7 (4.0) Comparator: 32.2 (4.4) Mean gestational age in weeks [at screening] (SD) Intervention: 27.0 (3.2) Comparator: 26.7 (3.7) Mean gestational age in weeks [at intervention] (SD) Not reported Mean BMI in kg/m^2 [at baseline] (SD) Not reported	<u>Mixed intervention:</u> Web/Smartphone-Based Lifestyle coaching program: • Habits-GDM app developed by endocrinologists, obstetricians, diabetes educators, and dietitians. • Women provided Bluetooth weighing scale linked to the app with weight by time graph displayed on app and app based prompts for weighing which increased to daily if exceeded optimal gestational weight change range. • App based on the Health Belief Model and focused on behaviour change for target weight and glycemia with education, monitoring, immediate feedback, and cues. • 12 interactive self-paced lessons on:	<u>Standard care:</u> • 1–2 weeks after diagnoses, women attended a 1-1.5 hour face-to-face group education session (4-6 women) run by a diabetes nurse educator and dietitian. Women with a 2 hour OGTT plasma glucose of ≥11.1 mmol/L had a 1 hour long individual session. • Sessions covered gestational diabetes pathophysiology and complications, healthy diet, carbohydrat	• glycaemic control: end of intervention: mean blood glucose levels • gestational weight change kg) • mode of birth: vaginal birth • mode of birth: caesarean • need for pharmacological intervention • large for gestational age > 90 centile • neonatal hypoglycaemia • neonatal mortality and morbidity	Strata in analysis: single pregnancy. Follow-up: end of intervention (no further detail) for glycaemic control, until birth for gestational weight change and need for pharmacological intervention, at birth for mode of birth outcomes, large for gestational age and neonatal mortality and morbidity (Mean (SD) gestational age in weeks: Intervention: 38.5 (1.9); Comparator: 38.7 (1.1)), or within 24 hours of birth for neonatal hypoglycaemia. All women: • Received usual care at the National

Study	Population	Intervention	Comparison	Outcomes	Comments
		diet, self monitoring of blood glucose, physical activity and weight tracking tools in addition to ability to message healthcare professionals. • Lesson content was similar to standard care education with the addition of gestational weight gain and greater detail in diet and physical activity advice. • App includes database of common foods in Singapore with total calories and carbohydrates displayed. • Self-monitored blood glucose readings automatically uploaded to the app from portable glucometer with prompts to perform 7-point capillary glucose profile on any 2 days of the week (increased to daily if on insulin) and weekly reports generated and reviewed by their health care teams as in standard care. • Automated messages prompting recording of diet in preceding 2-4 hours when 2-h postmeal glucose readings were >6.6 mmol/L.	e exchange, and future diabetes risk but not gestational weight change. • Blood glucose self monitoring by glucometer 7 times a day for 2-3 weeks (if insulin began, increased to 7 times daily). • Glucose readings were recorded in a paper diary. • Remaining care was provided by obstetricians. • 2-4 clinic visits weekly until 32 gestational weeks, then 2 weekly until 36 gestational weeks and weekly until birth. Frequency could be increased based on individual circumstances.		University Hospital. • If 2 hour plasma glucose on OGTT ≥11.1 mmol/L or insulin >20 units/day were referred to endocrinology services. • Additional advice on diet and lifestyle modification and initiation of insulin and/or metformin was individualized based on self monitoring blood glucose values. LGA reported as >4000g. Neonatal mortality and morbidity composite comprising: birth trauma (shoulder dystocia and soft tissue, bone, nerve, and intra-abdominal injuries), neonatal hypoglycaemia, hyperbilirubinemia (according to diagnosis by attending paediatricians), respiratory distress, neonatal intensive care unit admission within 24 hours of birth, and perinatal death.

App: application; ACOG: American College of Obstetricians and Gynecologists; ADA: American diabetes association; BMI: body mass index; bpm: beats per minute; CDE: certified diabetes educator; d: day; g: grams; GDM: gestational diabetes mellitus; GI: glycaemic index; GP: general practitioner; GWC: gestational weight change; h: hour; HbA1c: haemoglobin A1C; IOM: Institute of Medicine; kcal: kilocalories; kJ: kilojoules; kg: kilograms; LGA: large for gestational age; m: metres; mmol/L: millimoles per litre; min: minutes; N: number of participants; NHMRC: National Health and Medical Research Council; NR: not reported; OGTT: oral glucose tolerance test; PA: physical activity; RCT: randomised controlled trial; SD: Standard deviation; SEM: standard error measurement; TPB: Theory of planned behaviour; USA: United States of America; USDHHS: United States Department of Health and Human Services

See the full evidence tables in appendix D and the forest plots in appendix E.

Summary of the evidence

Comparison 1: Diet vs standard care for women with gestational diabetes in single pregnancy

Five studies were included under this comparison.

Evidence for diet vs standard care for single pregnancy showed that there was an important difference between diet and standard care for the outcome of need for pharmacological intervention, favouring standard care. There was no important difference between diet and standard care for glycaemic control: end of intervention fasting blood glucose, gestational weight change and vaginal birth and no evidence of important differences between diet and standard care for glycaemic control: during/at end of intervention fasting blood glucose, glycaemic control: end of intervention mean blood glucose, induction of labour, caesarean birth, pre-eclampsia, gestational hypertension, large for gestational age, neonatal hypoglycaemia, neonatal mortality or neonatal morbidity.

The evidence ranged from moderate to very low quality.

Comparison 2: High unsaturated fat diet vs low unsaturated fat diet with matching calories for women with gestational diabetes in single pregnancy

One study was included under this comparison.

Evidence for high unsaturated fat diet vs low unsaturated fat diet with matching calories for single pregnancy showed that there was important benefit for low unsaturated fat diet compared to high unsaturated fat diet with matching calories for the outcomes of glycaemic control: during intervention fasting blood glucose and gestational weight change. There was no evidence of important differences between high unsaturated fat diet and low unsaturated fat diet with matching calories for the outcomes of caesarean birth, pre-eclampsia, gestational hypertension, need for pharmacological intervention and large for gestational age.

The evidence ranged from moderate to very low quality.

Comparison 3: Low or low-moderate-glycaemic index (GI) diet vs moderate-GI with or without high fibre diet for women with gestational diabetes in single pregnancy

Three studies were included under this comparison.

Evidence for low or low-moderate-GI diet vs moderate-GI with or without high fibre diet for single pregnancy showed that there was no evidence of important differences between low or low-moderate-GI diet and moderate-GI with or without high fibre diet for the outcomes of glycaemic control: end of intervention blood glucose, gestational weight change, caesarean birth, vaginal birth, induction of labour, need for pharmacological intervention and large for gestational age.

The evidence ranged from low to very low quality.

Comparison 4: Low-carbohydrate diet vs high-carbohydrate diet for women with gestational diabetes in single pregnancy

Four studies were included under this comparison.

Evidence for low-carbohydrate diet vs high-carbohydrate diet for single pregnancy showed that there was no evidence of important differences between low-carbohydrate diet and high-carbohydrate diet for the outcomes of glycaemic control: end of intervention fasting blood glucose, gestational weight change, vaginal birth, induction of labour, caesarean birth, gestational hypertension, need for pharmacological intervention, large for gestational age, neonatal hypoglycaemia, neonatal mortality or neonatal morbidity composite and neonatal mortality.

The evidence was of very low quality.

Comparison 5: Physical activity vs standard care/control for women with gestational diabetes in single pregnancy

Eight studies were included under this comparison.

Evidence for physical activity vs standard care/control for single pregnancy showed that there was important benefit for physical activity compared to standard care/control for the outcomes of glycaemic control: fasting blood glucose at the end of the intervention. There were no important differences between physical activity and standard care/control for the outcome of gestational weight gain and no evidence of important differences for the outcomes of glycaemic control: during intervention fasting blood glucose, glycaemic control: haemoglobin A1C (HbA1c) at the end of the intervention, vaginal birth, induction of labour, caesarean birth, pre-eclampsia, gestational hypertension, need for pharmacological intervention, large for gestational age, neonatal hypoglycaemia and neonatal morbidity composite.

The evidence ranged from moderate to very low quality.

Comparison 6: Physical activity + mixed interventions vs standard care/control for women with gestational diabetes in single pregnancy

One study was included under this comparison.

Evidence for physical activity+mixed interventions vs standard care/control for single pregnancy showed that there was no important differences between physical activity+mixed interventions and standard care/control for the outcome gestational weight change and no evidence of important differences for outcomes of glycaemic control: n fasting blood glucose at the end of the intervention, caesarean birth, need for pharmacological intervention, large for gestational age and neonatal morbidity composite.

The evidence ranged from moderate to very low quality.

Comparison 7: Physical activity vs mixed interventions for women with gestational diabetes - single pregnancy

One study was included under this comparison.

Evidence for physical activity vs mixed interventions for single pregnancy showed that there was no important differences between physical activity and mixed interventions for the outcome gestational weight change and no evidence of important differences for outcomes of glycaemic control: fasting blood glucose at the end of the intervention, caesarean birth, need for pharmacological intervention, large for gestational age and neonatal morbidity composite.

The evidence ranged from moderate to very low quality

Comparison 8: Face to face physical activity vs home based physical activity for women with gestational diabetes in single pregnancy

One study was included under this comparison.

Evidence for face-to-face physical activity vs home based physical activity for single pregnancy showed that there was no evidence of important differences between face to face physical activity and home based physical activity for the outcome of need for pharmacological intervention.

The evidence was of very low quality.

Comparison 9: Mixed interventions vs standard care/control for women with gestational diabetes in single pregnancy

Eight studies were included under this comparison.

Evidence for mixed interventions vs standard care/control for single pregnancy showed that there was important benefit for mixed interventions compared to standard care for the neonatal mortality and morbidity composite outcome. There were no important differences between mixed interventions and standard care/control for the outcomes of gestational weight change (absolute difference), caesarean birth and large for gestational age. There was no evidence of important differences for glycaemic control: fasting blood glucose at the end of the intervention, gestational weight change (met/achieved Institutes of Medicine (IOM) guidelines), vaginal birth, induction of labour, hypertensive disorders (pre-eclampsia or gestational hypertension), need for pharmacological intervention, neonatal hypoglycaemia and neonatal mortality composite.

The evidence ranged from high to very low quality.

See appendix F for full GRADE tables.

Economic evidence

Included studies

One economic study was identified which was relevant to this question (Laurie 2023). See the literature search strategy in appendix B and economic study selection flow chart in appendix G.

Excluded studies

Economic studies not included in this review are listed, and reasons for their exclusion are provided in appendix K.

Summary of included economic evidence

See Table 3 for the economic evidence profile of the included study.

Table 3: Economic evidence profile of healthy lifestyle interventions for women with gestational diabetes

Study and country	Limitations	Applicability	Other comments	Incremental costs[1]	Incremental effects	ICER[1]	Uncertainty
Laurie 2023 Australia	Potentially serious[2]	Partially applicable[3]	Population: pregnant women with GDM following diagnosis at 28 weeks Interventions: Digital model for GDM management (systematic development and delivery of education videos, use of a national service smart phone app/portal and reduced schedule of face-to-face visits) vs. TAU Outcome: NA (cost analysis – equivalence stated but not proved) Time horizon: during pregnancy, from 28 weeks of GDM diagnosis - costs were estimated over 1 year of centre operation pre- and post-intervention Cost year: 2021 The cost of the app system was assumed to be zero	Healthcare: -£7 Patient: -£265	NA	NA	Patient cost-savings sensitive to unit cost of wages

GDM: gestational diabetes mellitus; NA: not applicable; TAU: treatment as usual; WTP
1 Costs converted to GBP using Purchasing Power Parity exchange rates
2 Cost analysis based on a prospective cohort study with retrospective control and further economic modelling assumption; resource use data based on expert opinion (healthcare costs) and a short survey (patient expenses); national and local unit costs used; time horizon: during pregnancy, from 28 weeks of GDM diagnosis - costs were estimated over 1 year of centre operation pre- and post-intervention. The study was described as cost-minimisation analysis, but effectiveness data, including proof of equivalence, were not provided.
3 Australian study, cost analysis so no QALYs used, healthcare + patient perspective, discounting not needed

Economic model

No economic modelling was undertaken for this review because the committee agreed that other topics were higher priorities for economic evaluation.

Economic evidence statement

- Evidence from an Australian prospective cohort study with retrospective controls and further economic modelling suggests that a digital model for gestational diabetes management that includes systematic development and delivery of education videos, use of a national service smart phone app/portal and reduced schedule of face-to-face visits may be cost-saving compared with treatment as usual. The study assumed clinical equivalence between the digital model and treatment as usual. The evidence is partially applicable to the UK context and is characterised by potentially serious limitations.

The committee's discussion and interpretation of the evidence

The outcomes that matter most

Maternal outcomes of glycaemic (glucose) control, gestational weight change, mode of delivery (vaginal birth/induction of labour/caesarean birth), hypertensive disorders of pregnancy (pre-eclampsia and gestational hypertension), need for pharmacological intervention and fetal/neonatal outcomes of large for gestational age, neonatal hypoglycaemia and neonatal mortality and morbidity (as a composite outcome if reported) were prioritised as critical outcomes of interest by the committee. These critical outcomes were decided after the committee's initial consideration of looking at the effect of dietary or physical activity interventions on weight gain, but as the majority of interventions focus on clinical outcomes related to maternal glycaemic control (such as large for gestational age, neonatal hypoglycaemia) rather than weight gain, it was agreed that a better approach would be to review this literature to address these outcomes, including any studies that also reported weight gain. Critical outcomes were also discussed in the context of women with gestational diabetes being at increased risk of having a macrosomic baby, trauma during birth to themselves and the baby, neonatal hypoglycaemia, perinatal death, induction of labour and caesarean section. Neonatal hypoglycaemia was identified as a critical outcome as this was discussed to be a complication of gestational diabetes mellitus. Infants exposed to hypoglycaemia show abnormalities on cranial magnetic resonance imaging (MRI) and are at risk for developmental delay at an older age, even in case of mild, transient hypoglycaemia. Different modes of birth were also of interest as women with gestational diabetes are advised to have baby before 41 weeks of pregnancy and induction of labour or a caesarean section may be recommended if labour does not start naturally by this time. The outcome of need for pharmacological intervention was also noted by the committee to act as a surrogate marker for glycaemic control and this was reported where available.

The quality of the evidence

The quality of the evidence was assessed using 'Grading of Recommendations Assessment, Development and Evaluation' (GRADE) methodology. The quality of the evidence ranged from very low to high with the majority of the evidence being of very low quality. Evidence tended to be downgraded due to serious or very serious risk of bias in the evidence, imprecision around the effect estimate or indirectness for some outcomes. Studies were downgraded for indirectness when >50% of studies in any given analysis reported macrosomia instead of large for gestational age, for the surrogate outcome of need for pharmacological intervention or where perinatal outcomes were reported as part of the composite for neonatal morbidity and mortality or neonatal morbidity outcome, for example, stillbirth or premature delivery.

The Risk of Bias in Systematic Reviews (ROBIS) checklist was used to assess the risk of bias of systematic reviews. The two Cochrane systematic reviews were rated at high risk of bias due to insufficient study characteristics reported (for example, body-mass index (BMI), maternal age, parity, education level, ethnicity, follow-up times, gestational diabetes diagnostic criteria or indication for treatment) which would have aided the interpretation of the evidence.

The risk of bias of individual included studies outside of the systematic reviews were assessed using the Cochrane risk of bias 2.0 tool for randomised controlled trials and the Cochrane risk of bias 2.0 cluster randomised trials tool for cluster randomised controlled trials. Brown 2017 and Han 2017 Cochrane systematic reviews assessed the risk of bias for the 15 randomised control trials (RCTs) using the Cochrane risk of bias 1.0 tool and found all studies to be of high or unclear risk of bias. For studies outside of the Cochrane systematic reviews, studies were judged to have some concerns commonly due to no information on allocation concealment, participants or researchers not blinded, missing outcome data with reasons not likely to be related to true value or no protocol or pre-specified analysis reported. Studies that were judged to be at high risk of bias did not perform intention to treat analyses, did not report any information on or reasons for missing data or had >5% of participants in each arm with missing data with no analysis performed to determine if result biased by missing outcome and potential for some missing outcome reasons to be related to true value.

The committee thought the evidence was applicable to the United Kingdom (UK) setting as all included studies were from high income countries.

Benefits and harms

The committee discussed the evidence for dietary interventions compared to standard care. This was based on mostly low to very low-quality evidence. Dietary interventions in these studies included diets that were energy restricted, high in fibre or ethnic specific. Whilst there was a difference relating to the need for pharmacological intervention the committee was made aware of weaknesses in this study including transfer of women between arms of the study. There was however no evidence of harm, but the comparison with standard care, in which diet is usually the first line treatment, confounds interpretation.

There was also some evidence of important benefit for low unsaturated fat diet (% content) when compared to high unsaturated fat isocaloric diet (content) for the outcome of glycaemic control during intervention (38 week) fasting blood glucose (mmol/L) and gestational weight change for different diet comparisons in women with a single pregnancy. No harm was indicated and this was based on moderate evidence from one study with very low-quality evidence.

For women with a single pregnancy there was also no evidence of benefit amongst all reported outcomes for either low or low-moderate-glycaemic index (GI) diet vs moderate-GI +/- high fibre diet. The role of fibre per se could not be determined by these protocols. Whilst a low carbohydrate diet is commonly used in standard care for gestational diabetes mellitus (GDM), there was no evidence of benefit for any outcomes for the comparison of low-carbohydrate diet vs high-carbohydrate diet. However, this was based on mostly very low-quality evidence and the committee discussed the studies generally had small sample sizes and were possibly not sufficiently powered.

There was a lack of robust evidence for benefits of dietary advice tailored to a woman's ethnicity/cultural dietary preference. The committee agreed that diet related ethnic and cultural sensitivities for all pregnant women should nonetheless be considered. This is discussed in evidence review Q.

The committee discussed that diet is the first line intervention in practice for gestational diabetes and that there is a large variation between diets offered for gestational diabetes with no standard agreed diet. The committee noted the variation between studies in the definition of low and high carbohydrate diets and commented that this was a general reflection of the lack of consistency of definitions in the literature. The committee also acknowledged that in most studies, interventions were offered very late in the pregnancy, and this could be one of the possible reasons for the observed limited effect of the interventions particularly for the outcome of gestational weight change.

The committee discussed the evidence of all diet-based interventions and acknowledged that there was no strong evidence for one diet compared to another, with particular mention of evidence on low carbohydrate or low GI diet compared to standard care. The committee also noted that a diet too low in carbohydrates might not be appropriate during pregnancy, however, no published study to date has evaluated this. The committee agreed there is often no standardised definition of standard care and this was seen within the variation of standard care across included studies which tended to include different diets +/- physical activity as well as education or counselling components. As diet is part of standard care and first line intervention, the committee noted that it would be unethical to perform a study including standard care where there was no diet involved. As a result, it was reasoned that this may be a contributing factor towards the lack of differences found between arms across many outcomes when a particular diet was compared to standard care.

The evidence on physical activity interventions compared to standard care showed an important benefit for glycaemic control for the physical activity arm across four studies, but the committee acknowledged that the evidence was of very low quality. For all other reported outcomes and for all other comparisons, there was no important difference between intervention and comparison. Because of lack of robust evidence, the committee did not make any specific recommendations on physical activity interventions for those with gestational diabetes.

Similarly, the evidence on mixed interventions, such as counselling, education, behavioural and app-based interventions, including glucose monitoring, showed no difference across reported outcomes compared to standard care or control arm. The committee also noted that there was no clear evidence for self-monitoring as no study looked at this as a standalone intervention. The committee also discussed that behavioural interventions such as education and counselling tended to be included as part of standard care in practice and across the studies which may have contributed to lack of differences found across reported outcomes. Due to lack of evidence, the committee did not make any specific recommendation for behavioural and self-monitoring interventions.

There was no evidence specific for deprived socioeconomic groups, women with disabilities, lesbian, gay, bisexual, transgender and queer (LGBQT+) people or for specific ethnic groups. Therefore, the committee did not make specific recommendations for any of these groups but agreed that the recommendations should consider individual circumstances and preferences. This is particularly relevant when discussing dietary preferences with people from ethnic minorities, and when discussing food related issues in the context of food insecurity and poverty.

The committee agreed by consensus that a person with gestational diabetes should be asked about their usual diet and physical activity. They also agreed the advice should be individualised and appropriate to individual circumstances and preferences. Tailoring advice makes it more likely that an individual will accept and follow it. The committee discussed that there was some guidance on motivational empathy in the general literature and the approach was generally incorporated by the committee when forming the recommendations towards lifestyle counselling, for example, understanding the woman’s circumstances and providing individualised and tailored advice. Based on the evidence and their experience the committee agreed that people with gestational diabetes should be advised that there is currently no convincing evidence that one particular diet is better than another. Instead, a diet that is most preferable and appropriate for the person with gestational diabetes should be discussed.

All available evidence (except one study on energy restricted diets with seven sets of twins) was in women with single pregnancies. The committee agreed that the evidence from single pregnancies could be extrapolated to women with multiple pregnancies and hence agreed that all recommendations would apply to both women with single and multiple pregnancies. There was no evidence available for women who had previously undergone bariatric surgery.

The committee also noted that NICE guideline on diabetes in pregnancy (NG3) recommends that all women with gestational diabetes are referred to a dietitian. The committee discussed that in current practice this does not always happen but should.

Due to a lack of standardised control arms in the evidence, the committee made a research recommendation to harmonise the definition of standard care (see appendix K for details).

Cost effectiveness and resource use

There was some evidence from Australia that a digital model for management of gestational diabetes might be cost-saving compared with standard care. However, this evidence was only partially applicable to the UK context and was characterised by potentially serious limitations. Most notably, the study assumed clinical equivalence between the digital model and treatment as usual. The committee made recommendations around discussion with the person and individualised advice on diet and physical activity according to their circumstances. These recommendations overall reflect current practice and may have small resource implications, relating to the health professionals’ extra time spent in antenatal appointments. However, they are likely to be partially offset by better outcomes and cost-savings further down the care pathway, resulting from timely and appropriate lifestyle (diet and physical activity) changes that contribute to better management of gestational diabetes.

Other factors the committee took into account

For this review question, the population in the evidence was women and no evidence was identified or reviewed for trans men or non-binary people. The protocol and literature searches were not designed to specifically look for evidence on trans men or non-binary people but they were also not excluded. However, there is a small chance evidence on them may not have been captured, if such evidence exists. In discussing the evidence, the committee considered whether the recommendations could apply to a broader population, and used gender inclusive language to promote equity, respect and effective communication with everyone. Healthcare professionals should use their clinical judgement when implementing the recommendations, taking into account each person’s circumstances, needs and preferences, and ensuring all people are treated with dignity and respect throughout their care.

Recommendations supported by this evidence review

This evidence review supports recommendations 1.2.18 to 1.2.19, and the recommendation for research on dietary interventions during pregnancy for people with gestational diabetes.

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Effectiveness

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Grant, Shannan M, Wolever, Thomas M S, O'Connor, Deborah L et al. (2011) Effect of a low glycaemic index diet on blood glucose in women with gestational hyperglycaemia. Diabetes research and clinical practice 91(1): 15-22

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Appendices

Appendix A Review protocols

Review protocol for review question: What are the most effective and cost-effective healthy lifestyle interventions for women with gestational diabetes?

Table 4: Review protocol

Field	Content
PROSPERO registration number	CRD42023427932
Review title	Healthy lifestyle interventions for women with gestational diabetes
Review question	What are the most effective and cost-effective healthy lifestyle interventions for women with gestational diabetes?
Objective	To determine which are the most effective and cost-effective effective healthy lifestyle interventions for women with gestational diabetes.
Searches	The following databases will be searched: Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Database of Systematic Reviews (CDSR) Embase MEDLINE Epistemonikos CINAHL CRD HTA International Health Technology Assessment database. Searches will be restricted by: Date: 1984 (NACNE guidelines were introduced in 1984 and they were bespoke nutrition guidelines. Before then there were not standardised interventions available)

Field	Content
	• English language only • human studies only. The full search strategies for MEDLINE database will be published in the final review. For each search, the principal database search strategy is quality assured by a second information scientist using an adaptation of the PRESS 2015 Guideline Evidence-Based Checklist.
Condition or domain being studied	Weight management and glucose control in pregnant women with gestational diabetes
Population	Inclusion: • pregnant women with gestational diabetes during a single or multiple pregnancy. Note: Do not exclude women who have had bariatric surgery Exclusion: • weight management for pregnant women with pre-existing diabetes.
Intervention	The following interventions will be considered: • diet based interventions (low-/moderate-/high-glycaemic index (GI) diets, low/high carbohydrate diet, energy restricted/no energy restricted diet, high/low unsaturated fat diet, probiotics/no probiotics diet, high-fibre/standard-fibre diet, soy protein/no soy protein diet 'dietary approaches to stop hypertension (DASH)' diet rich in fruits, vegetables, whole grains and low-fat dairy products, ethnic-specific diet). • To only consider the above dietary interventions in the review. physical activity-based interventions (look for all physical activity-based interventions for this category) • management of sedentary behaviour-based interventions (for example, reduce the time sitting) • behaviour-based interventions (counselling, education, coaching, any digital intervention) • monitoring-based interventions (for example, regular weighing, including self-weighing, apps/digital interventions) • multi-component interventions (a combination of the interventions listed above). Only consider interventions specified in the protocol.
Comparator	• standard care as defined by the study Interventions compared with:

Field	Content
	• each other • a combination of interventions. To also include same type of interventions with each other, for example, diet A vs diet B. The differences in diets in the dietary intervention are very important to review; this is the key question- which diet works best, so they need to be compared to each other
Types of study to be included	Include published full-text papers: • systematic reviews of RCTs • individual patient data (IPD) meta-analysis of RCTs • RCTs. Conference abstracts will not be included because these do not typically have sufficient information to allow full critical appraisal.
Other exclusion criteria	Setting: Countries other than high income countries (as defined by the OECD) Interventions: • complementary therapy (for example, herbal medicines or acupuncture) • bariatric surgery • pharmacological interventions • monitoring blood glucose including antenatal glucose monitoring/ HbA1c monitoring/continuous glucose monitoring. If any study or systematic review includes any of the above interventions, it will be excluded.
Context	The population of this guideline may overlap with the population of women included in other NICE guidelines (such as diabetes in pregnancy, postnatal care, antenatal care, intrapartum care, and complex social factors or obesity prevention).
Primary outcomes (critical outcomes)	Maternal outcomes: • glycaemic (glucose) control: look for dichotomous outcome, for continuous outcome: fasting blood glucose. If this outcome is not reported in the paper surrogate outcome will be used: need for pharmacological intervention. • gestational weight change. For example, gestational weight change from the first booking to the third trimester/birth or at different time points such as 1st, 2nd or 3rd trimester.

Field	Content
	Or as defined by the study. Gestational weight change reported in a continuous or dichotomous scale, but preference will be given to dichotomous • mode of delivery: vaginal birth/induction of labour/caesarean birth • hypertensive disorders of pregnancy (pre-eclampsia and gestational hypertension) Fetal/neonatal outcomes: • large for gestational age (LGA) >90th centile • neonatal hypoglycaemia • neonatal mortality and morbidity (include it as a composite outcome if reported.
Secondary outcomes (important outcomes)	• none identified The committee considered all outcomes as equally important for decision making and therefore have all been rated as critical (primary outcomes)
Data extraction (selection and coding)	All references identified by the searches and from other sources will be uploaded into EPPI and de-duplicated. Titles and abstracts of the retrieved citations will be screened to identify studies that potentially meet the inclusion criteria outlined in the review protocol. Dual sifting will be performed on at least 10% of records; 90% agreement is required. Disagreements will be resolved via discussion between the two reviewers, and consultation with senior staff if necessary. Full versions of the selected studies will be obtained for assessment. Studies that fail to meet the inclusion criteria once the full version has been checked will be excluded at this stage. Each study excluded after checking the full version will be listed, along with the reason for its exclusion. A standardised form will be used to extract data from studies. The following data will be extracted: study details (reference, country where study was carried out, type and dates), participant characteristics, inclusion and exclusion criteria, details of the interventions if relevant, setting and follow-up, relevant outcome data and source of funding. One reviewer will extract relevant data into a standardised form, and this will be quality assessed by a senior reviewer.
Risk of bias (quality) assessment	Quality assessment of individual studies will be performed using the following checklists: ROBIS tool for systematic reviews Wang et al checklist for assessing the methodological quality of IPD meta-analysis https://www.bmj.com/content/bmj/373/bmj.n736.full.pdf Cochrane RoB tool v.2 for RCTs

Field	Content
	The quality assessment will be performed by one reviewer and this will be quality assessed by a senior reviewer.
Strategy for data synthesis	Quantitative findings will be formally summarised in the review. Where multiple studies report on the same outcome for the same comparison, meta-analyses will be conducted using Cochrane Review Manager software. A fixed effect meta-analysis will be conducted and data will be presented as risk ratios if possible or odds ratios when required (for example, if only available in this form in included studies) for dichotomous outcomes, and mean differences or standardised mean differences for continuous outcomes. Heterogeneity in the effect estimates of the individual studies will be assessed using the I2 statistic. Alongside visual inspection of the point estimates and confidence intervals, I2 values of greater than 50% and 80% will be considered as significant and very significant heterogeneity, respectively. Heterogeneity will be explored as appropriate using sensitivity analyses and pre-specified subgroup analyses. If heterogeneity cannot be explained through subgroup analysis then a random effects model will be used for meta-analysis, or the data will not be pooled. The confidence in the findings across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group: http://www.gradeworkinggroup.org/ Minimally important differences: Default MIDs will be used for risk ratios and continuous outcomes only, unless the committee pre-specifies published or other MIDs for specific outcomes Minimally important differences: Mode of delivery, hypertensive disorders of pregnancy, glycaemic control, need for pharmacological therapy, large for gestational age, neonatal hypoglycaemia, neonatal mortality and morbidity: statistical significance Validated scales/continuous outcomes: published MIDs where available All other outcomes & where published MIDs are not available: 0.8 and 1.25 for all relative dichotomous outcomes; +/- 0.5x control group SD for continuous outcomes
Analysis of subgroups	Evidence will be stratified by: • single versus multiple pregnancies. Evidence will be sub-grouped by the following only in the event that there is significant heterogeneity in outcomes: • deprived socioeconomic group • women with disabilities, including learning disabilities and other physical and mental health conditions

Field	Content
	• LGBTQ+ women • ethnicity ○ White/ White British ○ Asian/Asian British ○ Black/African/Caribbean/Black British/Mixed/Multiple ethnic groups ○ other ethnic group • women who had bariatric surgery versus not. Where evidence is stratified or sub-grouped the committee will consider on a case-by-case basis if separate recommendations should be made for distinct groups. Separate recommendations may be made where there is evidence of a differential effect of interventions in distinct groups. If there is a lack of evidence in one group, the committee will consider, based on their experience, whether it is reasonable to extrapolate and assume the interventions will have similar effects in that group compared with others.
Type and method of review	☒ Intervention ☐ Diagnostic ☐ Prognostic ☐ Qualitative ☐ Epidemiologic ☐ Service Delivery ☐ Other (please specify)
Language	English
Country	England
Anticipated or actual start date	18/05/2022
Anticipated completion date	22/11/2023
Stage of review at time of this submission	<table><tr><td>Review stage</td><td>Started</td><td>Completed</td></tr></table>

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<table>
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<tr><td>Piloting of the study selection process</td><td>☐</td><td>☒</td></tr>
<tr><td>Formal screening of search results against eligibility criteria</td><td>☐</td><td>☒</td></tr>
<tr><td>Data extraction</td><td>☐</td><td>☒</td></tr>
<tr><td>Risk of bias (quality) assessment</td><td>☐</td><td>☒</td></tr>
<tr><td>Data analysis</td><td>☐</td><td>☒</td></tr>
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<tr><td>Named contact</td><td>5a. Named contact
National Institute for Health and Care Excellence (NICE)
5b. Named contact e-mail
mandcnutrition@nice.org.uk
5c. Organisational affiliation of the review
National Institute for Health and Care Excellence (NICE)</td></tr>
<tr><td>Review team members</td><td>Senior Systematic Reviewer
Systematic Reviewer</td></tr>
<tr><td>Funding sources/sponsor</td><td>This systematic review is being completed by the National Institute for Health and Care Excellence (NICE)</td></tr>
</table>

Field	Content
Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE https://www.nice.org.uk/guidance/indevelopment/gid-ng10191
Other registration details	None
URL for published protocol	crd.york.ac.uk/PROSPERO/display_record.php?RecordID=427932
Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: notifying registered stakeholders of publication publicising the guideline through NICE's newsletter and alerts issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
Keywords	Healthy weight gain, gestational diabetes, pregnancy, interventions, cost-effectiveness
Details of existing review of same topic by same authors	Not applicable
Current review status	☐ Ongoing ☒ Completed but not published ☐ Completed and published ☐ Completed, published and being updated ☐ Discontinued
Additional information	None

Field	Content
Details of final publication	www.nice.org.uk

App: application; CRD: Centre for reviews and dissemination; CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; CINAHL: Cumulated Index to Nursing and Allied Health Literature; CRD: The Centre for Reviews and Dissemination; DARE: Database of Abstracts of Reviews of Effects; EPPI: Evidence for Policy and Practice Information; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HbA1c: haemoglobin A1C; HTA: Health Technology Assessment; LGBTQ+: lesbian, gay, bisexual, transgender and queer; MID: minimally important difference; NACNE: National Advisory Committee on Nutrition Education; NGA: National Guideline Alliance; NHS: National health service; NICE: National Institute for Health and Care Excellence; OECD: Organisation for Economic Co-operation and Development; PRESS: Peer Review of Electronic Search Strategies; RCT: randomised controlled trial; RoB: risk of bias; ROBIS: Risk of Bias in Systematic Reviews; SD: standard deviation

Appendix B Literature search strategies

Literature search strategies for review question: What are the most effective and cost-effective healthy lifestyle interventions for women with gestational diabetes?

Effectiveness searches

Database: Medline

Date of last search: 05/06/2023

#	Searches
1	Diabetes, Gestational/
2	((antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*) adj2 (diabet* or hyperglyc* or IGR or IFG or IGT or FPG or ((glucose* or insulin* or glyc?emia) adj2 (intolerance* or regulation or fasting or resistance)))).ti,ab,kf.
3	GDM.ti,ab,kw.
4	exp pregnancy/ or Pregnant Women/ or Prenatal Care/
5	diabetes mellitus/ or diabetes mellitus, type 2/ or blood glucose/ or glucose intolerance/
6	4 and 5
7	((diabetes mellitus or (blood adj2 glucose)) adj2 (antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*)).ti,ab,kf.
8	or/1-3,6-7
9	Diabetes, Gestational/dh, th [Diet Therapy, Therapy]
10	Diabetes, Gestational/pc [Prevention & Control]
11	or/9-10
12	exp Diet/
13	Diet Therapy/ or Nutrition Therapy/ or Dietetics/
14	Glycemic Control/
15	exp Nutritive Value/
16	food/ or bread/ or exp cultured milk products/ or ice cream/ or milk/ or exp whey/ or exp dietary carbohydrates/ or exp dietary fats/ or dietary fiber/ or exp dietary proteins/ or exp probiotics/ or exp Edible Grain/ or exp vegetables/
17	exp Fruit/
18	((diet* or intake or consum* or food* or eat* or nutrition*) adj3 (glyc?emic or carbohydrate* or energy or calor* or fat* or oil* or probiotic* or fiber* or fibre* or soy* or fruit* or vegetable* or "whole grain*" or pattern*)).ti,ab,kf.
19	((diet* adj4 hypertension*) or DASH).ti,ab,kf.
20	(diet* adj3 ((high* or rais* or elevat* or increas*) adj2 "blood pressure*")).ti,ab,kf.
21	Sedentary Behavior/ or exp Exercise/
22	(exercis* or activ* or inactiv* or low energy or fitness or fit or aerobic* or gym* or movement or moving or sedent*).ti,ab,kf.
23	Fitness Trackers/
24	((wearable or fitness or activ*) adj3 (track* or device* or monitor*)).ti,ab,kf.
25	life style/ or healthy lifestyle/
26	(lifestyle* or life style*).ti,ab,kf.
27	(weigh or weighs or weighing or self weigh*).ti,ab,kf.
28	Self-Management/
29	Self Care/
30	((self or regular* or frequen*) adj2 (manag* or monitor* or regulat* or report* or care or track*)).ti,ab,kf.
31	Telemedicine/
32	(telemedicine* or tele medicine* or telehealth* or tele health* or ehealth or e health or mhealth or m health or mobile health or digital health).ti,ab,kf.
33	exp Communications Media/ or exp Social Networking/ or exp Internet/
34	(app or apps or blog* or booklet* or brochure* or dvd* or elearn* or e-learn* or email* or e-mail* or e mail* or facebook or facetime or face time or forum* or handout* or hand out* or helpline* or hotline* or internet* or ipad* or

#	Searches
	iphone* or leaflet* or myspace or online or magazine* or mobile or newsletter* or pamphlet* or palm pilot* or personal digital assistant* or pocket pc* or podcast* or poster? or skype* or smartphone* or smart phone* or social media or social network* or sms or telephone or text messag* or twitter or tweet* or video* or web* or wiki* or youtube* or fitbit* or smart watch* or smartwatch* or pedometer*).ti,ab,kf.
35	Mobile Applications/
36	(mobile* adj2 (app? or application*)).ti,ab,kf.
37	exp body weight changes/
38	((weight* adj3 (gain* or increas* or accelerat* or excess* or decreas* or retention or retain* or alter* or chang* or loss or lost or lose or losing or reduc* or status or manag* or maintain* or control* or health* or ideal* or optimal* or optimum or appropriate or recommend*)) or GWG).ti,ab,kf.
39	Weight Reduction Programs/
40	(weight adj2 (loss or manag* or reduc*) adj2 (program* or intervention* or group* or support* or organi?ation* or commercial*)).ti,ab,kf.
41	Counseling/
42	Behavior Therapy/ or exp Cognitive Behavioral Therapy/
43	Mentoring/
44	Consumer Health Information/ or exp Health Information Management/ or Health Communication/ or Health Promotion/ or Health Education/ or exp Patient Education as Topic/ or patient education handout/
45	Health Knowledge, Attitudes, Practice/
46	(therap* or intervention* or modif* or change* or treat* or support* or guid* or strateg* or program* or educat* or teach* or inform* or counsel* or mentor* or coach* or advi* or recommend*).ti.
47	mindful*.ti,ab,kf.
48	(health* adj2 (behavio* or belief* or believ*)).ti,ab,kf.
49	or/12-48
50	8 and 49
51	11 or 50
52	letter/
53	editorial/
54	news/
55	exp historical article/
56	Anecdotes as topic/
57	comment/
58	case reports/
59	(letter or comment*).ti.
60	or/52-59
61	randomized controlled trial/ or random*.ti,ab.
62	60 not 61
63	animals/ not humans/
64	exp Animals, Laboratory/
65	exp Animal Experimentation/
66	exp Models, Animal/
67	exp Rodentia/
68	(rat or rats or rodent* or mouse or mice).ti.
69	or/62-68
70	51 not 69
71	limit 70 to English language
72	randomized controlled trial.pt.
73	controlled clinical trial.pt.
74	pragmatic clinical trial.pt.
75	randomi#ed.ab.
76	placebo.ab.
77	drug therapy.fs.
78	randomly.ab.
79	trial.ab.

#	Searches
80	groups.ab.
81	or/72-80
82	Clinical Trials as topic.sh.
83	trial.ti.
84	or/72-76,78,82-83
85	meta-analysis/
86	meta-analysis as topic/
87	(meta analy* or metanaly* or metaanaly*).ti,ab.
88	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.
89	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
90	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
91	(search* adj4 literature).ab.
92	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
93	cochrane.jw.
94	or/85-93
95	71 and (84 or 94)
96	afghanistan/ or africa/ or africa, northern/ or africa, central/ or africa, eastern/ or "africa south of the sahara"/ or africa, southern/ or africa, western/ or albania/ or algeria/ or andorra/ or angola/ or "antigua and barbuda"/ or argentina/ or armenia/ or azerbaijan/ or bahamas/ or bahrain/ or bangladesh/ or barbados/ or belize/ or benin/ or bhutan/ or bolivia/ or borneo/ or "bosnia and herzegovina"/ or botswana/ or brazil/ or brunei/ or bulgaria/ or burkina faso/ or burundi/ or cabo verde/ or cambodia/ or cameroon/ or central african republic/ or chad/ or exp china/ or comoros/ or congo/ or cote d'ivoire/ or croatia/ or cuba/ or "democratic republic of the congo"/ or cyprus/ or djibouti/ or dominica/ or dominican republic/ or ecuador/ or egypt/ or el salvador/ or equatorial guinea/ or eritrea/ or eswatini/ or ethiopia/ or fiji/ or gabon/ or gambia/ or "georgia (republic)"/ or ghana/ or grenada/ or guatemala/ or guinea/ or guinea-bissau/ or guyana/ or haiti/ or honduras/ or independent state of samoa/ or exp india/ or indian ocean islands/ or indochina/ or indonesia/ or iran/ or iraq/ or jamaica/ or jordan/ or kazakhstan/ or kenya/ or kosovo/ or kuwait/ or kyrgyzstan/ or laos/ or lebanon/ or liechtenstein/ or lesotho/ or liberia/ or libya/ or madagascar/ or malaysia/ or malawi/ or mali/ or malta/ or mauritania/ or mauritius/ or mekong valley/ or melanesia/ or micronesia/ or monaco/ or mongolia/ or montenegro/ or morocco/ or mozambique/ or myanmar/ or namibia/ or nepal/ or nicaragua/ or niger/ or nigeria/ or oman/ or pakistan/ or palau/ or exp panama/ or papua new guinea/ or paraguay/ or peru/ or philippines/ or qatar/ or "republic of belarus"/ or "republic of north macedonia"/ or romania/ or exp russia/ or rwanda/ or "saint kitts and nevis"/ or saint lucia/ or "saint vincent and the grenadines"/ or "sao tome and principe"/ or saudi arabia/ or serbia/ or sierra leone/ or senegal/ or seychelles/ or singapore/ or somalia/ or south africa/ or south sudan/ or sri lanka/ or sudan/ or suriname/ or syria/ or taiwan/ or tajikistan/ or tanzania/ or thailand/ or timor-leste/ or togo/ or tonga/ or "trinidad and tobago"/ or tunisia/ or turkmenistan/ or uganda/ or ukraine/ or united arab emirates/ or uruguay/ or uzbekistan/ or vanuatu/ or venezuela/ or vietnam/ or west indies/ or yemen/ or zambia/ or zimbabwe/
97	"organisation for economic co-operation and development"/
98	australasia/ or exp australia/ or austria/ or baltic states/ or belgium/ or exp canada/ or chile/ or colombia/ or costa rica/ or czech republic/ or exp denmark/ or estonia/ or europe/ or finland/ or exp france/ or exp germany/ or greece/ or hungary/ or iceland/ or ireland/ or israel/ or exp italy/ or exp japan/ or korea/ or latvia/ or lithuania/ or luxembourg/ or mexico/ or netherlands/ or new zealand/ or north america/ or exp norway/ or poland/ or portugal/ or exp "republic of korea"/ or "scandinavian and nordic countries"/ or slovakia/ or slovenia/ or spain/ or sweden/ or switzerland/ or turkey/ or exp united kingdom/ or exp united states/
99	european union/
100	developed countries/
101	or/97-100
102	96 not 101
103	95 not 102
104	limit 103 to ed=19840101-20230605
105	limit 103 to dt=19840101-20230605
106	104 or 105

Database: Embase

Date of last search: 05/06/2023

#	Searches
1	pregnancy diabetes mellitus/

#	Searches
2	((antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*) adj2 (diabet* or hyperglyc* or IGR or IFG or IGT or FPG or ((glucose* or insulin* or glyc?emia) adj2 (intolerance* or regulation or fasting or resistance)))).ti,ab,kf.
3	GDM.ti,ab,kw.
4	exp pregnancy/ or pregnant woman/ or prenatal care/
5	diabetes mellitus/ or non insulin dependent diabetes mellitus/ or glucose blood level/ or glucose intolerance/
6	4 and 5
7	((diabetes mellitus or (blood adj2 glucose)) adj2 (antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*)).ti,ab,kf.
8	or/1-3,6-7
9	pregnancy diabetes mellitus/pc [Prevention]
10	pregnancy diabetes mellitus/th [Therapy]
11	9 or 10
12	exp diet/
13	dietetics/
14	diet therapy/ or diet restriction/ or low fat diet/ or diabetic diet/
15	glycemic control/
16	nutritional value/
17	glycemic index/ or glycemic load/
18	food/ or bread/ or bakery product/ or exp dairy product/ or exp carbohydrate intake/ or exp fat intake/ or dietary fiber/ or fiber intake/ or protein intake/ or probiotic agent/ or exp food grain/ or exp vegetable/ or exp fruit/
19	((diet* or intake or consum* or food* or eat* or nutrition*) adj3 (glyc?emic or carbohydrate* or energy or calor* or fat* or oil* or probiotic* or fiber* or fibre* or soy* or fruit* or vegetable* or "whole grain*" or pattern*)).ti,ab,kf.
20	((diet* adj4 hypertension*) or DASH).ti,ab,kf.
21	(diet* adj3 ((high* or rais* or elevat* or increas*) adj2 "blood pressure*")).ti,ab,kf.
22	sedentary lifestyle/
23	exp exercise/
24	(exercis* or activ* or inactiv* or low energy or fitness or fit or aerobic* or gym* or movement or moving or sedent*).ti,ab,kf.
25	exp activity tracker/
26	((wearable or fitness or activ*) adj3 (track* or device* or monitor*)).ti,ab,kf.
27	lifestyle/ or healthy lifestyle/
28	(lifestyle* or life style*).ti,ab,kf.
29	(weigh or weighs or weighing or self weigh*).ti,ab,kf.
30	self care/
31	((self or regular* or frequen*) adj2 (manag* or monitor* or regulat* or report* or care or track*)).ti,ab,kf.
32	exp telemedicine/
33	(telemedicine* or tele medicine* or telehealth* or tele health* or ehealth or e health or mhealth or m health or mobile health or digital health).ti,ab,kf.
34	exp mass communication/
35	exp social network/
36	(app or apps or blog* or booklet* or brochure* or dvd* or elearn* or e-learn* or email* or e-mail* or e mail* or facebook or facetime or face time or forum* or handout* or hand out* or helpline* or hotline* or internet* or ipad* or iphone* or leaflet* or myspace or online or magazine* or mobile or newsletter* or pamphlet* or palm pilot* or personal digital assistant* or pocket pc* or podcast* or poster? or skype* or smartphone* or smart phone* or social media or social network* or sms or telephone or text messag* or twitter or tweet* or video* or web* or wiki* or youtube* or fitbit* or smart watch* or smartwatch* or pedometer*).ti,ab,kf.
37	exp mobile application/
38	(mobile* adj2 (app? or application*)).ti,ab,kf.
39	exp body weight change/
40	((weight* adj3 (gain* or increas* or accelerat* or excess* or decreas* or retention or retain* or alter* or chang* or loss or lost or lose or losing or reduc* or status or manag* or maintain* or control* or health* or ideal* or optimal* or optimum or appropriate or recommend*)) or GWG).ti,ab,kf.
41	weight loss program/ or body weight management/
42	(weight adj2 (loss or manag* or reduc*) adj2 (program* or intervention* or group* or support* or organi?ation* or commercial*)).ti,ab,kf.

#	Searches
43	counseling/
44	behavior therapy/ or cognitive behavioral therapy/
45	mindfulness/
46	mentoring/
47	consumer health information/ or medical information system/ or medical information/
48	health education/ or diabetes education/ or health promotion/ or nutrition education/ or patient education/
49	attitude to health/
50	(therap* or intervention* or modif* or change* or treat* or support* or guid* or strateg* or program* or educat* or teach* or inform* or counsel* or mentor* or coach* or advi* or recommend*).ti.
51	mindful*.ti,ab,kf.
52	(health* adj2 (behavio* or belief* or believ*)).ti,ab,kf.
53	or/12-52
54	8 and 53
55	11 or 54
56	letter.pt. or letter/
57	note.pt.
58	editorial.pt.
59	case report/ or case study/
60	(letter or comment*).ti.
61	or/56-60
62	randomized controlled trial/ or random*.ti,ab.
63	61 not 62
64	animal/ not human/
65	nonhuman/
66	exp Animal Experiment/
67	exp Experimental Animal/
68	animal model/
69	exp Rodent/
70	(rat or rats or rodent* or mouse or mice).ti.
71	or/63-70
72	55 not 71
73	(conference abstract* or conference review or conference paper or conference proceeding).db,pt,su.
74	72 not 73
75	limit 74 to English language
76	random*.ti,ab.
77	factorial*.ti,ab.
78	(crossover* or cross over*).ti,ab.
79	((doubl* or singl*) adj blind*).ti,ab.
80	(assign* or allocat* or volunteer* or placebo*).ti,ab.
81	crossover procedure/
82	single blind procedure/
83	randomized controlled trial/
84	double blind procedure/
85	or/76-84
86	systematic review/
87	meta-analysis/
88	(meta analy* or metanaly* or metaanaly*).ti,ab.
89	((systematic or evidence) adj2 (review* or overview*)).ti,ab.
90	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
91	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
92	(search* adj4 literature).ab.

#	Searches
93	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
94	((pool* or combined) adj2 (data or trials or studies or results)).ab.
95	cochrane.jw.
96	or/86-95
97	75 and (85 or 96)
98	afghanistan/ or africa/ or "africa south of the sahara"/ or albania/ or algeria/ or andorra/ or angola/ or argentina/ or "antigua and barbuda"/ or armenia/ or exp azerbaijan/ or bahamas/ or bahrain/ or bangladesh/ or barbados/ or belarus/ or belize/ or benin/ or bhutan/ or bolivia/ or borneo/ or exp "bosnia and herzegovina"/ or botswana/ or exp brazil/ or brunei darussalam/ or bulgaria/ or burkina faso/ or burundi/ or cambodia/ or cameroon/ or cape verde/ or central africa/ or central african republic/ or chad/ or exp china/ or comoros/ or congo/ or cook islands/ or cote d'ivoire/ or croatia/ or cuba/ or cyprus/ or democratic republic congo/ or djibouti/ or dominica/ or dominican republic/ or ecuador/ or el salvador/ or egypt/ or equatorial guinea/ or eritrea/ or eswatini/ or ethiopia/ or exp "federated states of micronesia"/ or fiji/ or gabon/ or gambia/ or exp "georgia (republic)"/ or ghana/ or grenada/ or guatemala/ or guinea/ or guinea-bissau/ or guyana/ or haiti/ or honduras/ or exp india/ or exp indonesia/ or iran/ or exp iraq/ or jamaica/ or jordan/ or kazakhstan/ or kenya/ or kiribati/ or kosovo/ or kuwait/ or kyrgyzstan/ or laos/ or lebanon/ or liechtenstein/ or lesotho/ or liberia/ or libyan arab jamahiriya/ or madagascar/ or malawi/ or exp malaysia/ or maldives/ or mali/ or malta/ or mauritania/ or mauritius/ or melanesia/ or moldova/ or monaco/ or mongolia/ or "montenegro (republic)"/ or morocco/ or mozambique/ or myanmar/ or namibia/ or nauru/ or nepal/ or nicaragua/ or niger/ or nigeria/ or niue/ or north africa/ or oman/ or exp pakistan/ or palau/ or palestine/ or panama/ or papua new guinea/ or paraguay/ or peru/ or philippines/ or polynesia/ or qatar/ or "republic of north macedonia"/ or romania/ or exp russian federation/ or rwanda/ or sahel/ or "saint kitts and nevis"/ or "saint lucia"/ or "saint vincent and the grenadines"/ or saudi arabia/ or senegal/ or exp serbia/ or seychelles/ or sierra leone/ or singapore/ or "sao tome and principe"/ or solomon islands/ or exp somalia/ or south africa/ or south asia/ or south sudan/ or exp southeast asia/ or sri lanka/ or sudan/ or suriname/ or syrian arab republic/ or taiwan/ or tajikistan/ or tanzania/ or thailand/ or timor-leste/ or togo/ or tonga/ or "trinidad and tobago"/ or tunisia/ or turkmenistan/ or tuvalu/ or uganda/ or exp ukraine/ or exp united arab emirates/ or uruguay/ or exp uzbekistan/ or vanuatu/ or venezuela/ or viet nam/ or western sahara/ or yemen/ or zambia/ or zimbabwe/
99	exp "organisation for economic co-operation and development"/
100	exp australia/ or "australia and new zealand"/ or austria/ or baltic states/ or exp belgium/ or exp canada/ or chile/ or colombia/ or costa rica/ or czech republic/ or denmark/ or estonia/ or europe/ or exp finland/ or exp france/ or exp germany/ or greece/ or hungary/ or iceland/ or ireland/ or israel/ or exp italy/ or japan/ or korea/ or latvia/ or lithuania/ or luxembourg/ or exp mexico/ or netherlands/ or new zealand/ or north america/ or exp norway/ or poland/ or exp portugal/ or scandinavia/ or sweden/ or slovakia/ or slovenia/ or south korea/ or exp spain/ or switzerland/ or "Turkey (republic)"/ or exp united kingdom/ or exp united states/ or western europe/
101	european union/
102	developed country/
103	or/99-102
104	98 not 103
105	97 not 104
106	limit 105 to dc=19840101-20230605

Database: Cochrane Database of Systematic Reviews, Issue 6 of 12, June 2023 and Cochrane Central Register of Controlled Trials, Issue 6 of 12, June 2023

Date of last search: 05/06/2023

#	Searches
#1	MeSH descriptor: [Diabetes, Gestational] this term only
#2	((antenatal* or ante NEXT natal* or gestation* or maternal* or pregnan* or prenatal* or pre NEXT natal*) NEAR/2 (diabet* or hyperglyc* or IGR or IFG or IGT or FPG or ((glucose* or insulin* or glycemia or glycaemia) NEAR/2 (intolerance* or regulation or fasting or resistance)))):ti,ab,kw
#3	GDM:ti,ab,kw
#4	MeSH descriptor: [Pregnancy] explode all trees
#5	MeSH descriptor: [Pregnant Women] this term only
#6	MeSH descriptor: [Prenatal Care] this term only
#7	{OR #4-#6}
#8	MeSH descriptor: [Diabetes Mellitus] this term only
#9	MeSH descriptor: [Diabetes Mellitus, Type 2] this term only
#10	MeSH descriptor: [Blood Glucose] this term only
#11	MeSH descriptor: [Glucose Intolerance] this term only

#	Searches
#12	{OR #8-#11}
#13	#7 AND #12
#14	(("diabetes mellitus" or (blood NEAR/2 glucose)) NEAR/2 (antenatal* or ante NEXT natal* or gestation* or maternal* or pregnan* or prenatal* or pre NEXT natal*)):ti,ab,kw
#15	{OR #1-#3, #13-#14}
#16	MeSH descriptor: [Diabetes, Gestational] this term only and with qualifier(s): [diet therapy - DH, prevention & control - PC, therapy - TH]
#17	MeSH descriptor: [Diet] explode all trees
#18	MeSH descriptor: [Diet Therapy] this term only
#19	MeSH descriptor: [Nutrition Therapy] this term only
#20	MeSH descriptor: [Dietetics] this term only
#21	MeSH descriptor: [Glycemic Control] this term only
#22	MeSH descriptor: [Nutritive Value] explode all trees
#23	MeSH descriptor: [Food] this term only
#24	MeSH descriptor: [Bread] this term only
#25	MeSH descriptor: [Cultured Milk Products] explode all trees
#26	MeSH descriptor: [Ice Cream] this term only
#27	MeSH descriptor: [Milk] this term only
#28	MeSH descriptor: [Whey] explode all trees
#29	MeSH descriptor: [Dietary Carbohydrates] explode all trees
#30	MeSH descriptor: [Dietary Fats] explode all trees
#31	MeSH descriptor: [Dietary Fiber] this term only
#32	MeSH descriptor: [Dietary Proteins] explode all trees
#33	MeSH descriptor: [Probiotics] explode all trees
#34	MeSH descriptor: [Edible Grain] explode all trees
#35	MeSH descriptor: [Vegetables] explode all trees
#36	MeSH descriptor: [Fruit] explode all trees
#37	((diet* or intake or consum* or food* or eat* or nutrition*) NEAR/3 (glycemic or glycaemic or carbohydrate* or energy or calor* or fat* or oil* or probiotic* or fiber* or fibre* or soy* or fruit* or vegetable* or whole NEXT grain* or pattern*)):ti,ab,kw
#38	((diet* NEAR/4 hypertension*) or DASH):ti,ab,kw
#39	(diet* NEAR/3 ((high* or rais* or elevat* or increas*) NEAR/2 blood NEXT pressure*)):ti,ab,kw
#40	MeSH descriptor: [Sedentary Behavior] this term only
#41	MeSH descriptor: [Exercise] explode all trees
#42	(exercis* or activ* or inactiv* or "low energy" or fitness or fit or aerobic* or gym* or movement or moving or sedent*):ti,ab,kw
#43	MeSH descriptor: [Fitness Trackers] this term only
#44	((wearable or fitness or activ*) NEAR/3 (track* or device* or monitor*)):ti,ab,kw
#45	MeSH descriptor: [Life Style] this term only
#46	MeSH descriptor: [Healthy Lifestyle] this term only
#47	(lifestyle* or life NEXT style*):ti,ab,kw
#48	(weigh or weighs or weighing or self NEXT weigh*):ti,ab,kw
#49	MeSH descriptor: [Self-Management] this term only
#50	MeSH descriptor: [Self Care] this term only
#51	((self or regular* or frequen*) NEAR/2 (manag* or monitor* or regulat* or report* or care or track*)):ti,ab,kw
#52	MeSH descriptor: [Telemedicine] this term only
#53	(telemedicine* or tele NEXT medicine* or telehealth* or tele NEXT health* or ehealth or "e health" or mhealth or "m health" or "mobile health" or "digital health"):ti,ab,kw
#54	MeSH descriptor: [Communications Media] explode all trees
#55	MeSH descriptor: [Social Networking] explode all trees
#56	MeSH descriptor: [Internet] explode all trees
#57	(app or apps or blog* or booklet* or brochure* or dvd* or elearn* or e-learn* or email* or e-mail* or e NEXT mail* or facebook or facetime or "face time" or forum* or handout* or hand NEXT out* or helpline* or hotline* or internet* or ipad* or iphone* or leaflet* or myspace or online or magazine* or mobile or newsletter* or pamphlet* or palm NEXT

#	Searches
	pilot* or personal NEXT digital NEXT assistant* or pocket NEXT pc* or podcast* or poster or posters or skype* or smartphone* or smart NEXT phone* or "social media" or social NEXT network* or sms or telephone or text NEXT messag* or twitter or tweet* or video* or web* or wiki* or youtube* or fitbit* or smart NEXT watch* or smartwatch* or pedometer*):ti,ab,kw
#58	MeSH descriptor: [Mobile Applications] this term only
#59	(mobile* NEAR/2 (app or apps or application*)):ti,ab,kw
#60	MeSH descriptor: [Body Weight Changes] explode all trees
#61	((weight* NEAR/3 (gain* or increas* or accelerat* or excess* or decreas* or retention or retain* or alter* or chang* or loss or lost or lose or losing or reduc* or status or manag* or maintain* or control* or health* or ideal* or optimal* or optimum or appropriate or recommend*)) or GWG):ti,ab,kw
#62	MeSH descriptor: [Weight Reduction Programs] this term only
#63	(weight NEAR/2 (loss or manag* or reduc*) NEAR/2 (program* or intervention* or group* or support* or organisation* or organization* or commercial*)):ti,ab,kw
#64	MeSH descriptor: [Counseling] this term only
#65	MeSH descriptor: [Behavior Therapy] this term only
#66	MeSH descriptor: [Cognitive Behavioral Therapy] explode all trees
#67	MeSH descriptor: [Mentoring] this term only
#68	MeSH descriptor: [Consumer Health Information] this term only
#69	MeSH descriptor: [Health Information Management] explode all trees
#70	MeSH descriptor: [Health Communication] this term only
#71	MeSH descriptor: [Health Promotion] this term only
#72	MeSH descriptor: [Health Education] this term only
#73	MeSH descriptor: [Patient Education as Topic] explode all trees
#74	MeSH descriptor: [Patient Education Handout] this term only
#75	MeSH descriptor: [Health Knowledge, Attitudes, Practice] this term only
#76	(therap* or intervention* or modif* or change* or treat* or support* or guid* or strateg* or program* or educat* or teach* or inform* or counsel* or mentor* or coach* or advi* or recommend*):ti
#77	mindful*:ti,ab,kw
#78	(health* NEAR/2 (behavio* or belief* or believ*)):ti,ab,kw
#79	{OR #17-#78}
#80	#15 AND #79
#81	#16 OR #80
#82	conference:pt or (clinicaltrials or trialsearch):so
#83	#81 NOT #82

Database: Epistemonikos

Date of last search: 05/06/2023

#	Searches
1	(title:(gestational diabetes) OR abstract:(gestational diabetes))
2	title:((therap* OR intervention* OR modif* OR change* OR treat* OR support* OR guid* OR strateg* OR program* OR educat* OR teach* OR inform* OR counsel* OR mentor* OR coach* OR advi* OR recommend*))
3	1 AND 2 [Filters: protocol=no, classification=systematic-review, cochrane=missing, min_year=1984, max_year=2023]

Database: CINAHL

Date of last search: 05/06/2023

#	Searches
S75	S16 OR S73 Limiters - Published Date: 19840101-20230605; English Language; Exclude MEDLINE records; Human; Publication Type: Randomized Controlled Trial, Systematic Review
S74	S16 OR S73
S73	S15 AND S72
S72	S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR

#	Searches
	S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64 OR S65 OR S66 OR S67 OR S68 OR S69 OR S70 OR S71
S71	TI ((health* n2 (behavio* or belief* or believ*))) OR AB ((health* n2 (behavio* or belief* or believ*)))
S70	TI mindful* OR AB mindful*
S69	TI ((therap* or intervention* or modif* or change* or treat* or support* or guid* or strateg* or program* or educat* or teach* or inform* or counsel* or mentor* or coach* or advi* or recommend*))
S68	(MH "Attitude to Health+")
S67	(MH "Patient Education") OR (MH "Nutrition Education")
S66	(MH "Health Education") OR (MH "Diabetes Education")
S65	(MH "Health Information Networks")
S64	(MH "Health Promotion")
S63	(MH "Health Information Management")
S62	(MH "Consumer Health Information")
S61	(MH "Mentorship")
S60	(MH "Behavior Therapy") OR (MH "Cognitive Therapy+") OR (MH "Mindfulness+")
S59	(MH "Counseling")
S58	TI ((weight n2 (loss or manag* or reduc*) n2 (program* or intervention* or group* or support* or organi?ation* or commercial*))) OR AB ((weight n2 (loss or manag* or reduc*) n2 (program* or intervention* or group* or support* or organi?ation* or commercial*)))
S57	(MH "Weight Reduction Programs")
S56	TI (((weight* n3 (gain* or increas* or accelerat* or excess* or decreas* or retention or retain* or alter* or chang* or loss or lost or lose or losing or reduc* or status or manag* or maintain* or control* or health* or ideal* or optimal* or optimum or appropriate or recommend*)) or GWG)) OR AB (((weight* n3 (gain* or increas* or accelerat* or excess* or decreas* or retention or retain* or alter* or chang* or loss or lost or lose or losing or reduc* or status or manag* or maintain* or control* or health* or ideal* or optimal* or optimum or appropriate or recommend*)) or GWG))
S55	(MH "Body Weight Changes+")
S54	TI ((mobile* n2 (app? or application*))) OR AB ((mobile* n2 (app? or application*)))
S53	(MH "Mobile Applications")
S52	TI ((app or apps or blog* or booklet* or brochure* or dvd* or elearn* or e-learn* or email* or e-mail* or e mail* or facebook or facetime or face time or forum* or handout* or hand out* or helpline* or hotline* or internet* or ipad* or iphone* or leaflet* or myspace or online or magazine* or mobile or newsletter* or pamphlet* or palm pilot* or personal digital assistant* or pocket pc* or podcast* or poster? or skype* or smartphone* or smart phone* or social media or social network* or sms or telephone or text messag* or twitter or tweet* or video* or web* or wiki* or youtube* or fitbit* or smart watch* or smartwatch* or pedometer*)) OR AB ((app or apps or blog* or booklet* or brochure* or dvd* or elearn* or e-learn* or email* or e-mail* or e mail* or facebook or facetime or face time or forum* or handout* or hand out* or helpline* or hotline* or internet* or ipad* or iphone* or leaflet* or myspace or online or magazine* or mobile or newsletter* or pamphlet* or palm pilot* or personal digital assistant* or pocket pc* or podcast* or poster? or skype* or smartphone* or smart phone* or social media or social network* or sms or telephone or text messag* or twitter or tweet* or video* or web* or wiki* or youtube* or fitbit* or smart watch* or smartwatch* or pedometer*))
S51	(MH "Internet+")
S50	(MH "Social Networking+")
S49	(MH "Communications Media+")
S48	TI ((telemedicine* or tele medicine* or telehealth* or tele health* or ehealth or e health or mhealth or m health or mobile health or digital health)) OR AB ((telemedicine* or tele medicine* or telehealth* or tele health* or ehealth or e health or mhealth or m health or mobile health or digital health))
S47	(MH "Telemedicine")
S46	TI (((self or regular* or frequen*) n2 (manag* or monitor* or regulat* or report* or care or track*))) OR AB (((self or regular* or frequen*) n2 (manag* or monitor* or regulat* or report* or care or track*)))
S45	(MH "Self Care")
S44	(MH "Self-Management")
S43	TI ((weigh or weighs or weighing or self weigh*)) OR AB ((weigh or weighs or weighing or self weigh*))
S42	TI ((lifestyle* or life style*)) OR AB ((lifestyle* or life style*))
S41	(MH "Life Style")
S40	TI (((wearable or fitness or activ*) n3 (track* or device* or monitor*))) OR AB (((wearable or fitness or activ*) n3 (track* or device* or monitor*)))
S39	(MH "Fitness Trackers")

#	Searches
S38	TI ((exercis* or activ* or inactiv* or low energy or fitness or fit or aerobic* or gym* or movement or moving or sedent*)) OR AB ((exercis* or activ* or inactiv* or low energy or fitness or fit or aerobic* or gym* or movement or moving or sedent*))
S37	(MH "Exercise+")
S36	(MH "Life Style, Sedentary")
S35	TI ((diet* n3 ((high* or rais* or elevat* or increas*) n2 "blood pressure*"))) OR AB ((diet* n3 ((high* or rais* or elevat* or increas*) n2 "blood pressure*")))
S34	TI (((diet* n4 hypertension*) or DASH)) OR AB (((diet* n4 hypertension*) or DASH))
S33	TI (((diet* or intake or consum* or food* or eat* or nutrition*) n3 (glyc?emic or carbohydrate* or energy or calor* or fat* or oil* or probiotic* or fiber* or fibre* or soy* or fruit* or vegetable* or "whole grain*" or pattern*))) OR AB (((diet* or intake or consum* or food* or eat* or nutrition*) n3 (glyc?emic or carbohydrate* or energy or calor* or fat* or oil* or probiotic* or fiber* or fibre* or soy* or fruit* or vegetable* or "whole grain*" or pattern*)))
S32	(MH "Fruit+")
S31	(MH "Vegetables+")
S30	(MH "Cereals+")
S29	(MH "Probiotics+")
S28	(MH "Dietary Fiber")
S27	(MH "Dietary Fats+")
S26	(MH "Dietary Carbohydrates+")
S25	(MH "Dietary Proteins+")
S24	(MH "Dairy Products+")
S23	(MH "Bread")
S22	(MH "Food")
S21	(MH "Nutritive Value+")
S20	(MH "Glycemic Control")
S19	(MH "Dietetics")
S18	(MH "Diet Therapy+")
S17	(MH "Diet+")
S16	(MH "Diabetes Mellitus, Gestational/DH/PC/TH")
S15	S12 OR S13 OR S14
S14	S1 OR S2 OR S3
S13	TI (((diabetes mellitus or (blood n2 glucose)) n2 (antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*)) OR AB (((diabetes mellitus or (blood n2 glucose)) n2 (antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*))
S12	S10 AND S11
S11	S8 OR S9
S10	S4 OR S5 OR S6 OR S7
S9	(MH "Blood Glucose") or (MH "Glucose Intolerance")
S8	(MH "Diabetes Mellitus") OR (MH "Diabetes Mellitus, Type 2")
S7	(MH "Prenatal Care")
S6	(MH "Expectant Mothers")
S5	(MH "Pregnancy, Multiple+")
S4	(MH "Pregnancy+")
S3	TI GDM OR AB GDM
S2	TI (((antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*) n2 (diabet* or hyperglyc* or IGR or IFG or IGT or FPG or ((glucose* or insulin* or glyc?emia) n2 (intolerance* or regulation or fasting or resistance))))) OR AB (((antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*) n2 (diabet* or hyperglyc* or IGR or IFG or IGT or FPG or ((glucose* or insulin* or glyc?emia) n2 (intolerance* or regulation or fasting or resistance)))))
S1	(MH "Diabetes Mellitus, Gestational")

Economic Searches:

Database: Medline

Date of last search: 05/06/2023

#	Searches
1	Diabetes, Gestational/
2	((antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*) adj2 (diabet* or hyperglyc* or IGR or IFG or IGT or FPG or ((glucose* or insulin* or glyc?emia) adj2 (intolerance* or regulation or fasting or resistance)))).ti,ab,kf.
3	GDM.ti,ab,kw.
4	exp pregnancy/ or Pregnant Women/ or Prenatal Care/
5	diabetes mellitus/ or diabetes mellitus, type 2/ or blood glucose/ or glucose intolerance/
6	4 and 5
7	((diabetes mellitus or (blood adj2 glucose)) adj2 (antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*)).ti,ab,kf.
8	or/1-3,6-7
9	Diabetes, Gestational/dh, th [Diet Therapy, Therapy]
10	Diabetes, Gestational/pc [Prevention & Control]
11	or/9-10
12	exp Diet/
13	Diet Therapy/ or Nutrition Therapy/ or Dietetics/
14	Glycemic Control/
15	exp Nutritive Value/
16	food/ or bread/ or exp cultured milk products/ or ice cream/ or milk/ or exp whey/ or exp dietary carbohydrates/ or exp dietary fats/ or dietary fiber/ or exp dietary proteins/ or exp probiotics/ or exp Edible Grain/ or exp vegetables/
17	exp Fruit/
18	((diet* or intake or consum* or food* or eat* or nutrition*) adj3 (glyc?emic or carbohydrate* or energy or calor* or fat* or oil* or probiotic* or fiber* or fibre* or soy* or fruit* or vegetable* or "whole grain*" or pattern*)).ti,ab,kf.
19	((diet* adj4 hypertension*) or DASH).ti,ab,kf.
20	(diet* adj3 ((high* or rais* or elevat* or increas*) adj2 "blood pressure*")).ti,ab,kf.
21	Sedentary Behavior/ or exp Exercise/
22	(exercis* or activ* or inactiv* or low energy or fitness or fit or aerobic* or gym* or movement or moving or sedent*).ti,ab,kf.
23	Fitness Trackers/
24	((wearable or fitness or activ*) adj3 (track* or device* or monitor*)).ti,ab,kf.
25	life style/ or healthy lifestyle/
26	(lifestyle* or life style*).ti,ab,kf.
27	(weigh or weighs or weighing or self weigh*).ti,ab,kf.
28	Self-Management/
29	Self Care/
30	((self or regular* or frequen*) adj2 (manag* or monitor* or regulat* or report* or care or track*)).ti,ab,kf.
31	Telemedicine/
32	(telemedicine* or tele medicine* or telehealth* or tele health* or ehealth or e health or mhealth or m health or mobile health or digital health).ti,ab,kf.
33	exp Communications Media/ or exp Social Networking/ or exp Internet/
34	(app or apps or blog* or booklet* or brochure* or dvd* or elearn* or e-learn* or email* or e-mail* or e mail* or facebook or facetime or face time or forum* or handout* or hand out* or helpline* or hotline* or internet* or ipad* or iphone* or leaflet* or myspace or online or magazine* or mobile or newsletter* or pamphlet* or palm pilot* or personal digital assistant* or pocket pc* or podcast* or poster? or skype* or smartphone* or smart phone* or social media or social network* or sms or telephone or text messag* or twitter or tweet* or video* or web* or wiki* or youtube* or fitbit* or smart watch* or smartwatch* or pedometer*).ti,ab,kf.
35	Mobile Applications/
36	(mobile* adj2 (app? or application*)).ti,ab,kf.
37	exp body weight changes/
38	((weight* adj3 (gain* or increas* or accelerat* or excess* or decreas* or retention or retain* or alter* or chang* or loss or lost or lose or losing or reduc* or status or manag* or maintain* or control* or health* or ideal* or optimal* or optimum or appropriate or recommend*)) or GWG).ti,ab,kf.

#	Searches
39	Weight Reduction Programs/
40	(weight adj2 (loss or manag* or reduc*) adj2 (program* or intervention* or group* or support* or organi?ation* or commercial*)).ti,ab,kf.
41	Counseling/
42	Behavior Therapy/ or exp Cognitive Behavioral Therapy/
43	Mentoring/
44	Consumer Health Information/ or exp Health Information Management/ or Health Communication/ or Health Promotion/ or Health Education/ or exp Patient Education as Topic/ or patient education handout/
45	Health Knowledge, Attitudes, Practice/
46	(therap* or intervention* or modif* or change* or treat* or support* or guid* or strateg* or program* or educat* or teach* or inform* or counsel* or mentor* or coach* or advi* or recommend*).ti.
47	mindful*.ti,ab,kf.
48	(health* adj2 (behavio* or belief* or believ*)).ti,ab,kf.
49	or/12-48
50	8 and 49
51	11 or 50
52	letter/
53	editorial/
54	news/
55	exp historical article/
56	Anecdotes as topic/
57	comment/
58	case reports/
59	(letter or comment*).ti.
60	or/52-59
61	randomized controlled trial/ or random*.ti,ab.
62	60 not 61
63	animals/ not humans/
64	exp Animals, Laboratory/
65	exp Animal Experimentation/
66	exp Models, Animal/
67	exp Rodentia/
68	(rat or rats or rodent* or mouse or mice).ti.
69	or/62-68
70	51 not 69
71	limit 70 to English language
72	Economics/
73	Value of life/
74	exp "Costs and Cost Analysis"/
75	exp Economics, Hospital/
76	exp Economics, Medical/
77	exp Resource Allocation/
78	Economics, Nursing/
79	Economics, Pharmaceutical/
80	exp "Fees and Charges"/
81	exp Budgets/
82	budget*.ti,ab.
83	cost*.ti,ab.
84	(economic* or pharmaco?economic*).ti,ab.
85	(price* or pricing*).ti,ab.
86	(financ* or fee or fees or expenditure* or saving*).ti,ab.
87	(value adj2 (money or monetary)).ti,ab.

#	Searches
88	resourc* allocat*.ti,ab.
89	(fund or funds or funding* or funded).ti,ab.
90	(ration or rations or rationing* or rationed).ti,ab.
91	ec.fs.
92	or/72-91
93	exp models, economic/
94	*Models, Theoretical/
95	*Models, Organizational/
96	markov chains/
97	monte carlo method/
98	exp Decision Theory/
99	(markov* or monte carlo).ti,ab.
100	econom* model*.ti,ab.
101	(decision* adj2 (tree* or analy* or model*)).ti,ab.
102	or/93-101
103	quality-adjusted life years/
104	sickness impact profile/
105	(quality adj2 (wellbeing or well being)).ti,ab.
106	sickness impact profile.ti,ab.
107	disability adjusted life.ti,ab.
108	(qal* or qtime* or qwb* or daly*).ti,ab.
109	(euroqol* or eq5d* or eq 5*).ti,ab.
110	(qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab.
111	(health utility* or utility score* or disutilit* or utility value*).ti,ab.
112	(hui or hui1 or hui2 or hui3).ti,ab.
113	(health* year* equivalent* or hye or hyes).ti,ab.
114	discrete choice*.ti,ab.
115	rosser.ti,ab.
116	(willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab.
117	(sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab.
118	(sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab.
119	(sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab.
120	(sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab.
121	(sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab.
122	or/103-121
123	71 and (92 or 112 or 122)
124	limit 123 to ed=19840101-20230605
125	limit 123 to dt=19840101-20230605
126	124 or 125

Database: Embase

Date of last search: 05/06/2023

#	Searches
1	pregnancy diabetes mellitus/
2	((antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*) adj2 (diabet* or hyperglyc* or IGR or IFG or IGT or FPG or ((glucose* or insulin* or glyc?emia) adj2 (intolerance* or regulation or fasting or resistance)))).ti,ab,kf.
3	GDM.ti,ab,kw.
4	exp pregnancy/ or pregnant woman/ or prenatal care/
5	diabetes mellitus/ or non insulin dependent diabetes mellitus/ or glucose blood level/ or glucose intolerance/
6	4 and 5

#	Searches
7	((diabetes mellitus or (blood adj2 glucose)) adj2 (antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*)).ti,ab,kf.
8	or/1-3,6-7
9	pregnancy diabetes mellitus/pc [Prevention]
10	pregnancy diabetes mellitus/th [Therapy]
11	9 or 10
12	exp diet/
13	dietetics/
14	diet therapy/ or diet restriction/ or low fat diet/ or diabetic diet/
15	glycemic control/
16	nutritional value/
17	glycemic index/ or glycemic load/
18	food/ or bread/ or bakery product/ or exp dairy product/ or exp carbohydrate intake/ or exp fat intake/ or dietary fiber/ or fiber intake/ or protein intake/ or probiotic agent/ or exp food grain/ or exp vegetable/ or exp fruit/
19	((diet* or intake or consum* or food* or eat* or nutrition*) adj3 (glyc?emic or carbohydrate* or energy or calor* or fat* or oil* or probiotic* or fiber* or fibre* or soy* or fruit* or vegetable* or "whole grain*" or pattern*)).ti,ab,kf.
20	((diet* adj4 hypertension*) or DASH).ti,ab,kf.
21	(diet* adj3 ((high* or rais* or elevat* or increas*) adj2 "blood pressure*")).ti,ab,kf.
22	sedentary lifestyle/
23	exp exercise/
24	(exercis* or activ* or inactiv* or low energy or fitness or fit or aerobic* or gym* or movement or moving or sedent*).ti,ab,kf.
25	exp activity tracker/
26	((wearable or fitness or activ*) adj3 (track* or device* or monitor*)).ti,ab,kf.
27	lifestyle/ or healthy lifestyle/
28	(lifestyle* or life style*).ti,ab,kf.
29	(weigh or weighs or weighing or self weigh*).ti,ab,kf.
30	self care/
31	((self or regular* or frequen*) adj2 (manag* or monitor* or regulat* or report* or care or track*)).ti,ab,kf.
32	exp telemedicine/
33	(telemedicine* or tele medicine* or telehealth* or tele health* or ehealth or e health or mhealth or m health or mobile health or digital health).ti,ab,kf.
34	exp mass communication/
35	exp social network/
36	(app or apps or blog* or booklet* or brochure* or dvd* or elearn* or e-learn* or email* or e-mail* or e mail* or facebook or facetime or face time or forum* or handout* or hand out* or helpline* or hotline* or internet* or ipad* or iphone* or leaflet* or myspace or online or magazine* or mobile or newsletter* or pamphlet* or palm pilot* or personal digital assistant* or pocket pc* or podcast* or poster? or skype* or smartphone* or smart phone* or social media or social network* or sms or telephone or text messag* or twitter or tweet* or video* or web* or wiki* or youtube* or fitbit* or smart watch* or smartwatch* or pedometer*).ti,ab,kf.
37	exp mobile application/
38	(mobile* adj2 (app? or application*)).ti,ab,kf.
39	exp body weight change/
40	((weight* adj3 (gain* or increas* or accelerat* or excess* or decreas* or retention or retain* or alter* or chang* or loss or lost or lose or losing or reduc* or status or manag* or maintain* or control* or health* or ideal* or optimal* or optimum or appropriate or recommend*)) or GWG).ti,ab,kf.
41	weight loss program/ or body weight management/
42	(weight adj2 (loss or manag* or reduc*) adj2 (program* or intervention* or group* or support* or organi?ation* or commercial*)).ti,ab,kf.
43	counseling/
44	behavior therapy/ or cognitive behavioral therapy/
45	mindfulness/
46	mentoring/
47	consumer health information/ or medical information system/ or medical information/
48	health education/ or diabetes education/ or health promotion/ or nutrition education/ or patient education/

#	Searches
49	attitude to health/
50	(therap* or intervention* or modif* or change* or treat* or support* or guid* or strateg* or program* or educat* or teach* or inform* or counsel* or mentor* or coach* or advi* or recommend*).ti.
51	mindful*.ti,ab,kf.
52	(health* adj2 (behavio* or belief* or believ*)).ti,ab,kf.
53	or/12-52
54	8 and 53
55	11 or 54
56	letter.pt. or letter/
57	note.pt.
58	editorial.pt.
59	case report/ or case study/
60	(letter or comment*).ti.
61	or/56-60
62	randomized controlled trial/ or random*.ti,ab.
63	61 not 62
64	animal/ not human/
65	nonhuman/
66	exp Animal Experiment/
67	exp Experimental Animal/
68	animal model/
69	exp Rodent/
70	(rat or rats or rodent* or mouse or mice).ti.
71	or/63-70
72	55 not 71
73	(conference abstract* or conference review or conference paper or conference proceeding).db,pt,su.
74	72 not 73
75	limit 74 to English language
76	health economics/
77	exp economic evaluation/
78	exp health care cost/
79	exp fee/
80	budget/
81	funding/
82	resource allocation/
83	budget*.ti,ab.
84	cost*.ti,ab.
85	(economic* or pharmaco?economic*).ti,ab.
86	(price* or pricing*).ti,ab.
87	(financ* or fee or fees or expenditure* or saving*).ti,ab.
88	(value adj2 (money or monetary)).ti,ab.
89	resourc* allocat*.ti,ab.
90	(fund or funds or funding* or funded).ti,ab.
91	(ration or rations or rationing* or rationed).ti,ab.
92	or/76-91
93	quality adjusted life year/
94	"quality of life index"/
95	short form 12/ or short form 20/ or short form 36/ or short form 8/
96	sickness impact profile/
97	(quality adj2 (wellbeing or well being)).ti,ab.
98	sickness impact profile.ti,ab.
99	disability adjusted life.ti,ab.

#	Searches
100	(qal* or qtime* or qwb* or daly*).ti,ab.
101	(euroqol* or eq5d* or eq 5*).ti,ab.
102	(qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab.
103	(health utility* or utility score* or disutilit* or utility value*).ti,ab.
104	(hui or hui1 or hui2 or hui3).ti,ab.
105	(health* year* equivalent* or hye or hyes).ti,ab.
106	discrete choice*.ti,ab.
107	rosser.ti,ab.
108	(willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab.
109	(sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab.
110	(sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab.
111	(sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab.
112	(sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab.
113	(sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab.
114	or/93-113
115	statistical model/
116	exp economic aspect/
117	115 and 116
118	*theoretical model/
119	*nonbiological model/
120	stochastic model/
121	decision theory/
122	decision tree/
123	monte carlo method/
124	(markov* or monte carlo).ti,ab.
125	econom* model*.ti,ab.
126	(decision* adj2 (tree* or analy* or model*)).ti,ab.
127	or/117-126
128	75 and (92 or 114 or 127)
129	limit 128 to dc=19840101-20230605

Database: CRD HTA (last updated 31st March 2018)

Date of last search: 05/06/23

#	Searches
1	MeSH DESCRIPTOR Diabetes, Gestational IN HTA
2	((((antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*) adj2 (diabet* or hyperglyc* or IGR or IFG or IGT or FPG)))) and (Project record:ZDT OR Full publication record:ZDT) IN HTA
3	((((glucose* or insulin* or glyc?emia) adj2 (intolerance* or regulation or fasting or resistance)))) and (Project record:ZDT OR Full publication record:ZDT) IN HTA
4	((GDM)) and (Project record:ZDT OR Full publication record:ZDT) IN HTA
5	MeSH DESCRIPTOR pregnancy EXPLODE ALL TREES IN HTA
6	MeSH DESCRIPTOR Pregnant Women IN HTA
7	MeSH DESCRIPTOR Prenatal Care IN HTA
8	MeSH DESCRIPTOR diabetes mellitus IN HTA
9	MeSH DESCRIPTOR diabetes mellitus, type 2 IN HTA
10	MeSH DESCRIPTOR blood glucose IN HTA
11	MeSH DESCRIPTOR glucose intolerance IN HTA
12	#5 OR #6 OR #7
13	#8 OR #9 OR #10 OR #11
14	#12 AND #13

#	Searches
15	((((diabetes mellitus or (blood adj2 glucose)) adj2 (antenatal* or ante natal* or gestation* or maternal* or pregnan* or prenatal* or pre natal*)))) and (Project record:ZDT OR Full publication record:ZDT) IN HTA
16	#1 OR #2 OR #3 OR #4 OR #14 OR #15
17	MeSH DESCRIPTOR Diabetes, Gestational WITH QUALIFIERS DH, TH, PC IN HTA
18	#16 OR #17

Database: INAHTA International HTA Database

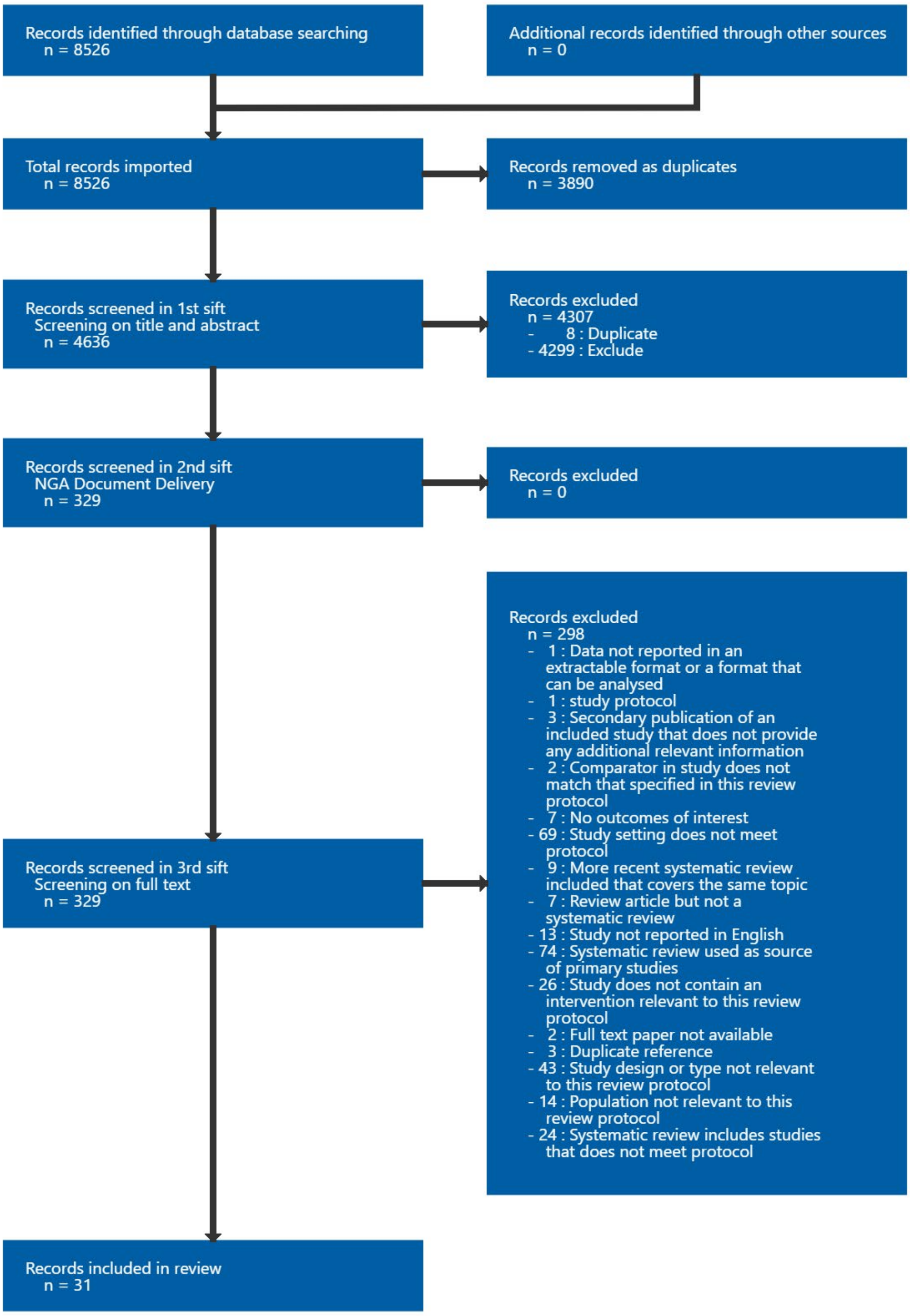
Date of last search: 05/06/2023

#	Searches
16	#15 OR #14 OR #13 OR #3 OR #2 OR #1
15	(((blood AND glucose)) AND (antenatal* or "ante natal" or gestation* or maternal* or pregnan* or prenatal* or "pre natal")))[Title] OR (((blood AND glucose)) AND (antenatal* or "ante natal" or gestation* or maternal* or pregnan* or prenatal* or "pre natal")))[abs]
14	(("diabetes mellitus" AND (antenatal* or "ante natal" or gestation* or maternal* or pregnan* or prenatal* or "pre natal")))[Title] OR (("diabetes mellitus" AND (antenatal* or "ante natal" or gestation* or maternal* or pregnan* or prenatal* or "pre natal")))[abs]
13	#12 AND #7
12	#11 OR #10 OR #9 OR #8
11	Glucose Intolerance[mh]
10	Blood Glucose[mh]
9	Diabetes Mellitus, Type 2[mh]
8	Diabetes Mellitus[mh]
7	#6 OR #5 OR #4
6	Prenatal Care[mh]
5	Pregnant Women[mh]
4	Pregnancy[mhe]
3	(GDM)[Title] OR (GDM)[abs]
2	(((antenatal* or "ante natal" or gestation* or maternal* or pregnan* or prenatal* or "pre natal") AND (diabet* or hyperglyc* or IGR or IFG or IGT or FPG)))[Title] OR (((antenatal* or "ante natal" or gestation* or maternal* or pregnan* or prenatal* or "pre natal") AND (diabet* or hyperglyc* or IGR or IFG or IGT or FPG)))[abs]
1	Diabetes, Gestational[mh]

Appendix C Effectiveness evidence study selection

Study selection for: What are the most effective and cost-effective healthy lifestyle interventions for women with gestational diabetes?

Figure 1: Effectiveness evidence study selection flow chart


Records identified through database searching
n = 8526
Additional records identified through other sources
n = 0
Total records imported
n = 8526
Records removed as duplicates
n = 3890
Records screened in 1st sift
Screening on title and abstract
n = 4636
Records excluded
n = 4307
- 8 : Duplicate
- 4299 : Exclude
Records screened in 2nd sift
NGA Document Delivery
n = 329
Records excluded
n = 0
Records screened in 3rd sift
Screening on full text
n = 329
Records excluded
n = 298
- 1 : Data not reported in an extractable format or a format that can be analysed
- 1 : study protocol
- 3 : Secondary publication of an included study that does not provide any additional relevant information
- 2 : Comparator in study does not match that specified in this review protocol
- 7 : No outcomes of interest
- 69 : Study setting does not meet protocol
- 9 : More recent systematic review included that covers the same topic
- 7 : Review article but not a systematic review
- 13 : Study not reported in English
- 74 : Systematic review used as source of primary studies
- 26 : Study does not contain an intervention relevant to this review protocol
- 2 : Full text paper not available
- 3 : Duplicate reference
- 43 : Study design or type not relevant to this review protocol
- 14 : Population not relevant to this review protocol
- 24 : Systematic review includes studies that does not meet protocol
Records included in review
n = 31

Appendix D Evidence tables

Evidence tables for review question: What are the most effective and cost-effective healthy lifestyle interventions for women with gestational diabetes?

Table 5: Evidence tables

Avery, 1997

Bibliographic Reference	Avery, M D; Leon, A S; Kopher, R A; Effects of a partially home-based exercise program for women with gestational diabetes.; Obstetrics and gynecology; 1997; vol. 89 (no. 1); 10-5

Study details

Country/ies where study was carried out	USA
Study type	Randomised controlled trial (RCT)
Study dates	Not reported
Inclusion criteria	Diagnosed with gestational diabetes by physician or certified nurse-midwife. Gestational age of 34 weeks or less. 18-40 years of age. No further significant medical or obstetric complications. Was not at time of study performing continuous 30-minute periods of physical activity more than two times per week Could read and write English.

Exclusion criteria	Not specified, however, women were excluded due to medical reasons (no detail) or if physical activity was recommended to them by the care provider.
Patient characteristics	**Mean age in years (SD)** Intervention: 32.2 (4.9) Comparator: 30.4 (5.1) **Parity (mean, SD)** Intervention: 1.5 (NR) Comparator: 0.4 (NR) **Mean gestational age in weeks [at screening] (SD)** NR **Mean gestational age in weeks [at intervention] (SD)** NR **Mean BMI in kg/m^2 [at baseline] (SD)** Intervention: 32.2 (5.9) Control: 30.0 (5.1) **BMI class (n, %)** NR **Ethnicity (n, %)** Intervention: Caucasian: 15 (100)

	Asian: 0 (0) Comparator: Caucasian: 12 (86) Asian: 2 (12) **Education level (n, %)** NR **Income status (n, %)** NR Setting: Large midwestern health maintenance organisation.
Intervention(s)/control	**Physical activity:** Involved physical activity for 30 minutes 3-4 times a week until the end of pregnancy. Physical activity involved 5-minutes of warm up and cool down, 20 minutes cycle with ergometer or walking at 70% of estimated maximal heart rate. An investigator was present for 2 of the sessions and included maternal and fetal monitoring. Unsupervised exercise was undertaken 1-2 times a week and were taught to check and record their heart rate. **Comparator:** Stayed on dietary therapy and as requested by the investigators, did not change their usual physical activity. The investigator called weekly to check on progress and women were asked to note the date, type and amount of exercise they undertook in their blood sugar record book. All women had been educated in home blood glucose monitoring and dietary counselling prior to entering the study. Fasting and 2-hour postprandial blood glucose was monitored three days per week by all women and read on a reflectance meter at the next clinic appointment. Daily home blood glucose results were recorded in log books.
Duration of follow-up	Not reported.

Sources of funding	Multiple sources of funding (academic, governmental, other). Type of funding from Boehringer Manheim Corporation was unclear.
Sample size	N total = 29 Physical activity n = 15 Standard care n = 14
Other information	Sourced from Brown 2017 Cochrane systematic review. Gestational weeks at diagnosis (mean, SD): Intervention: 28.7 (3.0); Control: 26.3 (8.1). Pre-pregnancy BMI kg/m^2 (mean, SD): Intervention: 28.4 (7.6); 25.5 (5.5). Gestational diabetes diagnostic criteria: O'Sullivan and Mahan criteria (1964) and national consensus screening guidelines (Metzger 1991). Timing: not reported. Screening: not reported. Diagnosis: not reported. Treatment target: not reported. ITT numbers used for analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status. Glycaemic outcomes were not able to be reported as the study reports average rates of change in daily blood glucose levels, or baseline values.

BMI: body mass index; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; N: number of participants; NR: not reported; SD: standard deviation; USA: United States of America.

Study arms

Physical activity (n = 15)

Standard care (n = 14)

Outcomes

Outcome	Physical activity, n = 15	Standard care, n = 14
Gestational weight change (kg) Follow-up not reported; Final weight reported; converted from lb to kg Mean (SD)	83.2 (15.5)	79.6 (15.5)
Mode of birth: Caesarean Follow-up at birth No of events	n = 3; % = 20	n = 3; % = 21.4
Gestational hypertension Gestational age at diagnosis not reported; diagnosed before birth No of events	n = 0; % = 0	n = 1; % = 7.1
Need for pharmacological intervention Exogenous insulin therapy; Follow-up not reported No of events	n = 4; % = 26.7	n = 2; % = 14.3
Large for gestational age > 90 centile Follow-up at birth; Defined in text as >4000g No of events	n = 3; % = 20	n = 3; % = 21.4
Neonatal hypoglycaemia Follow-up after birth; defined as blood glucose concentration <2.5mmol/L at 1, 3, or 5 hours after birth No of events	n = 0; % = 0	n = 0; % = 0

g: grams; kg: kilograms; lb: pounds; mmol/L: millimole per litre; n: number of participants; SD: standard deviation

Critical appraisal

This study was included in the Cochrane review (Brown 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane review (Brown 2017). See the Brown 2017 evidence table in Appendix D for the risk of bias assessment of the Cochrane review.

Bo, 2014

Bibliographic Reference	Bo, S; Rosato, R; Ciccone, G; Canil, S; Gambino, R; Poala, C B; Leone, F; Valla, A; Grassi, G; Ghigo, E; Cassader, M; Menato, G; Simple lifestyle recommendations and the outcomes of gestational diabetes. A 2 x 2 factorial randomized trial.; Diabetes, obesity & metabolism; 2014; vol. 16 (no. 10); 1032-5

Study details

Country/ies where study was carried out	Italy
Study type	Randomised controlled trial (RCT)
Study dates	2009-2012
Inclusion criteria	Women who were pregnant with gestational diabetes diagnosis based on a 75 g OGTT. Gestational age 24-26 weeks. Age 18-50 years. Singleton pregnancy.
Exclusion criteria	BMI > 40 kg/m^2 Any known diseases, medications or obstetrical absolute/relative contraindications to physical activity
Patient characteristics	**Mean age in years (SD)** Physical activity: 35.9 (4.8)

	Physical activity and mixed: 35.5 (4.4) Mixed: 35.1 (4.4) Control (diet): 33.9 (5.3) **Parity (n, %)** Nulliparous: Physical activity: 22 (45.0) Physical activity and mixed: 24 (48.0) Mixed: 17 (49.0) Control (diet): 25 (50.0) **Mean gestational age in weeks [at screening] (SD)** Not reported **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean BMI in kg/m^2 [at baseline] (SD)** Physical activity: 27.3 (4.1) Physical activity and mixed: 27.0 (3.9) Mixed: 26.9 (4.6) Control (diet): 26.8 (4.1) **BMI class (n, %)** Not reported

	Ethnicity (%) Not reported **Education level (n, %)** Not reported **Income status (n, %)** Not reported The study setting: Hospital
Intervention(s)/control	**Physical activity:** Advised to briskly walk at least 20 minutes/day (140 minutes/week; Borg's scale target rating 12–14) and individually-prescribed diet recommendations*. **Physical activity and mixed:** Advised to walk briskly at least 20 minutes/day every day (140 min/week; Borg's scale target rating 12–14) plus individually oral/written recommendations for helping with healthy dietary choices (that is, lowering carbohydrate intake, strategies for out-of-home eating, healthy cooking and food shopping and related behavioural suggestions) and debunking false myths about diet in pregnancy. In addition to individually-prescribed diet recommendations* **Mixed:** Individually oral/written recommendations for helping with healthy dietary choices (that is, lowering carbohydrate intake, strategies for out-of-home eating, healthy cooking and food shopping and related behavioural suggestions) and debunking false myths about diet in pregnancy. In addition to individually-prescribed diet recommendations*. **Control (diet):** Individually-prescribed diet recommendations*. *All women were given an individually-prescribed diet (carbohydrates 48% to 50%, proteins 18% to 20%, fats 30% to 35%, fibre 20 g to 25 g/day, no alcohol).

	All women self-monitored blood glucose 4-6 times daily (preprandial and 2 h postprandial) via glucometer.
Duration of follow-up	At gestational age of 38 weeks or before delivery (if pre-term).
Sources of funding	Not industry funded.
Sample size	N total = 200 Physical activity n = 51 Diet n = 50 Mixed n = 49 Physical activity with diet n = 50
Other information	Sourced from Brown 2017 and Han 2017 Cochrane systematic reviews. Gestational diabetes diagnostic criteria: Not reported. Timing: 24-26 gestational weeks. Screening: Not reported. Diagnosis: 75 g OGTT no further details. Treatment target: Treatment glycaemic targets not detailed but insulin was started in the presence of fetal abdominal ultrasound > 70th percentile and or maternal hyperglycaemia (no details). The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status. ITT numbers used for analysis.

BMI: body mass index; g: grams; h: hour/s; ITT: intention to treat; kg: kilograms; m: metres; min: minutes; n: number of participants; NR: not reported; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

Physical activity (n = 51)

Control (diet) (n = 50)

Mixed (n = 49)

Physical activity and mixed (n = 50)

Outcomes

Outcome	Physical activity, n = 51	Control (diet), n = 50	Mixed, n = 49	Physical activity and mixed, n = 50
Glycaemic control: fasting blood glucose concentration at the end of the intervention **(mmol/L)** Converted from mg/dL to mmol/L Mean (SD)	4 (0.6)	4.1 (0.6)	4.1 (0.6)	4 (0.6)
Gestational weight change (kg) Final weight; assessed at gestational age of 38 weeks or before delivery if pre-term Mean (SD)	73.2 (11)	74.1 (13)	74 (11.4)	73.2 (11.4)
Mode of birth: Caesarean Follow-up at birth No of events	n = NR; % = 17.7	n = NR; % = 26	n = NR; % = 20.4	n = NR; % = 16
Need for pharmacological therapy Insulin; Follow-up to 38 gestational weeks or before delivery (if pre-term) No of events	n = NR; % = 5.9	n = NR; % = 10	n = NR; % = 6.1	n = NR; % = 6

Outcome	Physical activity, n = 51	Control (diet), n = 50	Mixed, n = 49	Physical activity and mixed, n = 50
Large for gestational age > 90 centile Follow-up at birth No of events	n = NR; % = 9.8	n = NR; % = 14	n = NR; % = 10.2	n = NR; % = 10
Neonatal morbidity Follow-up unclear; Composite defined in-text as newborn complications which included: Large for gestational age, pre-term birth (delivery <37 gestational weeks) and any neonatal conditions requiring a specific treatment or a prolonged in-hospital stay No of events	n = NR; % = 3.9	n = NR; % = 10	n = NR; % = 4.1	n = NR; % = 2

g: grams; kg: kilograms; mg/dL: milligrams per decilitre; mmol/L: millimole per litre; n: number of participants; NR: not reported; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Brown 2017 and Han 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane reviews (Brown 2017 and Han 2017). See the Brown 2017 and Han 2017 evidence tables in Appendix D for the risk of bias assessments of respective Cochrane reviews.

Borgen, 2019

Bibliographic Reference	Borgen, Iren; Smastuen, Milada Cvancarova; Jacobsen, Anne Flem; Garnweidner-Holme, Lisa Maria; Fayyad, Seraj; Noll, Josef; Lukasse, Mirjam; Effect of the Pregnant+ smartphone application in women with gestational diabetes mellitus: a randomised controlled trial in Norway.; BMJ open; 2019; vol. 9 (no. 11); e030884

Study details

Country/ies where study was carried out	Norway

Study type	Randomised controlled trial (RCT)
Study dates	2015-2017
Inclusion criteria	Pregnant women with a 2-hour OGTT blood glucose level of ≥9mmol/L. <33 gestational weeks. 18 years of age or older. Owned a smartphone. Understood Norwegian, Urdu or Somali.
Exclusion criteria	Type 1 or 2 diabetes. Twin pregnancy. Lactose or gluten intolerance.
Patient characteristics	**Age in years (n, %)** Intervention: ≤29: 30 (26.1) 30-37: 66 (57.4) ≥38: 19 (16.5) Comparator: ≤29: 27 (22.0) 30-37: 62 (50.4) ≥38: 34 (27.6)

	Parity (n, %) Intervention: Primiparous: 47 (40.9) Multiparous: 68 (59.1) Comparator: Primiparous: 63 (51.2) Multiparous: 60 (48.8) **Mean gestational age in weeks [at screening] (SD)** Not reported 76.5% in the intervention arm and 76.4% in the comparator arm were at 25-32 gestational weeks at diagnosis. **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD)** Not reported **BMI class (n, %)** Intervention: 17–24 kg/m^2: 43 (37.4) 25–30 kg/m^2: 28 (34.1) 31–40 kg/m^2: 17 (14.8) ≥41 kg/m^2: 2 (1.7)

	Comparator: 17–24 kg/m^2: 39 (33.3) 25–30 kg/m^2: 46 (48.0) 31–40 kg/m^2: 22 (17.9) ≥41 kg/m^2: 1 (0.8) **Ethnicity (n, %)** Not reported **Education level (n, %)** Intervention: Primary school/no education: 10 (8.7) High school: 20 (17.4) College or university <4 years: 32 (27.8) College or university ≥4 years: 53 (46.1) Comparator: Primary school/no education: 13 (10.6) High school: 37 (30.1) College or university: <4 years 27 (22.0) College or university: ≥4 years 46 (37.4) **Employment status (n, %)** Intervention:

	Employed or self-employed: 93 (80.9) Not employed or not self-employed: 22 (19.1) Comparator: Employed or self-employed: 87 (70.7) Not employed or not self-employed: 36 (29.3) Study setting: Outpatient diabetes clinics in Oslo region.
Intervention(s)/control	**Mixed intervention:** Pregnant+ app and usual care. Pregnant+ app downloaded by women to their smartphone in hospital or at home. The app aimed to support gestational diabetes management by adapting a healthy diet, being physically active and providing blood glucose level feedback. The app contained four icons: 'Blood glucose': real-time glucose values from a glucometer displayed in graph or table with simple visual indication of normal or high levels. Blood glucose values were recorded manually or automatically uploaded via the Bluetooth. Women had the option to print blood glucose values to assist discussion with their health professionals. 'Physical activity': Displayed advantages of performing physical activities with written examples and accompanying images of how to perform different activities such as swimming, stretching and strength training during pregnancy. Women could also record personal goals. 'Food and beverages': Culturally adapted information provided about healthy diet and recommendations for healthy drinks. Culturally tailored food items were illustrated based on language selection and a link to Norwegian Diabetes Foundation provided which includes recipes and further information. 'Diabetes information': General information about gestational diabetes. Specific information provided about each woman's follow-up in pregnancy and postpartum. The app also provided information about advantages of breastfeeding and a frequently asked question section as well as a small glossary. **Standard care:**

	Usual care provided by midwives or diabetes nurses within consultations every 2 weeks. Information was provided on healthy diet (reducing sugar-rich products, greater consumption of whole grains and vegetables and frequent small meals) and encouragement of regular physical activity according to pregnancy stage. Women taught how to measure and record blood glucose levels either on a sheet of paper or in a diary to be shown at consultations. If a woman in this arm independently downloaded the app, access was restricted to a link to the Norwegian Directorate of Health with generic gestational diabetes information and a link to the Norwegian Federation of Diabetes. All women received glucometers and lancets from the study coordinators.
Duration of follow-up	Until 3 months postpartum
Sources of funding	Not industry funded.
Sample size	N total = 238 Mixed intervention n = 115 Standard care n = 123
Other information	Gestational diabetes diagnostic criteria (guidelines not reported): Timing: not reported. Screening: not reported. Diagnosis: fasting blood glucose sample (value not reported) followed by 75 g OGTT and 2 h ≥9mmol/L. Treatment target: not reported. ITT numbers used for analysis. The study did not report information on disability, LGBTQ+ or previous bariatric surgery status.

	Glycaemic outcomes could not be reported as the study only provided these at 3 months postpartum.

App: application; BMI: body mass index; g: grams; h: hour/s; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; min: minutes; n: number of participants; NR: not reported; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

Mixed intervention (n = 115)

Standard care (n = 123)

Outcomes

Outcome	Mixed intervention, n = 115	Standard care, n = 123
Mode of birth: Vaginal birth Follow-up at birth No of events	n = 90; % = 78.3	n = 86; % = 69.9
Mode of birth: Induction of labour Follow-up at birth No of events	n = 54; % = 47	n = 66; % = 53.7
Mode of birth: Caesarean Follow-up at birth No of events	n = 32; % = 27.8	n = 35; % = 28.5
Need for pharmacological intervention Follow-up unclear; Intervention n = 112 and comparator n = 121 No of events	n = 39; % = 33.9	n = 43; % = 35
Metformin Follow-up unclear; Intervention n = 112 and comparator n = 121	n = 10; % = 8.9	n = 15; % = 12.4

Outcome	Mixed intervention, n = 115	Standard care, n = 123
No of events		
Insulin Follow-up unclear; Intervention n = 112 and comparator n = 121 No of events	n = 21; % = 18.8	n = 24; % = 19.8
Metformin and insulin Follow-up unclear; Intervention n = 112 and comparator n = 121 No of events	n = 8; % = 7.1	n = 4; % = 3.3
Large for gestational age > 90 centile >4000 grams (macrosomia); Follow-up at birth with data extracted from medical records. No of events	n = 12; % = 10.4	n = 15; % = 12.2

n: number of participants

Critical appraisal – Cochrane Risk of Bias tool v2.0 for RCTs

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Randomisation and allocation performed by computer based program. No significant baseline differences between arms to suggest issues with randomisation process.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(intervention were aware of their assigned intervention during the trial but it is unlikely to have an impact on the intervention. Intention to treat analysis performed with all participants reported to receive allocated interventions.)*

Section	Question	Answer
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Data for all outcomes of interest were available for all women.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Health professionals providing care during labour were most likely blinded. Outcomes were objective. The statistician was blinded to the allocation of the participants until the primary outcome analysis was completed.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low *(Data were in accordance with a pre-specified analysis plan. Numerical result unlikely to have been selected on basis of multiple outcome measurements or analyses.)*
Overall bias and Directness	Risk of bias judgement	Low *(The study is judged to be at low risk of bias for all domains for this result.)*
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	N/A

N/A: not applicable; RCTs: randomised controlled trials; RCTs: randomised controlled trials.

Brankston, 2004

Bibliographic Reference	Brankston, Gabrielle N; Mitchell, B F; Ryan, Edmond A; Okun, Nanette B; Resistance exercise decreases the need for insulin in overweight women with gestational diabetes mellitus.; American journal of obstetrics and gynecology; 2004; vol. 190 (no. 1); 188-93

Study details

Country/ies where study was carried out	Canada
Study type	Randomised controlled trial (RCT)
Study dates	Not reported
Inclusion criteria	Women with gestational diabetes that are otherwise healthy. Aged 20-40 years. Gestational age of 26-32 weeks. BMI <40 kg/m^2. Did not smoke. Were not in a regular exercise program.
Exclusion criteria	Not reported
Patient characteristics	**Mean age in years (SD)** Intervention: 31.3 (5.0) Comparator: 30.5 (4.4) **Parity (n, %)** NR **Mean gestational age in weeks [at screening] (SD)** Intervention: 29.6 (2.1) Comparator: 29.0 (2.0)

	Mean gestational age in weeks [at intervention] (SD) NR **Mean pre-pregnancy BMI in kg/m^2 (SD)** Intervention: 28.0 (5.7) Comparator: 25.9 (3.4) **BMI class (n, %)** NR **Ethnicity (n, %)** NR **Education level (n, %)** NR **Income status (n, %)** NR Setting: Outpatient clinics at two hospitals.
Intervention(s)/control	**Physical activity:** Progressive physical conditioning program. Three introductory sessions with supervision from an experienced instructor with weekly contact to ensure safety and adherence. Women were instructed to perform resistance training circuit-type exercises 3 times per week. The level of physical activity to reach was advised to be “somewhat hard”. Women were educated on heart rate self-monitoring in order to avoid exceeding 140 beats/min during exercise and recorded each physical activity session in a log book. The intervention was in addition to standard diabetic diet*. **Comparator:**

	Standard diabetic diet* and were asked not to start a structured physical activity program during pregnancy. *Standard diabetic diet: 40% carbohydrate, 20% protein, 40% fat, calculated at 24 to 30 kcal/kg per day on the basis of the woman's ideal pre-pregnant body weight. Both groups performed daily fasting and 1 or 2 h postprandial measurements home glucose monitoring with portable glucometers that had memory capabilities.
Duration of follow-up	Not reported
Sources of funding	Not reported
Sample size	Total N = 32 Physical activity n = 16 Standard care n = 16
Other information	Sourced from Brown 2017 Cochrane systematic review. 3 women were advised against exercising due to gestational hypertension and were excluded. Gestational diabetes diagnostic criteria: Canadian Diabetes Association guidelines. Timing: Not reported. Screening: 50 g oral glucose, 1 h plasma glucose. If ≥10.3 mmol/L (185 mg/ dL) qualified diagnosis of gestational diabetes. Diagnosis: 75 g OGTT, 2 of 3 values met or exceeded: fasting, ≥5.3 mmol/L (95 mg/dL); 1 h, ≥10.6 mmol/L (191 mg/dL); 2 h, ≥ 8.9 mmol/L (160 mg/dL). Treatment target: Insulin therapy was initiated if values were continuously higher than any of 3 of the following at any time during diet therapy: mean fasting, ≥5.3 mmol/L (95 mg/dL); mean 1 h post-prandial, ≥7.8 mmol/L (140 mg/dL); or 2 h postprandial, ≥6.7 mmol/L (120 mg/dL). Regimens were individualised and short-acting insulin was prescribed before meals and intermediate-acting insulin was prescribed at bedtime.

	The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status. ITT numbers were not able to be used for analysis as not all allocation numbers were available.

BMI: body mass index; g: grams; h: hour/s; ITT: intention to treat; kcal/kg: kilocalories per kilogram; kg: kilograms; m: metres; mmol/L: millimole per litre; min: minutes; mg/ dL: milligrams per decilitre; n: number of participants; NR: not reported; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

Physical activity (n = 16)

Standard care (n = 16)

Outcomes

Outcome	Physical activity, n = 16	Standard care, n = 16
Glycaemic control: fasting blood glucose concentration (mmol/L) at the end of the intervention n = 12 for both arms Mean (SD)	4.7 (0.39)	5.1 (0.65)
Gestational weight change (kg) Total pregnancy weight gain; Follow-up unclear No of events	n = 7; % = 43.8	n = 9; % = 56.3
Need for pharmacological intervention Insulin; Follow-up not reported No of events	n = 7; % = 43.8	n = 9; % = 56.3

kg: kilograms; mmol/L: millimole per litre; n: number of participants; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Brown 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane review (Brown 2017). See the Brown 2017 evidence table in Appendix D for the risk of bias assessment of the Cochrane review.

Brown, 2017

Bibliographic Reference	Brown, J.; Ceysens, G.; Boulvain, M.; Exercise for pregnant women with gestational diabetes for improving maternal and foetal outcomes; Cochrane Database of Systematic Reviews; 2017; vol. 2017 (no. 6); cd012202

Study details

Country/ies where study was carried out	5 RCTs were included from this review (Avery 1997, Bo 2014, Brankston 2004, Halse 2014 (Halse 2015), Jovanovic-Peterson 1989) Included countries from these 5 RCTs: Australia, Canada, Italy, USA
Study type	Systematic review of randomised controlled trials
Study dates	Systematic review inclusion dates: No date restrictions. All databases searched 27 August 2016.
Inclusion criteria	Systematic review inclusion criteria: **Types of studies** Published or unpublished randomised controlled trials in full-text or abstract format. Cluster-randomised trials were eligible. Conference abstracts were handled in the same way as full-text publications. **Types of participants** Pregnant women diagnosed with gestational diabetes mellitus (GDM) (as defined by trialist). **Types of interventions**

	Any type of exercise programme (+/- standard care) targeted at women with GDM at any stage of pregnancy compared with 1) standard care or 2) another intervention. **Types of outcome measures:** Extensive, included all of the maternal and neonatal/infant outcomes relevant for this review.
Exclusion criteria	Women with known pre-gestational diabetes (type 1 or type 2 diabetes) were excluded. Quasi-randomised and cross-over trials were not eligible for inclusion.
Patient characteristics	See Appendix D evidence tables for individual study characteristics.
Intervention(s)/control	See Appendix D evidence tables for individual intervention/control details.
Duration of follow-up	For included studies in this review: Avery 1997: Not reported; Bo 2014: At gestational age of 38 weeks or before delivery (if pre-term); Brankston 2004: Not reported, Halse 2014: to mean (SD) 34.6 (0.3) gestational weeks, Jovanovic-Peterson 1989: Not reported
Sources of funding	Not industry funded
Sample size	N = 5 RCTs included in this systematic review ranging from total sample size N = 19 (Jovanovic-Peterson 1989) to N = 194 (Bo 2014) (Cochrane review total RCTs = 11)

RCT: randomised control trial; USA: United States of America.

Outcomes

See Appendix D evidence tables for individual study outcomes.

Critical appraisal – Risk of Bias in Systematic Reviews (ROBIS) checklist

Section	Question	Answer
Study eligibility criteria	Concerns regarding specification of study eligibility criteria	Low *(Review adhered to objectives and eligibility criteria were appropriate.)*
Identification and selection of studies	Concerns regarding methods used to identify and/or select studies	Low *(Search databases and methods were appropriate with no restrictions to date or language applied. Two reviewers independently assessed study inclusion.)*
Data collection and study appraisal	Concerns regarding methods used to collect data and appraise studies	High *(Data extraction and risk of bias was performed by two reviewers. Certain baseline characteristics (such as BMI, maternal age, parity, education level, ethnicity) were not reported; follow-up times were not reported; gestational diabetes diagnostic criteria or indication for treatment were also not always reported which would have aided the interpretation of the evidence. All other important study characteristics were reported. All relevant results collected for synthesis.)*
Synthesis and findings	Concerns regarding the synthesis and findings	Low *(All analyses were appropriate and pre-defined with heterogeneity and biases addressed.)*
Overall study ratings	Overall risk of bias	High
Overall study ratings	Applicability as a source of data	Fully applicable

BMI: body mass index.

Carolan-Olah, 2019

Bibliographic Reference	Carolan-Olah, Mary; Sayakhot, Padaphet; A randomized controlled trial of a web-based education intervention for women with gestational diabetes mellitus.; Midwifery; 2019; vol. 68; 39-47

Study details

Country/ies where study was carried out	Australia
Study type	Randomised controlled trial (RCT)
Study dates	2014-2015
Inclusion criteria	Pregnant women aged 18-45 with a recent diagnosis of gestational diabetes. Attending the Hospital Maternity Diabetes Clinic.
Exclusion criteria	Pre-existing type 1 or 2 diabetes. Not able to write or understand English.
Patient characteristics	**Mean age in years (SD)** NR, total mean (range) 31.7 (19-43) years **Parity (n, %)** NR **Mean gestational age in weeks [at screening] (SD)** NR **Mean gestational age in weeks [at intervention] (SD)** NR **Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD)** NR **BMI class (n, %)**

	Intervention: Underweight (<18.5 kg/m^2): 0 (0) Healthy weight (18.5–24.9 kg/m^2): 21 (40.4) Overweight (25–29.9 kg/m^2): 11 (21.2) Obese (≥30 kg/m^2): 20 (38.5) Comparator: Underweight (<18.5 kg/m^2): 0 (0) Healthy weight (18.5–24.9 kg/m^2): 17 (29.3) Overweight (25–29.9 kg/m^2): 15 (25.9) Obese (≥30 kg/m^2): 26 (44.8) **Ethnicity (%)** NR **Education level (n, %)** Intervention: Year 12 or below: 12 (23.1) Certificate, advanced diploma or diploma:13 (25) Bachelor degree: 17 (32.7) Postgraduate degree (for example, Graduate diploma, Masters or PhD): 10 (19.2) Comparator: Year 12 or below: 17 (29.3)

	Certificate, advanced diploma or diploma:16 (27.6) Bachelor degree: 13 (22.4) Postgraduate degree (for example, Graduate diploma, Masters or PhD): 12 (20.7) **Work status (n %)** Intervention Full time: 16 (39.8) Part time: 11 (21.2) Other (for example, no paid work or unemployed): 25 (48.1) Comparator Full time: 20 (34.5) Part time: 8 (13.8) Other (for example, No paid work or unemployed): 30 (51.7) The study setting: Maternity diabetes clinic within a large metropolitan hospital.
Intervention(s)/control	**Mixed intervention:** Web-based educational intervention with four modules relating to gestational diabetes and four information resources. The four modules covered healthy food choices, healthy habits/ lifestyle, emotions, family and food, and testing blood glucose levels and the four information resources were based on nutrition recommendations and provided information on what is gestational diabetes, healthy diet and exercise, what to do if still hungry and healthy purchases. After each section, a quiz was displayed. **Standard care:** Single clinic-based educational class as part of usual care which was held for 1.5 h by a hospital dietician and diabetes educators at the beginning of a gestational diabetes diagnosis. 5-8 women would usually attend a class covering blood

	glucose monitoring instructions, healthy diet information, which foods to avoid/limit as well as physical activity and healthy lifestyle.
Duration of follow-up	12 weeks postpartum.
Sources of funding	Not industry funded.
Sample size	N total = 116 Mixed intervention n = 56 Standard care n = 60
Other information	Gestational diabetes diagnostic criteria: NR but likely Australasian Diabetes in Pregnancy (ADIPS) criteria: Timing: not reported. Screening: not reported. Diagnosis: fasting plasma glucose 5.1–6.9 mmol/L, or 1 h glucose ≥10 mmol/L, or 2 h glucose 8.5–11 mmol/L. Treatment target: not reported. Women were recruited at about 28–32 gestational weeks. The hospital where the study was based served a low socio-economic area with high migrant populations (76.9% and 62.1% in the study intervention and comparator were born overseas, respectively) with lower access to pregnancy healthcare as well as lower health literacy. ITT numbers used for analysis. The study did not report information on disability, LGBTQ+ or previous bariatric surgery status. The study reported all other potentially relevant outcomes at postpartum.

BMI: body mass index; h: hour/s; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; n: number of participants; NR: not reported; PhD: Doctor of Philosophy; SD: standard deviation.

Study arms

Mixed intervention (n = 56)

Standard care (n = 60)

Outcomes

Outcome	Mixed intervention, n = 56	Standard care, n = 60
Large for gestational age > 90 centile >4000g (macrosomia) with follow-up at birth (information obtained from medical records at 12w postpartum); intervention n = 52, comparator n = 58 No of events	n = 2; % = 3.8	n = 1; % = 1.7

g: grams; n: number of participants; w: weeks.

Critical appraisal – Cochrane Risk of Bias tool v2.0 for RCTs

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Allocation was by a computer generated list of random numbers. No information was provided on blinding of allocation sequence. No major significant differences between baseline differences to suggest problem with randomisation process.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Some concerns *(Participants and those that delivered the intervention were not blinded to allocation, however unlikely to have impacted the intervention. In addition, those allocated to standard care were not given the password to the web intervention. The analysis was not ITT and did not include 6 women that withdrew from the study after birth which was unlikely to impact the result.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(There were more participants with missing outcome data than number of events for outcome, however, it is unlikely that missingness in the outcome depended on*

Section	Question	Answer
		it's true value as withdrawal of the participants occurred after outcome occurrence.)
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Measurement of outcome was appropriate and unlikely to differ between arms.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low *(The trial was registered prospectively with the protocol approved by the hospital human research committee and while a statistical analysis plan is not published, it was likely prospective. Numerical result unlikely to have been selected on basis of multiple outcome measurements or analyses.)*
Overall bias and Directness	Risk of bias judgement	Some concerns *(The study is judged to raise some concerns in at least one domain for this result, but not to be at high risk of bias for any result.)*
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	N/A

ITT: intention to treat; NA: not applicable; RCTs: randomised controlled trials.

Christie, 2022

Bibliographic Reference	Christie, Hannah E; Chang, Courtney R; Jardine, Isabelle R; Francois, Monique E; Three short postmeal walks as an alternate therapy to continuous walking for women with gestational diabetes.; Applied physiology, nutrition, and metabolism = Physiologie appliquee, nutrition et metabolisme; 2022; vol. 47 (no. 10); 1031-1037

Study details

Country/ies where study was carried out	Australia

Study type	Randomised controlled trial (RCT)
Study dates	2018-2020
Inclusion criteria	Women diagnosed with gestational diabetes based on International Association of Diabetes in Pregnancy Study Group (IADPSG) criteria (see other information). Aged >18 years. <30 weeks gestational weeks.
Exclusion criteria	Unable to perform physical activity. Multiple gestation. High-risk pregnancy. Taking pre-existing hypertension medications. Cardiac disease, renal disease, thyroid disease, or psychosis. Treatment with metformin or corticosteroids.
Patient characteristics	**Mean age in years (SD)** Intervention: 35 (4) Comparator: 34 (4) **Parity (n, %)** Not reported **Mean gestational age in weeks [at screening] (SD)** Not reported

	Mean gestational age in weeks [at intervention] (SD) Not reported **Mean BMI in kg/m^2 [at baseline] (SD)** Not reported **BMI class (n, %)** Not reported **Ethnicity (%)** Not reported **Education level (n, %)** Not reported **Income status (n, %)** Not reported The study setting: Local health district.
Intervention(s)/control	**Physical activity:** Three 10-minute rounds of continuous walking, within 60 minutes of breakfast, lunch, and dinner. **Standard care:** 30 minutes of moderate intensity daily continuous physical activity, undertaken at any time as per physical activity guidelines provided in standard care. All women: Walking encouraged as main form of exercise with examples provided of how to integrate into daily routine.

	Underwent 3 days of baseline standard care, followed by 3 days of their allocation. Baseline standard care involved a group education session at local health district diabetes service. This involved guideline based nutrition education (NHMRC 2013) focusing on carbohydrates and with low GI index carbohydrates (around two exchanges 15g each) for all meals and snacks; self-monitoring blood glucose and physical activity as described above for standard care. Wore a continuous glucose monitor and inclinometer for 6 days under free-living conditions between 28-30 gestational weeks. Recorded their meal times.
Duration of follow-up	At time of finishing 3 day intervention.
Sources of funding	Not industry funded.
Sample size	N total = 32 Physical activity n = 17 Standard care n = 15
Other information	Gestational diabetes diagnostic criteria IADPSG criteria (Duran et al. 2014). Timing: Not reported. Screening: Not reported. Diagnosis: Not reported. Treatment target: Not reported. ITT numbers per allocation could not be used for analysis as they were not reported, instead reported numbers provided were used (those that completed the intervention). The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status.

BMI: body mass index; GI: glycaemic index; IADPSG: International Association of Diabetes in Pregnancy Study Group; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; n: number of participants; SD: standard deviation.

Study arms

Physical activity (n = 17)

Standard care (n = 15)

Outcomes

Outcome	Physical activity, n = 17	Standard care, n = 15
Glycaemic control: during intervention fasting blood glucose (mmol/L) Mean over 3 days of intervention Mean (SD)	5 (0.4)	4.9 (0.4)

mmol/L: millimole per litre; n: number of participants; SD: standard deviation.

Critical appraisal – Cochrane Risk of Bias tool v2.0 for RCTs

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Randomisation was performed by a third party computer random number generator, however, no information was provided on allocation concealment. There were significant differences between groups for BMI at baseline (Intervention mean (SD) 30.4 (6.65); control 25.1 (4.66)) and is unclear if this was compatible with chance as there were no other significant baseline differences.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Some concerns *(No information on whether participants and those that delivered the intervention were blinded to allocation, however unlikely to have impacted the intervention. The analysis was not intention to treat and did not include 6 women that withdrew from the study (of the total participants (N = 41) n = 5*

Section	Question	Answer
		due to skin irritations from the continuous glucose monitor and n = 2 for personal reasons, no information on which allocation), however, unlikely to have a substantial impact on the result.)
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(Intention to treat analysis was not used. The primary reason for withdrawal from the study due to skin irritations from the continuous glucose monitor was directly related to missing outcome data (12% of total included women (n = 5/41); numbers by allocation not reported).)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Method of outcome measurement was appropriate and was unlikely to have differed between groups. Outcomes were objective. No information whether outcome assessors were aware of allocation but was unlikely to affect assessment of outcome.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(No information provided on whether the trial was analysed in accordance with a pre-specified analysis plan. Numerical result unlikely to have been selected on basis of multiple outcome measurements or analyses.)*
Overall bias and Directness	Risk of bias judgement	High *(The study is judged to be at high risk of bias in at least one domain for this result.)*
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	N/A

BMI: body mass index; n: number of participants; N/A: not applicable; RCTs: randomised controlled trials; SD: standard deviation.

Cypryk, 2007

Bibliographic Reference	Cypryk, Katarzyna; Kaminska, Patrycja; Kosinski, Marcin; Pertynska-Marczewska, Magdalena; Lewinski, Andrzej; A comparison of the effectiveness, tolerability and safety of high and low carbohydrate diets in women with gestational diabetes.; Endokrynologia Polska; 2007; vol. 58 (no. 4); 314-9

Study details

Country/ies where study was carried out	Poland
Study type	Randomised controlled trial (RCT)
Study dates	Not reported.
Inclusion criteria	Caucasian women with newly diagnosed gestational diabetes.
Exclusion criteria	Not reported.
Patient characteristics	**Mean age in years (SD)** Not reported, overall 28.7 (3.7) **Parity (n, %)** Not reported **Mean gestational age in weeks [at screening] (SD)** Not reported **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean BMI in kg/m^2 [at baseline] (SD)** Not reported

	BMI class (n, %) Not reported **Ethnicity (n, %)** Caucasian: Low-carbohydrate diet: 15 (100) High-carbohydrate diet: 15 (100) **Education level (n, %)** Not reported **Income status (n, %)** Not reported Study setting: Outpatient diabetes and metabolic diseases hospital clinic.
Intervention(s)/control	**Low-carbohydrate diet:** Daily total energy divided as carbohydrate: 45%, protein: 25%, fat: 30% (based on daily total energy of 1800 kcal) and advised by a qualified dietician. Women were encouraged to follow the diet until birth. **High-carbohydrate diet:** Daily total energy divided as carbohydrate: 60%, protein: 25%, fat: 15% (based on daily total energy of 1800 kcal). Women were encouraged to follow the diet until birth. All women: 3-4 days prior to the intervention, blood glucose was recorded from the women's diaries to obtain average 24 h glycaemia under normal diet conditions. All were educated by a qualified dietician.

	For the first 14 days of the intervention, women were instructed to self-monitor their blood glucose at home 4 times a day (fasting and 2 h after breakfast, lunch and dinner) and to be recorded in the home blood glucose monitoring diary. On day 15, nutritional recommendation compliance was checked and diaries were reviewed. Urine ketones were checked daily.
Duration of follow-up	Not reported.
Sources of funding	Not reported.
Sample size	Total N = 30 Low-carbohydrate diet: n = 15 High-carbohydrate diet: n = 15
Other information	Sourced from Han 2017 Cochrane systematic review. Gestational diabetes diagnostic criteria: WHO criteria. Timing: 24-26 gestational weeks. Screening: Not reported. Diagnosis: 1 or more value met or exceeded: Fasting ≥ 7.0 mmol/L; 75 g glucose load 2 h ≥ 7.8 mmol/L. Treatment target: Not reported, blood glucose values aimed at: fasting ≤90 mg/dl and 2 h after each meal ≤120 mg/dL. Gestational age in weeks at delivery (mean, SD): Low-carbohydrate diet: 38.9 (1.4); High-carbohydrate diet: 38.8 (1.2). The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status. ITT numbers used for analysis.

BMI: body mass index; g: grams; h: hour/s; ITT: intention to treat; kcal: kilocalories; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mg/ dL: milligrams per decilitre; n: number of participants; mmol/L: millimole per litre; SD: standard deviation; WHO: World Health Organization.

Study arms

Low-carbohydrate diet (n = 15)

High-carbohydrate diet (n = 15)

Outcomes

Outcome	Low-carbohydrate diet, n = 15	High-carbohydrate diet, n = 15
Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) Converted from mg/dL to mmol/L Mean (SD)	4.5 (0.4)	4.2 (0.4)
Mode of birth: Vaginal birth Follow-up at birth; Per protocol n not reported No of events	n = 7; % = NR	n = 9; % = NR
Mode of birth: Caesarean Follow-up at birth; Per protocol n not reported No of events	n = 7; % = NR	n = 5; % = NR
Need for pharmacological therapy Follow-up not reported; Per protocol n not reported No of events	n = 2; % = NR	n = 1; % = NR
Large for gestational age > 90 centile Reported as >4000g; Follow-up at birth; Per protocol n not reported No of events	n = 0; % = 0	n = 0; % = 0

mmol/L: millimole per litre; mg/ dL: milligrams per decilitre; n: number of participants; NR: not reported; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Han 2017). The risk of bias of this study was not assessed separately. The risk of bias for this study was used from the Cochrane review (Han 2017). See the details of Appendix D risk of bias assessment of Han 2017 Cochrane review in Appendix D

Downs, 2017

Bibliographic Reference	Downs, Danielle Symons; Dinallo, Jennifer M; Birch, Leann L; Paul, Ian M; Ulbrecht, Jan S; Randomized Face-to-Face vs. Home Exercise Interventions in Pregnant Women with Gestational Diabetes.; Psychology of sport and exercise; 2017; vol. 30; 73-81

Study details

Country/ies where study was carried out	USA
Study type	Randomised controlled trial (RCT)
Study dates	Not reported.
Inclusion criteria	Pregnant women diagnosed with gestational diabetes. Age ≥18 years. Able to speak and comprehend English. Living in areas in and around Central Pennsylvania. Provided written consent to study and written clearance from healthcare provider.
Exclusion criteria	Contraindications to exercise (ACOG, 2002).

Patient characteristics	**Mean age in years (SD)** Not reported **Parity (n, %)** Not reported **Mean gestational age in weeks [at screening] (SD)** Not reported **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD)** Not reported **BMI class (n, %)** Not reported **Ethnicity (n, %)** Not reported **Education level (n, %)** Not reported **Income status (n, %)** Not reported The study setting: University clinic research centre.
Intervention(s)/control	**Physical activity (face to face):**

	Initial in person consultation to explain intervention and receive study materials including education binder, schedules and parking/childcare instructions. Face to face exercise education, motivational support/self-efficacy enhancement. Moderate intensity exercise (for example, treadmill walking/jogging, cycle ergometer, low-impact aerobics) on 2 days/week delivered in a 70-min session (for example, 10 min warm-up, 30-40 min exercise, 10-min cooldown, 10-15 min stretching; ACOG, 2002; Padayachee & Coombes, 2015) and led by a certified fitness instructor. Educational curriculum (mailed a week prior to call) was based on the Diabetes Prevention Program and included content on exercise as a way of life, committing to lifestyle change, eating for exercise, managing stress, and staying motivated, The TPB content was developed by the first author (for example, benefits/positive attitude characteristics of exercise; sources of and strategies to improve normative/social support, perceived control, and self-regulation; overcoming barriers to exercise such as goal-setting, exercise self-monitoring, and overcoming negative self-talk; motivational tools including positive affirmations/encouraging quotes; and interactive discussions with the instructor on these topics). A registered nurse was present during sessions to monitor negative symptoms and evaluate blood glucose values (that is, women self-checked blood glucose before/after exercise sessions; ADA, 2011). Above in addition to standard care. **Physical activity (home based):** Initial in person consultation to explain intervention and receive study materials including education binder, schedules and parking/childcare instructions. Same education/motivational support/self-efficacy enhancement as the face to face group but it was delivered every 2 weeks in a 45min phone session led by a certified fitness instructor. Participants were encouraged to exercise on their own to meet guidelines. **Standard care:** Standard prenatal care from their healthcare provider which involved diet advice for gestational diabetes and encouragement to exercise based on USDHHS 2008 guidelines. All women:

	At baseline assessment undertook a treadmill walking protocol to estimate fitness levels and negative symptoms. Women were also provided an activity monitor with written instructions for wearing it over the following 7 days for free-living assessment of activity.
Duration of follow-up	Until birth.
Sources of funding	Not industry funded
Sample size	N total = 65 Physical activity (face to face): n = 22 Physical activity (home based): n = 22 Standard care: n = 21
Other information	The study only reported study characteristics for women that completed the study. Gestational diabetes diagnostic criteria not reported. Timing: 16 gestational weeks. Screening: 50 g 2 hr glucose tolerance test if > 130 mmol/L. Diagnosis: 100 g OGTT fasting blood sugar 92 mmol/L, 1 h 180 mmol/L, 2 h 153 mmol/L with one abnormal value Treatment target: Not reported. ITT numbers used for analysis. Both physical activity arms were combined in order to compare to the control in the same analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status.

ACOG: American College of Obstetricians and Gynecologists; ADA: American diabetes association; BMI: body mass index; g: gram; hr: hour/s; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; min: minutes; mmol/L: millimole per litre; n: number of participants; OGTT: oral glucose tolerance test; SD: standard deviation; TPB: Theory of planned behaviour; USA: United States of America; USDHHS: United States Department of Health and Human Services.

Study arms

Physical activity (face to face) (n = 22)

Physical activity (home based) (n = 22)

Standard care (n = 21)

Outcomes

Outcome	Physical activity (face to face), n = 22	Physical activity (home based), n = 22	Standard care, n = 21
Glycaemic control: during intervention: fasting blood glucose levels (mmol/L) At 24 gestational weeks Custom value	Mean (SD) = 82 (NR)	Mean (SD) = 91 (NR)	Mean (SD) = 89 (NR)
Glycaemic control: fasting blood glucose levels at the end of the intervention (mmol/L) At 36 gestational weeks Custom value	Mean (SD) = 78 (NR)	Mean (SD) = 83 (NR)	Mean (SD) = 85 (NR)
Need for pharmacological intervention Follow-up until birth; ITT numbers used as n per arm for this outcome is unclear No of events	n = 8; % = 36.4	n = 13; % = 59.1	n = 8; % = 38.1

ITT: intention to treat; mmol/L: millimole per litre; n: number of participants; NR: not reported; SD: standard deviation.

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Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Allocation was random although method of concealment was not described. No significant baseline differences between groups.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Some concerns *(No information provided on whether participants and those that delivered the intervention were blinded to allocation, however unlikely to have impacted the intervention. The analysis was not intention-to-treat and in addition to not including women with missing data, did not include in analysis those who dropped out due to no time (F2F n = 3/22, Home n = 3/22, Control n = 3/21), complications (Home n = 1/22), and moved (Home n = 1/22). Impact on the results of number of participants excluded from the analysis is unclear but does not appear to strongly be related to prognostic factors.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(Women with >5% missing outcome data were excluded from analysis (F2F: 27% n = 6/22; home 18% n = 4/22; control 14% n = 3/21) and it was not clear whether missingness in the outcome depended on true value.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(The method of measurement was appropriate. Although outcome assessors were likely aware of the intervention received, this is unlikely to affect results.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(No protocol available. Numerical result unlikely to have been selected on basis of multiple outcome measurements or analyses.)*
Overall bias and Directness	Risk of bias judgement	Some concerns *(The study is judged to raise some concerns in at least one domain for this result, but not to be at high risk of bias for any domain.)*

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	N/A

F2F: face to face; n: number of participants; N/A: number of participanst; RCTs: randomised controlled trials.

Durnwald, 2016

Bibliographic Reference	Durnwald, Celeste P; Kallan, Michael J; Allison, Kelly C; Sammel, Mary D; Wisch, Susan; Elovitz, Michal; Parry, Samuel; A Randomized Clinical Trial of an Intensive Behavior Education Program in Gestational Diabetes Mellitus Women Designed to Improve Glucose Levels on the 2-Hour Oral Glucose Tolerance Test.; American journal of perinatology; 2016; vol. 33 (no. 12); 1145-51

Study details

Country/ies where study was carried out	USA
Study type	Randomised controlled trial (RCT)
Study dates	2013-2015
Inclusion criteria	Women with gestational diabetes attending the study's tertiary care hospital.
Exclusion criteria	≥33 gestational weeks. Women with possible overt type 2 diabetes (gestational diabetes diagnosis <20 gestational weeks). Multiple gestations. Chronic steroid therapy.

Patient characteristics	**Mean age in years (SD)** Intervention: 31.4 (6.3) Comparator: 32.5 (4.8) **Parity (n, %)** Not reported, median (IQR) was reported as mixed intervention: 0 (0, 2) and standard care:1 (0, 1) **Mean gestational age in weeks [at screening] (SD)** Mixed intervention: 30.8 (2.1) Standard care: 30.6 (2.4) **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean BMI in kg/m^2 [at baseline] (SD)** Not reported **BMI class (n, %)** Not reported **Ethnicity (n, %)** Black: Mixed intervention: 25 (51.0) Standard care: 21 (40.4) Caucasian Mixed intervention: 16 (32.7)

	Standard care: 23 (44.2) Asian Mixed intervention: 7 (14.3) Standard care: 6 (11.5) Other Mixed intervention: 1 (2.0) Standard care: 2 (3.8) Hispanic ethnicity (separately reported): Mixed intervention: 1 (2.0) Standard care: 3 (2.0) **Education level (n, %)** Not reported **Income status (n, %)** Not reported The study setting: Tertiary care hospital.
Intervention(s)/control	**Mixed intervention:** Intensive behaviour education program with at least 2 nutrition counselling sessions: The first session involved standard care nutrition counselling with added motivational messaging. The second session provided personalized feedback after review of 1 week food diary. Healthy food choices and optimal weight gain were reinforced with focus on healthy attitudes and behaviours in pregnancy.

	Women were also provided with a manual (8 pregnancy, 4 postpartum chapters) "The Healthy Gestational Diabetes Pregnancy Program" adapted from a diabetes prevention program which focused on food and inactivity behavioural modification techniques, tips for new healthy attitudes and behaviours and physical activity recommendations focused on increased walking. The manual targeted healthy lifestyle choices, motivational messaging and further exercise and nutritional facts. Women reviewed chapters weekly with a research nurse in a 20-30 minute call. Personalised goals were formed for the following week and discussed at the start of the next call. Received a pedometer. **Standard care:** One off nutrition counselling session with a nutritionist/certified diabetic educator with diet advice based on dietary guidelines consistent with the American Diabetes Association diabetic diet and healthy weight gain advice based on Institute of Medicine guidelines. All women: Underwent specialised prenatal care for diabetes within a pregnancy program led by maternal fetal medicine specialists. Used a portable glucometer for daily self blood glucose monitoring involving fasting and 1 h postprandial measurements. Weekly or biweekly office visit (based on gestational age) for review of blood glucose data by study personnel and insulin or glyburide was initiated if criteria met (see other information).
Duration of follow-up	Until 6-12 weeks postpartum
Sources of funding	Not industry funded
Sample size	N total = 100 Mixed intervention n = 49 Standard care n = 51
Other information	7 (14.3%) women in mixed intervention and 5 (9.6%) in standard care had a history of gestational diabetes.

	Mean (SD) pre-pregnancy BMI (kg/m^2) reported as 30.7 (6.8) for mixed intervention and 32.2 (9.4) for standard care. Gestational diabetes diagnostic criteria: Method not stated or Carpenter and Coustan. Timing: Not reported. Screening: 1 h glucose challenge test of ≥7.5 mmol/L. Diagnosis: Either 1 h glucose challenge test ≥11.1 mmol/L or following above screening test 100g 3 h OGTT if 2 or more values are abnormal from fasting ≥ 5.3 mmol/L, 1 h ≥ 10.0 mmol/L, 2 h value ≥ 8.7 mmol/L, 3 h ≥ 7.8 mmol/L. Treatment target: Initiation of insulin or glyburide if >30% of blood glucose levels were above the designated target values of fasting ≤95 mg/dL and 1 h postprandial ≤140 mg/dL. Once treatment began, doses were altered if >20% of values were above targets. ITT numbers used for analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status. Glycaemic outcomes could not be reported as these were postpartum values only.

BMI: body mass index; g: grams; h: hour/s; ITT: intention to treat; IQR: interquartile range; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mg/dL: milligrams per decilitre; mmol/L: millimole per litre; n: number of participants; OGTT: oral glucose tolerance test; SD: standard deviation; USA: United States of America.

Study arms

Mixed intervention (n = 49)

Intensive behaviour education program

Standard care (n = 52)

Outcomes

Outcome	Mixed intervention, n = 49	Standard care, n = 52
Gestational weight change (kg) Total gestational weight change; Follow-up from (mean (SD) gestational age at randomisation for mixed intervention = 30.8 (2.1); standard care = 30.6 (2.4) to birth Mean (SD)	2.4 (4.6)	2.5 (5)
Mode of birth: Induction of labour Follow-up at birth No of events	n = 26; % = 53.1	n = 27; % = 51.9
Mode of birth: Caesarean Follow-up at birth No of events	n = 18; % = 36.7	n = 21; % = 40.4
Elective repeat caesarean Follow-up at birth No of events	n = 3; % = 6.1	n = 10; % = 19.2
Hypertensive disorders (pre-eclampsia or gestational hypertension) Gestational age at diagnosis not reported, diagnosed before birth No of events	n = 11; % = 22.4	n = 8; % = 15.4
Need for pharmacological intervention Insulin or glyburide (no further details); Follow-up not reported No of events	n = 23; % = 46.9	n = 19; % = 36.5

Outcome	Mixed intervention, n = 49	Standard care, n = 52
Large for gestational age > 90 centile Reported as birthweight >4000g; Follow-up at birth No of events	n = 5; % = 10.2	n = 6; % = 11.5
Neonatal hypoglycaemia Follow-up not reported No of events	n = 5; % = 10.2	n = 4; % = 7.7

g: grams; n: number of participants; SD: standard deviation.

Critical appraisal – Cochrane Risk of Bias tool v2.0 for RCTs

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Participants were randomized 1:1 using a computer-generated random number table of random-sized permuted blocks. No information about allocation sequence concealment. No significant baseline differences between groups to suggest a problem with the randomisation process.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(No information on whether participants were aware of their allocation. Likely that the nutritionist/certified diabetic educator delivering the intervention were aware of the allocation but unlikely that this impacted the intervention. Appropriate intention-to treat analysis was performed. No deviations were reported, however there was a low adherence to the intervention, however, this deviation would be consistent with what would occur outside of the trial context.)*

Section	Question	Answer
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(The study does not report information on missing outcomes for outcomes of interest)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Method of outcome measurement was appropriate and was unlikely to have differed between groups. Outcomes were objective. No information whether outcome assessors were aware of allocation but was unlikely to affect assessment of outcome)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(No information provided on whether the trial was analysed in accordance with a pre-specified analysis plan. Numerical result unlikely to have been selected on basis of multiple outcome measurements or analyses.)*
Overall bias and Directness	Risk of bias judgement	High *(The study is judged to be at high risk of bias in at least one domain for this result)*
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	N/A

N/A: not applicable; RCTs: randomised controlled trials.

Ferrara, 2011

Bibliographic Reference	Ferrara, Assiamira; Hedderson, Monique M; Albright, Cheryl L; Ehrlich, Samantha F; Quesenberry, Charles P Jr; Peng, Tiffany; Feng, Juanran; Ching, Jenny; Crites, Yvonne; A pregnancy and postpartum lifestyle intervention in women with gestational diabetes mellitus reduces diabetes risk factors: a feasibility randomized control trial.; Diabetes care; 2011; vol. 34 (no. 7); 1519-25

Study details

Country/ies where study was carried out	USA
Study type	Randomised controlled trial (RCT)
Study dates	2005-2008
Inclusion criteria	Women diagnosed with gestational diabetes mellitus (GDM) based on American Diabetes Association (ADA) criteria. 20 to 45 years of age.
Exclusion criteria	<18 years of age. Multiple gestation. Diabetic retinopathy diagnosis. High-risk pregnancy due to drug and alcohol misuse, chronic health conditions or complications due to pregnancy. Thyroid diseases diagnosed within 30 days prior. Does not speak English.
Patient characteristics	**Age in years (n, %)** Intervention: 21-24: 3 (3.1) 25-29: 18 (18.8) 30+: 75 (78.1) Comparator: 21-24: 4 (4.0)

	25-29: 21 (20.8) 30+: 76 (75.3) **Parity (n, %)** Intervention: Nulliparous: 38 (39.6) Primiparous: 40 (41.7) Multiparous: 18 (18.7) Comparator: Nulliparous: 42 (41.6) Primiparous: 41 (40.6) Multiparous: 18 (17.9) **Mean gestational age in weeks [at baseline] (SD)** Intervention: 31.8 (5.6) Comparator: 31.0 (6.1) **Mean gestational age in weeks [at intervention] (SD)** Not reported (soon after GDM diagnosis) **Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD)** Intervention: NR Comparator: NR **BMI class (n, %)**

	Intervention: 20–24.9 kg/m^2: 15 (15.6%) 25.0–29.9 kg/m^2: 26 (27.1%) ≥30.0 kg/m^2: 55 (57.3%) Comparator: 20–24.9 kg/m^2: 15 (14.9%) 25.0–29.9 kg/m^2: 33 (32.7%) ≥30.0 kg/m^2: 53 (52.5%) **Ethnicity (n, %)** Intervention: Non-Hispanic white: 19 (19.8) Black/African American: 5 (5.2) Asian or Pacific Islander: 47 (49.0) Hispanic origin: 18 (18.8) Other: 4 (4.2) Missing: 3 (3.1) Comparator: Non-Hispanic white: 19 (18.8) Black/African American: 4 (4.0) Asian or Pacific Islander: 55 (54.5)

	Hispanic origin: 19 (18.8) Other: 2 (2.0) Missing: 2 (2.0) **Education level (n, %)** Intervention: High school or less: 16 (6.7) Some college: 23 (24.0) College graduate: 30 (31.3) Postgraduate: 23 (24.0) Missing: 4 (4.2) Comparator: High school or less: 7 (6.9) Some college: 24 (23.8) College graduate: 31 (30.7) Postgraduate: 37 (36.6) Missing: 2 (2.0) Study setting: Kaiser Permanente Medical Care Program of Northern California (KPNC).
Intervention(s)/control	**Mixed intervention:** Diet and exercise and breastfeeding intervention (DEBI) provided by two dieticians based on Social Cognitive Theory and Transtheoretical Model. The intervention consisted of three phases - prenatal, postpartum and maintenance (6 months).

	The prenatal phase involved an individual face to face session (approximately 1 h) and two individual telephone counselling sessions (each lasting mean (SD) 31.2 (17.7) min). Sessions involved: Education on increased risk of type 2 diabetes and advised to meet the IOM guidelines. Obese women were told not to exceed a gestational weight gain of 11.4 kg as advised for overweight women in the IOM guidelines at the time. Advice to follow the ADA diet and moderate intensity physical activity for 150 minutes per week. Discussion of written intervention materials about portion size, low GI or fat foods and food label literacy (during telephone counselling sessions) Lactation consultant also provided advice towards the end of pregnancy until 6 weeks postpartum. **Usual care:** Printed educational information on gestational diabetes during prenatal period and newsletters on infant safety and general health in postnatal period.
Duration of follow-up	Up to 12 months postpartum
Sources of funding	Not industry funded
Sample size	N total=197 Mixed intervention n=96 Standard care n=101
Other information	Trial name: Diet and exercise and breastfeeding intervention (DEBI). Gestational diabetes diagnostic criteria: American Diabetes Association (ADA) 2000 criteria: Timing: Not reported Screening: 50 g 1 h glucose challenge Diagnosis: 100 g OGTT; 3 h

	Treatment target: not reported ITT numbers used for analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status. Other potentially relevant outcomes could not be reported as these were postpartum values only.

ADA: American Diabetes Association; BMI: body mass index; g: gra,s; GI: glycaemic index; h: hour/s; IOM: Institute of Medicine; IOM: Institute of Medicine; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; min: minutes; n: number of participants; NR: not reported; OGTT: oral glucose tolerance test; USA: United States of America; SD: standard deviation.

Study arms

Mixed intervention (n = 96)

Standard care (n = 101)

Outcomes

Outcome	Mixed intervention, n = 96	Standard care, n = 101
Need for pharmacological intervention During pregnancy after gestational diabetes diagnosis. Outcome extracted from medical records. Glyburide (n, %) intervention: 5 (5.2); control: 4 (4.0); Insulin (n, %) intervention: 27 (28.1); control: 36 (35.6) No of events	n = 32; % = 33.3	n = 40; % = 39.6
Large for gestational age > 90 centile Follow-up at birth; Outcome extracted from medical records. Reported as infant birth weight >4000g No of events	n = 15; % = 16.1	n = 11; % = 10.5

g: grams; n: number of participants.

Critical appraisal – Cochrane Risk of Bias tool v2.0 for RCTs

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(The allocation sequence was random by use of computer randomisation program and probably adequately concealed. No significant differences between groups at baseline.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(Participants and those delivering the intervention were aware of their assigned intervention during the trial but it is unlikely to have an impact on the intervention. Participants analysed according to assignment of intervention with all data reported.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(All data were reported for all participants for outcomes of interest.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Method of outcome measurement was appropriate and was unlikely to have differed between groups. Researchers collecting baseline and follow-up data were blinded to allocation.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low *(The study protocol was approved by the Kaiser Permanente Medical Care Program of Northern California review board with a likely pre-specified analysis plan although is not accessible online. The trial is registered on clinicaltrials.gov website which was posted after the commencement of the trial. Numerical result unlikely to have been selected on basis of multiple outcome measurements or analyses.)*
Overall bias and Directness	Risk of bias judgement	Low *(The study is judged to be at low risk of bias for all domains for this result.)*
Overall bias and Directness	Overall Directness	Directly applicable

Section	Question	Answer
Overall bias and Directness	Risk of bias variation across outcomes	N/A

N/A: not applicable; RCTs: randomised controlled trials.

Garner, 1997

Bibliographic Reference	Garner, P; Okun, N; Keely, E; Wells, G; Perkins, S; Sylvain, J; Belcher, J; A randomized controlled trial of strict glycemic control and tertiary level obstetric care versus routine obstetric care in the management of gestational diabetes: a pilot study.; American journal of obstetrics and gynecology; 1997; vol. 177 (no. 1); 190-5

Study details

Country/ies where study was carried out	Canada
Study type	Randomised controlled trial (RCT)
Study dates	1991-1994
Inclusion criteria	Women who were pregnant with gestational diabetes diagnosis in otherwise low-risk pregnancies.
Exclusion criteria	Multiple gestation. Maternal-fetal blood group incompatibility. Known congenital anomaly. Previous evidence of placenta praevia or abruptio placentae. significant maternal disease including chronic hypertension, connective tissue disease, endocrine disorders, and chronic hepatic disease. Long-term medical therapy affecting glucose metabolism such as steroids and β-mimetic tocolytic agents.

	Imminent delivery.
Patient characteristics	**Mean age in years (SD)** Energy-restricted diet: 30.7 (4.8) No energy-restricted diet: 30.7 (4.6) **Parity (n, %)** Not reported **Mean gestational age in weeks [at screening] (SD)** Not reported **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD)** Not reported **BMI class (n, %)** Not reported **Ethnicity (%)** Not reported **Education level (n, %)** Not reported **Income status (n, %)** Not reported

	Setting: Two teaching hospital teaching units
Intervention(s)/control	**Diet (Energy-restricted diet):** Dietary counselling and calorie-restricted diet of 35 kcal/kg ideal body weight per day, with emphasis on spacing of meals and snacks to limit glucose spikes. Education on home glucose monitoring with semi-quantitative whole blood glucose reagent strips. Those who required insulin supplementation (see other information for details) had individualised dosing and were carefully monitored. Women were seen every two weeks for ultrasound, amniotic fluid volume, and cardiac size assessment. **Standard care (No energy-restricted diet):** Women were asked to maintain unrestricted healthy diet for pregnancy based on the Canada Food Guide standards. For comparison with intervention arm, women performed 2 glucose concentrations per week at home with semi-quantitative whole blood glucose reagent strips. After this, women went back to their primary obstetric care provider and did not return to the gestational diabetes teaching unit. The study defined women in this arm who may have had previously undetected type 1 or 2 diabetes as 'failed control' whereby if women had persistent fasting capillary blood glucose > 7.8 mmol/L or 1-hour postprandial concentration > 11.1 mmol/L they were transferred to the treatment arm and placed on diet, insulin, and fetal monitoring.
Duration of follow-up	Up to 38 gestational weeks
Sources of funding	Not reported
Sample size	N total = 300 Diet (Energy-restricted diet): n = 150 Standard care (No energy-restricted diet): n = 150

Other information	Sourced from Han 2017 Cochrane systematic review Gestational diabetes diagnostic criteria: Hatem et al. criteria (1988): Timing: 24-32 gestational weeks Screening: 75 g glucose screening test 1 h cut off 8.0 mmol/L Diagnosis: 75 g OGTT 2 h: > 7.5 mmol/L for the second trimester; 2 h: > 9.6 mmol/L for the third trimester. Treatment target: If fasting or postprandial plasma glucose concentrations went above targeted values of fasting glucose concentrations < 4.4 mmol/L and 1 h postprandial glucose concentrations < 7.8 mmol/L) on 2 or more occasions The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status. ITT numbers used for analysis - data from 'failed control' group (n = 16 (10.6% of control arm)) was analysed with the standard care (no energy-restricted diet group) data.

BMI: body mass index; cal: calories; g: grams; h: hour/s; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; n: number of participants; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

Diet (Energy-restricted diet) (n = 150)

Standard care (No energy-restricted diet) (n = 150)

Outcomes

Outcome	Diet (Energy-restricted diet), n = 150	Standard care (No energy-restricted diet), n = 150
Glycaemic control: fasting glucose at the end of the intervention (mmol/L) energy-restricted diet n = 150, no energy-restricted diet n = 149 Mean (SD)	4.47 (0.82)	4.7 (1.04)

Outcome	Diet (Energy-restricted diet), n = 150	Standard care (No energy-restricted diet), n = 150
Gestational weight change (kg) Final weight, followed up at delivery; energy-restricted diet n=150, no energy-restricted diet n = 149; Follow-up not reported Mean (SD)	81.45 (16.18)	84.6 (20.11)
Mode of birth: Vaginal birth Follow-up at birth; energy-restricted diet n = 150, no energy-restricted diet n = 149 No of events	n = 118; % = 78.7	n = 121; % = 81.2
Mode of birth: Caesarean Follow-up at birth; energy-restricted diet n = 150, no energy-restricted diet n = 149 No of events	n = 30; % = 20	n = 28; % = 18.8
Need for pharmacological intervention Follow-up not reported; energy-restricted diet n = 150, no energy-restricted diet n = 149; 16 events in no energy-restricted diet arm correspond to the "failed controls" originally in this arm but put on the intervention diet and given insulin. No of events	n = 3; % = 24	n = 16; % = 10.7
Large for gestational age > 90 centile Reported as >4500g; Follow-up at birth; energy-restricted diet n = 150, no energy-restricted diet n = 149 No of events	n = 6; % = 4	n = 6; % = 4

Outcome	Diet (Energy-restricted diet), n = 150	Standard care (No energy-restricted diet), n = 150
Neonatal hypoglycaemia Follow-up not reported; energy-restricted diet n = 150, no energy-restricted diet n = 149 No of events	n = 21; % = 14	n = 13; % = 8.7
Neonatal mortality Follow-up not reported; energy-restricted diet n = 150, no energy-restricted diet n = 150 No of events	n = 0; % = 0	n = 0; % = 0

g: grams; mmol/L: millimole per litre; n: number of participants; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Han 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane review (Han 2017). See the Han 2017 evidence table in Appendix D for the risk of bias assessment of the Cochrane review.

Grant, 2011

Bibliographic Reference	Grant, Shannan M; Wolever, Thomas M S; O'Connor, Deborah L; Nisenbaum, Rosane; Josse, Robert G; Effect of a low glycaemic index diet on blood glucose in women with gestational hyperglycaemia.; Diabetes research and clinical practice; 2011; vol. 91 (no. 1); 15-22

Study details

Country/ies where study was carried out	Canada
Study type	Randomised controlled trial (RCT)

Study dates	2006-2007
Inclusion criteria	Pregnant women diagnosed with gestational diabetes and referred to the Diabetes in Pregnancy, St. Michael's Hospital, Canada. Aged 18-45 years.
Exclusion criteria	Multiple pregnancy. Acute or chronic illness affecting carbohydrate metabolism. History of type 1 or 2 diabetes. Use of insulin treatment before study consent. Gestational age >34 weeks. Not able to communicate in English with no translator available.
Patient characteristics	**Mean age in years (SD)** NR **Parity (n, %)** NR **Mean gestational age in weeks [at screening] (SD)** NR **Mean gestational age in weeks [at intervention] (SD)** NR **Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD)** NR

	BMI class (n, %) NR **Ethnicity (n, %)** NR **Education level (n, %)** NR **Income status (n, %)** NR Study setting: Hospital.
Intervention(s)/control	**Low-moderate GI diet:** Women selected their choice of starch from a low-GI key food exchange list. **Moderate-high GI diet:** Women selected their choice of starch from an intermediate- and high-GI food exchange list, which comprised the standard gestational diabetes diet for clinic patients. All women: Standard medical nutrition therapy: Education on Diabetes Food Guide and Canadian dietary recommendations; dietician recommendation of starch choices/servings intake based on individual gestational energy requirements and Acceptable Macronutrient Distribution Ranges. Received about $20 per week worth of non-perishable study foods and all blood testing strips. Performed blood glucose self-monitoring 4 times a day from baseline to week 8 (fasting, 2 h after breakfast, lunch and dinner)

	If lifestyle modification was not made within 2-3 weeks, insulin therapy was initiated (See other information for further details).
Duration of follow-up	Until birth
Sources of funding	Not industry funded
Sample size	Total N=29 Low-moderate GI diet n = 13 Moderate-high GI diet n = 16
Other information	Sourced from Han 2017 Cochrane systematic review Study reports data for women with impaired glucose tolerance and gestational diabetes; 1 dropped out due to pre-eclampsia (arm not reported). Extraction and analysis based on data for women diagnosed with gestational diabetes. Gestational diabetes diagnostic criteria: Canadian Diabetes Association (2008) Timing: Not reported Screening: Not reported Diagnosis: 76 g OGTT with 2 values reaching or above the following: Fasting: 5.3 mmol/L; 1 h: 10.6 mmol/L; 2 h: 8.9 mmol/L. Treatment target: Insulin initiated if not meeting target range of fasting 3.8–5.2 mmol/L; 2 h postprandial 5.0–6.6 mmol/L within 2-3 weeks of lifestyle modification. Decision to initiate insulin and adjust dosage were made by the blinded clinic physician. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status. ITT numbers used for analysis. Data for the gestational diabetes population is taken from Han 2017 as this was based on author correspondence.

BMI: body mass index; g: grams; h: hour/s; GI: glycaemic index; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; n: number of participants; NR: not reported; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

Low-moderate GI diet (n = 13)

Moderate-high GI diet (n = 16)

Outcomes

Outcome	Low-moderate GI diet, n = 13	Moderate-high GI diet, n = 16
Need for pharmacological intervention Insulin; Follow-up to birth n low-moderate GI=10, n moderate high GI=16 No of events	n = 1; % = 10	n = 4; % = 25
Large for gestational age > 90 centile Follow-up at birth; n low-moderate GI=13, n moderate high GI=16 No of events	n = 1; % = 7.7	n = 4; % = 25

GI: glycaemic index; n: number of participants.

Critical appraisal

This study was included in the Cochrane review (Han 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane review (Han 2017). See the Han 2017 evidence table in Appendix D for the risk of bias assessment of the Cochrane review.

Halse, 2014 (Halse, 2015)

Bibliographic Reference	Halse, Rhiannon E; Wallman, Karen E; Newnham, John P; Guelfi, Kym J; Home-based exercise training improves capillary glucose profile in women with gestational diabetes.; Medicine and science in sports and exercise; 2014; vol. 46 (no. 9); 1702-9

Halse, Rhiannon E, Wallman, Karen E, Dimmock, James A et al. (2015) Home-Based Exercise Improves Fitness and Exercise Attitude and Intention in Women with GDM. Medicine and science in sports and exercise 47(8): 1698-704

Study details

Country/ies where study was carried out	Australia
Study type	Randomised controlled trial (RCT)
Study dates	Not reported
Inclusion criteria	Pregnant women within 1 week of diagnosis of gestational diabetes. Singleton pregnancy. Gestational age 26-30 weeks. No complications at 18 week anatomy scan. BMI ≤ 45 kg/m^2. Not undergoing structured physical activity. Medically cleared to undergo physical activity.
Exclusion criteria	<18 years of age. Not able to understand what participation would involve. Taking any medications at the time of recruitment. Low-lying placenta. pre-existing diabetes (type 1 or 2). Cardiac disease.

Patient characteristics	**Mean age in years (SD)** Intervention: 34 (5) Comparator: 32 (3) **Parity (mean, SD)** Intervention: 1 (1) Comparator: 1 (1) **Mean gestational age in weeks [at screening] (SD)** Intervention: 28.8 (0.8) Comparator: 28.8 (1.0) **Mean gestational age in weeks [at intervention] (SD)** Intervention: 28.8 (0.8) Comparator: 28.8 (1.0) **Mean BMI in kg/m^2 [at baseline] (SD)** Intervention: 32.2 (5.9) Comparator: 30.0 (5.1) **BMI class [at study entry] (n, %)** Intervention: Overweight (BMI 25–29.9 kg/m^2): 7 (35) Obese (BMI ≥30 kg/m^2): 6 (30) Comparator:

	Overweight (BMI 25–29.9 kg/m^2): 9 (45) Obese (BMI ≥30 kg/m^2): 5 (25) **Ethnicity (n, %)** NR **Education level (n, %)** NR **Income status (n, %)** NR Setting: Hospital diabetes service.
Intervention(s)/control	**Physical activity:** Home-based exercise program with 5 sessions per week until week 34 of gestation. Three sessions were supervised by an exercise physiologist and was on an upright stationary cycle ergometer (provided to participants) and on alternate days 2 sessions were not supervised with instruction to perform moderate-intensity aerobic activity of their choosing and record exercise via diary and ratings of perceived exertion scale. Sessions were 25-30 minutes in week 1, increasing to 40-45 minutes by week 4. The supervised sessions involved steady state and interval cycling with conditioning ranging from low to moderate intensity cycling and resistance added if needed. There were also brief bouts of vigorous intensity exercise. Intervention was in addition to conventional management* of gestational diabetes. **Standard care:** conventional management of gestational diabetes* and maintained usual physical activity for the period of the intervention. *Conventional management involved an assessment of glycaemic control and counselling by a diabetes educator and dietician.

	For all participants glucose levels were self-monitored at home via personal glucometers with daily fasting and 120 minutes postprandial glucose levels after breakfast, lunch and dinner which were recorded. Food and drink diaries were provided to participants for the first and last 7 days of the intervention.
Duration of follow-up	Intervention period was mean (SD): 6 (1) weeks. All were followed-up until mean (SD) 34.6 (0.3) gestational weeks.
Sources of funding	Not industry funded
Sample size	N total = 40 Physical activity n = 20 Standard care n = 20
Other information	Sourced from Brown 2017 Cochrane systematic review. Gestational diabetes diagnostic criteria: Australasian Diabetes in Pregnancy Society (ADIPS, 1998). Timing: 28 weeks. Screening: Not reported. Diagnosis: 75 g OGTT plasma glucose level at fasting of ≥ 5.5 mmol/L and/or at 2 h of ≥ 8.0 mmol/L. Treatment target: not reported. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status. However, participants were reported to be a low-income population. ITT numbers used for analysis. Halse 2015 is a secondary paper to Halse 2014 and includes gestational weight change and mode of birth outcomes.

BMI: body mass index; g: grams; h: hours; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; n: number of participants; NR: not reported; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

Physical activity (n = 20)

Standard care (n = 20)

Outcomes

Outcome	Physical activity, n = 20	Standard care, n = 20
Glycaemic control: HbA1c at the end of the intervention (%) Mean (SD)	5.3 (0.4)	5.4 (0.3)
Gestational weight change (kg) Over the intervention period; Mean 38.8 gestational weeks at baseline to follow-up at mean (SD) 34.6 (0.3) gestational weeks Mean (SD)	0.8 (1.3)	1 (1.8)
Mode of birth: Vaginal birth Follow-up at birth; Extracted from medical records after delivery; per protocol n not reported No of events	n = 11; % = 55	n = 13; % = 68
Mode of birth: Induction of labour Follow-up at birth; Extracted from medical records after delivery; per protocol n not reported No of events	n = 4; % = 20	n = 1; % = 5
Mode of birth: Caesarean Follow-up at birth; Extracted from medical records after delivery; per protocol n not reported No of events	n = 5; % = 25	n = 5; % = 26

Outcome	Physical activity, n = 20	Standard care, n = 20
Need for pharmacological intervention Insulin; Follow-up at 34 gestational weeks; per protocol n not reported No of events	n = 2; % = 10	n = 2; % = 10

HbA1c: haemoglobin A1C; kg: kilograms; n: number of participants; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Brown 2017). The risk of bias of this study was not assessed separately. The risk of bias for this study was used from the Cochrane review (Brown 2017). See the details of Appendix D risk of bias assessment of Brown 2017 Cochrane review in Appendix D

Han, 2017

Bibliographic Reference	Han, Shanshan; Middleton, Philippa; Shepherd, Emily; Van Ryswyk, Emer; Crowther, Caroline A; Different types of dietary advice for women with gestational diabetes mellitus.; The Cochrane database of systematic reviews; 2017; vol. 2; cd009275

Study details

Country/ies where study was carried out	11 RCTs across 12 studies were included from this review (Bo 2014, Garner 1997, Grant 2011, Lauszus 2001, Louie 2011, Magee 1990, Moreno-Castilla 2013, Moses 2009, Rae 2000, Reece 1995, Valentini 2012). Included countries from these 11 RCTs: Australia, Canada, Denmark, Italy, Poland, Spain, USA.
Study type	Systematic review of randomised controlled trials.
Study dates	Systematic review inclusion dates:
Inclusion criteria	Systematic review inclusion criteria:

	Types of studies All published randomised controlled trials and cluster-randomised trials comparing the effects of different types of dietary advice for gestational diabetes (GDM) management. Published abstracts if relevant outcome data available. **Types of participants** Pregnant women with GDM. No age, gestation, parity or plurality restrictions. Diagnostic criteria for GDM based on oral glucose tolerance test OGTT) results defined by studies. Trials recruiting pregnant women with normal glycaemia, GDM or pre-existing diabetes mellitus could be included if subgroup data for women with GDM could be extracted separately. **Types of interventions** Interventions assessing any type of dietary advice for women with GDM with trials comparing two or more different types of dietary advice interventions. Studies with two or more forms of the same type of dietary advice were eligible, that is, standard dietary advice compared with individualised dietary advice, individual dietary education sessions compared with group dietary education sessions. Studies with different intensities of dietary intervention were eligible, that is, single dietary counselling session compared with multiple dietary counselling sessions. **Types of outcome measures:** Extensive, included all of the maternal and neonatal/infant outcomes relevant for this review.
Exclusion criteria	Quasi-randomised trials and cross-over trials.
Patient characteristics	See Appendix D evidence tables for individual study characteristics.
Intervention(s)/control	See Appendix D evidence tables for individual intervention/control details.
Duration of follow-up	For studies included in this review: Bo 2014: At gestational age of 38 weeks or before delivery (if pre-term), Garner 1997: Up to 38 gestational weeks; Grant 2011: until birth; Lauszus 2001: until birth, Louie 2011: until birth (mean 39 gestational weeks); Magee 1990: At end of 2 week hospital stay; Moreno-Castilla 2013: until birth (mean 38-39 gestational weeks), Moses 2009: until 35-37 gestational weeks, Rae 2000: until 5 days after birth; Reece 1995: not reported; Valentini 2012: until birth.

Sources of funding	Not industry funded.
Sample size	N = 11 RCTs included in this systematic review ranging from total sample size N = 12 (Magee 1990) to N = 300 (Garner 1997) (Cochrane review total RCTs = 19)

GDM: gestational diabetes mellitus; OGTT: oral glucose tolerance test; RCT: randomised controlled trial; USA: United States of America.

Outcomes

See Appendix D evidence tables for individual study outcomes.

Critical appraisal – Risk of Bias in Systematic Reviews (ROBIS) checklist

Section	**Question**	**Answer**
Study eligibility criteria	Concerns regarding specification of study eligibility criteria	Low *(Review adhered to objectives and eligibility criteria were appropriate.)*
Identification and selection of studies	Concerns regarding methods used to identify and/or select studies	Low *(Search databases and methods were appropriate with no restrictions to date or language applied. Two reviewers independently assessed study inclusion.)*
Data collection and study appraisal	Concerns regarding methods used to collect data and appraise studies	High *(Data extraction and risk of bias was performed by two reviewers. Certain baseline characteristics (such as BMI, maternal age, parity, education level, ethnicity) were not reported; follow-up times were also not reported which would have aided the interpretation of the evidence. All relevant results collected for synthesis.)*

Section	Question	Answer
Synthesis and findings	Concerns regarding the synthesis and findings	Low *(All analyses were appropriate and pre-defined with heterogeneity and biases addressed.)*
Overall study ratings	Overall risk of bias	High *(The review is judged to be at high risk of bias in at least one domain for this result.)*
Overall study ratings	Applicability as a source of data	Fully applicable

BMI: body mass index.

Hedderson, 2018

Bibliographic Reference	Hedderson, Monique M; Brown, Susan D; Ehrlich, Samantha F; Tsai, Ai-Lin; Zhu, Yeyi; Quesenberry, Charles P; Crites, Yvonne; Ferrara, Assiamira; A Tailored Letter Based on Electronic Health Record Data Improves Gestational Weight Gain Among Women With Gestational Diabetes Mellitus: The Gestational Diabetes' Effects on Moms (GEM) Cluster-Randomized Controlled Trial.; Diabetes care; 2018; vol. 41 (no. 7); 1370-1377

Study details

Country/ies where study was carried out	USA
Study type	Cluster randomised controlled trial
Study dates	2011-2012
Inclusion criteria	Pregnant women diagnosed with gestational diabetes according to Carpenter and Coustan criteria between 2011-2012. Age ≥18 years. Women at Kaiser Permanente Northern California medical facilities.

Exclusion criteria	Pregnant with multiples. Diagnosed with gestational diabetes >34 gestational weeks. Missing essential data such as pre-pregnancy BMI.
Patient characteristics	**Mean age in years (SD)** Not reported **Parity (n, %)** Mixed intervention: Primiparous: 406 (42.0) Multiparous: 548 (56.7) Standard care: Primiparous: 427 (40.8) Multiparous: 600 (57.3) **Mean gestational age in weeks [at screening] (SD)** Not reported **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD)** Not reported **BMI class (n, %)** Not reported

	Ethnicity (n, %) Asian Mixed intervention: 420 (43.4) Standard care: 423 (40.4) Non-Hispanic white Mixed intervention: 231 (23.9) Standard care: 269 (25.7) Hispanic Mixed intervention: 215 (22.2) Standard care: 235 (22.5) African American Mixed intervention: 38 (3.9) Standard care: 50 (4.8) Multiracial Mixed intervention: 32 (3.3) Standard care: 33 (3.2) Other Mixed intervention: 18 (1.9) Standard care: 13 (1.2) Pacific Islander

	Mixed intervention: 11 (1.1) Standard care: 22 (2.1) Missing Mixed intervention: 2 (0.2) Standard care: 2 (0.2) **Education level (n, %)** Not reported **Income status (n, %)** Not reported The study setting: Kaiser Permanente Northern California medical facilities.
Intervention(s)/control	**Mixed intervention:** Tailored letter Women received a letter with six tailored messages: 1) weight history information (pre-pregnancy weight/BMI and weight at diagnosis); 2) recommendation for total gestational weight change specific to pre-pregnancy BMI (corresponding to the lower limit of the Institute of Medicine range except for those underweight, then not above the midpoint); 3) a corresponding end-of-pregnancy weight goal tailored to pre-pregnancy BMI (4) recommendation for weight management based on gestational weight trajectory; 5) lifestyle advice to meet end-of-pregnancy weight goals; and 6) information on impact of GWC on pregnancy and postpartum health. Message components 3) to 6) were tailored to the woman's gestational weight trajectory based on end of pregnancy weight goal and divided into categories: gaining too slowly, on track, gaining too quickly and exceeded. All letters included lifestyle advice (for example, choose produce, lean protein, low- or non fat dairy, replace sugar-sweetened beverages with water, 30 min daily brisk walks unless advised otherwise) as well as a risk statement (excessive weight gain during a gestational diabetes pregnancy increases risks for poor glucose control during pregnancy and postpartum weight retention).

	Letters were at eighth grade reading level and sent in English or Spanish whichever preferred. In addition to standard care. **Standard care:** In addition to care from their GP, all women with gestational diabetes at the Kaiser Permanente Northern California corresponded with a nurse via telephone from the Regional Perinatal Service Center to facilitate glycaemic control. Women received via mail health education materials from the Perinatal Center just after diagnosis and then 1-2 calls each week to review self-monitored glucose data and receive advice on nutrition and physical activity. Nurses were contactable by phone 7 days a week and dieticians 5 days a week. Health education materials and calls did not cover gestational weight gain content.
Duration of follow-up	Until birth (mean (SD) gestational age not reported)
Sources of funding	Not industry funded
Sample size	Total cluster N = 44 Total (adjusted) N = 1178 Mixed intervention n = 22 clusters; n (adjusted) = 564 Standard care n = 22 clusters; n (adjusted) = 614 ICC = 0.02 (conservative) Average cluster size: (1187+1293)/(22+22) = 56.36 Design effect: 1 + (56.36-1) x 0.02 = 2.1064 Effective sample size: Intervention n = 564

	Comparator n = 614
Other information	Gestational diabetes diagnostic criteria Carpenter and Coustan. Timing: Not reported. Screening: Not reported. Diagnosis: Not reported. Treatment target: Not reported. ITT numbers used for analysis. This study did not report glycaemic outcomes.

BMI: body mass index; GP: general practitioner; ICC: intracluster correlation coefficient; ITT: intention to treat; min: minutes; n: number of participants; SD: standard deviation; USA: United States of America.

Study arms

Mixed intervention (N = 22)

22 clusters; N (adjusted) = 564

Standard care (n = 22)

22 clusters; n (adjusted) = 614

Outcomes

Outcome	Mixed intervention, n = 22	Standard care, n = 22
Gestational weight change - Met/achieved IOM guidelines (%) Total; Follow-up until birth Custom value	Relative risk (95%CI) = 1.08 (1.00-1.16)	N/A

Outcome	Mixed intervention, n = 22	Standard care, n = 22
Pre-pregnancy BMI 13.9-24.9 kg/m^2 Follow-up until birth Custom value	Relative risk (95%CI) = 1.07 (1.00-1.15)	N/A
Pre-pregnancy BMI 25.0-59.7 kg/m^2 Follow-up until birth Custom value	Relative risk (95%CI) = 1.08 (0.98-1.18)	N/A
Mode of birth: Caesarean Follow-up at birth; Adjusted numbers used Intervention n = 564, Comparator n = 614 No of events	n = 292; % = 51.8	n = 347; % = 56.5
Large for gestational age > 90 centile Follow-up at birth; in text as "large for gestational age" with no further details provided; Adjusted numbers used Intervention n = 564, Comparator n = 614 No of events	n = 92; % = 16.3	n = 129; % = 21

BMI: body mass index; CI: confidence interval; IOM: Institute of Medicine; kg: kilograms; m: metres; n: number of participants; N/A: not applicable.

Critical appraisal – Cochrane Risk of Bias tool (RoB 2.0) Cluster randomised trials

Section	Question	Answer
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	Low *(All individuals were identified before randomisation of clusters. No significant differences between groups at baseline)*

Section	Question	Answer
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	Low *(No information whether participants were aware they were in a trial or allocation. All investigators, data collectors, and health care providers were blinded to condition assignment. No information provided for deviations from intended intervention, however, unlikely that deviations from intended intervention occurred at the cluster level.)*
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low *(Data for this outcome were available for nearly all, participants randomized)*
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	Low *(All study investigators, biostatistician, data collectors (study interviewers and medical assistants who measure weight and blood pressure at the medical facilities), health care providers, and staff were blinded as to group allocation. Treatment group allocation was only known by the programmer of the study database.)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low *(Numerical result unlikely to have been selected on basis of multiple outcome measurements or analyses)*
Overall bias and Directness	Risk of bias judgement	Low *(The study is judged to be at low risk of bias for all domains for this result)*
Overall bias and Directness	Overall Directness	Directly applicable

Jovanovic-Peterson, 1989

Bibliographic Reference	Jovanovic-Peterson, L; Durak, E P; Peterson, C M; Randomized trial of diet versus diet plus cardiovascular conditioning on glucose levels in gestational diabetes.; American journal of obstetrics and gynecology; 1989; vol. 161 (no. 2); 415-9

Study details

Country/ies where study was carried out	USA
Study type	Randomised controlled trial (RCT)
Study dates	Not reported.
Inclusion criteria	Women who were pregnant with gestational diabetes diagnosed based on standard protocol.
Exclusion criteria	Maternal morbidity (for example, placenta praevia).
Patient characteristics	**Mean age in years (SD)** Intervention: 29.5 (2.5) Comparator: 31.1 (2.8) **Parity (n, %)** Not reported **Mean gestational age in weeks [at screening] (SD)** Not reported **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD)**

	Not reported **BMI class (n, %)** Not reported **Ethnicity (%)** Not reported **Education level (n, %)** Not reported **Income status (n, %)** Not reported The study setting: Not reported
Intervention(s)/control	**Physical activity:** Supervised aerobic physical activity using an arm ergometer for 20 minutes, 3 times a week for 6 weeks. Intervention was in addition to standard care gestational diabetes diet*. For physical activity, the target heart rate was (220-age in years) x 70% unless > 140 bpm after which the target was 140 bpm. The physical exercise session never went over 50% maximal oxygen consumption. **Comparator:** Standard care diet* divided into 3 meals and 3 snacks without any structured exercise program for 6 weeks. *Standard gestational diabetes diet: 24-30 kcal/kg/24 hours; 20% protein, 40% carbohydrate, 40% fat. All women performed glucose self-monitoring 4 times per day (before breakfast and 1 h postprandial).
Duration of follow-up	Not reported

Sources of funding	Not reported
Sample size	N total = 19 Physical activity n = 10 Standard care n = 9
Other information	Sourced from Brown 2017 Cochrane systematic review. 6 women exercised between 4-5 pm and 4 between 10-11 am. Diagnostic criteria: No details. Setting: Not reported. Screening: 50 g 1 h glucose challenge. Diagnosis: Fasting and 1 h tolerance test but no other details provided. Treatment target: Insulin started if the fasting plasma glucose level was >105 mg/dL and/or the 1 h postprandial plasma glucose level was >140 mg/dL. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status. However, participants were reported to be a low-income population. ITT numbers used for analysis.

Am: ante meridiem; BMI: body mass index; bpm: beats per minute; g: grams; h: hour/s;ITT: intention to treat; kcal/kg: kilocalories per kilogram; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mg/dL: milligrams per decilitre; n: number of participants; pm: post meridiem; SD: standard deviation; USA: United States of America.

Study arms

Physical activity (n = 10)

Standard care (n = 9)

Outcomes

Outcome	Physical activity, n = 10	Standard care, n = 9
Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) 1 h; Converted from mg/dL to mmol/L Mean (SD)	3.9 (0.4)	4.9 (0.3)
Pre-eclampsia Gestational age at diagnosis not reported, diagnosed before birth No of events	n = 0; % = 0	n = 0; % = 0
Need for pharmacological therapy Insulin; Follow-up not reported No of events	n = 0; % = 0	n = 0; % = 0
Large for gestational age > 90 centile >4500g, follow-up at birth No of events	n = 0; % = 0	n = 0; % = 0
Neonatal morbidity All infants reported to be healthy with no sign of morbidity, follow-up not reported No of events	n = 0; % = 0	n = 0; % = 0
Neonatal mortality and morbidity composite All infants reported to be healthy with no sign of morbidity, follow-up not reported No of events	n = 0; % = 0	n = 0; % = 0

g: grams; h: hour; mg/dL: milligrams per decilitre; mmol/L: millimole per litre; n: number of participants; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Brown 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane review (Brown 2017). See the Brown 2017 evidence table in Appendix D for the risk of bias assessment of the Cochrane review.

Lauszus, 2001

Bibliographic Reference	Lauszus, F F; Rasmussen, O W; Henriksen, J E; Klebe, J G; Jensen, L; Lauszus, K S; Hermansen, K; Effect of a high monounsaturated fatty acid diet on blood pressure and glucose metabolism in women with gestational diabetes mellitus.; European journal of clinical nutrition; 2001; vol. 55 (no. 6); 436-43

Study details

Country/ies where study was carried out	Denmark
Study type	Randomised controlled trial (RCT)
Study dates	Not reported.
Inclusion criteria	Women diagnosed with gestational diabetes mellitus (GDM) from positive 3 h 75 g OGTT (see other information) before the gestational age of 34 weeks.
Exclusion criteria	Taking hypoglycaemic, anti-lipidaemic or antihypertensive medication.
Patient characteristics	**Mean age in years (SD)** High unsaturated fat diet: 31 (1.0) Low unsaturated fat diet: 29 (1.0) **Parity (n, %)** Not reported **Mean gestational age in weeks [at screening] (SD)**

	Not reported **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean BMI in kg/m^2 [at baseline] (SD)** High unsaturated fat diet: 35.3 (2.4) Low unsaturated fat diet: 32.2 (1.5) **BMI class (n, %)** Not reported **Ethnicity (n, %)** Not reported **Education level (n, %)** Not reported **Income status (n, %)** Not reported The study setting: Details unclear
Intervention(s)/control	**High unsaturated fat diet:** High-monounsaturated fat diet from 34 gestational weeks. Primary source of monounsaturated fatty acid was a hybrid sunflower oil with a high content of oleic acid (80%) and provided to the women. Snacks were given as almonds and hazelnuts.

	Low unsaturated fat diet: High-carbohydrate diet from 34 gestational weeks. Bread, potato and rice enriched the diet. All women: All women were asked to consume a high-carbohydrate diet from gestational diabetes diagnosis until the 34th gestational week. Apart from diet, women continued their normal eating pattern and activities of daily living. Women visited the dietitian weekly and weighed with diet reviewed and energy intake adjustments if body weight differed by >500 g from the planned weight. Intravenous glucose tolerance test undertaken at baseline, 33rd, 36th and 38th gestational weeks with blood samples for measurements of plasma glucose and insulin concentrations taken at time 0, 2, 3, 4, 5, 6, 8, 10, 14, 19, 30, 40, 60, 90, 120 and 180 min.
Duration of follow-up	Until birth
Sources of funding	Partially industry funded. Grants for the study were from the Mimi and Victor Larsens Foundation, Nordisk Insulin Foundation, Novo Nordisk Foundation, and the Institute of Experimental Clinical Research, Aarhus University, Denmark.
Sample size	N total = 27 High unsaturated fat diet n = 13 Low unsaturated fat diet n = 14
Other information	Sourced from Han 2017 Cochrane systematic review. Gestational diabetes diagnostic criteria: Not reported. Timing: Not reported.

	Screening: Two independent fasting capillary plasma glucose values >4.6 mmol/L. Diagnosis: 75 g OGTT; 3 h; bloods taken every 30 minutes; gestational diabetes was defined as 2 or more plasma glucose concentrations above 3 standard deviations of the mean. Treatment target: not reported. Numbers included were used in analysis as numbers per arm for those allocated prior to exclusion was unclear. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status.

BMI: body mass index; g: grams; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; min: minutes; mmol/L: millimole per litre; n: number of participants; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

High unsaturated fat diet (n = 13)

Low unsaturated fat diet (n = 14)

Outcomes

Outcome	High unsaturated fat diet, n = 13	Low unsaturated fat diet, n = 14
Glycaemic control: during intervention (38 week) fasting blood glucose (mmol/L) Mean (SD)	4.7 (0.3)	4.2 (0.2)
Gestational weight change (kg) Final weight; Follow-up at 38 gestational weeks Mean (SD)	100.5 (6.5)	88.6 (5.1)
Mode of birth: Caesarean Follow-up at birth;	n = 1; % = NR	n = 1; % = NR

Outcome	High unsaturated fat diet, n = 13	Low unsaturated fat diet, n = 14
No of events		
Pre-eclampsia Gestational age at diagnosis not reported, diagnosed before birth No of events	n = 0; % = 0	n = 0; % = 0
Hypertensive disorders (gestational hypertension) Gestational age at diagnosis not reported; diagnosed before birth No of events	n = 1; % = NR	n = 2; % = NR
Need for pharmacological intervention Likely insulin; Follow-up unclear No of events	n = 0; % = 0	n = 0; % = 0
Large for gestational age > 90 centile >4500g based on methods; Follow-up at birth No of events	n = 4; % = NR	n = 8; % = NR

g: grams; kg: kilograms; mmol/L: millimole per litre; n: number of participants; NR: not reported; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Han 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane review (Han 2017). See the Han 2017 evidence table in Appendix D for the risk of bias assessment of the Cochrane review.

Louie, 2011

Bibliographic Reference	Louie, Jimmy Chun Yu; Markovic, Tania P; Perera, Nimalie; Foote, Deborah; Petocz, Peter; Ross, Glynis P; Brand-Miller, Jennie C; A randomized controlled trial investigating the effects of a low-glycemic index diet on pregnancy outcomes in gestational diabetes mellitus.; Diabetes care; 2011; vol. 34 (no. 11); 2341-6

Study details

Country/ies where study was carried out	Australia
Study type	Randomised controlled trial (RCT)
Study dates	Not reported.
Inclusion criteria	Diagnosed with gestational diabetes. Aged 18-45 years. 20-32 gestational weeks. Otherwise healthy singleton pregnancy.
Exclusion criteria	Special dietary requirements (including vegetarianism/veganism). Pre-existing diabetes. Pregnancy by assisted reproduction. Smoking or alcohol consumption during pregnancy.
Patient characteristics	**Mean age in years (SD)** Intervention: 34.0 (4.1) Comparator: 32.4 (4.5) **Parity (n, %)**

	Nulliparous Intervention: 29 (61.7) Comparator: 29 (64.4) **Mean gestational age in weeks [at screening] (SD)** Not reported **Mean gestational age in weeks [at intervention] (SD)** Intervention: 29.0 (4.0) Comparator: 29.7 (3.5) **Mean BMI in kg/m^2 [at baseline] (SD)** Not reported **BMI class (n, %)** Not reported **Ethnicity (n, %)** Asian: Intervention: (59.6) Comparator: (55.6) Caucasian: Intervention: (31.9) Comparator: (40.0) Others:

	Intervention: (8.5) Comparator: (4.4) **Education level (n, %)** Not reported **Income status (n, %)** Not reported The study setting: Hospital diabetes antenatal clinic.
Intervention(s)/control	**Low-GI diet:** Diet glycaemic index target of ≤ 50 with all other nutrients identical to the comparator group. **High-fibre moderate-GI diet:** Diet glycaemic index target of about 60 which was similar to the Australian population average glycaemic index. All women: Had similar healthy diets consisting of protein (15%-25% total daily energy intake), fat (25%-30% total daily energy intake), and carbohydrate (40%-5% total daily energy intake). Recorded food 3-day food intake for 2 weekdays and 1 weekend day at baseline and 36-37 gestational weeks. Were provided 2 booklets on food models to help with estimation of portion sizes. At least 3 face to face visits with the study dietician, coinciding with antenatal appointments. Food sample baskets provided with primary foods for the allocated diet. Received routine gestational diabetes care including instructions to self-monitor blood glucose before breakfast and 1 h after meals. The treating endocrinologist reviewed women every 2-4 weeks prior to 36 weeks and then every week until birth.

	Blood samples taken at baseline and around 36 gestational weeks.
Duration of follow-up	Until birth (Gestational weeks mean (SD): intervention 39.1 (0.1); comparator 39.2 (0.1)).
Sources of funding	Not industry funded.
Sample size	Total N = 99 Low-GI diet n = 50 High fibre diet moderate GI-diet n = 49
Other information	Sourced from Han 2017 Cochrane systematic review. Gestational diabetes diagnostic criteria: modified version of Australasian Diabetes in Pregnancy Society (ADIPS): Timing: 20-32 gestational weeks, earlier if high risk. Screening: Not reported. Diagnosis: 75 g OGTT with 1 or more values at or above: Fasting: ≥ 5.5 mmol/L; 1 h blood glucose ≥ 10.0 mmol/L; 2 h blood glucose: ≥ 8.0 mmol/L. Treatment target: Insulin treatment started when the mean fasting blood glucose or 1 h postprandial blood glucose in the previous week was above 5.2 and 7.5 mmol/L, respectively. ITT numbers used for analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status.

BMI: body mass index; g: grams; GI: glycaemic index; h: hour/s; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; n: number of participants; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

Low-GI diet (n = 50)

High fibre moderate-GI diet (n = 49)

Outcomes

Outcome	Low-GI diet, n = 50	High fibre moderate-GI diet, n = 49
Glycaemic control: blood glucose at the end of the intervention (mmol/L) Low-GI diet n = 42, High fibre moderate-GI diet n = 32 Mean (SD)	4.3 (0.6)	4.4 (0.6)
Gestational weight change (kg) Follow-up to last weight recorded before birth as recorded in medical records; Low-GI diet n = 44, High fibre moderate-GI diet n = 43 Mean (SD)	11.9 (0.7)	13.1 (0.9)
Gestational weight change - Met/achieved IOM guidelines (%) Follow-up to last weight recorded before birth as recorded in medical records; 2009 Institute of Medicine (IOM) guidelines; Low-GI diet n = 44, High fibre moderate-GI diet n = 43 No of events	n = 19; % = 43.2	n = 14; % = 32.6
Mode of birth: Caesarean (emergency) Emergency caesarean only reported; Follow-up at birth (mean 39 gestational weeks); Low-GI diet n = 44, High fibre moderate-GI diet n = 44 No of events	n = 9; % = 20.5	n = 5; % = 11.6
Need for pharmacological therapy Insulin; Follow-up at 36-37 gestational weeks; Low-GI diet n = 47, High fibre moderate-GI diet n = 45 No of events	n = 25; % = 53.2	n = 29; % = 65.1

Outcome	Low-GI diet, n = 50	High fibre moderate-GI diet, n = 49
Large for gestational age > 90 centile Follow-up at birth (mean 39 gestational weeks); Low-GI diet n = 47, High fibre moderate-GI diet n = 45 No of events	n = 6; % = 12.8	n = 2; % = 4.4

GI: glycaemic index; IOM: Institute of Medicine; kg: kilograms; mmol/L: millimole per litre; n: number of participants; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Han 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane review (Han 2017). See the Han 2017 evidence table in Appendix D for the risk of bias assessment of the Cochrane review.

Magee, 1990

Bibliographic Reference	Magee, M S; Knopp, R H; Benedetti, T J; Metabolic effects of 1200-kcal diet in obese pregnant women with gestational diabetes.; Diabetes; 1990; vol. 39 (no. 2); 234-40

Study details

Country/ies where study was carried out	USA
Study type	Randomised controlled trial (RCT)
Study dates	Not reported.
Inclusion criteria	Women with gestational diabetes who were obese (defined as: pre-pregnancy weight > 120% of ideal body weight based on the corrected 1959 Metropolitan Life Insurance tables).
Exclusion criteria	Not reported.

Patient characteristics	**Mean age in years (SD)** Intervention: 30 (4) Comparator: 36 (5) **Parity (n, %)** Not reported **Mean gestational age in weeks [at screening] (SD)** Not reported **Mean gestational age in weeks [at intervention] (SD)** Intervention: 31 (7) Comparator: 30 (3) **Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD)** Not reported **BMI class (n, %)** Obese: Intervention: 5 (100) Control: 7 (100) **Ethnicity (n, %)** Not reported **Education level (n, %)** Not reported

	Income status (n, %) Not reported The study setting: University hospital metabolic ward.
Intervention(s)/control	Women were hospitalised for 2 weeks, all receiving the same standard care diet during the first week and started their allocated diet during the second week: **Diet (energy-restricted diet):** Energy-restricted diet of 1200 kcal/day with serving size reduction of the first week diet without changes to any other aspects of the diet. **Standard care: (no energy-restricted diet):** Remained on the standard diet that was started in the first week which was about 2400 kcal/day. During the first week: 25% total energy for breakfast, lunch and dinner; 12.5% total energy for afternoon tea and supper consisting of 50% carbohydrate, 30% fat, 20% protein, with 11g of total dietary fibre per 500 kcal.
Duration of follow-up	At end of 2 week hospital stay.
Sources of funding	Not industry funded.
Sample size	Total N = 12 Diet (energy restricted) n = 7 Standard care (no energy-restricted diet) n = 5
Other information	Sourced from Han 2017 Cochrane systematic review. Gestational diabetes diagnostic criteria: Carpenter and Coustan.

	Timing: 28 gestational weeks. Screening: 50 g 1 h; plasma glucose ≥7.8mmol/L. Diagnosis: 100 g 3 h OGTT with three or more values: Fasting: 5.3 mmol/L; 1 h: 10 mmol/L; 2 h 8.6 mmol/L; 3 h: 7.8 mmol/L. Treatment target: not reported ITT numbers used for analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status.

BMI: body mass index; g: grams; h: hour/s; ITT: intention to treat; kcal: kilocalories; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; n: number of participants; OGTT: oral glucose tolerance test; SD: standard deviation; USA: United States of America.

Study arms

Diet (energy restricted) (n = 7)

Standard care (no energy-restricted diet) (n = 5)

Outcomes

Outcome	Diet (energy restricted), n = 7	Standard care (no energy-restricted diet), n = 5
Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) Standardised Mean (SD)	4.9 (0.7)	5.2 (0.9)

mmol/L: millimole per litre; n: number of participants; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Han 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane review (Han 2017). See the Han 2017 evidence table in Appendix D for the risk of bias assessment of the Cochrane review.

Mendelson, 2008

Bibliographic Reference	Mendelson, Sherri Garber; McNeese-Smith, Donna; Koniak-Griffin, Deborah; Nyamathi, Adeline; Lu, Michael C; A community-based parish nurse intervention program for Mexican American women with gestational diabetes.; Journal of obstetric, gynecologic, and neonatal nursing : JOGNN; 2008; vol. 37 (no. 4); 415-25

Study details

Country/ies where study was carried out	USA
Study type	Randomised controlled trial (RCT)
Study dates	Not reported
Inclusion criteria	Diagnosed with gestational diabetes mellitus and referred for treatment 18 to 40 years of age Mexican ancestry (self-reported) 12-32 gestational weeks Singleton pregnancy Ability to speak, read and write in English or Spanish
Exclusion criteria	Not reported
Patient characteristics	**Mean age in years (SD)** Intervention: 30.6 (5.6) Comparator: 31.5 (5.2) **Parity (n, %)**

	Intervention: Primiparous: 8 (16) Multiparous: 12 (23) Comparator: Primiparous: 41 (84) Multiparous: 39 (76) **Mean gestational age in weeks [at screening] (SD)** 28.7 (7.6) for total sample, not reported by arm **Mean gestational age in weeks [at intervention] (SD)** NR **Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD)** NR **BMI class (n, %)** NR **Ethnicity (n, %)** All participants were Mexican **Education level (n, %)** NR **Income status (n, %)** NR

	The study setting: Outpatient clinic for gestational diabetes
Intervention(s)/control	**Mixed intervention group:** A Parish nurse intervention program with enhanced education and support delivered by nurses fluent in Spanish. A supplemental 1 h discussion led by Parish nurses on: Medical recommendations to control gestational diabetes and addressing participant concerns or misunderstanding Spiritual principles such as encouragement of prayer and spiritual connection within the participant's belief system. Education addressing diabetes mechanisms, types and risk factors; how to control diabetes with diet, exercise and medical treatment as well as nutrition therapy (food groups and measurements). **Standard care:** Standard education program on diet, exercise, blood glucose testing as well as insulin administration if needed in one on one 1 h sessions delivered through handouts, demonstration and discussion.
Duration of follow-up	Not reported
Sources of funding	Not industry funded
Sample size	N total = 100 Mixed intervention n = 49 Standard care n = 51
Other information	Gestational diabetes diagnostic criteria: Not reported. Timing: Not reported. Screening: Not reported. Diagnosis: Not reported.

	Treatment target: Not reported. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status. However, participants were reported to be a low-income population. ITT numbers used for analysis.

BMI: body mass index; h: hour/s; ITT: intention to treat; LGBTQ+: lesbian, gay, bisexual, transgender and queer; n: number of participants; NR: not reported; SD: standard deviation; USA: United States of America.

Study arms

Mixed intervention (n = 49)

Standard care (n = 51)

Outcomes

Outcome	Mixed intervention, n = 49	Standard care, n = 51
Glycaemic control: fasting glucose at the end of the intervention (mmol/L) Mean (SD)	5.6 (0.5)	5.2 (1)
Large for gestational age > 90 centile Defined in text as macrosomia; Follow-up at birth No of events	n = 19; % = 38.8	n = 22; % = 43.1

n: number of participants; SD: standard deviation.

Critical appraisal – Cochrane Risk of Bias tool v2.0 for RCTs

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Random number tables used although allocation concealment was unclear. No significant differences between groups at baseline.)*

Section	Question	Answer
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Some concerns *(Women were not blinded but nurses delivering the intervention were blind to allocation (based on correspondence with authors noted in Brown J, Alwan NA, West J, Brown S, McKinlay CJD, Farrar D, Crowther CA. Lifestyle interventions for the treatment of women with gestational diabetes. Cochrane Database of Systematic Reviews 2017, Issue 5. Art. No.: CD011970. DOI: 10.1002/14651858.CD011970.pub2.). Intention to treat analysis nor deviations were reported.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Not all data was available for the outcome of HbA1c which was reported to be due to inconsistent testing at baseline and at delivery and unlikely that missingness in the outcome depended on it's true value.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Method of outcome measurement was appropriate and was unlikely to have differed between groups. No information whether outcome assessors were aware of allocation but was unlikely to affect assessment of outcome.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(No information on protocol or pre-specified analysis plan although the study gained Institutional Review Board approval. Numerical result unlikely to have been selected on basis of multiple outcome measurements or analyses.)*
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	N/A

DOI: Digital Object Identifier; HbA1c: haemoglobin A1C; N/A: not applicable; RCTs: randomised controlled trials.

Mijatovic, 2020

Bibliographic Reference	Mijatovic, Jovana; Louie, Jimmy Chun Yu; Buso, Marion E C; Atkinson, Fiona S; Ross, Glynis P; Markovic, Tania P; Brand-Miller, Jennie C; Effects of a modestly lower carbohydrate diet in gestational diabetes: a randomized controlled trial.; The American journal of clinical nutrition; 2020; vol. 112 (no. 2); 284-292

Study details

Country/ies where study was carried out	Australia
Study type	Randomised controlled trial (RCT)
Study dates	2016-2018
Inclusion criteria	Women with a gestational diabetes diagnosis. Age 18-45 years. Singleton pregnancy. 24-32 gestational weeks.
Exclusion criteria	Intake of alcohol or smoked cigarettes. Diet was gluten-free, vegetarian, or vegan. Had assisted reproduction. Unable to understand English. Had major surgery (for example, gastric bypass) in past 5 years. Comorbidities other than obesity, hypertension, or dyslipidemia.
Patient characteristics	**Mean age in years (SD)**

	Low-carbohydrate diet: 32.5 (0.9) High-carbohydrate diet: 34.2 (0.9) **Parity (n, %)** Nulliparous: Low-carbohydrate diet: 14 (58.3) High-carbohydrate diet: 10 (45.5) **Mean gestational age in weeks [at screening] (SD)** Low-carbohydrate diet: 28.4 (0.5) High-carbohydrate diet: 28.6 (0.6) **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean BMI in kg/m^2 [at baseline] (SD)** Not reported **BMI class (n, %)** Not reported **Ethnicity (n, %)** Asian Low-carbohydrate diet: 13 (54.2) High-carbohydrate diet: 16 (72.7) East Asian

	Low-carbohydrate diet: 1 (7.7) High-carbohydrate diet: 5 (31.3) South Asian Low-carbohydrate diet: 9 (69.2) High-carbohydrate diet: 4 (25.0) Southeast Asian Low-carbohydrate diet: 3 (23.1) High-carbohydrate diet: 7 (43.7) Caucasian Low-carbohydrate diet: 11 (45.8) High-carbohydrate diet: 7 (31.8) **Education level (n, %)** Secondary: Low-carbohydrate diet: 4 (16.7) High-carbohydrate diet: 3 (13.6) Tertiary: Low-carbohydrate diet: 10 (83.3) High-carbohydrate diet: 19 (86.4) **Income status (n, %)** Not reported

	The study setting: Antenatal clinics of two hospitals.
Intervention(s)/control	**Low-carbohydrate diet:** Absolute carbohydrate target of 135 g/d without energy restriction, based on the estimated average requirement for carbohydrate intake during pregnancy. **High-carbohydrate diet:** Absolute carbohydrate target of 180–200 g/d. All women: Were provided a pictorial booklet displaying carbohydrate content, target portion number, and glycaemic index . Women who had lower carbohydrate consumption at baseline were encouraged to at more high-fibre, low-GI foods, and this particularly applied to those allocated to the high carbohydrate diet. Blood glucose monitoring was part of standard care with 4 finger prick tests per day, the first in the morning following an overnight fast, and remainder at 1or 2 h after each of the 3 main meals Study visits every 2 weeks at same time as antenatal appointment At baseline and end of 6 week intervention, women recorded three 24 h food diary entries (including 2 weekdays and 1 weekend day) and a 2 day blood ketone diary.
Duration of follow-up	Until birth (Mean (SD) gestational age: Low-carbohydrate diet: 38.7 ± 0.2; High-carbohydrate diet: 38.6 ± 0.2)
Sources of funding	Not industry funded
Sample size	Total N = 46 Low-carbohydrate diet n = 24 High-carbohydrate diet n = 22

Other information	Trial name: MAMI 1 (Macronutrient Adjustments in Mothers with gestational diabetes study 1). Mean (SD) pre-pregnancy BMI kg/m^2: Low-carbohydrate diet: 25.8 (1.0); High-carbohydrate diet 27.8 (1.5). Gestational diabetes diagnostic criteria: The Australasian Diabetes in Pregnancy Society (ADIPS; 1998) or The International Association of the Diabetes and Pregnancy Study Groups (IADPSG) depending on hospital. Timing: 26-28 gestational weeks. Screening: Not reported Diagnosis: 75 g OGTT using one of ADIPS: fasting blood glucose concentration (BGC) ≥5.5 mmol/L or 2 h ≥8.0 mmol/L; IADPSG: fasting BGC ≥5.1 mmol/L, 1 h ≥10.0 mmol/L, or 2 h ≥8.5 mmol/L. Treatment target: Based on hospital, either BGC target of ≤5.3 mmol/L and 2-h postmeal ≤6.8 mmol/L or a fasting BGC ≤5.2 mmol/L and 1 h postmeal ≤7.5 mmol/L. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status. However, participants were reported to be a low-income population. ITT numbers used for analysis.

BMI: body mass index; g/d: grams per day; GI: glycaemic index; h: hour/s; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; n: number of participants; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

Low-carbohydrate diet (n = 24)

High-carbohydrate diet (n = 22)

Outcomes

Outcome	Low-carbohydrate diet, n = 24	High-carbohydrate diet, n = 22
Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) Low-carbohydrate diet n = 13; high-carbohydrate diet n = 16 Mean (SD)	4.9 (0.1)	4.9 (0.1)
Gestational weight change (kg) Total gestational weight change from pre-pregnancy to last weight taken before birth; Low-carbohydrate diet n = 24; high-carbohydrate diet n = 21 Mean (SD)	10.9 (0.9)	8.2 (1.5)
Gestational weight change - Met/achieved IOM guidelines (%) Last weight taken before birth; Low-carbohydrate diet n = 24; high-carbohydrate diet n = 21 No of events	n = 4; % = 16.7	n = 6; % = 28.6
Mode of birth: Vaginal birth Follow-up at birth; Low-carbohydrate diet n = 24; high-carbohydrate diet n = 21 No of events	n = 17; % = 70.8	n = 11; % = 52.4
Mode of birth: Induction of labour Follow-up at birth; Low-carbohydrate diet n= 24; high-carbohydrate diet n = 21 No of events	n = 16; % = 66.7	n = 6; % = 28.6
Mode of birth: Caesarean Follow-up at birth; Low-carbohydrate diet n = 24; high-carbohydrate diet n = 21 No of events	n = 7; % = 29.2	n = 10; % = 47.6

Outcome	Low-carbohydrate diet, n = 24	High-carbohydrate diet, n = 22
Emergency caesarean Follow-up at birth; Low-carbohydrate diet n = 24; high-carbohydrate diet n = 21 No of events	n = 4; % = 16.7	n = 2; % = 9.5
Elective caesarean Follow-up at birth; Low-carbohydrate diet n = 24; high-carbohydrate diet n = 21 No of events	n = 3; % = 12.5	n = 8; % = 38.1
Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) Low-carbohydrate diet n=13; high-carbohydrate diet n=16 Mean (SD)		
Need for pharmacological therapy Insulin; Those initiated after baseline; Follow-up until birth No of events	n = 8; % = 33.3	n = 5; % = 22.7
Large for gestational age > 90 centile Follow-up at birth; Low-carbohydrate diet n = 24; high-carbohydrate diet n = 20 No of events	n = 0; % = 0	n = 1; % = 4.5

IOM: Institute of Medicine; kg: kilograms; mmol/L: millimole per litre; n: number of participants; SD: standard deviation.

Critical appraisal – Cochrane Risk of Bias tool v2.0 for RCTs

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Allocation was random and concealed in opaque envelopes and revealed to*

Section	Question	Answer
		the dietitian on the first visit. Some differences were present between groups for pre-pregnancy BMI class (for example, low carbohydrate compared to high carbohydrate: n = 12/24 (50%) compared to n = 8/22 (36.4%) healthy pre-pregnancy BMI; n = 2/24 (8.3%) compared to n = 4/22 (18.2%) obese I BMI) but likely due to chance than randomisation process.)
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Some concerns *(Participants and all personnel other than the research dietitian were blinded to allocation and no deviations were reported. Intention-to-treat analysis was performed, however, this excluded one woman in the low-carbohydrate arm considered an outlier due to persistent nausea resulting in very low energy intake.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(Loss to follow-up occurred for 18% (n=4/22) of participants in the low-carbohydrate (LC) and 33% (n=8/24) of participants in the high- carbohydrate (HC) arms due to delivery before final data collection (n=3 in HC arm; n = 7 in LC arm), lost interest (n = 1 in LC arm) or medical reasons (n = 1 in HC arm). No analysis performed to determine if result biased by missing outcome and it is unclear whether that missingness in the outcome for the woman who withdrew due to medical reasons depended on its true value)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Methods of outcome measurement are appropriate and unlikely to have differed between arms. All personnel other than the research dietitian were blinded to allocation.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low *(The trial was prospectively registered on ANZCTR with likely finalised analysis plan before unblinded outcome data were available for analysis. Numerical result unlikely to have been selected on basis of multiple outcome measurements or analyses.)*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High *(The study is judged to be at high risk of bias in at least one domain for this result.)*
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	N/A

ANZCTR: Australian New Zealand Clinical Trials Registry; BMI: body mass index; HC: high carbohydrate; LC: low carbohydrate; n: number of participants; N/A: not applicable; RCTs: randomised controlled trials.

Moreno-Castilla, 2013

Bibliographic Reference	Moreno-Castilla, Cristina; Hernandez, Marta; Bergua, Merce; Alvarez, Maria C; Arce, Maria A; Rodriguez, Karen; Martinez-Alonso, Montserrat; Iglesias, Montserrat; Mateu, Magdalena; Santos, Maria D; Pacheco, Linda R; Blasco, Yolanda; Martin, Eva; Balsells, Nuria; Aranda, Nuria; Mauricio, Didac; Low-carbohydrate diet for the treatment of gestational diabetes mellitus: a randomized controlled trial.; Diabetes care; 2013; vol. 36 (no. 8); 2233-8

Study details

Country/ies where study was carried out	Spain
Study type	Randomised controlled trial (RCT)
Study dates	2008-2011
Inclusion criteria	Diagnosis of gestational diabetes. Aged 18-45 years. Singleton pregnancy.

	≤ 35 gestational weeks.
Exclusion criteria	Those choosing not to follow a prescribed diet. Not able to understand Spanish. Pregnancy co-morbidities other than obesity, hypertension, and/or dyslipidaemia.
Patient characteristics	**Mean age in years (SD)** Intervention: 33.5 (3.7) Comparator: 32.1 (4.4) **Parity (n, %)** Nulliparous: Intervention: 40 (53.3) Comparator: 37 (49.3) **Mean gestational age in weeks [at screening] (SD)** Intervention: 30.4 (3.0) Comparator: 30.1 (3.5) **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD)** Not reported **BMI class (n, %)**

	Not reported **Ethnicity (n, %)** Non-Caucasian: Intervention: 1 (1.3) Comparator: 6 (8.0) **Education level (n, %)** Not reported **Income status (n, %)** Not reported The study setting: Diabetes and pregnancy outpatient hospital clinic.
Intervention(s)/control	**Low-carbohydrate diet:** Diet consisting of carbohydrate with 40% of total daily calorie amount; fat with 40% of total daily calorie amount and mainly by higher olive oil consumption; protein with 20% of total daily calorie amount. **High-carbohydrate diet:** Diet consisting of carbohydrate with 55% of total daily calorie amount; fat with 25% of total daily calorie amount; protein with 20% of total daily calorie amount. All women: Calculation of the energy content for each woman's diet was based on pre-gestational weight with a minimum of 1800 kcal/day.
Duration of follow-up	Until birth (Gestational age mean (SD): low-carbohydrate diet 39.0 (2.1); high-carbohydrate diet 38.9 (1.8)).
Sources of funding	No information.
Sample size	N total = 150

	Low-carbohydrate diet n = 75 High-carbohydrate diet n = 75
Other information	Sourced from Han 2017 Cochrane systematic review. Gestational diabetes diagnostic criteria: 2006 National Diabetes and Pregnancy clinical guidelines (screening and diagnosis) Timing: 24-28 gestational weeks Screening: 50 g OGTT; ≥ 7.8 mmol/L Diagnosis: 100 g 3 h OGTT; National Diabetes Data Group criteria: 2 or more values at or above: Fasting: 5.8 mmol/L;1h 10.6 mmol/L; 2 h 9.2 mmol/L; 3 h 8.1 mmol/L. Treatment target: Insulin treatment initiated if at least two self-monitoring blood glucose values at the same time point of the day in a 1-week time interval above glycaemic targets: fasting and preprandial glycemia ≤5.3 mmol/L and 1 h postprandial glycemia ≤7.8 mmol/L. ITT numbers used for analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status. This study did not report glycaemic outcomes.

BMI: body mass index; ITT: intention to treat; g: grams; h: hour/s; kcal/day: kilocalories per day; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; n: number of participants; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

Low-carbohydrate diet (n = 75)

High-carbohydrate diet (n = 75)

Outcomes

Outcome	Low-carbohydrate diet, n = 75	High-carbohydrate diet, n = 75
Gestational weight change (kg) Converted from lb to kg; follow-up to last recorded predelivery weight within 4 weeks preceding delivery from medical records; low-carbohydrate diet n = 73; high carbohydrate diet n = 72 Mean (SD)	1.4 (2)	2.3 (2.3)
Mode of birth: Caesarean Follow-up at birth; low-carbohydrate diet n = 74; high carbohydrate diet n = 75 No of events	n = 25; % = 33.8	n = 20; % = 26.7
Gestational hypertension Gestational age at diagnosis not reported; diagnosed before birth; low-carbohydrate diet n = 75; high carbohydrate diet n = 75 No of events	n = 4; % = 5.3	n = 10; % = 13.3
Need for pharmacological intervention Insulin; Follow-up unclear; Follow-up unclear; low-carbohydrate diet n = 75; high carbohydrate diet n = 75 No of events	n = 41; % = 54.7	n = 41; % = 54.7
Large for gestational age > 90 centile Follow-up at birth; low-carbohydrate diet n = 74; high carbohydrate diet n = 75 No of events	n = 3; % = 4.1	n = 6; % = 8
Neonatal hypoglycaemia Follow-up at birth; low-carbohydrate diet n = 74; high carbohydrate diet n = 75 No of events	n = 9; % = 12.2	n = 10; % = 13.2

Outcome	Low-carbohydrate diet, n = 75	High-carbohydrate diet, n = 75
Neonatal mortality Follow-up at birth; low-carbohydrate diet n = 74; high carbohydrate diet n = 75 No of events	n = 0; % = 0	n = 0; % = 0

kg: kilograms; lb: pounds; n: number of participants; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Han 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane review (Han 2017). See the Han 2017 evidence table in Appendix D for the risk of bias assessment of the Cochrane review.

Moses, 2009

Bibliographic Reference	Moses, Robert G; Barker, Megan; Winter, Meagan; Petocz, Peter; Brand-Miller, Jennie C; Can a low-glycemic index diet reduce the need for insulin in gestational diabetes mellitus? A randomized trial.; Diabetes care; 2009; vol. 32 (no. 6); 996-1000

Study details

Country/ies where study was carried out	Australia
Study type	Randomised controlled trial (RCT)
Study dates	2007-2008
Inclusion criteria	Diagnosis of gestational diabetes. Aged 18-40 years.

	Singleton pregnancy. No history of gestational diabetes. Did not smoke. Seen for the first dietary visit between 28-32 gestational weeks. Could follow the protocol requirements.
Exclusion criteria	Conditions or medications that might alter glucose concentrations. Not consenting to following prescribed diet.
Patient characteristics	**Mean age in years (SEM)** Intervention: 30.8 (0.7) Comparator: 31.3 (0.8) **Parity (n, %)** NR **Mean gestational age in weeks [at screening] (SEM)** Intervention: 30.3 (0.2) Comparator: 29.9 (0.2) **Mean gestational age in weeks [at intervention] (SD)** NR **Mean BMI in kg/m^2 [at baseline] (SD)** Intervention: 32.0 (1.2)

	Comparator: 32.8 (1.4) **BMI class (n, %)** NR **Ethnicity (n, %)** NR **Education level (n, %)** NR **Income status (n, %)** NR The study setting: Diabetes centre.
Intervention(s)/control	**Low-moderate GI diet:** Diet based on previously verified low-GI food, including pasta, grain breads, and unprocessed breakfast cereals with a high-fibre content. Women were told to avoid white bread, processed commercial breakfast cereals, potatoes, and some rice types. **Moderate-high GI diet:** Diet with a high-fibre and low-sugar content and no specific advice around GI index. Advised to eat potatoes, whole wheat bread, and specific high-fibre, moderate-to-high GI breakfast cereals. All women: Given a home glucose meter and instructed to measure after fasting and 1 hour after beginning each of their 3 major meals at least every second day; Had a minimum of 4 diabetes centre visits with a dietitian providing dietary assessment; if insulin was required, visited as necessary for adjustments.

	Given a booklet explaining carbohydrate choices and the amount of carbohydrate food in 1 serving (based on 15 g portions); Were advised to have 3 small meals and 2-3 snacks with a specified number of carbohydrate servings.
Duration of follow-up	Until 35-37 gestational weeks
Sources of funding	Not industry funded
Sample size	N total = 63 Low-moderate GI diet: n = 31 Moderate-high GI diet: n = 32
Other information	Sourced from Han 2017 Cochrane systematic review. Gestational diabetes diagnostic criteria: Australasian Diabetes in Pregnancy (ADIPS) criteria: Timing: not reported Screening: not reported Diagnosis: 75 g OGTT with 1 or more values at or above fasting plasma glucose ≥ 5.5 mmol/L, 2 h glucose ≥ 8.0 mmol/L Treatment target: Insulin initiated if >1 per week fasting glucose was ≥5.5 mmol/L and/or 1 h postprandial glucose was ≥8.0 mmol/L. Women allocated to the low-glycaemic index diet who met this criteria initiated insulin immediately. Women on the higher–glycaemic index diet meeting this criteria was switched to the low-glycaemic index diet, with responses reviewed over 1 week. 9/19 women in the high-glycaemic index group who met the treatment target criteria and then started the low GI diet no longer met the criteria for insulin initiation. ITT numbers used for analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status.

	This study only reported glycaemic index outcomes.

BMI: body mass index; g: grams; GI: glycaemic index; h: hour; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; n: number of participants; NR: not reported; OGTT: oral glucose tolerance test; SEM: standard error measurement; SD: standard deviation.

Study arms

Low-moderate GI diet (n = 31)

Moderate-high GI diet (n = 32)

Outcomes

Outcome	Low-moderate GI diet , n = 31	Moderate-high GI diet, n = 32
Mode of birth: Caesarean Follow-up at birth No of events	n = 7; % = 22.6	n = 11; % = 34.4
Mode of birth: Vaginal birth Total; Follow-up at birth No of events	n = 24; % = 77.4	n = 21; % = 65.6
Mode of birth: Vaginal birth - non operative No of events	n = 21; % = 67.7	n = 16; % = 50
Mode of birth: Vaginal birth - operative No of events	n = 3; % = 9.6	n = 5; % = 15.6
Mode of birth: Induction of labour Follow-up at birth	n = 6; % = 19.4	n = 7; % = 21.9

Outcome	Low-moderate GI diet , n = 31	Moderate-high GI diet, n = 32
No of events		
Need for pharmacological intervention Insulin; Follow-up until birth; an additional n = 9 in the moderate-high GI group initially met criteria to start insulin but once starting low-moderate GI diet no longer met these thresholds; insulin initiated at mean (SD) 32.1 (0.4) gestational weeks for low–moderate GI group and at 32.3 (0.5) gestational weeks for moderate-high GI group No of events	n = 9; % = 29	n = 10; % = 31.3
Large for gestational age > 90 centile Follow-up at birth No of events	n = 3; % = 9.7	n = 3; % = 9.4

GI: glycaemic index; n: number of participants; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Han 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane review (Han 2017). See the Han 2017 evidence table in Appendix D for the risk of bias assessment of the Cochrane review.

Rae, 2000

Bibliographic Reference	Rae, A; Bond, D; Evans, S; North, F; Roberman, B; Walters, B; A randomised controlled trial of dietary energy restriction in the management of obese women with gestational diabetes.; The Australian & New Zealand journal of obstetrics & gynaecology; 2000; vol. 40 (no. 4); 416-22

Study details

Country/ies where study was carried out	Australia
Study type	Randomised controlled trial (RCT)
Study dates	1992-1995
Inclusion criteria	Women diagnosed with gestational diabetes. ≤ 35 gestational weeks and 6 days gestation. >110% of ideal body weight for height (adjusted for expected pregnancy weight gain and using a BMI of 25 as equal to 100% ideal body weight).
Exclusion criteria	Not reported
Patient characteristics	**Mean age in years (SD)** Intervention: 30.2 (NR) Comparator: 30.6 (NR) **Parity (n, %)** Nulliparous: Intervention: 18 (NR) Comparator: 17 (NR) **Mean gestational age in weeks [at screening] (SD)** Not reported **Mean gestational age in weeks [at intervention] (SD)** Not reported

	Mean BMI in kg/m^2 [at baseline] (SD) Not reported, at diagnosis reported for intervention: 37.9 (0.7); comparator: 38.0 (0.7) **BMI class (n, %)** Not reported **Ethnicity (n, %)** Not reported **Education level (n, %)** Not reported **Income status (n, %)** Not reported The study setting: Hospital diabetes service.
Intervention(s)/control	**Energy-restricted diet:** Diabetic diet of 6800-7600 kJ energy per day and represented 70% of the Recommended Dietary Intake for pregnant women (30% energy restriction). **No energy-restricted diet:** Diabetic diet without energy restriction of 8600-9500 kJ energy per day. All women: Research dietitian gave diabetes education at each antenatal visit Hyperglycaemia control, blood glucose capillary self-monitoring: pre- and 2 hours post every meal 6 times daily, for a minimum of 2 days per week. Medical staff judged insulin initiation (see criteria in other information).

	Metabolic monitoring for HbA1c, serum beta-hydroxybutyrate, urinary ketone. 3-day food intake diaries to assess diet adherence.
Duration of follow-up	Until 5 days after birth
Sources of funding	Not industry funded
Sample size	N total = 125 Diet (energy-restricted diet) n = 67 Standard care (no energy-restricted diet) n = 58
Other information	Sourced from Han 2017 Cochrane systematic review. 7 sets of twins were included in the study, 3 sets in the energy-restricted diet group and 4 sets in the no energy-restricted diet group. Gestational diabetes diagnostic criteria: Australasian Diabetes in Pregnancy Society (ADIPS). Timing: Not reported. Screening: Not reported. Diagnosis: 75 g 2 h OGTT: fasting blood glucose >5.4 mmol/L and/or 2 h blood glucose >7.9 mmol/L. Treatment target: Insulin initiated if fasting blood glucose > 5.5 mmol/L or 2 h: > 7.0 mmol/L on 2 or more occasions in any 72 h period at the same pre- or postprandial epoch. ITT numbers used for analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status.

BMI: body mass index; ITT: intention to treat; g: grams; h: hour; HbA1c: haemoglobin A1C; kg: kilograms; kJ: kilojoules; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; n: number of participants; NR: not reported; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

Diet (energy-restricted diet) (n = 67)

Standard care (no energy-restricted diet) (n = 58)

Outcomes

Outcome	Diet (energy-restricted diet), n = 67	Standard care (no energy-restricted diet), n = 58
Glycaemic control: fasting glucose during/at the end of the intervention (mmol/L) Diet n = 66; standard care n = 58 Mean (SD)	4.9 (0.79)	4.8 (0.73)
Gestational weight change (kg) Total gestational weight change from pre-pregnancy to birth; Diet n = 66; standard care n = 58 Mean (SD)	11.56 (10.48)	9.68 (10.66)
Mode of birth: Vaginal birth Total; Follow-up at birth; Diet n = 66; standard care n = 58 No of events	n = 39; % = 59.1	n = 37; % = 67.8
Vaginal birth - not operative Follow-up at birth; Diet n = 66; standard care n = 58 No of events	n = 31; % = 47.7	n = 30; % = 53.6

Outcome	Diet (energy-restricted diet), n = 67	Standard care (no energy-restricted diet), n = 58
Mode of birth: induction of labour Follow-up at birth; Diet n = 66; standard care n = 58 No of events	n = 29; % = 43.9	n = 23; % = 39.7
Mode of birth: Caesarean Follow-up at birth; Diet n = 66; standard care n = 58 No of events	n = 26; % = 39.4	n = 19; % = 32.8
Pre-eclampsia Gestational age at diagnosis not reported, diagnosed before birth; Diet n = 66; standard care n = 58 No of events	n = 14; % = 21.2	n = 12; % = 20.7
Need for pharmacological intervention Insulin; Follow-up not reported; Diet n = 66; standard care n = 58 No of events	n = 11; % = 16.7	n = 9; % = 15.5
Large for gestational age > 90 centile Follow-up unclear, reports anthropomorphic features collected 5 days after birth without reference to weight; Diet n = 66; standard care n = 58	n = 19; % = 28.8	n = 14; % = 24.1

Outcome	Diet (energy-restricted diet), n = 67	Standard care (no energy-restricted diet), n = 58
No of events		
Neonatal hypoglycaemia Follow-up unclear; Diet n = 66; standard care n = 58 No of events	n = 22; % = 33.3	n = 25; % = 43.1
Neonatal mortality Follow-up not reported; Diet n = 66; standard care n = 58 No of events	n = 0; % = 0	n = 0; % = 0

kg: kilograms; n: number of participants; mmol/L: millimole per litre; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Han 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane review (Han 2017). See the Han 2017 evidence table in Appendix D for the risk of bias assessment of the Cochrane review.

Reece, 1995

Bibliographic Reference	Reece, E.A.; Hagay, Z.; Gay, L.J.; O'Connor, T.; DeGennaro, N.; Homko, C.J.; Wiznitzer, A.; A randomized clinical trial of a fiber-enriched diabetic diet vs. the standard American Diabetes Association-recommended diet in the management of diabetes mellitus in pregnancy; Journal of Maternal-Fetal Investigation; 1995; vol. 5 (no. 1); 8-12

Study details

Country/ies where study was carried out	USA
Study type	Randomised controlled trial (RCT)
Study dates	Not reported
Inclusion criteria	Women diagnosed with gestational diabetes. 24-29 gestational weeks.
Exclusion criteria	Gestational diabetes diagnosed >29 gestational weeks.
Patient characteristics	**Mean age in years (SD)** Not reported **Parity (n, %)** Not reported **Mean gestational age in weeks [at screening] (SD)** Not reported **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean pre-pregnancy BMI in kg/m^2 [at baseline] (SD)** Not reported **BMI class (n, %)** Not reported

	Ethnicity (n, %) Not reported **Education level (n, %)** Not reported **Income status (n, %)** Not reported The study setting: Not reported.
Intervention(s)/control	**Diet (high-fibre diet):** Diet of 80 g fibre per day with fat comprising 20% daily energy intake, and carbohydrate comprising 60% of daily energy intake. **Standard care (standard-fibre diet):** American Diabetes Association (ADA) diet comprising 20 g fibre per day; with fat comprising 30% daily energy intake and carbohydrate comprising 50% of daily energy intake. All women: Self-monitoring of capillary blood glucose 6 times a day (before and after each meal), two times a week with women asked to record these as much as possible.
Duration of follow-up	Not reported
Sources of funding	Not reported
Sample size	Total N = 22 Diet (high-fibre diet) n = 11 Standard care (standard-fibre diet) n = 11

Other information	Sourced from Han 2017 Cochrane systematic review. The study included a mixed diabetes population and only data for women with gestational diabetes was considered and extracted. Gestational diabetes diagnostic criteria: Not reported. Timing: Not reported. Screening: Not reported. Diagnosis: Not reported. Treatment target: Not reported. ITT numbers used for analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status.

BMI: body mass index; g: grams; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; n: number of participants; SD: standard deviation; USA: United States of America.

Study arms

Diet (high-fibre diet) (n = 11)

Standard care (standard-fibre diet) (n = 11)

Outcomes

Outcome	Diet (high-fibre diet), n = 11	Standard care (standard-fibre diet), n = 11
Glycaemic control during/at end of intervention: mean blood glucose (mmol/L) Mean (SD)	4.9 (0.6)	4.9 (0.5)

Outcome	Diet (high-fibre diet), n = 11	Standard care (standard-fibre diet), n = 11
Gestational weight change (kg) Reported as "mean net [or maternal] weight gain"; Follow-up unclear Mean (SD)	14.3 (6.8)	11.9 (3.8)
Need for pharmacological intervention Insulin; Follow-up unclear No of events	n = 0; % = 0	n = 0; % = 0

kg: kilograms; n: number of participants; mmol/L: millimole per litre; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Han 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane review (Han 2017). See the Han 2017 evidence table in Appendix D for the risk of bias assessment of the Cochrane review.

Sklempe Kokic, 2018

Bibliographic Reference	Sklempe Kokic, Iva; Ivanisevic, Marina; Biolo, Gianni; Simunic, Bostjan; Kokic, Tomislav; Pisot, Rado; Combination of a structured aerobic and resistance exercise improves glycaemic control in pregnant women diagnosed with gestational diabetes mellitus. A randomised controlled trial.; Women and birth : journal of the Australian College of Midwives; 2018; vol. 31 (no. 4); e232-e238

Study details

Country/ies where study was carried out	Croatia
Study type	Randomised controlled trial (RCT)

Study dates	2014-2015
Inclusion criteria	Women diagnosed with gestational diabetes (International Association of the Diabetes and Pregnancy Study Groups criteria). Age 20-40 years. Maximum 30 gestational weeks at inclusion.
Exclusion criteria	Medical history of diabetes and miscarriages. Pharmacological treatment before enrolment. Existing comorbidities, and contraindications for exercise (following American College of Obstetricians and Gynecologists criteria).
Patient characteristics	**Mean age in years (SD)** Intervention: 32.78 (3.83) Comparator: 31.95 (4.91) **Parity (n, %)** Not reported **Mean gestational age in weeks [at screening] (SD)** Not reported **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean BMI in kg/m^2 [at baseline] (SD)** Not reported

	BMI class (n, %) Not reported **Ethnicity (n, %)** Not reported **Education level (n, %)** Secondary level Intervention: 7 (38.9) Comparator: 7 (35.0) Tertiary level: Intervention: 11 (61.1) Comparator: 13 (65.0) **Income status (n, %)** Not reported The study setting: University hospitals
Intervention(s)/control	**Physical activity:** Supervised moderate aerobic and resistance physical activity program held two times a week for 50-55 minutes. The program was which was structured and personalised. The aerobic component was performed on a treadmill with heart rate monitoring (target heart rate within aerobic zone of 65–75% of maximum heart rate). The program continued throughout pregnancy with minimum duration of 6 weeks. Also asked to undertake 30 minutes of brisk walking per day and record this activity in a diary. In addition to standard care

	Standard care: Standard prenatal care for gestational diabetes and allowed to carry out their own exercise. All women: Consumed recommended diet for gestational diabetes: 1800 kcal per day with 20% proteins (90 g), 30% fat (60 g) and 50% carbohydrates (225 g) over three main meals and three snacks
Duration of follow-up	Until birth (Mean (SD) gestational age not reported)
Sources of funding	Not industry funded
Sample size	N total = 42 Physical activity n = 20 Standard care n = 22
Other information	Pre-pregnancy BMI in (kg/m^2; mean SD): Intervention: 24.39 (4.89); Comparator 25.29 (4.65) Gestational diabetes diagnostic criteria: International Association of the Diabetes and Pregnancy Study Groups (IADPSG) Timing: Not reported Screening: Not reported Diagnosis: 75 g OGTT, further details not reported Treatment target: Not reported ITT numbers used for analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status.

BMI: body mass index; g: grams; ITT: intention to treat; kcal: kilocalories; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; n: number of participants; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

Physical activity (n = 20)

Standard care (n = 22)

Outcomes

Outcome	Physical activity, n = 20	Standard care, n = 22
Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) Physical activity n = 18; Standard care n = 20 Mean (SD)	4.32 (0.26)	4.44 (0.46)
Mode of birth: induction of labour Follow-up at birth; Physical activity n = 18; Standard care n = 20 No of events	n = 3; % = 16.7	n = 7; % = 35
Mode of birth: Caesarean Follow-up at birth; Physical activity n = 18; Standard care n = 20 No of events	n = 5; % = 28	n = 5; % = 25
Need for pharmacological therapy Not defined; Follow-up unclear No of events	n = 0; % = 0	n = 0; % = 0
Neonatal hypoglycaemia Follow-up after birth; Physical activity n = 18; Standard care n = 20 No of events	n = 0; % = 0	n = 0; % = 0

n: number of participants; mmol/L: millimole per litre; SD: standard deviation.

Critical appraisal – Cochrane Risk of Bias tool v2.0 for RCTs

Section	**Question**	**Answer**
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(The allocation sequence was random by use of computer randomisation program and probably adequately concealed with staff involved in exercise sessions having no influence on the randomisation procedure. No significant differences between groups at baseline.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Some concerns *(Participants were aware of their allocation and those delivering the intervention were likely aware of allocation, although physicians to the women were blinded to allocation. There is no reason to believe that deviations from the intended intervention arose due to trial context. The study did not perform intention-to-treat analysis and a complete analysis was not available for 10% (n = 18/20) of women in the intervention (n = 2 dropped out without reason) and 11% (n = 20/22) of women in the comparator arm (n = 1 dropped out with no reason and n = 1 moved). Impact on the results of number of participants excluded from the analysis is unclear and whether these are related to prognostic factors.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(>5% participants lost to follow up from both arms. Unclear if missingness in the outcome depends on its true value as reason for drop out not provided.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Method of measuring outcome was appropriate and it is unlikely that measurements of the outcome differed between arms. Outcomes were objective. Physicians and lab technicians were blinded to allocation.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low *(Likely pre-specified analysis plan finalised before blinded outcome data were*

Section	Question	Answer
		available for analysis as trial was registered on clinicaltrials.gov at the beginning of the study period and there was a protocol. Numerical result unlikely to have been selected on basis of multiple outcome measurements or analyses.)
Overall bias and Directness	Risk of bias judgement	High *(The study is judged to be at high risk of bias in at least one domain for this result.)*
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	N/A

N: number of participants; N/A: not applicable; RCTs: randomised controlled trials.

Trout, 2016

Bibliographic Reference	Trout, Kimberly K; Homko, Carol J; Wetzel-Effinger, Lisa; Mulla, Wadia; Mora, Ricardo; McGrath, Joanna; Basel-Brown, Lisa; Arcamone, Angelina; Sami, Parichehr; Makambi, Kepher H; Macronutrient Composition or Social Determinants? Impact on Infant Outcomes With Gestational Diabetes Mellitus.; Diabetes spectrum : a publication of the American Diabetes Association; 2016; vol. 29 (no. 2); 71-8

Study details

Country/ies where study was carried out	USA
Study type	Randomised controlled trial (RCT)
Study dates	Not reported
Inclusion criteria	Women diagnosed with gestational diabetes by Carpenter-Coustan criteria.

	Gestational age ≤35 weeks. Age 18-45 years. Gestational diabetes controlled by diet alone or diet and oral medication (for example, glyburide).
Exclusion criteria	Multifetal pregnancy. Pregestational diabetes. Required insulin for their diabetes at the time of enrolment. Any other significant medical or psychiatric comorbidities (for example, cardiovascular disease or preexisting hypertension). Smokers, consuming alcohol or taking illicit drugs.
Patient characteristics	**Mean age in years (SD)** Baseline values not reported; at birth reported: Low-carbohydrate diet: 30.09 (6.15) High-carbohydrate diet: 29.63 (5.19) **Parity (n, %)** Not reported **Mean gestational age in weeks [at screening] (SD)** Not reported **Mean gestational age in weeks [at intervention] (SD)** "At study entry" Low-carbohydrate diet: 29.17 (2.78)

	High-carbohydrate diet: 30.50 (2.85) **Mean BMI in kg/m^2 [at baseline] (SD)** Timepoint of measurement undefined: Low-carbohydrate diet: 33.84 (8.84) High-carbohydrate diet: 31.80 (8.68) **BMI class (n, %)** Not reported **Ethnicity (n, %)** Not reported per allocation **Education level (n, %)** Not reported **Income status (n, %)** Not reported The study setting: Urban teaching hospital or suburban community hospital.
Intervention(s)/control	**Low-carbohydrate diet:** Women were placed on a lower-carbohydrate diet of 35–40% of total calories. **High-carbohydrate diet:** Women followed the usual pregnancy diet of 50–55% carbohydrates. All women: Received standard care by their obstetric provider.

	Diabetes education self-management training by a certified diabetes educator (CDE) and training on carbohydrate gram counting by CDE or research team. Women practiced weighing/measuring foods and carbohydrate content calculations via pocket sized book provided. After CDE consultation, total maximum daily carbohydrate gram count in relation to total daily caloric intake was tailored. Were provided instructional sheet with written examples of healthy foods and sample food menu plans. Encouraged to distribute the total carbohydrate allocation over 3 meals and snacks per day. Taught how to use a portable self-monitoring blood glucometer and asked to perform self-monitoring of blood glucose 4 times a day (fasting and 2 h after meals). Self-monitored urine ketones every morning, checked by staff at prenatal visits. Were asked to bring their blood glucose and food logs or meter records to their prenatal care appointments to discuss with their CDE, perinatal nurses, or providers Were clinically evaluated every 2 weeks until 36 weeks' gestation, and then weekly.
Duration of follow-up	Until birth (Mean (SD) Gestational weeks at delivery: Low-carbohydrate diet 37.78 (1.66); High-carbohydrate diet: 37.76 (1.74))
Sources of funding	Not reported
Sample size	N total = 68 Low-carbohydrate diet n = 37 High-carbohydrate diet n = 31
Other information	Women were recruited from two sites (site A urban teaching hospital n = 54 and site B suburban community hospital n = 14). Those from site A had a significantly lower median household income, greater number living below the poverty line (42.9% v 4.3%, respectively) as well as significantly lower access to Medicaid-funded health insurance (96% v 28.6%, respectively).

	Gestational diabetes diagnostic criteria: Carpenter-Coustan. Timing: 24-28 gestational weeks. Screening: 50 g oral glucose tolerance test regardless of time of day or interval since last meal; 1 h plasma glucose ≥7.5mmol/L. Diagnosis: 100 g OGTT; details not reported. Treatment target: Initiation of pharmacological therapy such as insulin was at the discretion of participants' providers and not the research team. ITT numbers used for analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status.

BMI: body mass index; CDE: certified diabetes educator; g: grams; h: hour; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; n: number of participants; OGTT: oral glucose tolerance test; SD: standard deviation; USA: United States of America.

Study arms

Low-carbohydrate diet (n = 37)

High-carbohydrate diet (n = 31)

Outcomes

Outcome	Low-carbohydrate diet, n = 37	High-carbohydrate diet, n = 31
Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) Converted from mg/dL to mmol/L Mean (SD)	5 (0.5)	5.1 (0.7)

Outcome	Low-carbohydrate diet, n = 37	High-carbohydrate diet, n = 31
Gestational weight change (kg) Study entry to birth corresponding to mean (SD) gestational age low-carbohydrate diet: (29.17 (2.78) to 37.78 (1.66) weeks); high-carbohydrate diet: 30.50 (2.85) to 37.76 (1.74) weeks); converted from lb to kg Mean (SD)	2.2 (2.8)	2 (2.8)
Mode of birth: Induction of labour Follow-up at birth; ITT numbers used No of events	n = 13; % = 35.3	n = 11; % = 34.4
Mode of birth: Caesarean Follow-up at birth; primary caesarean section; ITT numbers used No of events	n = 11; % = 29.4	n = 13; % = 40.6
Need for pharmacological intervention Follow-up not reported; ITT numbers used No of events	n = 3; % = 8.8	n = 2; % = 6.3
Large for gestational age > 90 centile Follow-up at birth; Defined as ≥4000g; ITT numbers used No of events	n = 4; % = 11.8	n = 4; % = 12.5
Neonatal hypoglycaemia Follow-up not reported; ITT numbers used No of events	n = 4; % = 9.7	n = 8; % = 26.9

Outcome	Low-carbohydrate diet, n = 37	High-carbohydrate diet, n = 31
Neonatal mortality and morbidity Follow-up not reported; Composite neonatal complications includes macrosomia, shoulder dystocia, respiratory distress syndrome, hypoglycaemia, and admission to neonatal intensive care unit, bone fractures, nerve palsies, neonatal deaths; There were no instances of the last three outcomes listed in the composite; ITT numbers used No of events	n = 12; % = 32.4	n = 10; % = 31.1

g: grams; ITT: intention to treat; kg: kilograms; lb: pounds; mg/dL: milligrams per decilitre; mmol/L: millimole per litre; n: number of participants; SD: standard deviation.

Critical appraisal – Cochrane Risk of Bias tool v2.0 for RCTs

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(No information provided on randomisation and sequence allocation methods. No significant differences between groups at baseline apart from gestational age at study entry which was probably comparable with chance.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(No information whether participants were aware of allocation while it is likely that the certified diabetes educator was aware of allocation. A low number of women completed nutrition logs (n = 26/68; arm based information not reported) which is suggested by the study to be potentially due to non-adherence to the diet, however, this deviation would be consistent with what would occur outside of the trial context.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(The study provides no information about whether there was any missing outcome data.)*

Section	Question	Answer
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Method of outcome measurement was appropriate and was unlikely to have differed between groups. Outcomes were objective. No information whether outcome assessors were aware of allocation but was unlikely to affect assessment of outcome.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(No information provided on whether the trial was analysed in accordance with a pre-specified analysis plan. Numerical result unlikely to have been selected on basis of multiple outcome measurements or analyses.)*
Overall bias and Directness	Risk of bias judgement	High *(The study is judged to be at high risk of bias in at least one domain for this result.)*
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	N/A

N: number of participants; NA: not applicable; RCTs: randomised controlled trials.

Valentini, 2012

Bibliographic Reference	Valentini, Romina; Dalfra, Maria Grazia; Masin, Michela; Barison, Antonella; Marialisa, Marcon; Pegoraro, Eva; Lapolla, Annunziata; A pilot study on dietary approaches in multiethnicity: two methods compared; International journal of endocrinology; 2012; vol. 2012

Study details

Country/ies where study was carried out	Italy

Study type	Randomised controlled trial (RCT)
Study dates	January 2008-June 2008
Inclusion criteria	Pregnant immigrant women with gestational diabetes
Exclusion criteria	Not reported
Patient characteristics	**Mean age in years (SD)** Intervention: 28.9 (3.3) Comparator: 30.2 (4.7) **Parity (n, %)** Not reported **Mean gestational age in weeks [at screening] (SD)** Not reported **Mean gestational age in weeks [at intervention] (SD)** Not reported **Mean BMI in kg/m^2 [at baseline] (SD)** Not reported **BMI class (n, %)** Not reported **Ethnicity (n, %)** Not reported

	Education level (n, %) Not reported **Income status (n, %)** Not reported The study setting: University Metabolic Disease and Diabetology Unit.
Intervention(s)/control	**Diet (ethnic-specific diet):** Photographic atlas was used to prescribe a diet including common foods from the women's home countries. Dishes broken down into the ingredient components, displayed as raw and cooked with measures such as cups, or spoonfuls handfuls or pinches preferred over kitchen scales. Food pyramids of the home country were employed. **Standard care (standard healthy diet):** Meal plan based on the American diabetes associations (ADA) guidelines for gestational diabetes. All women: Both diets had the same nutrient components: ethnic-specific diet comprising carbohydrate: 55%, fat: 28%, protein: 17%, fibre: 21 g and standard care diet comprising carbohydrate: 53%, fat: 28%, protein: 18%, fibre: 26 g; and energy intake was from 1800 to 2200 Kcal, depending on pre-pregnancy BMI. Prior to meal plan creation, women underwent a dietary assessment to assess essential nutrient intake adequacy, excessive eating, identify avoided foods and allergies/intolerances. Taught about target serving sizes via food models, using measures in cups, glasses, and bowls Nurses taught women how to self-monitor blood glucose levels with targets of fasting plasma glucose < 5.3 mmol/L and 1 h postprandial plasma glucose < 7.2 mmol/L. Those on diet without initiated insulin therapy undertook 2 measurements per day (fasting and 1 h postprandial glucose on alternate meals over the course of a week) and those on diet with

	insulin therapy initiated undertook 4 measurements per day (fasting and 1 h after breakfast, lunch, and dinner). See other information for criteria information. Women saw a specialist every 2 weeks.
Duration of follow-up	Until birth
Sources of funding	Not reported
Sample size	N total = 20 Diet (ethnic-specific diet) n = 10 Standard care (standard healthy diet) n = 10
Other information	Sourced from Han 2017 Cochrane systematic review. Mean (SD) gestational age at diagnosis: Intervention: 21.3 (6.8); Comparator: 27.1 (5.9). Gestational diabetes diagnostic criteria was 4th International Workshop Conference on gestational diabetes (Metzger et al 1998): Timing: 24-28 gestational weeks. Screening: Glucose challenge test, no further details reported Diagnosis: 100 g OGTT, ≥ 2 values were at or above: Fasting: 5.3mmol/L; 1 h 10.0 mmol/L; 2 h 8.6 mmol/L; 3 h 7.8 mmol/L. Treatment target: Insulin initiated when fasting plasma glucose and/or 1 h postprandial plasma glucose was over the following values in more than one measurement: fasting plasma glucose <5.3 mmol/L and 1 h postprandial plasma glucose <7.2 mmol/L. ITT numbers used for analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status.

	This study did not report glycaemic outcomes.

BMI: body mass index; g: grams; h: hour/s; ITT: intention to treat; kcal: kilocalories; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; n: number of participants; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

Diet (ethnic-specific diet) (n = 10)

Standard care (standard healthy diet) (n = 10)

Outcomes

Outcome	Diet (ethnic-specific diet), n = 10	Standard care (standard healthy diet), n = 10
Gestational weight change (kg) Total gestational weight change; follow-up until birth Mean (SD)	12.1 (4.3)	14.3 (6.9)
Mode of birth: Caesarean Follow-up at birth No of events	n = 6; % = 60	n = 5; % = 50
Gestational hypertension Gestational age at diagnosis not reported; diagnosed before birth No of events	n = 0; % = 0	n = 1; % = 10
Need for pharmacological intervention Insulin; Follow-up until birth No of events	n = 2; % = 20	n = 1; % = 10

Outcome	Diet (ethnic-specific diet), n = 10	Standard care (standard healthy diet), n = 10
Large for gestational age > 90 centile Follow-up at birth No of events	n = 0; % = 0	n = 3; % = 30
Neonatal hypoglycaemia Follow-up at birth No of events	n = 0; % = 0	n = 0; % = 0
Neonatal morbidity Composite outcome including hypoglycaemia, neonatal asphyxia, respiratory distress syndrome, and hyperbilirubinemia, hypocalcaemia; Follow-up at birth No of events	n = 0; % = 0	n = 0; % = 0

kg: kilograms; n: number of participants; SD: standard deviation.

Critical appraisal

This study was included in the Cochrane review (Han 2017). The risk of bias for this study was not assessed separately and was used from the Cochrane review (Han 2017). See the Han 2017 evidence table in Appendix D for the risk of bias assessment of the Cochrane review.

Yew, 2021

Bibliographic Reference	Yew, Tong Wei; Chi, Claudia; Chan, Shiao-Yng; van Dam, Rob M; Whitton, Clare; Lim, Chang Siang; Foong, Pin Sym; Fransisca, Winni; Teoh, Chieu Leng; Chen, Jeannie; Ho-Lim, Su Tin; Lim, Su Lin; Ong, Kai Wen; Ong, Peck-Hoon; Tai, Bee Choo; Tai, E Shyong; A Randomized Controlled Trial to Evaluate the Effects of a Smartphone Application-Based Lifestyle Coaching Program on Gestational Weight Gain, Glycemic Control, and Maternal and Neonatal Outcomes in Women With Gestational Diabetes Mellitus: The SMART-GDM Study.; Diabetes care; 2021; vol. 44 (no. 2); 456-463

Study details

Country/ies where study was carried out	Singapore
Study type	Randomised controlled trial (RCT)
Study dates	2017-2018
Inclusion criteria	Women with diagnosis of gestational diabetes from universal screening at the national university hospital Diagnosed between 12-30 gestational weeks Had finished face-to-face gestational sessions as part of usual care.
Exclusion criteria	Not reported
Patient characteristics	**Mean age in years (SD)** Intervention: 31.7 (4.0) Comparator: 32.2 (4.4) **Parity (n, %)** Nulliparous: Intervention: 82 (48.2) Comparator: 83 (48.8) **Mean gestational age in weeks [at screening] (SD)** Intervention: 27.0 (3.2) Comparator: 26.7 (3.7) **Mean gestational age in weeks [at intervention] (SD)**

	Not reported **Mean BMI in kg/m^2 [at baseline] (SD)** Not reported **BMI class (n, %)** Not reported **Ethnicity (n, %)** Chinese: Intervention: 75 (44.1) Comparator: 74 (43.5) Non-Chinese (included Malays, Indians, and other minority ethnic groups such as Burmese, Filipino, Pakistani, Sikh, Sri Lankan, Thai, and Vietnamese) Intervention: 95 (55.9) Comparator: 96 (56.5) **Education level (n, %)** Not reported **Income status (n, %)** Not reported The study setting: National university hospital.
Intervention(s)/control	**Mixed intervention:** Web/Smartphone-Based Lifestyle coaching program: Habits-GDM app developed by endocrinologists, obstetricians, diabetes educators, and dietitians.

	Women provided Bluetooth weighing scale linked to the app with weight by time graph displayed on app and app based prompts for weighing which increased to daily if exceeded optimal gestational weight change range. App based on the Health Belief Model and focused on behaviour change for target weight and glycemia with education, monitoring, immediate feedback, and cues. 12 interactive self-paced lessons on: diet, self monitoring of blood glucose, physical activity and weight tracking tools in addition to ability to message healthcare professionals. Lesson content was similar to standard care education with the addition of gestational weight gain and greater detail in diet and physical activity advice. App includes database of common foods in Singapore with total calories and carbohydrates displayed. Self-monitored blood glucose readings automatically uploaded to the app from portable glucometer with prompts to perform 7-point capillary glucose profile on any 2 days of the week (increased to daily if on insulin) and weekly reports generated and reviewed by their health care teams as in standard care. Automated messages prompting recording of diet in preceding 2-4 h when 2 h postmeal glucose readings were >6.6 mmol/L. **Standard care:** 1-2 weeks after diagnoses, women attended a 1-1.5 h face to face group education session (4-6 women) run by a diabetes nurse educator and dietitian. Women with a 2 hOGTT plasma glucose of ≥11.1 mmol/L had a 1 h long individual session. Sessions covered gestational diabetes pathophysiology and complications, healthy diet, carbohydrate exchange, and future diabetes risk but not gestational weight change. Blood glucose self monitoring by glucometer 7 times a day for 2-3 weeks (if insulin began, increased to 7 times daily). Glucose readings were recorded in a paper diary. Remaining care was provided by obstetricians.

	2-4 clinic visits weekly until 32 gestational weeks, then 2 weekly until 36 gestational weeks and weekly until birth. Frequency could be increased based on individual circumstances. All women: Received usual care at the National University Hospital. If 2 h plasma glucose on OGTT ≥11.1 mmol/L or insulin >20 units/day were referred to endocrinology services Additional advice on diet and lifestyle modification and initiation of insulin and/or metformin was individualized based on self monitoring blood glucose values.
Duration of follow-up	Until birth (Mean (SD) gestational age in weeks: Intervention: 38.5 (1.9); Comparator: 38.7 (1.1))
Sources of funding	Not industry funded
Sample size	N total = 340 Mixed intervention n = 170 Standard care n =170
Other information	Trial name: Web/Smartphone-Based Lifestyle Coaching Program in Pregnant Women With Gestational Diabetes (SMART-GDM) Mean (SD) pre-pregnancy BMI (kg/m^2): Intervention: 25.5 (5.5); Comparator: 25.6 (5.7). Women with history of gestational diabetes (n, %): intervention: 19 (11.3); Comparator: 21 (12.7). Note seven women had an unknown history of GDM. Gestational diabetes diagnostic criteria: World Health Organisation 2013. Timing: 12-30 gestational weeks. Screening: Not reported.

	Diagnosis: 75 g OGTT; Abnormal plasma glucose values on one or more of the following: fasting: ≥5.1, 1 h: ≥10.0, and 2 h: ≥8.5 mmol/L Treatment target: Generally, insulin initiated when ≥2 readings within a 7-point capillary glucose profile on any 2 days of a week were >5.5 mmol/L (premeal) or >6.6 mmol/L (2 h postmeal). ITT numbers used for analysis. The study did not report information on deprivation, disability, LGBTQ+ or previous bariatric surgery status.

App: application; BMI: body mass index; g: grams; GDM: gestational diabetes mellitus; h: hour/s; ITT: intention to treat; kg: kilograms; LGBTQ+: lesbian, gay, bisexual, transgender and queer; m: metres; mmol/L: millimole per litre; n: number of participants; OGTT: oral glucose tolerance test; SD: standard deviation.

Study arms

Mixed intervention (n = 170)

Lifestyle coaching program (Behaviour and monitoring based)

Standard care (n = 170)

Outcomes

Outcome	Mixed intervention, n = 170	Standard care, n = 170
Glycaemic control: mean blood glucose levels at the end of the intervention (mmol/L) Mean (SD)	5.4 (0.53)	5.54 (0.53)
Gestational weight change (kg) Adjusted for insulin treatment for gestational diabetes mellitus and baseline excessive gestational weight gain; Follow-up at birth: Mean (SD) gestational age in weeks: Intervention: 38.5 (1.9); Comparator: 38.7 (1.1)) Custom value	Adj mean difference (95%CI) = 0.47 (-0.35-1.28)	N/A

Outcome	Mixed intervention, n = 170	Standard care, n = 170
Mode of birth: Vaginal birth Follow-up at birth; Intervention n = 168; Comparator n = 165 No of events	n = 111; % = 66.1	n = 106; % = 64.2
Non assisted vaginal birth Follow-up at birth; Intervention n = 168; Comparator n = 165 No of events	n = 104; % = 61.9	n = 97; % = 58.8
Assisted vaginal birth Follow-up at birth; Intervention n = 168; Comparator n = 165 No of events	n = 7; % = 4.2	n = 9; % = 5.5
Mode of birth: Caesarean Follow-up at birth; Intervention n = 168; Comparator n = 165 No of events	n = 57; % = 33.9	n = 59; % = 35.6
Elective caesarean Follow-up at birth; Intervention n = 168; Comparator n = 165 No of events	n = 30 % = 17.9	n = 26; % = 15.8
Emergency caesarean Follow-up at birth; Intervention n = 168; Comparator n = 165 No of events	n = 27; % = 16.1	n = 33; % = 20
Need for pharmacological intervention Insulin; Follow-up until birth; Missing data for 7 women (2 in intervention, 1 in comparator)	n = 17; % = 10	n = 27; % = 15.9

Outcome	Mixed intervention, n = 170	Standard care, n = 170
No of events		
Large for gestational age > 90 centile Follow-up at birth; Reported as >4000g; Intervention n = 168; Comparator n = 165 No of events	n = 0; % = 0	n = 2; % = 1.2
Neonatal hypoglycaemia Defined as capillary blood glucose <2.6 mmol/ L within 24 h of birth; Follow-up within 24 h of birth; Intervention n = 168; Comparator n = 165 No of events	n = 24; % = 14.3	n = 37; % = 22.4
Neonatal mortality and morbidity Composite comprising: birth trauma (shoulder dystocia and soft tissue, bone, nerve, and intra-abdominal injuries), neonatal hypoglycaemia, hyperbilirubinemia (according to diagnosis by attending paediatricians), respiratory distress, neonatal intensive care unit admission within 24 h of birth, and perinatal death. Follow-up at birth; Intervention n = 168; Comparator n = 165 No of events	n = 64; % = 38.1	n = 88; % = 53.3

CI: confidence interval; g: grams; h: hour/s; kg: kilograms; mmol/L: millimole per litre; n: number of participants; NA: not applicable; SD: standard deviation.

Critical appraisal – Cochrane Risk of Bias tool v2.0 for RCTs

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Allocation was random and performed by a statistical software and concealed with assignment of intervention made through a call centre. No information was provided on blinding of allocation sequence. No major significant*

Section	Question	Answer
		differences between baseline differences to suggest problem with randomisation process.)
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(No information on participant blinding and clinicians delivering the intervention were not blinded to allocation, however unlikely to have impacted the intervention. In addition, the intervention app was password protected. Deviations due to allocation error occurred for n = 1 in intervention and n = 1 in control arm who were subsequently swapped to appropriate allocation, otherwise no deviations reported due to experimental context Participants were analysed according to intention-to-treat.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(All or nearly all data were available for all outcomes of interest for both arms (Delivery outcomes: Intervention n = 168/170; comparator n = 165/170; Blood glucose outcomes: Intervention n = 170/170 and comparator n = 169/170))*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Method of outcome measurement was appropriate and was unlikely to have differed between groups. Clinical staff weighing the women were not aware that they were participating in the study or allocation, no information provided otherwise to blinding of assessors.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low *(Prespecified analysis plan stated, and the trial was prospectively registered. Numerical result unlikely to have been selected on basis of multiple outcome measurements or analyses.)*
Overall bias and Directness	Risk of bias judgement	Low *(The study is judged to be at low risk of bias for all domains for this result.)*
Overall bias and Directness	Overall Directness	Directly applicable

Section	Question	Answer
Overall bias and Directness	Risk of bias variation across outcomes	N/A

n: number of participants; N/A: not applicable; RCTs: randomised controlled trials.

Appendix E Forest plots

Forest plots for review question: What are the most effective and cost-effective healthy lifestyle interventions for women with gestational diabetes?

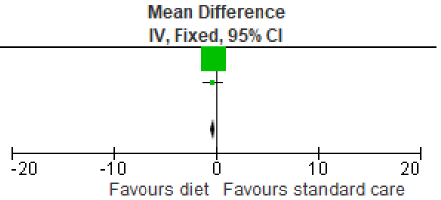
This section includes forest plots only for outcomes that are meta-analysed. Outcomes from single studies are not presented here; the quality assessment for such outcomes is provided in the GRADE profiles in appendix F.

Comparison 1. Diet vs standard care for healthy lifestyle interventions for women with gestational diabetes in single pregnancy

Figure 2: Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) (better indicated by lower values)

	Diet			Standard care				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Garner 1997	4.47	0.82	150	4.7	1.04	150	95.2%	-0.23 [-0.44, -0.02]
Magee 1990	4.9	0.7	7	5.2	0.9	5	4.8%	-0.30 [-1.24, 0.64]
Total (95% CI)			**157**			**155**	**100.0%**	**-0.23 [-0.44, -0.03]**

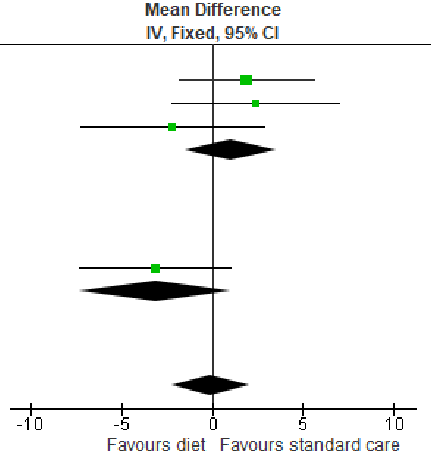
Heterogeneity: Chi² = 0.02, df = 1 (P = 0.89); I² = 0%
Test for overall effect: Z = 2.21 (P = 0.03)



CI: confidence interval; df: degrees of freedom; IV: inverse variance; mmol/L: millimoles per litre; SD: standard deviation

Figure 3: Gestational weight change (kg) (Follow-up to birth or unclear; better indicated by lower values)

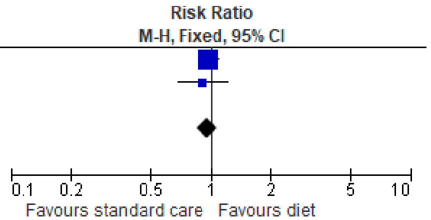
Study or Subgroup	Diet Mean	Diet SD	Diet Total	Standard care Mean	Standard care SD	Standard care Total	Weight	Mean Difference IV, Fixed, 95% CI
1.1.1 Gestational weight change (kg) (Follow-up to birth or unclear)								
Rae 2000	11.56	10.48	67	9.68	10.66	58	33.3%	1.88 [-1.84, 5.60]
Reece 1995	14.3	6.8	11	11.9	3.8	11	21.7%	2.40 [-2.20, 7.00]
Valentini 2012	12.1	4.3	10	14.3	6.9	10	18.1%	-2.20 [-7.24, 2.84]
Subtotal (95% CI)			**88**			**79**	**73.1%**	**1.02 [-1.49, 3.53]**
Heterogeneity: Chi² = 2.12, df = 2 (P = 0.35); I² = 6%								
Test for overall effect: Z = 0.80 (P = 0.42)								
1.1.2 Final weight (kg) (Follow-up NR)								
Garner 1997	81.45	16.18	150	84.6	20.11	150	26.9%	-3.15 [-7.28, 0.98]
Subtotal (95% CI)			**150**			**150**	**26.9%**	**-3.15 [-7.28, 0.98]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.49 (P = 0.13)								
Total (95% CI)			**238**			**229**	**100.0%**	**-0.10 [-2.25, 2.04]**
Heterogeneity: Chi² = 4.98, df = 3 (P = 0.17); I² = 40%								
Test for overall effect: Z = 0.09 (P = 0.93)								
Test for subgroup differences: Chi² = 2.86, df = 1 (P = 0.09), I² = 65.1%								



CI: confidence interval; df: degrees of freedom; IV: inverse variance; kg: kilograms; NR: not reported; SD: standard deviation

Figure 4: Mode of birth: Vaginal birth (Follow-up at birth)

Study or Subgroup	Favours standard care Events	Favours standard care Total	Standard care Events	Standard care Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Garner 1997 (1)	118	150	121	150	75.3%	0.98 [0.87, 1.09]
Rae 2000	39	67	37	58	24.7%	0.91 [0.69, 1.21]
Total (95% CI)		**217**		**208**	**100.0%**	**0.96 [0.86, 1.07]**
Total events	157		158			
Heterogeneity: Chi² = 0.20, df = 1 (P = 0.66); I² = 0%						
Test for overall effect: Z = 0.73 (P = 0.46)						

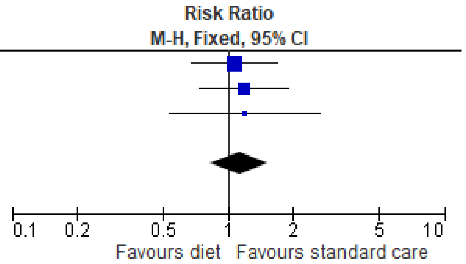


Footnotes
(1) "Vaginal delivery was successful" (did not specify whether normal/operative)

CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; NR: not reported; SD: standard deviation

Figure 5: Mode of birth: Caesarean (Follow-up at birth)

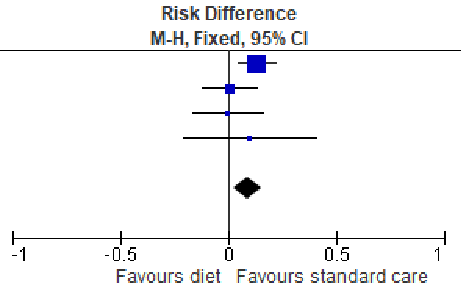
Study or Subgroup	Diet Events	Diet Total	Standard care Events	Standard care Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Garner 1997	30	150	28	150	52.5%	1.07 [0.67, 1.70]
Rae 2000	26	67	19	58	38.2%	1.18 [0.74, 1.91]
Valentini 2012	6	10	5	10	9.4%	1.20 [0.54, 2.67]
Total (95% CI)		**227**		**218**	**100.0%**	**1.13 [0.83, 1.54]**
Total events	62		52			
Heterogeneity: Chi² = 0.11, df = 2 (P = 0.95); I² = 0%						
Test for overall effect: Z = 0.75 (P = 0.45)						



CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; NR: not reported; SD: standard deviation

Figure 6: Need for pharmacological intervention (Follow-up until birth or NR)

Study or Subgroup	Diet Events	Diet Total	Standard care Events	Standard care Total	Weight	Risk Difference M-H, Fixed, 95% CI
Garner 1997	36	150	16	150	64.3%	0.13 [0.05, 0.22]
Rae 2000	11	67	9	58	26.7%	0.01 [-0.12, 0.14]
Reece 1995	0	11	0	11	4.7%	0.00 [-0.16, 0.16]
Valentini 2012	2	10	1	10	4.3%	0.10 [-0.21, 0.41]
Total (95% CI)		**238**		**229**	**100.0%**	**0.09 [0.03, 0.16]**
Total events	49		26			
Heterogeneity: Chi² = 3.81, df = 3 (P = 0.28); I² = 21%						
Test for overall effect: Z = 2.74 (P = 0.006)						

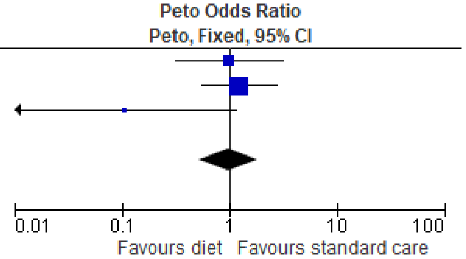


CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; NR: not reported; SD: standard deviation

Figure 7: Large for gestational age > 90 centile (Follow-up at birth or unclear)

	Diet		Standard care			Peto Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	Peto, Fixed, 95% CI
Garner 1997	6	150	6	150	29.9%	1.00 [0.32, 3.17]
Rae 2000	19	67	14	58	63.1%	1.24 [0.56, 2.74]
Valentini 2012	0	10	3	10	7.0%	0.11 [0.01, 1.17]
Total (95% CI)		**227**		**218**	**100.0%**	**0.98 [0.52, 1.84]**
Total events	25		23			

Heterogeneity: Chi² = 3.63, df = 2 (P = 0.16); I² = 45%
Test for overall effect: Z = 0.06 (P = 0.95)

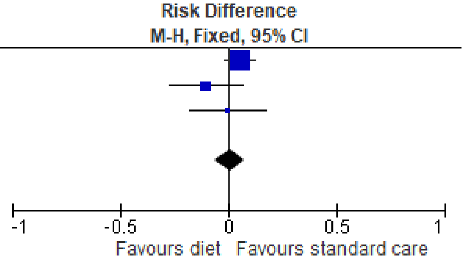


CI: confidence interval; df: degrees of freedom; NR: not reported; SD: standard deviation

Figure 8: Neonatal hypoglycaemia (Follow-up at birth or unclear)

	Diet		Standard care			Risk Difference
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Garner 1997	21	150	13	150	67.5%	0.05 [-0.02, 0.12]
Rae 2000	22	67	25	58	28.0%	-0.10 [-0.27, 0.07]
Valentini 2012	0	10	0	10	4.5%	0.00 [-0.17, 0.17]
Total (95% CI)		**227**		**218**	**100.0%**	**0.01 [-0.06, 0.08]**
Total events	43		38			

Heterogeneity: Chi² = 3.21, df = 2 (P = 0.20); I² = 38%
Test for overall effect: Z = 0.21 (P = 0.83)

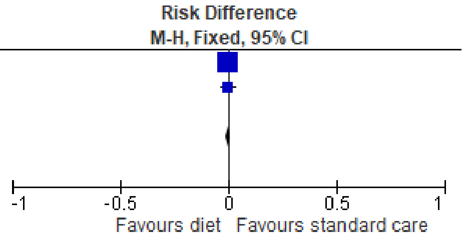


CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; SD: standard deviation

Figure 9: Neonatal mortality (Follow-up NR)

	Diet		Standard care			Risk Difference
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Garner 1997	0	150	0	150	70.7%	0.00 [-0.01, 0.01]
Rae 2000	0	67	0	58	29.3%	0.00 [-0.03, 0.03]
Total (95% CI)		**217**		**208**	**100.0%**	**0.00 [-0.01, 0.01]**
Total events	0		0			

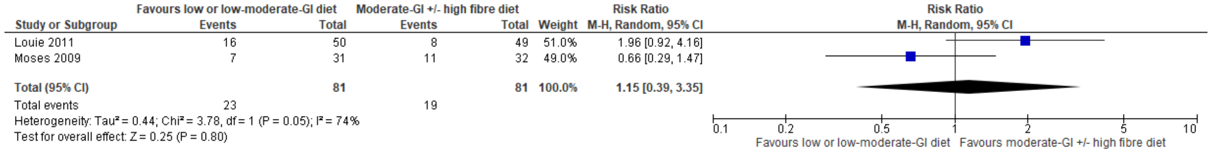
Heterogeneity: Chi² = 0.00, df = 1 (P = 1.00); I² = 0%
Test for overall effect: Z = 0.00 (P = 1.00)



CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; NR: not reported; SD: standard deviation

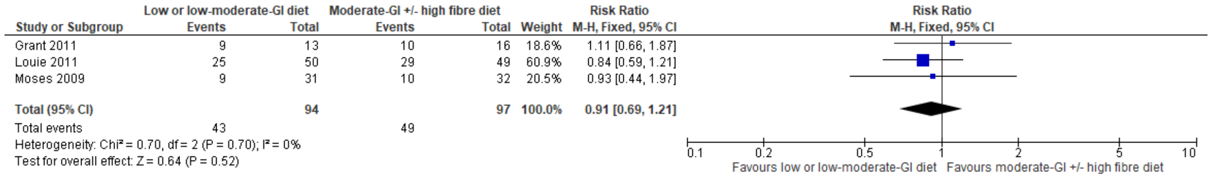
Comparison 2. Low or low-moderate-GI diet vs moderate-GI +/- high fibre diet for healthy lifestyle interventions for women with gestational diabetes in single pregnancy

Figure 10: Mode of birth: Caesarean (Follow-up at birth)



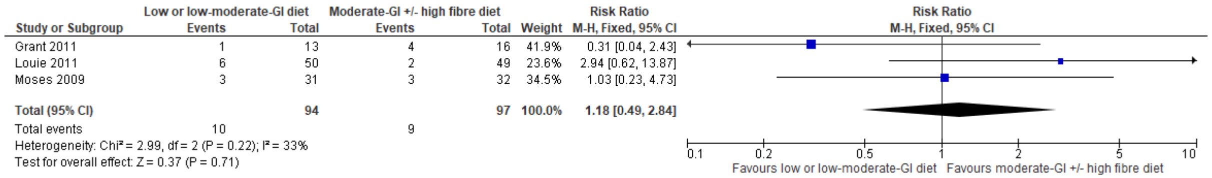
CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; SD: standard deviation

Figure 11: Need for pharmacological intervention (Follow-up to 37 GW or until birth)



CI: confidence interval; df: degrees of freedom; GW: gestational weeks; M-H: Mantel-Haenszel; SD: standard deviation

Figure 12: Large for gestational age > 90 centile (Follow-up at birth)



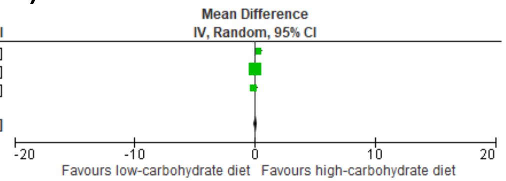
CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; SD: standard deviation

Comparison 3. Low-carbohydrate diet vs high-carbohydrate diet for healthy lifestyle interventions for women with gestational diabetes in single pregnancy

Figure 13: Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) (Better indicated by lower values)

	Low-carbohydrate diet			High-carbohydrate diet				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Cypryk 2007	4.5	0.4	15	4.2	0.4	15	23.5%	0.30 [0.01, 0.59]
Mijatovic 2020	4.9	0.1	24	4.9	0.1	22	53.8%	0.00 [-0.06, 0.06]
Trout 2016	5	0.5	37	5.1	0.7	31	22.7%	-0.10 [-0.39, 0.19]
Total (95% CI)			**76**			**68**	**100.0%**	**0.05 [-0.13, 0.23]**

Heterogeneity: Tau² = 0.02; Chi² = 4.59, df = 2 (P = 0.10); I² = 56%
Test for overall effect: Z = 0.52 (P = 0.61)

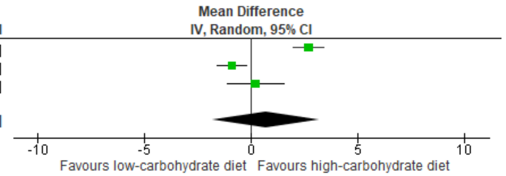


CI: confidence interval; df: degrees of freedom; IV: inverse variance; mmol/L: millimoles per litre; SD: standard deviation

Figure 14: Gestational weight change (kg) (Follow-up between 4w of birth to ≥37 GW; better indicated by lower values)

	Low-carbohydrate diet			High-carbohydrate diet				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Mijatovic 2020	10.9	0.9	24	8.2	1.5	22	34.0%	2.70 [1.98, 3.42]
Moreno-Castilla 2013	1.4	2	75	2.3	2.3	75	34.1%	-0.90 [-1.59, -0.21]
Trout 2016	2.2	2.8	37	2	2.8	31	31.8%	0.20 [-1.14, 1.54]
Total (95% CI)			**136**			**128**	**100.0%**	**0.68 [-1.82, 3.17]**

Heterogeneity: Tau² = 4.61; Chi² = 50.58, df = 2 (P < 0.00001); I² = 96%
Test for overall effect: Z = 0.53 (P = 0.60)

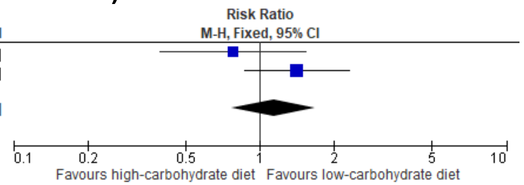


CI: confidence interval; df: degrees of freedom; GW: gestational weeks; IV: inverse variance; kg: kilograms SD: standard deviation

Figure 15: Mode of birth: Vaginal birth (Follow-up at birth)

	Low-carbohydrate diet		High-carbohydrate diet			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Cypryk 2007	7	15	9	15	43.9%	0.78 [0.39, 1.54]
Mijatovic 2020	17	24	11	22	56.1%	1.42 [0.87, 2.31]
Total (95% CI)		**39**		**37**	**100.0%**	**1.14 [0.77, 1.69]**
Total events	24		20			

Heterogeneity: Chi² = 1.97, df = 1 (P = 0.16); I² = 49%
Test for overall effect: Z = 0.63 (P = 0.53)

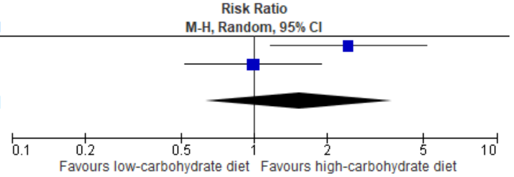


CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; NR: not reported; SD: standard deviation

Figure 16: Mode of birth: Induction of labour (Follow-up at birth)

Study or Subgroup	Low-carbohydrate diet Events	Low-carbohydrate diet Total	High-carbohydrate diet Events	High-carbohydrate diet Total	Weight	Risk Ratio M-H, Random, 95% CI
Mijatovic 2020	16	24	6	22	48.0%	2.44 [1.17, 5.12]
Trout 2016	13	37	11	31	52.0%	0.99 [0.52, 1.89]
Total (95% CI)		**61**		**53**	**100.0%**	**1.53 [0.63, 3.70]**
Total events	29		17			

Heterogeneity: Tau² = 0.28; Chi² = 3.26, df = 1 (P = 0.07); I² = 69%
Test for overall effect: Z = 0.94 (P = 0.35)

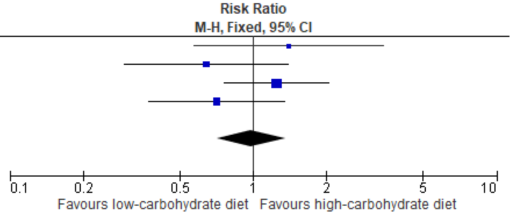


CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; NR: not reported; SD: standard deviation

Figure 17: Mode of birth: Caesarean (Follow-up at birth)

Study or Subgroup	Low-carbohydrate diet Events	Low-carbohydrate diet Total	High-carbohydrate diet Events	High-carbohydrate diet Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Cypryk 2007	7	15	5	15	10.1%	1.40 [0.57, 3.43]
Mijatovic 2020	7	24	10	22	21.0%	0.64 [0.30, 1.39]
Moreno-Castilla 2013	25	75	20	75	40.3%	1.25 [0.76, 2.05]
Trout 2016	11	37	13	31	28.5%	0.71 [0.37, 1.35]
Total (95% CI)		**151**		**143**	**100.0%**	**0.98 [0.71, 1.36]**
Total events	50		48			

Heterogeneity: Chi² = 3.66, df = 3 (P = 0.30); I² = 18%
Test for overall effect: Z = 0.11 (P = 0.92)

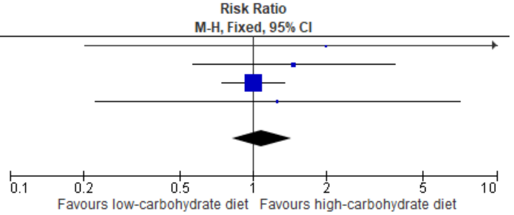


CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; NR: not reported; SD: standard deviation

Figure 18: Need for pharmacological intervention (Follow-up NR or to ≥37 GW)

Study or Subgroup	Low-carbohydrate diet Events	Low-carbohydrate diet Total	High-carbohydrate diet Events	High-carbohydrate diet Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Cypryk 2007	2	15	1	15	2.0%	2.00 [0.20, 19.78]
Mijatovic 2020	8	24	5	22	10.6%	1.47 [0.56, 3.81]
Moreno-Castilla 2013	41	75	41	75	83.0%	1.00 [0.75, 1.34]
Trout 2016	3	37	2	31	4.4%	1.26 [0.22, 7.05]
Total (95% CI)		**151**		**143**	**100.0%**	**1.08 [0.82, 1.43]**
Total events	54		49			

Heterogeneity: Chi² = 0.97, df = 3 (P = 0.81); I² = 0%
Test for overall effect: Z = 0.54 (P = 0.59)

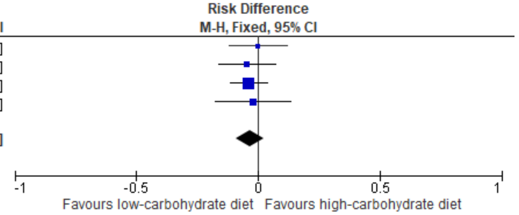


CI: confidence interval; df: degrees of freedom; GW: gestational weeks; M-H: Mantel-Haenszel; NR: not reported; SD: standard deviation

Figure 19: Large for gestational age > 90 centile (Follow-up at birth)

Study or Subgroup	Low-carbohydrate diet Events	Low-carbohydrate diet Total	High-carbohydrate diet Events	High-carbohydrate diet Total	Weight	Risk Difference M-H, Fixed, 95% CI
Cypryk 2007	0	15	0	15	10.3%	0.00 [-0.12, 0.12]
Mijatovic 2020	0	24	1	22	15.7%	-0.05 [-0.16, 0.07]
Moreno-Castilla 2013	3	74	6	75	51.0%	-0.04 [-0.12, 0.04]
Trout 2016	4	37	4	31	23.1%	-0.02 [-0.18, 0.13]
Total (95% CI)		**150**		**143**	**100.0%**	**-0.03 [-0.09, 0.03]**
Total events	7		11			

Heterogeneity: Chi² = 0.38, df = 3 (P = 0.94); I² = 0%
Test for overall effect: Z = 1.09 (P = 0.27)

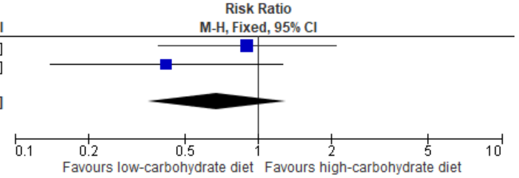


CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; NR: not reported; SD: standard deviation

Figure 20: Neonatal hypoglycaemia (Follow-up at birth or NR)

Study or Subgroup	Low-carbohydrate diet Events	Low-carbohydrate diet Total	High-carbohydrate diet Events	High-carbohydrate diet Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Moreno-Castilla 2013	9	75	10	75	53.5%	0.90 [0.39, 2.09]
Trout 2016	4	37	8	31	46.5%	0.42 [0.14, 1.26]
Total (95% CI)		**112**		**106**	**100.0%**	**0.68 [0.35, 1.30]**
Total events	13		18			

Heterogeneity: Chi² = 1.17, df = 1 (P = 0.28); I² = 14%
Test for overall effect: Z = 1.17 (P = 0.24)



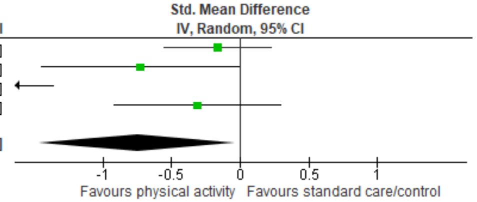
CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; NR: not reported; SD: standard deviation

Comparison 4. Physical activity vs standard care/control for healthy lifestyle interventions for women with gestational diabetes in single pregnancy

Figure 21: Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) (better indicated by lower values)

Study or Subgroup	Physical activity Mean	Physical activity SD	Physical activity Total	Standard care/control Mean	Standard care/control SD	Standard care/control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Bo 2014 (1)	4	0.6	51	4.1	0.6	50	31.1%	-0.17 [-0.56, 0.23]
Brankston 2004	4.7	0.39	16	5.1	0.65	16	25.5%	-0.73 [-1.45, -0.01]
Jovanovic-Peterson 1989	3.9	0.4	10	4.9	0.3	9	16.0%	-2.68 [-3.99, -1.37]
Sklempe Kokic 2018	4.32	0.26	20	4.44	0.46	22	27.5%	-0.31 [-0.92, 0.30]
Total (95% CI)			**97**			**97**	**100.0%**	**-0.75 [-1.47, -0.03]**

Heterogeneity: Tau² = 0.39; Chi² = 13.82, df = 3 (P = 0.003); I² = 78%
Test for overall effect: Z = 2.04 (P = 0.04)

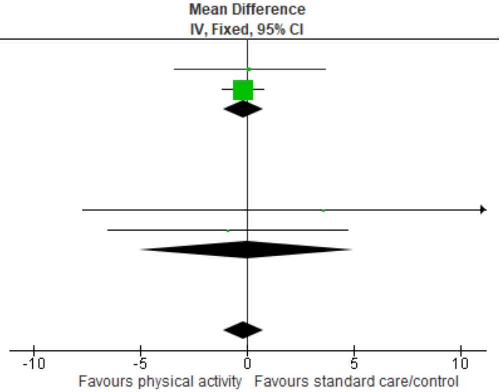


Footnotes
(1) Exercise v diet

CI: confidence interval; df: degrees of freedom; IV: inverse variance; mmol/L: millimoles per litre; SD: standard deviation

Figure 22: Gestational weight change (kg) (Follow-up until mean 36.4-38 GW or NR; better indicated by lower values)

Study or Subgroup	Physical activity Mean	SD	Total	Standard care/control Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
5.1.1 Gestational weight change (kg) (Follow-up at mean 34.6 GW or NR)								
Brankston 2004	11.3	4.4	16	11.2	5.7	16	6.8%	0.10 [-3.43, 3.63]
Halse 2014	0.8	1.3	20	1	1.8	20	89.8%	-0.20 [-1.17, 0.77]
Subtotal (95% CI)			**36**			**36**	**96.6%**	**-0.18 [-1.12, 0.76]**
Heterogeneity: Chi² = 0.03, df = 1 (P = 0.87); I² = 0%								
Test for overall effect: Z = 0.37 (P = 0.71)								
5.1.2 Final weight (kg) (Follow-up at 38 GW)								
Avery 1997	83.2	15.5	15	79.6	15.5	14	0.7%	3.60 [-7.69, 14.89]
Bo 2014 (1)	73.2	11	25	74.1	13	50	2.7%	-0.90 [-6.52, 4.72]
Subtotal (95% CI)			**40**			**64**	**3.4%**	**-0.01 [-5.04, 5.02]**
Heterogeneity: Chi² = 0.49, df = 1 (P = 0.48); I² = 0%								
Test for overall effect: Z = 0.00 (P = 1.00)								
Total (95% CI)			**76**			**100**	**100.0%**	**-0.17 [-1.10, 0.75]**
Heterogeneity: Chi² = 0.52, df = 3 (P = 0.91); I² = 0%								
Test for overall effect: Z = 0.37 (P = 0.71)								
Test for subgroup differences: Chi² = 0.00, df = 1 (P = 0.95), I² = 0%								

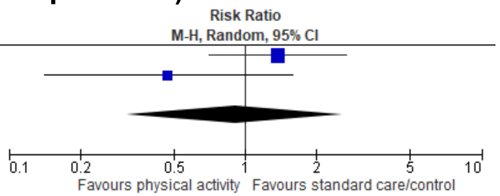


Footnotes
(1) Exercise v diet

CI: confidence interval; df: degrees of freedom; GW: gestational weeks; IV: inverse variance; kg: kilograms; NR: not reported; SD: standard deviation

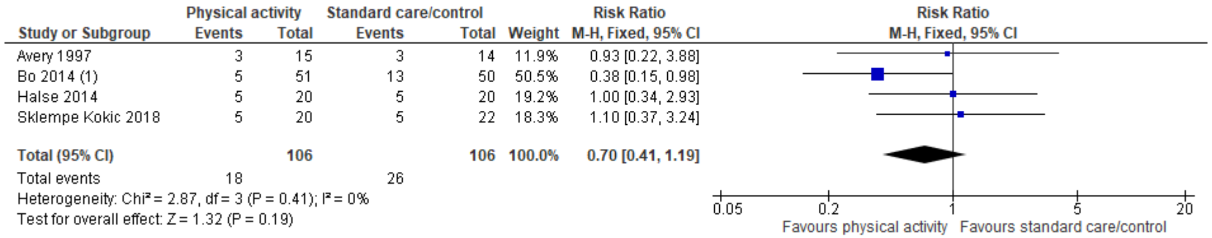
Figure 23: Mode of birth: Induction of labour (Follow-up at birth)

Study or Subgroup	Physical activity Events	Total	Standard care/control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Halse 2014	11	20	8	20	61.0%	1.38 [0.71, 2.68]
Sklempe Kokic 2018	3	20	7	22	39.0%	0.47 [0.14, 1.58]
Total (95% CI)		**40**		**42**	**100.0%**	**0.91 [0.32, 2.59]**
Total events	14		15			
Heterogeneity: Tau² = 0.36; Chi² = 2.43, df = 1 (P = 0.12); I² = 59%						
Test for overall effect: Z = 0.19 (P = 0.85)						



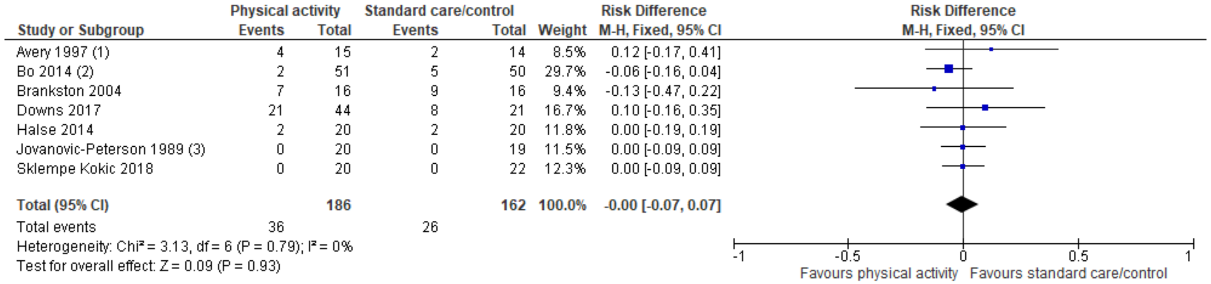
CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; SD: standard deviation

Figure 24: Mode of birth: Caesarean (Follow-up at birth)



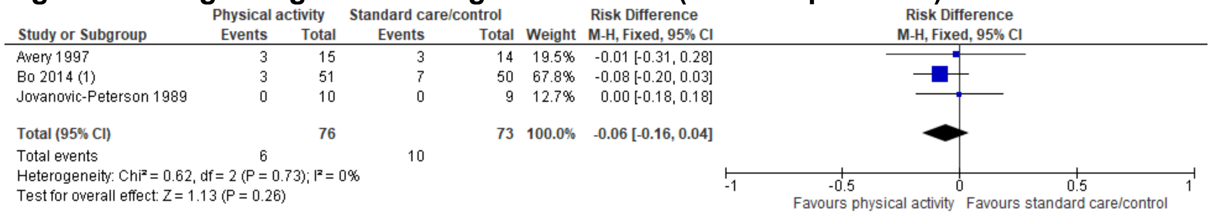
CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; SD: standard deviation

Figure 25: Need for pharmacological intervention (Follow-up 34-38 GW or NR)



CI: confidence interval; df: degrees of freedom; GW: gestational weeks; M-H: Mantel-Haenszel; NR: not reported; SD: standard deviation

Figure 26: Large for gestational age > 90 centile (Follow-up at birth)

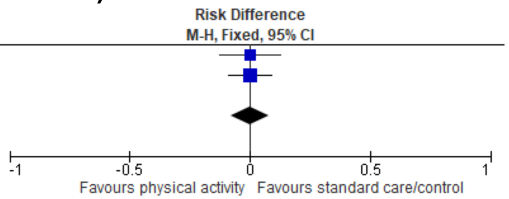


CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; SD: standard deviation

Figure 27: Neonatal hypoglycaemia (Follow-up after birth)

Study or Subgroup	Physical activity Events	Physical activity Total	Standard care/control Events	Standard care/control Total	Weight	Risk Difference M-H, Fixed, 95% CI
Avery 1997	0	15	0	14	40.9%	0.00 [-0.12, 0.12]
Sklempe Kokic 2018	0	20	0	22	59.1%	0.00 [-0.09, 0.09]
Total (95% CI)		**35**		**36**	**100.0%**	**0.00 [-0.08, 0.08]**
Total events	0		0			

Heterogeneity: Chi² = 0.00, df = 1 (P = 1.00); I² = 0%
Test for overall effect: Z = 0.00 (P = 1.00)

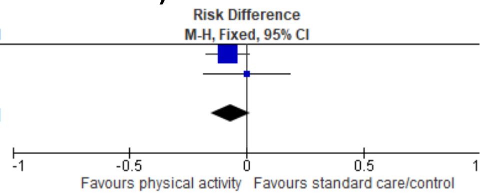


CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; SD: standard deviation

Figure 28: Neonatal morbidity (Follow-up unclear or after birth)

Study or Subgroup	Physical activity Events	Physical activity Total	Standard care/control Events	Standard care/control Total	Weight	Risk Difference M-H, Fixed, 95% CI
Bo 2014 (1)	1	51	5	50	84.2%	-0.08 [-0.17, 0.01]
Jovanovic-Peterson 1989	0	10	0	9	15.8%	0.00 [-0.18, 0.18]
Total (95% CI)		**61**		**59**	**100.0%**	**-0.07 [-0.15, 0.02]**
Total events	1		5			

Heterogeneity: Chi² = 0.60, df = 1 (P = 0.44); I² = 0%
Test for overall effect: Z = 1.59 (P = 0.11)



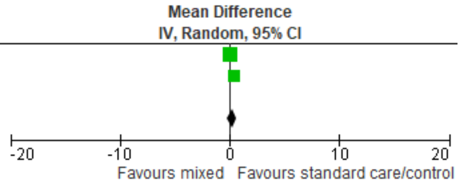
CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; SD: standard deviation

Comparison 5. Mixed vs standard care/control for healthy lifestyle interventions for women with gestational diabetes in single pregnancy

Figure 29: Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) (better indicated by lower values)

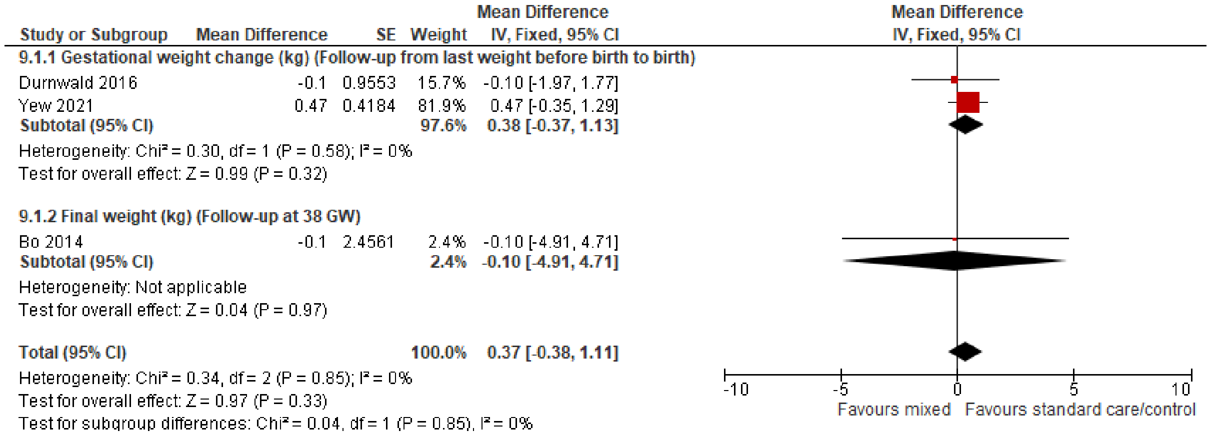
Study or Subgroup	Mixed Mean	Mixed SD	Mixed Total	Standard care/control Mean	Standard care/control SD	Standard care/control Total	Weight	Mean Difference IV, Random, 95% CI
Bo 2014	4.1	0.6	49	4.1	0.6	50	53.2%	0.00 [-0.24, 0.24]
Mendelson 2008	5.6	0.5	49	5.2	1	51	46.8%	0.40 [0.09, 0.71]
Total (95% CI)			**98**			**101**	**100.0%**	**0.19 [-0.20, 0.58]**

Heterogeneity: Tau² = 0.06; Chi² = 4.08, df = 1 (P = 0.04); I² = 75%
Test for overall effect: Z = 0.94 (P = 0.35)



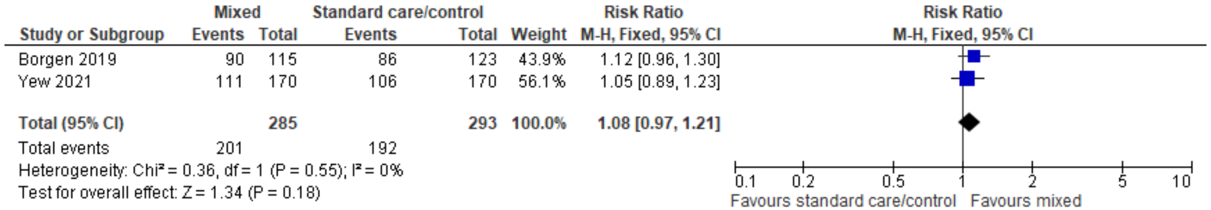
CI: confidence interval; df: degrees of freedom; mmol/L: millimoles per litre; IV: inverse variance; SD: standard deviation

Figure 30: Gestational weight change (kg) (Follow-up from last weight before birth or within 2 weeks of birth to birth; better indicated by lower values)



CI: confidence interval; df: degrees of freedom; GW: gestational weeks; IV: inverse variance; kg: kilograms; SD: standard deviation

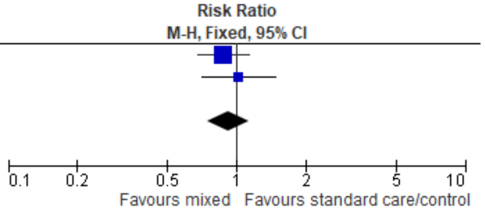
Figure 31: Mode of birth: Vaginal birth (Follow-up at birth)



CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; SD: standard deviation

Figure 32: Mode of birth: Induction of labour (Follow-up at birth)

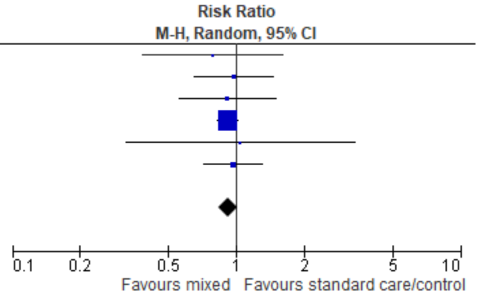
Study or Subgroup	Mixed Events	Mixed Total	Standard care/control Events	Standard care/control Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Borgen 2019	54	115	66	123	70.9%	0.88 [0.68, 1.13]
Durnwald 2016	26	49	27	52	29.1%	1.02 [0.71, 1.48]
Total (95% CI)		**164**		**175**	**100.0%**	**0.92 [0.74, 1.13]**
Total events	80		93			
Heterogeneity: Chi² = 0.46, df = 1 (P = 0.50); I² = 0%						
Test for overall effect: Z = 0.80 (P = 0.42)						



CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; NR: not reported; SD: standard deviation

Figure 33: Mode of birth: Caesarean (Follow-up at birth)

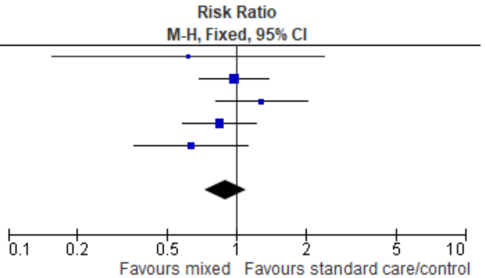
Study or Subgroup	Mixed Events	Mixed Total	Standard care/control Events	Standard care/control Total	Weight	Risk Ratio M-H, Random, 95% CI
Bo 2014	10	49	13	50	1.7%	0.78 [0.38, 1.62]
Borgen 2019	32	115	35	123	5.3%	0.98 [0.65, 1.47]
Durnwald 2016	18	49	21	52	3.6%	0.91 [0.56, 1.49]
Hedderson 2018	292	564	347	613	78.7%	0.91 [0.82, 1.02]
Mendelson 2008	5	49	5	51	0.6%	1.04 [0.32, 3.37]
Yew 2021	57	170	59	170	10.1%	0.97 [0.72, 1.30]
Total (95% CI)		**996**		**1059**	**100.0%**	**0.92 [0.84, 1.01]**
Total events	414		480			
Heterogeneity: Tau² = 0.00; Chi² = 0.43, df = 5 (P = 0.99); I² = 0%						
Test for overall effect: Z = 1.72 (P = 0.09)						



CI: confidence interval; df: degrees of freedom; M-H: Mantel-Haenszel; SD: standard deviation

Figure 34: Need for pharmacological intervention (Follow-up to 38 GW, birth or unclear)

Study or Subgroup	Mixed Events	Mixed Total	Standard care/control Events	Standard care/control Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bo 2014	3	49	5	50	3.8%	0.61 [0.15, 2.42]
Borgen 2019	39	115	43	123	31.7%	0.97 [0.68, 1.38]
Durnwald 2016	23	49	19	52	14.1%	1.28 [0.81, 2.05]
Ferrara 2011	32	96	40	101	29.8%	0.84 [0.58, 1.22]
Yew 2021	17	170	27	170	20.6%	0.63 [0.36, 1.11]
Total (95% CI)		**479**		**496**	**100.0%**	**0.89 [0.73, 1.10]**
Total events	114		134			
Heterogeneity: Chi² = 4.40, df = 4 (P = 0.35); I² = 9%						
Test for overall effect: Z = 1.08 (P = 0.28)						

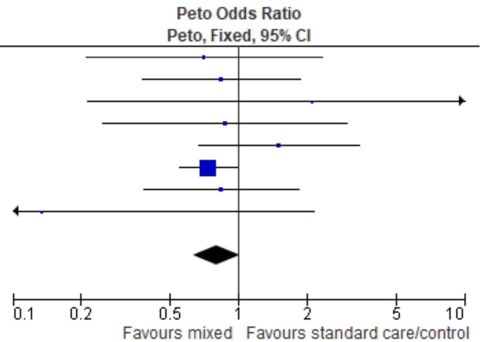


CI: confidence interval; df: degrees of freedom; GW: gestational weeks; M-H: Mantel-Haenszel; SD: standard deviation

Figure 35: Large for gestational age > 90 centile (Follow-up at birth)

Study or Subgroup	Mixed Events	Mixed Total	Standard care/control Events	Standard care/control Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Bo 2014	5	49	7	50	3.9%	0.70 [0.21, 2.34]
Borgen 2019	12	115	15	123	8.7%	0.84 [0.38, 1.87]
Carolan-Olah 2019	2	56	1	60	1.1%	2.12 [0.22, 20.78]
Durnwald 2016	5	49	6	52	3.6%	0.87 [0.25, 3.04]
Ferrara 2011 (1)	15	96	11	101	8.2%	1.51 [0.66, 3.44]
Hedderson 2018	92	564	129	613	65.0%	0.73 [0.55, 0.98]
Mendelson 2008 (2)	19	49	22	51	8.9%	0.84 [0.38, 1.85]
Yew 2021	0	170	2	170	0.7%	0.13 [0.01, 2.16]
Total (95% CI)		**1148**		**1220**	**100.0%**	**0.80 [0.63, 1.01]**
Total events	150		193			

Heterogeneity: Chi² = 4.99, df = 7 (P = 0.66); I² = 0%
Test for overall effect: Z = 1.86 (P = 0.06)

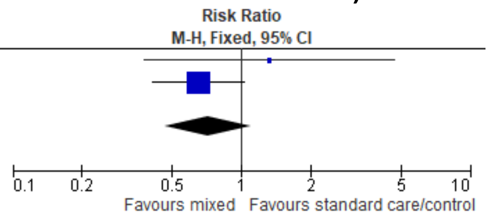


CI: confidence interval; df: degrees of freedom; GW: gestational weeks; NR: not reported; SD: standard deviation

Figure 36: Neonatal hypoglycaemia (Follow-up within 24 hours of birth or NR)

Study or Subgroup	Mixed Events	Mixed Total	Standard care/control Events	Standard care/control Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Durnwald 2016	5	49	4	52	9.5%	1.33 [0.38, 4.66]
Yew 2021	24	170	37	170	90.5%	0.65 [0.41, 1.04]
Total (95% CI)		**219**		**222**	**100.0%**	**0.71 [0.46, 1.10]**
Total events	29		41			

Heterogeneity: Chi² = 1.10, df = 1 (P = 0.30); I² = 9%
Test for overall effect: Z = 1.52 (P = 0.13)



CI: confidence interval; df: degrees of freedom; NR: not reported; M-H: Mantel-Haenszel; SD: standard deviation

Appendix F GRADE tables

GRADE tables for review question: What are the most effective and cost-effective healthy lifestyle interventions for women with gestational diabetes?

Table 6: Evidence profile for comparison 1: Diet vs standard care for women with gestational diabetes in single pregnancy

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Diet	Standard care (Single pregnancy)	Relative (95% CI)	Absolute		
Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) (Better indicated by lower values)												
2[1, 2]	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	157	155	-	MD 0.23 lower (0.44 to 0.03 lower)	MODERATE NO IMP. DIFF	CRITICAL
Glycaemic control: fasting blood glucose during/at the end of the intervention (mmol/L) (Better indicated by lower values)												
1[1](Rae 2000)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	serious[4]	none	67	58	-	MD 0.1 higher (0.17 lower to 0.37 higher)	LOW NO EV OF IMP DIFF.	CRITICAL
Glycaemic control: mean blood glucose during/at end of intervention (mmol/L) (Better indicated by lower values)												
1[1](Reece 1995)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	serious[5]	none	11	11	-	MD 0 higher (0.46 lower to 0.46 higher)	LOW NO EV OF IMP DIFF.	CRITICAL
Gestational weight change (kg) (Follow-up at birth or unclear; better indicated by lower values)												
4[1, 2]	randomised trials	very serious[6]	no serious inconsistency	no serious indirectness	no serious imprecision	none	238	229	-	MD 0.1 lower (2.25 lower to 2.04 higher)	LOW NO IMP. DIFF	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Diet	Standard care (Single pregnancy)	Relative (95% CI)	Absolute		
Mode of birth: Vaginal birth (Follow-up at birth)												
2[1, 2]	randomised trials	very serious[6]	no serious inconsistency	no serious indirectness	no serious imprecision	none	157/217 (72.4%)	158/208 (76%)	RR 0.96 (0.86 to 1.07)	30 fewer per 1000 (from 106 fewer to 53 more)	LOW NO IMP DIFF.	CRITICAL
Mode of birth: Induction of labour (Follow-up at birth)												
1[1] (Rae 2000)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[7]	none	29/67 (43.3%)	23/58 (39.7%)	RR 1.09 (0.72 to 1.66)	36 more per 1000 (from 111 fewer to 262 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Mode of birth: Caesarean (Follow-up at birth)												
3[1, 2]	randomised trials	very serious[6]	no serious inconsistency	no serious indirectness	very serious[7]	none	62/227 (27.3%)	52/218 (23.9%)	RR 1.13 (0.83 to 1.54)	31 more per 1000 (from 41 fewer to 129 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Pre-eclampsia (Gestational age at diagnosis not reported, diagnosed before birth)												
1[1](Rae 2000)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[7]	none	14/67 (20.9%)	12/58 (20.7%)	RR 1.01 (0.51 to 2.01)	2 more per 1000 (from 100 fewer to 331 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Gestational hypertension (Gestational age at diagnosis not reported, diagnosed before birth)												
1[1](Valentini 2012)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[7]	none	0/10 (0%)	1/10 (10%)	pOR 0.14 (0 to 6.82)[8]	85 fewer per 1000 (from 340 fewer to 140 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Need for pharmacological intervention (Follow-up until birth or NR)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Diet**	**Standard care (Single pregnancy)**	**Relative (95% CI)**	**Absolute**		
4[1, 2]	randomised trials	very serious[6]	no serious inconsistency	serious[9]	very serious[7]	none	49/238 (20.6%)	26/229 (11.4%)[10]	RD 0.09 (0.03 to 0.16)[11]	92 fewer per 1000 (from 30 more to 160 more)	VERY LOW IMP. DIFF	CRITICAL
Large for gestational age > 90 centile (Follow-up at birth or unclear[12])												
3[1, 2]	randomised trials	very serious[6]	no serious inconsistency	serious[13]	very serious[7]	none	25/227 (11%)	23/218 (10.6%)	pOR 0.98 (0.52 to 1.84)[8]	2 fewer per 1000 (from 48 fewer to 73 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Neonatal hypoglycaemia (Follow-up at birth or unclear)												
3[1, 2]	randomised trials	very serious[6]	no serious inconsistency	no serious indirectness	very serious[7]	none	43/227 (18.9%)	38/218 (17.4%)	RD 0.01 (-0.06 to 0.08)[11]	7 more per 1000 (from 59 fewer to 80 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Neonatal morbidity (Follow-up to birth)												
1[1,14] (Valentini 2012)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[7]	none	0/10 (0%)	0/10 (0%)	RD 0.00 (-0.17 to 0.17)[11]	0 more per 1000 (from 170 fewer to 170 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Neonatal mortality (Follow-up NR)												
2[1, 2]	randomised trials	very serious[6]	no serious inconsistency	no serious indirectness	very serious[7]	none	0/217 (0%)	0/208 (0%)	RD 0.00 (-0.01 to 0.01)[11]	0 more per 1000 (from 10 fewer to 10 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL

CI: confidence interval; Diff: difference; GW: gestational weeks; MD: mean difference; Imp: important; kg: kilograms; mmol/L: millimoles per litre; NR: not reported; pOR: peto odds ratio; RD: risk difference; RR: risk ratio.

1 Details of diets in this comparison: Energy-restricted diet vs no energy-restricted diet (Garner 1997, Magee 1990, Rae 2000); High-fibre diet vs standard-fibre diet (Reece 1995); Ethnic-specific diet vs standard healthy diet (Valentini 2012).
2 See corresponding forest plot in appendix E for studies contributing to this outcome.
3 Serious risk of bias in the evidence contributing to the outcomes as per RoB1 from Cochrane review studies and RoB2 from individual studies from our search.
4 95%CI crosses 1 MID (0.5x control SD at follow-up was used for: during/at end of intervention fasting blood glucose = 0.37).
5 95% CI crosses 1 MID (0.5x control SD at follow-up was used for: during/at end of intervention mean blood glucose = 0.25).
6 Very serious risk of bias in the evidence contributing to the outcomes as per RoB1 from Cochrane review studies.
7 Total event rate <150 for RR or <200 for POR or RD.
8 Peto odds ratio used as <1% events in one arm.
9 Surrogate outcome for glycaemic control.
10 For Garner 1997 Intention to treat numbers used. 16 events in standard care arm correspond to the "failed controls" originally in this arm but put on the intervention diet and given insulin.
11 Risk difference used as one or more studies with zero events in both arms.
12 Rae 2000 states that anthropomorphic measurements were performed at about 5 days of age with mention of midarm circumference and skinfold thickness measures but does not specifically mention birthweight.
13 1/3 studies report macrosomia (Garner 1997; birthweight >4500g).
14 Composite outcome: hypoglycaemia, neonatal asphyxia, respiratory distress syndrome, and hyperbilirubinemia, hypocalcaemia.

Table 7: Evidence profile for comparison 2: High unsaturated fat diet vs low unsaturated fat diet with matching calories for women with gestational diabetes in single pregnancy

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**High unsaturated fat diet**	**Low unsaturated fat diet with matching calories (Single pregnancy)**	**Relative (95% CI)**	**Absolute**		
Glycaemic control: during intervention (38 week) fasting blood glucose (mmol/L) (Better indicated by lower values)												
1 (Lauszus 2001)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	13	14	-	MD 0.5 higher (0.31 to 0.69 higher)	MODERATE **IMP. BENEFIT** **for low unsaturated fat diet**	CRITICAL
Gestational weight change (kg) (Follow-up at 38 GW; Better indicated by lower values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	High unsaturated fat diet	Low unsaturated fat diet with matching calories (Single pregnancy)	Relative (95% CI)	Absolute		
1 (Lauszus 2001)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	13	14	-	MD 11.9 higher (7.47 to 16.33 higher)	MODERATE IMP. BENEFIT **For low unsaturated fat diet**	CRITICAL
Mode of birth: Caesarean (Follow-up at birth)												
1 (Lauszus 2001)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	1/13 (7.7%)	1/14 (7.1%)	RR 1.08 (0.07 to 15.5)	66 fewer per 1000 (from 134 fewer to 609 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Pre-eclampsia (Gestational age at diagnosis not reported, diagnosed before birth)												
1 (Lauszus 2001)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	0/13 (0%)	0/14 (0%)	RD 0.00 (-0.13 to 0.13)[3]	0 more per 1000 (from 130 fewer to 130 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Gestational hypertension (Gestational age at diagnosis not reported, diagnosed before birth)												
1 (Lauszus 2001)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	1/13 (7.7%)	2/14 (14.3%)	RR 0.54 (0.06 to 5.26)	66 fewer per 1000 (from 134 fewer to 609 more)	LOW NO EV OF IMP DIFF.	CRITICAL
Need for pharmacological intervention (Follow-up at 38 GW)												
1 (Lauszus 2001)	randomised trials	serious[1]	no serious inconsistency	serious[4]	very serious[2]	none	0/13 (0%)	0/14 (0%)	RD 0.00 (-0.13 to 0.13)[3]	0 fewer per 1000 (from 130 fewer to 130 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	High unsaturated fat diet	Low unsaturated fat diet with matching calories (Single pregnancy)	Relative (95% CI)	Absolute		
Large for gestational age > 90 centile (Follow-up at birth)												
1 (Lauszus 2001)	randomised trials	serious[1]	no serious inconsistency	serious[5]	very serious[2]	none	4/13 (30.8%)	8/14 (57.1%)	RR 0.54 (0.21 to 1.37)	263 fewer per 1000 (from 451 fewer to 211 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL

CI: confidence interval; Diff: difference; GW: gestational weeks; MD: mean difference; Imp: important; kg: kilograms; mmol/L: millimoles per litre; NR: not reported; RD: risk difference; RR: risk ratio.
1 Serious risk of bias in the evidence contributing to the outcomes as per RoB1 from Cochrane review studies.
2 Total event rate <150 for RR or <200 for POR or RD.
3 Risk difference used as single study with 0 events in both arms.
4 Surrogate outcome for glycaemic control.
5 Reported as macrosomia (birthweight >4500g).

Table 8: Evidence profile for comparison 3: Low or low-moderate-GI diet vs moderate-GI +/- high fibre diet for women with gestational diabetes in single pregnancy

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Low or low-moderate-GI diet	Moderate-GI +/- high fibre diet (Single pregnancy)	Relative (95% CI)	Absolute		
Glycaemic control: blood glucose at the end of the intervention (mmol/L) (Better indicated by lower values)												
1 (Louie 2011)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	50	49	-	MD 0.1 lower (0.34 lower to 0.14 higher)	LOW NO EV OF IMP DIFF.	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Low or low-moderate-GI diet	Moderate-GI +/- high fibre diet (Single pregnancy)	Relative (95% CI)	Absolute		
Gestational weight change (kg) (Follow-up at last weight recorded before birth) (Better indicated by lower values)												
1 (Louie 2011)	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	serious[4]	none	50	49	-	MD 1.2 lower (3.29 lower to 0.89 higher)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Gestational weight change - Met/achieved IOM guidelines (%) (Follow-up at last weight recorded before birth)												
1 (Louie 2011)	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	very serious[5]	none	22/50 (44%)	16/49 (32.7%)	RR 1.35 (0.81 to 2.24)	114 more per 1000 (from 62 fewer to 405 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Mode of birth: Caesarean (Follow-up at birth)												
2[6]	randomised trials	very serious[3]	serious[7]	no serious indirectness	very serious[5]	none	23/81 (28.4%)	19/81 (23.5%)	RR 1.15 (0.39 to 3.35)	35 more per 1000 (from 143 fewer to 551 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Mode of birth: Vaginal birth (Follow-up at birth)												
1 (Moses 2009)	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	very serious[5]	none	24/31 (77.4%)	21/32 (65.6%)	RR 1.18 (0.86 to 1.62)	118 more per 1000 (from 92 fewer to 407 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Mode of birth: Induction of labour (Follow-up at birth)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Low or low-moderate-GI diet	Moderate-GI +/- high fibre diet (Single pregnancy)	Relative (95% CI)	Absolute		
1 (Moses 2009)	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	very serious[5]	none	6/31 (19.4%)	7/32 (21.9%)	RR 0.88 (0.33 to 2.34)	26 fewer per 1000 (from 147 fewer to 293 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Need for pharmacological intervention (Follow-up at 37 GW or until birth)												
3[6]	randomised trials	very serious[3]	no serious inconsistency	serious[8]	very serious[5]	none	43/94 (45.7%)	49/97 (50.5%)	RR 0.91 (0.69 to 1.21)	45 fewer per 1000 (from 157 fewer to 106 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL
Large for gestational age > 90 centile (Follow-up at birth)												
3[6]	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	very serious[5]	none	10/94 (10.6%)	9/97 (9.3%)	RR 1.18 (0.49 to 2.84)	17 more per 1000 (from 47 fewer to 171 more)	VERY LOW NO EV OF IMP DIFF.	CRITICAL

CI: confidence interval; Diff: difference; GW: gestational weeks; MD: mean difference; Imp: important; kg: kilograms; mmol/L: millimoles per litre; NR: not reported; RD: risk difference; RR: risk ratio
1 Serious risk of bias in the evidence contributing to the outcomes as per RoB1 from Cochrane review studies and RoB2 from individual studies from our search.
2 95% CI crosses 1 MID (0.5x control SD at follow-up was used for: end of intervention blood glucose = 0.28).
3 Very serious risk of bias in the evidence contributing to the outcomes as per RoB1 from Cochrane review.
4 95%CI crosses 1 MID (x0.5 control group SD at follow-up, for outcome GWC = 2.95).
5 Total event rate <150.
6 See corresponding forest plot in appendix E for studies contributing to this outcome.
7 Serious heterogeneity (I2=74%). No sufficient number of studies to conduct for subgroup analysis. Random effects analysis used.
8 Surrogate outcome for glycaemic control.

Table 9: Evidence profile for comparison 4: Low-carbohydrate diet vs high-carbohydrate diet for women with gestational diabetes in single pregnancy

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Low-carbohydrate diet	High-carbohydrate diet (Single pregnancy)	Relative (95% CI)	Absolute		
Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) (Better indicated by lower values)												
3[1]	randomised trials	very serious[2]	serious[3]	no serious indirectness	serious[4]	none	76	68	-	MD 0.05 higher (0.13 lower to 0.23 higher)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Gestational weight change (kg) Follow-up between 4w of birth to ≥37 GW (Better indicated by lower values)												
3[1]	randomised trials	very serious[2]	very serious[5]	no serious indirectness	very serious[6]	none	136	128	-	MD 0.68 higher (1.82 lower to 3.17 higher)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Gestational weight change - Met/achieved IOM guidelines (%) (Follow-up at ≥37 GW)												
1 (Mijatovic 2020)	randomised trials	serious[7]	no serious inconsistency	no serious indirectness	very serious[8]	none	10/24 (41.7%)	3/22 (13.6%)	RR 3.06 (0.96 to 9.68)	281 more per 1000 (from 5 fewer to 1000 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Mode of birth: Vaginal birth (Follow-up at birth)												
2[1]	randomised trials	very serious[2]	no serious inconsistency	no serious indirectness	very serious[8]	none	24/39 (61.5%)	20/37 (54.1%)	RR 1.14 (0.77 to 1.69)	76 more per 1000 (from 124 fewer to 373 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Mode of birth: Induction of labour (Follow-up at birth)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Low-carbohydrate diet**	**High-carbohydrate diet (Single pregnancy)**	**Relative (95% CI)**	**Absolute**		
2[1]	randomised trials	very serious[2]	serious[9]	no serious indirectness	very serious[8]	none	29/61 (47.5%)	17/53 (32.1%)	RR 1.53 (0.63 to 3.7)	170 more per 1000 (from 119 fewer to 866 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Mode of birth: Caesarean (Follow-up at birth)												
4[1]	randomised trials	very serious[2]	no serious inconsistency	no serious indirectness	very serious[8]	none	50/151 (33.1%)	48/143 (33.6%)	RR 0.98 (0.71 to 1.36)	7 fewer per 1000 (from 97 fewer to 121 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Gestational hypertension (Gestational age at diagnosis not reported, diagnosed before birth)												
1 (Moreno-Castilla 2013)	randomised trials	serious[7]	no serious inconsistency	no serious indirectness	very serious[8]	none	4/75 (5.3%)	10/75 (13.3%)	RR 0.4 (0.13 to 1.22)	80 fewer per 1000 (from 116 fewer to 29 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Need for pharmacological intervention (Follow-up NR or at ≥37 GW)												
4[1]	randomised trials	very serious[2]	no serious inconsistency	serious[10]	very serious[8]	none	54/151 (35.8%)	49/143 (34.3%)	RR 1.08 (0.82 to 1.43)	27 more per 1000 (from 62 fewer to 147 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Large for gestational age > 90 centile (Follow-up at birth)												
4[1]	randomised trials	very serious[2]	no serious inconsistency	serious[11]	very serious[8]	none	7/150 (4.7%)	11/143 (7.7%)	RD -0.03 (-0.09 to 0.03)[12]	32 fewer per 1000 (from 90 fewer to 30 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Low-carbohydrate diet**	**High-carbohydrate diet (Single pregnancy)**	**Relative (95% CI)**	**Absolute**		
Neonatal hypoglycaemia (Follow-up at birth or NR)												
2[1]	randomised trials	very serious[2]	no serious inconsistency	no serious indirectness	very serious[8]	none	13/112 (11.6%)	18/106 (17%)	RR 0.68 (0.35 to 1.3)	54 fewer per 1000 (from 110 fewer to 51 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Neonatal mortality and morbidity (Follow-up NR)												
1[13] (Trout 2016)	randomised trials	serious[7]	no serious inconsistency	no serious indirectness	very serious[8]	none	12/37 (32.4%)	10/31 (32.3%)	RR 1.01 (0.5 to 2.01)	3 more per 1000 (from 161 fewer to 326 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Neonatal mortality (Follow-up at birth)												
1 (Moreno-Castilla 2013)	randomised trials	serious[7]	no serious inconsistency	no serious indirectness	very serious[8]	none	0/75 (0%)	0/75 (0%)	RD 0.00 (-0.03 to 0.03)[14]	0 more per 1000 (from 30 fewer to 30 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL

CI: confidence interval; Diff: difference; GW: gestational weeks; MD: mean difference; Imp: important; kg: kilograms; mmol/L: millimoles per litre; NR: not reported; RD: risk difference; RR: risk ratio

1 See corresponding forest plot in appendix E for studies contributing to this outcome.
2 Very serious risk of bias in the evidence contributing to the outcomes as per RoB1 from Cochrane review studies and/or RoB2 from individual studies from our search.
3 Serious heterogeneity (I2=56%). No sufficient number of studies to conduct subgroup analysis. Random effects analysis used.
4 95% CI crosses 1 MID (0.5x control SD at follow-up was used for: end of intervention: fasting blood glucose = 0.2).
5 Very serious heterogeneity (I2=96%). No sufficient number of studies to conduct subgroup analysis. Random effects analysis used.
6 95%CI crosses 2 MIDs (x0.5 control group SD at follow-up, for outcome GWC 1.5).
7 Serious risk of bias in the evidence contributing to the outcomes as per RoB1 from Cochrane review studies and/or RoB2 from individual studies from our search.
8 Total event rate <150 for RR or <200 for POR or RD.

9 Serious heterogeneity (I2=69%). No sufficient number of studies to conduct subgroup analysis. Random effects analysis used.
10 Surrogate outcome for glycaemic control.
11 2/4 studies report macrosomia (Cypryk 2007, Trout 2016; birthweight >4000g).
12 Risk difference used as multiple studies with 0 events in one or both arms.
13 Composite outcome includes perinatal outcome. Composite includes: macrosomia, shoulder dystocia, respiratory distress syndrome, hypoglycaemia, and admission to neonatal intensive care unit, bone fractures, nerve palsies, neonatal deaths.
14 Risk difference used as one study with 0 events in both arms.

Table 10: Evidence profile for comparison 5: Physical activity vs standard care/control for women with gestational diabetes in single pregnancy

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Physical activity**	**Standard care/control (Single pregnancy)**	**Relative (95% CI)**	**Absolute**		
Glycaemic control: during intervention fasting blood glucose (mmol/L) (Better indicated by lower values)												
1 (Christie 2022)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	17	15	-	MD 0.10 higher (0.18 lower to 0.38 higher)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) (Better indicated by lower values)												
4[3]	randomised trials	very serious[4]	serious[5]	no serious indirectness	serious[6]	none	97	97	-	SMD 0.75 lower (1.47 to 0.03 lower)	VERY LOW **IMP. BENEFIT**	CRITICAL
Glycaemic control: HbA1c at the end of the intervention (%) (Better indicated by lower values)												
1 (Halse 2014)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[6]	none	20	20	-	MD 0.10 lower (0.32 lower to 0.12 higher)	LOW NO EVID IMP. DIFF	CRITICAL
Gestational weight change (kg) (Follow-up at mean 36.4 GW-38 GW or NR; Better indicated by lower values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physical activity	Standard care/control (Single pregnancy)	Relative (95% CI)	Absolute		
4[3]	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	76	100	-	MD 0.17 lower (1 lower to 0.75 higher)	MODERATE NO IMP. DIFF	CRITICAL
Mode of birth: Vaginal birth (Follow-up at birth)												
1 (Halse 2014)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	none	13/20 (65%)	11/20 (55%)	RR 1.18 (0.71 to 1.97)	99 more per 1000 (from 160 fewer to 534 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Mode of birth: Induction of labour (Follow-up at birth)												
2[3]	randomised trials	serious[1]	serious[8]	no serious indirectness	very serious[7]	none	14/40 (35%)	15/42 (35.7%)	RR 0.91 (0.32 to 2.59)	32 fewer per 1000 (from 243 fewer to 568 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Mode of birth: Caesarean (Follow-up at birth)												
4[3]	randomised trials	very serious[4]	no serious inconsistency	no serious indirectness	very serious[7]	none	22/106 (20.8%)	26/106 (24.5%)	RR 0.70 (0.41 to 1.19)	74 fewer per 1000 (from 145 fewer to 47 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Pre-eclampsia (Gestational age at diagnosis not reported, diagnosed before birth)												
1 (Jovanovic-Peterson 1989)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	none	0/10 (0%)	0/9 (0%)	RD 0.00 (-0.18 to 0.18)[9]	0 more per 1000 (from 180 fewer to 180 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Gestational hypertension (Gestational age at diagnosis not reported; diagnosed before birth)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physical activity	Standard care/control (Single pregnancy)	Relative (95% CI)	Absolute		
1 (Avery 1997)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[7]	none	0/15 (0%)	1/14 (7.1%)	pOR 0.13 (0 to 6.37)[10]	62 fewer per 1000 (from 71 fewer to 257 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Need for pharmacological intervention (Follow-up at 34-38 GW or NR)												
7[3]	randomised trials	very serious[4]	no serious inconsistency	serious[11]	very serious[7]	none	36/186 (19.9%)	26/162 (18.5%)	RD 0.00 (-0.07 to 0.07)[9]	8 fewer per 1000 (from 80 fewer to 60 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Large for gestational age > 90 centile (Follow-up at birth)												
3[3]	randomised trials	very serious[4]	no serious inconsistency	serious[12]	very serious[4]	none	6/76 (10.5%)	10/73 (20.5%)	RD -0.06 (-0.16 to 0.04)[9]	58 fewer per 1000 (from 160 fewer to 40 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Neonatal hypoglycaemia (Follow-up after birth)												
2[3]	randomised trials	very serious[4]	no serious inconsistency	no serious indirectness	very serious[4]	none	0/35 (0%)	0/36 (0%)	RD 0.00 (-0.08 to 0.08)[9]	0 more per 1000 (from 80 fewer to 80 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Neonatal morbidity (Follow-up unclear or after birth)												
2[3,13]	randomised trials	serious[1]	no serious inconsistency	serious[14]	very serious[4]	none	1/61 (1.6%)	5/59 (8.5%)	RD -0.07 (-0.15 to 0.02)[9]	69 fewer per 1000 (from 150 fewer to 20 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL

CI: confidence interval; Diff: difference; GW: gestational weeks; MD: mean difference; Imp: important; kg: kilograms; mmol/L: millimoles per litre; NR: not reported; pOR: peto odds ratio; RD: risk difference; RR: risk ratio

1 Serious risk of bias in the evidence contributing to the outcomes as per RoB1 from Cochrane review studies and/or RoB 2 from individual studies from our search.

2 95%CI crosses 2 MIDs (x0.5 control group SD at follow-up, for outcome during intervention fasting blood glucose = 0.2).
3 See corresponding forest plot in appendix E for studies contributing to this outcome.
4 Very serious risk of bias in the evidence contributing to the outcomes as per RoB1 from Cochrane review studies and/or RoB 2 from individual studies from our search.
5 Serious heterogeneity (I2=78%). No sufficient number of studies to conduct subgroup analysis. Random effects analysis used. 6 95%CI crosses 1 MID (x0.5 control group SD at follow-up, for outcome end of intervention fasting blood glucose = 0.27; for outcome end of intervention HbA1c (%) = 0.15).
7 Total event rate <150 for RR or <200 for POR or RD.
8 Serious heterogeneity (I2=59%). No sufficient number of studies to conduct subgroup analysis. Random effects analysis used.
9 Risk difference used as zero events in both arms one or multiple studies.
10 Peto odds ratio used as 0 events in one arm.
11 Surrogate outcome for glycaemic control.
12 2/3 studies reported macrosomia (Avery 1997; Jovanovic-Peterson 1989; birthweight >4000 g; >4500g, respectively).
13 Bo 2014 composite outcome: large for gestational age (LGA; birthweight > 90th percentile), pre-term birth (gestational age at delivery <37 weeks) and any neonatal conditions requiring a specific treatment or a prolonged in-hospital stay; Jovanovic-Peterson 1989 reported "all infants reported to be healthy with no sign of morbidity".
14 Bo 2014: Composite outcome includes perinatal outcome.

Table 11: Evidence profile for comparison 6: Physical activity + mixed vs standard care/control for women with gestational diabetes – single pregnancy

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physical activity+mixed	Standard care/control (Single pregnancy)	Relative (95% CI)	Absolute		
Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) (Better indicated by lower values)												
1 (Bo 2014)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	50	50	-	MD 0.1 lower (0.34 lower to 0.14 higher)	LOW NO EVID IMP. DIFF	CRITICAL
Gestational weight change (kg) (Follow-up at 38 GW) (Better indicated by lower values)												
1 (Bo 2014)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	50	50	-	MD 0.9 lower (5.69 lower to 3.89 higher)	MODERATE NO IMP. DIFF	CRITICAL
Mode of birth: Caesarean (Follow-up at birth)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physical activity+mixed	Standard care/control (Single pregnancy)	Relative (95% CI)	Absolute		
1 (Bo 2014)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	8/50 (16%)	13/50 (26%)	RR 0.62 (0.28 to 1.35)	99 fewer per 1000 (from 187 fewer to 91 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Need for pharmacological intervention (Follow-up at 38 GW)												
1 (Bo 2014)	randomised trials	serious[1]	no serious inconsistency	serious[4]	very serious[3]	none	3/50 (6%)	5/50 (10%)	RR 0.6 (0.15 to 2.38)	40 fewer per 1000 (from 85 fewer to 138 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Large for gestational age > 90 centile (Follow-up at birth)												
1 (Bo 2014)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	5/50 (10%)	7/50 (14%)	RR 0.71 (0.24 to 2.1)	41 fewer per 1000 (from 106 fewer to 154 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Neonatal morbidity (Follow-up unclear)												
1 (Bo 2014)	randomised trials	serious[1]	no serious inconsistency	serious[5]	very serious[3]	none	1/50 (2%)	5/50 (10%)	RR 0.2 (0.02 to 1.65)	80 fewer per 1000 (from 98 fewer to 65 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL

CI: confidence interval; Diff: difference; GW: gestational weeks; MD: mean difference; Imp: important; kg: kilograms; mmol/L: millimoles per litre; NR: not reported RR: risk ratio
1 Serious risk of bias in the evidence contributing to the outcomes as per RoB1 from Cochrane review study.
2 95% CI crosses 1 MID (0.5x control SD at follow-up was used for: end of intervention: fasting blood glucose = 0.3).
3 Total event rate <150.
4 Surrogate outcome for glycaemic control.
5 Composite outcome includes perinatal outcome. Composite defined in-text as newborn complications which included: large for gestational age, pre-term birth (delivery <37 gestational weeks) and any neonatal conditions requiring a specific treatment or a prolonged in-hospital stay.

Table 12: Evidence profile for comparison 7: Physical activity vs mixed for women with gestational diabetes - single pregnancy

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physical activity	Mixed (Single pregnancy)	Relative (95% CI)	Absolute		
Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) (Better indicated by lower values)												
1 (Bo 2014)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	51	49	-	MD 0.1 lower (0.34 lower to 0.14 higher)	LOW NO EVID IMP. DIFF	CRITICAL
Gestational weight change (kg) (Follow-up at 38 weeks; Better indicated by lower values)												
1 (Bo 2014)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	51	49	-	MD 0.8 lower (5.19 lower to 3.59 higher)	MODERATE NO IMP. DIFF	CRITICAL
Mode of birth: Caesarean (Follow-up at birth)												
1 (Bo 2014)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	4/51 (7.8%)	10/49 (20.4%)	RR 0.38 (0.13 to 1.14)	127 fewer per 1000 (from 178 fewer to 29 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Need for pharmacological intervention (Follow-up at 38 GW)												
1 (Bo 2014)	randomised trials	serious[1]	no serious inconsistency	serious[4]	very serious[3]	none	1/51 (2%)	3/49 (6.1%)	RR 0.32 (0.03 to 2.98)	42 fewer per 1000 (from 59 fewer to 121 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Large for gestational age > 90 centile (Follow-up at birth)												
1 (Bo 2014)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	2/51 (3.9%)	5/49 (10.2%)	RR 0.38 (0.08 to 1.89)	63 fewer per 1000 (from 94 fewer to 91 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Physical activity	Mixed (Single pregnancy)	Relative (95% CI)	Absolute		
Neonatal morbidity (Follow-up unclear)												
1 (Bo 2014)	randomised trials	serious[1]	no serious inconsistency	serious[5]	very serious[3]	none	1/51 (2%)	2/49 (4.1%)	RR 0.48 (0.04 to 5.13)	21 fewer per 1000 (from 39 fewer to 169 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL

CI: confidence interval; Diff: difference; GW: gestational weeks; MD: mean difference; Imp: important; kg: kilograms; mmol/L: millimoles per litre; NR: not reported; RR: risk ratio
1 Serious risk of bias in the evidence contributing to the outcomes as per RoB1 from Cochrane review study.
2 95% CI crosses 1 MID (0.5x control SD at follow-up was used for: end of intervention: fasting blood glucose = 0.3).
3 Total event rate <150.
4 Surrogate outcome for glycaemic control.
5 Composite outcome includes perinatal outcome. Composite defined in-text as newborn complications which included: large for gestational age, pre-term birth (delivery <37 gestational weeks) and any neonatal conditions requiring a specific treatment or a prolonged in-hospital stay.

Table 13: Evidence profile for comparison 8: Face to face physical activity vs home based physical activity for women with gestational diabetes in single pregnancy

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Face to face physical activity	Home based physical activity (Single pregnancy)	Relative (95% CI)	Absolute		
Need for pharmacological intervention (Follow-up at birth)												
1 (Downs 2017)	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[3]	none	8/22 (36.4%)	13/22 (59.1%)	RR 0.62 (0.32 to 1.18)	225 fewer per 1000 (from 402 fewer to 106 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL

CI: confidence interval; Diff: difference; GW: gestational weeks; MD: mean difference; Imp: important; kg: kilograms; mmol/L: millimoles per litre; NR: not reported; pOR: peto odds ratio; RD: risk difference; RR: risk ratio

1 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2.
2 Surrogate outcome for glycaemic control.
3 Total event rate <150.

Table 14: Evidence profile for comparison 9: Mixed vs standard care/control for women with gestational diabetes in single pregnancy

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Mixed**	**Standard care/control (Single pregnancy)**	**Relative (95% CI)**	**Absolute**		
Glycaemic control: fasting blood glucose at the end of the intervention (mmol/L) (Better indicated by lower values)												
2[1]	randomised trials	very serious[2]	serious[3]	no serious indirectness	serious[4]	none	98	101	-	MD 0.19 higher (0.2 lower to 0.58 higher)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Glycaemic control: mean blood glucose at the end of the intervention (mmol/L) (Better indicated by lower values)												
1 (Yew 2021)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	170	170	-	MD 0.14 lower (0.25 lower to 0.03 lower)	HIGH NO IMP. DIFF	CRITICAL
Gestational weight change (kg) (Follow-up from last weight before birth or within 2 weeks of birth to birth; Better indicated by lower values)												
3[1]	randomised trials	serious[5]	no serious inconsistency	serious[6]	no serious imprecision	none	268	272	-	MD 0.37 higher (0.38 lower to 1.11 higher)[7]	LOW NO IMP. DIFF	CRITICAL
Gestational weight change - Met/achieved IOM guidelines (%) (Follow-up within 2 weeks of birth)												
1 (Hedderson 2018)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	22[8]	22[8]	RR 1.08 (0.99 to 1.18)	80 more per 1000 (from 10 fewer to 160 more)	HIGH NO EVID IMP. DIFF	CRITICAL
Mode of birth: Vaginal birth (Follow-up at birth)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mixed	Standard care/control (Single pregnancy)	Relative (95% CI)	Absolute		
2[1]	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[9]	none	201/285 (70.5%)	192/293 (65.5%)	RR 1.08 (0.97 to 1.21)	52 more per 1000 (from 20 fewer to 138 more)	MODERATE NO EVID IMP. DIFF	CRITICAL
Mode of birth: Induction of labour (Follow-up at birth)												
2[1]	randomised trials	serious[5]	no serious inconsistency	serious[6]	serious[9]	none	80/164 (48.8%)	93/175 (53.1%)	RR 0.92 (0.74 to 1.13)	43 fewer per 1000 (from 138 fewer to 69 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Mode of birth: Caesarean (Follow-up at birth)												
6[1]	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	no serious imprecision	none	414/996 (41.6%)[10]	480/1059 (45.3%)[10]	RR 0.92 (0.84 to 1.01)	36 fewer per 1000 (from 73 fewer to 5 more)	MODERATE NO IMP. DIFF	CRITICAL
Hypertensive disorders (pre-eclampsia or gestational hypertension) (Gestational age at diagnosis not reported, diagnosed before birth)												
1 (Durnwald 2016)	randomised trials	very serious[2]	no serious inconsistency	serious[6]	very serious[11]	none	11/49 (22.4%)	8/52 (15.4%)	RR 1.46 (0.64 to 3.32)	71 more per 1000 (from 55 fewer to 357 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Need for pharmacological intervention (Follow-up at 38 GW, birth or unclear)												
5[1]	randomised trials	serious[5]	no serious inconsistency	serious[12]	serious[9]	none	114/479 (23.8%)	134/496 (27%)	RR 0.89 (0.73 to 1.1)	30 fewer per 1000 (from 73 fewer to 27 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Large for gestational age > 90 centile (Follow-up at birth)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mixed	Standard care/control (Single pregnancy)	Relative (95% CI)	Absolute		
8[1]	randomised trials	serious[5]	no serious inconsistency	serious[13]	no serious imprecision	none	150/1148 (13.1%)[14]	193/1220 (15.8%)[14]	pOR 0.8 (0.63 to 1.01)[15]	28 fewer per 1000 (from 52 fewer to 1 more)	LOW NO IMP. DIFF	CRITICAL
Neonatal hypoglycaemia (Follow-up within 24 hours of birth or NR)												
2[1]	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	very serious[11]	none	29/219 (13.2%)	41/222 (18.5%)	RR 0.71 (0.46 to 1.1)	54 fewer per 1000 (from 100 fewer to 18 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL
Neonatal mortality and morbidity (Follow-up at birth)												
1 (Yew 2021)	randomised trials	no serious risk of bias	no serious inconsistency	serious[16]	serious[9]	none	64/170 (37.6%)	88/170 (51.8%)	RR 0.73 (0.57 to 0.93)	140 fewer per 1000 (from 36 fewer to 223 fewer)	LOW IMP. BENEFIT	CRITICAL
Neonatal morbidity (Follow-up unclear)												
1 (Bo 2014)	randomised trials	serious[5]	no serious inconsistency	serious[17]	very serious[11]	none	2/49 (4.1%)	5/50 (10%)	RR 0.41 (0.08 to 2.01)	59 fewer per 1000 (from 92 fewer to 101 more)	VERY LOW NO EVID IMP. DIFF	CRITICAL

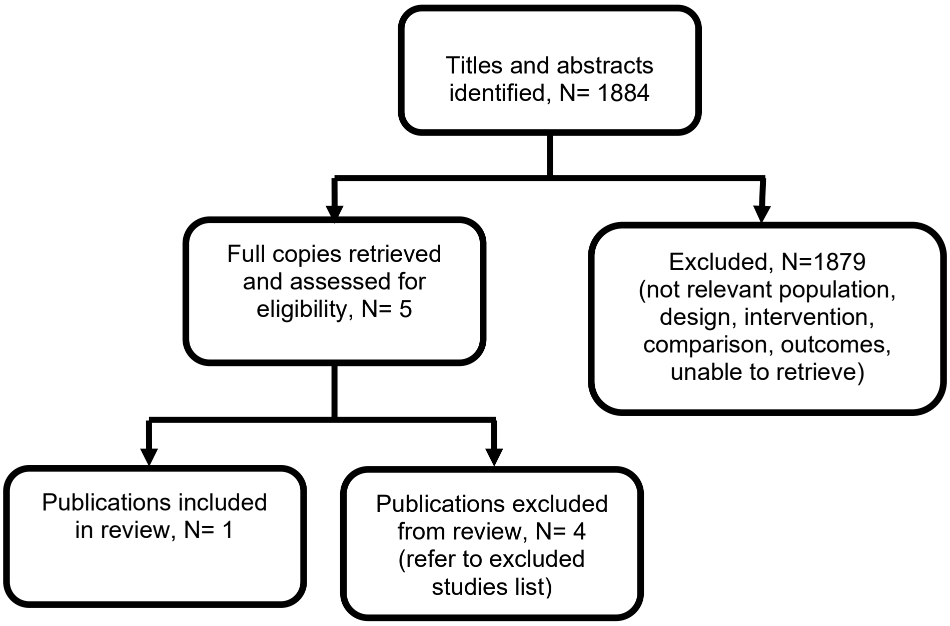
CI: confidence interval; Diff: difference; GW: gestational weeks; MD: mean difference; Imp: important; kg: kilograms; mmol/L: millimoles per litre; NR: not reported; pOR: peto odds ratio; RD: risk difference; RR: risk ratio
1 See corresponding forest plot in appendix E for studies contributing to this outcome.
2 Very serious risk of bias in the evidence contributing to the outcomes as per RoB1 from Cochrane review studies and RoB2 from individual studies from our search.
3 Serious heterogeneity (I2=75%). No number of studies to conduct subgroup analysis. Random effects analysis used.
4 95%CI crosses 1 MID (0.5x control SD for: end of intervention fasting blood glucose = 0.4)
5 Serious risk of bias in the evidence contributing to the outcomes as per RoB1 from Cochrane review studies and/or RoB2 from individual studies from our search.
6 Intervention for Durnwald 2016 partially indirect as one component was aimed at breastfeeding.
7 Adjusted estimate used for Yew 2021: adjusted for insulin treatment for gestational diabetes mellitus and baseline excessive gestational weight change.
8 Unit of randomization numbers provided as cluster RCT. Individual intention to treat N were 1187 for intervention and 1293 for comparator. Number of events per cluster were unavailable.

9 Total events between 150-300
10 Adjusted sample size used for Hedderson 2018: ICC=0.02; Average cluster size=56.36, Design effect: 2.1064, n mixed (adjusted) = 564; n standard care (adjusted) = 614
11 Total events <150 for RR or <200 for POR.
12 Surrogate outcome for glycaemic control.
13 6/8 studies report macrosomia (Borgen 2019, Durnwald 2016, Carolan-Olah 2019, Ferrara 2011, Yew 2021 birthweight >4000g; Mendelson 2008 reported in-text as macrosomia)
14 Adjusted sample size used for Hedderson 2018: ICC=0.02; Average cluster size=56.36, Design effect: 2.1064, N mixed (adjusted)=564; N standard care (adjusted)=614
15 Peto odds ratio used as 0 events in one arm of one study
16 Composite outcome includes perinatal outcome. Composite includes: birth trauma (shoulder dystocia and soft tissue, bone, nerve, and intra-abdominal injuries), neonatal hypoglycaemia, hyperbilirubinemia (according to diagnosis by attending pediatricians), respiratory distress, neonatal intensive care unit admission within 24 h of birth, and perinatal death.
17 Composite includes perinatal outcome. Composite includes large for gestational age (birthweight > 90th percentile), pre-term birth (gestational age at delivery <37 weeks) and any neonatal conditions requiring a specific treatment or a prolonged in-hospital stay.

Appendix G Economic evidence study selection

Study selection for: What are the most effective and cost-effective healthy lifestyle interventions for women with gestational diabetes?

Figure 37: Economic evidence study selection flow chart



Appendix H Economic evidence tables

Economic evidence tables for review question: What are the most effective and cost-effective healthy lifestyle interventions for women with gestational diabetes?

Table 15: Economic evidence table for healthy lifestyle interventions for women with gestational diabetes

Study ID Country Type of study	Interventions and comparators	Study population Study design Data sources	Costs and outcomes: description and values	Results: Cost-effectiveness	Comments
Laurie 2023 Australia Cost analysis (the study was described as cost-minimisation analysis, but effectiveness data, including proof of equivalence, were not provided)	Digital model for GDM management (systematic development and delivery of education videos, use of a national service smart phone app/portal and reduced schedule of face to face visits) Treatment as usual (TAU)	Women with GDM following diagnosis at 28 weeks Cohort study with retrospective control & further modelling assumptions Data sources: Resource use: expert opinion for healthcare, short survey of study population for patient costs Unit costs: local and national sources	Healthcare costs included: staff, self-monitoring blood glucose meter provision, medications, education videos, insulin; smartphone app was free Patient costs included: lost wages, childcare and travel expenses Cost-saving per person: Healthcare: -$15 Patient: -$567 Outcome: N/A	N/A Patient cost-savings sensitive to unit cost of wages	• Perspective: healthcare system + patient • Currency: AUD ($) • Cost year: 2021 • Time horizon: during pregnancy, from 28 weeks of GDM diagnosis - costs were estimated over 1 year of centre operation pre- and post-intervention • Discounting: N/A • Applicability: Partial • Quality: potentially serious methodological limitations

GDM: gestational diabetes mellitus; N/A: non-applicable; TAU: treatment as usual

Appendix I Economic model

Economic model for review question: What are the most effective and cost-effective healthy lifestyle interventions for women with gestational diabetes?

No economic analysis was conducted for this review question.

Appendix J Excluded studies

Excluded studies for review question: What are the most effective and cost-effective healthy lifestyle interventions for women with gestational diabetes?

Excluded effectiveness evidence studies

Table 16: Excluded studies and reasons for their exclusion

Study	Reason
(2017) Effect of systematic diet guidance on compliance and Maternal-Infant outcomes in patients with gestational diabetes mellitus. World chinese journal of digestology 25(14): 1311-1315	- Study setting does not meet protocol Study not conducted in a high income country (China)
(2013) Different types of dietary advice for women with gestational NEW diabetes mellitus. Essentially MIDIRS 4(5): 14-14	- Full text paper not available Unable to locate full text article
Abboud, Myriam, Rizk, Rana, AlAnouti, Fatme et al. (2020) The Health Effects of Vitamin D and Probiotic Co-Supplementation: A Systematic Review of Randomized Controlled Trials. Nutrients 13(1)	- Systematic review includes studies that does not meet protocol Systematic review includes studies with population not specific to gestational diabetes. One included study reported on gestational diabetes and was conducted in a country that was not high income (Iran)
Adesina, Nurudeen, Dogan, Huseyin, Green, Sue et al. (2021) Effectiveness and Usability of Digital Tools to Support Dietary Self-Management of Gestational Diabetes Mellitus: A Systematic Review. Nutrients 14(1)	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol (not randomised controlled trials, not conducted in high income countries, inappropriate population of women without gestational diabetes). Additional studies were checked
Afaghi, Ahmad; Ghanei, Laleh; Ziaee, Amir (2013) Effect of low glycemic load diet with and without wheat bran on glucose control in gestational diabetes mellitus: A randomized trial. Indian journal of endocrinology and metabolism 17(4): 689-92	- Study setting does not meet protocol Study not conducted in a high income country (Iran)

Study	Reason
Afifah, E., Nurdiati, D.S., Hadi, H. et al. (2022) Social Nervous Exercise Intervention and Its Association with Fasting Blood Glucose on Diabetes Mellitus Gestational. Open Access Macedonian Journal of Medical Sciences 10: 129-136	- Study setting does not meet protocol Study not conducted in a high income country (Indonesia)
Ahmadi, S, Jamilian, M, Tajabadi-Ebrahimi, M et al. (2016) The effects of synbiotic supplementation on markers of insulin metabolism and lipid profiles in gestational diabetes: a randomised, double-blind, placebo-controlled trial. British journal of nutrition 116(8): 1394-1401	- Study setting does not meet protocol Study is included in Okesene-Gafa 2020 Cochrane review but is not conducted in a high income country (Iran) and therefore does not meet protocol inclusion criteria
Akalpler, O. and Bagriacik, E. (2023) Education programs for gestational diabetes mellitus: A systematic review. Human Nutrition and Metabolism 33: 200195	- Systematic review includes studies that does not meet protocol Systematic review includes studies with inappropriate population (women at risk of GDM). Relevant included references were checked
Akbari, M., Mosazadeh, M., Lankarani, K.B. et al. (2017) The Effects of Vitamin D Supplementation on Glucose Metabolism and Lipid Profiles in Patients with Gestational Diabetes: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Hormone and Metabolic Research 49(9): 647-653	- Systematic review used as source of primary studies Systematic review contains studies that do not meet protocol inclusion criteria (intervention is co-supplements, one study retracted, not high income country). All studies have been checked
Al Hashmi, Iman; Nandy, Karabi; Seshan, Vidya (2019) Non-Medical Strategies to Improve Pregnancy Outcomes of Women with Gestational Diabetes Mellitus: A literature review. Sultan Qaboos University medical journal 19(1): e4-e10	- Review article but not a systematic review Literature review and not a systematic review. Included studies have been checked.
Al-Hashmi, I, Hodge, F, Nandy, K et al. (2018) The Effect of a Self-Efficacy-Enhancing Intervention on Perceived Self-Efficacy and Actual Adherence to Healthy Behaviours Among Women with Gestational Diabetes Mellitus. Sultan Qaboos University medical journal 18(4): e513-e519	- No outcomes of interest Study focuses on self efficacy and adherence and reports no outcomes of interest.

Study	Reason
Al-ofi, E.A., Mosli, H.H., Ghamri, K.A. et al. (2019) Management of postprandial hyperglycaemia and weight gain in women with gestational diabetes mellitus using a novel telemonitoring system. Journal of International Medical Research 47(2): 754-764	- Study does not contain an intervention relevant to this review protocol Adjustments of insulin/medication described as part of the intervention protocol after weekly review of monitoring data by diabetic care team and therefore does not meet protocol inclusion criteria
Allehdan, Sabika S, Basha, Asma S, Asali, Fida F et al. (2019) Dietary and exercise interventions and glycemic control and maternal and newborn outcomes in women diagnosed with gestational diabetes: Systematic review. Diabetes & metabolic syndrome 13(4): 2775-2784	- Systematic review used as source of primary studies All of the studies included in the systematic review overlap with Brown 2017 Cochrane systematic review included in this review or another Cochrane systematic review by Brown 2017 on lifestyle interventions for gestational diabetes that was not eligible for inclusion with included studies checked
Allehdan, Sabika, Basha, Asma, Hyassat, Dana et al. (2022) Effectiveness of carbohydrate counting and Dietary Approach to Stop Hypertension dietary intervention on managing Gestational Diabetes Mellitus among pregnant women who used metformin: A randomized controlled clinical trial. Clinical nutrition (Edinburgh, Scotland) 41(2): 384-395	- Study setting does not meet protocol Study is not conducted in a high income country (Jordan)
Alsheikh, M.H. (2020) Effect of exercise on glycaemic control and pregnancy outcomes in women with gestational diabetes mellitus: A review. Indian Journal of Physiology and Pharmacology 64(2): 102-108	- Systematic review used as source of primary studies Systematic review contains studies that do not meet protocol inclusion criteria (population at risk of gestational diabetes, secondary study analysing experimental arm only) or are included in Brown 2017 Cochrane systematic review included in this review. Additional references have been checked
Alwan, Nisreen; Tuffnell, Derek J; West, Jane (2009) Treatments for gestational diabetes. The Cochrane database of systematic reviews: cd003395	- Systematic review includes studies that does not meet protocol Earlier Cochrane review including pharmaceutical treatments for gestational diabetes as interventions. Subsequently

Study	Reason
	split into three reviews to separately cover insulin treatment, oral anti-diabetic pharmacological therapies and lifestyle interventions for gestational diabetes (which have been assessed).
Amason, JS, Lee, S, Aduddell, K et al. (2016) Pilot Feasibility Study of an Educational Intervention in Women With Gestational Diabetes. JOGNN: journal of obstetric, gynecologic & neonatal nursing 45(4): 515-527	- Study design or type not relevant to this review protocol Pilot study is not randomised, no subsequent studies identified
Amirani, Elaheh; Asemi, Zatollah; Taghizadeh, Mohsen (2022) The effects of selenium plus probiotics supplementation on glycemic status and serum lipoproteins in patients with gestational diabetes mellitus: A randomized, double-blind, placebo-controlled trial. Clinical nutrition ESPEN 48: 56-62	- Study does not contain an intervention relevant to this review protocol Intervention contains co-supplement of selenium which does not meet protocol inclusion criteria
Andersen, M.B., Fuglsang, J., Ostenfeld, E.B. et al. (2021) Postprandial interval walking-effect on blood glucose in pregnant women with gestational diabetes. American Journal of Obstetrics and Gynecology MFM 3(6): 100440	- Study design or type not relevant to this review protocol Randomised cross-over trial design which is not considered to be appropriate for the review question
Aroda, V R, Christophi, C A, Edelstein, S L et al. (2015) The effect of lifestyle intervention and metformin on preventing or delaying diabetes among women with and without gestational diabetes: the Diabetes Prevention Program outcomes study 10-year follow-up. The Journal of clinical endocrinology and metabolism 100(4): 1646-53	- Population not relevant to this review protocol Observational follow-up study to randomised controlled trial where population was those without diabetes
Asemi, Z, Hashemi, T, Karamali, M et al. (2013) Effects of vitamin D supplementation on glucose metabolism, lipid concentrations, inflammation, and oxidative stress in gestational diabetes: a double-blind randomized controlled clinical trial. American journal of clinical nutrition 98(6): 1425-1432	- Study design or type not relevant to this review protocol Study has been retracted and therefore does not meet protocol inclusion criteria

Study	Reason
Asemi, Z; Karamali, M; Esmaillzadeh, A (2014) Favorable Effects of Vitamin D Supplementation on Pregnancy Outcomes in Gestational Diabetes: a Double Blind Randomized Controlled Clinical Trial. Hormone and metabolic research 47(8): 565-570	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Asemi, Z, Samimi, M, Tabassi, Z et al. (2014) The effect of DASH diet on pregnancy outcomes in gestational diabetes: a randomized controlled clinical trial. European journal of clinical nutrition 68(4): 490-5	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Asemi, Zatollah, Samimi, Mansooreh, Tabassi, Zohreh et al. (2013) A randomized controlled clinical trial investigating the effect of DASH diet on insulin resistance, inflammation, and oxidative stress in gestational diabetes. Nutrition (Burbank, Los Angeles County, Calif.) 29(4): 619-24	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Asemi, Zatollah, Tabassi, Zohreh, Samimi, Mansooreh et al. (2013) Favourable effects of the Dietary Approaches to Stop Hypertension diet on glucose tolerance and lipid profiles in gestational diabetes: a randomised clinical trial. The British journal of nutrition 109(11): 2024-30	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Awad, E., Ahmed, H., Yousef, A. et al. (2019) Effect of antenatal exercise on mode of delivery in gestational diabetic females: A single-blind randomized controlled trial. Physiotherapy Quarterly 27(2): 1-5	- Study setting does not meet protocol Study not conducted in a high income country (Egypt)
Babadi, Mahtab, Khorshidi, Ahmad, Aghadavood, Esmat et al. (2019) The Effects of Probiotic Supplementation on Genetic and Metabolic Profiles in Patients with Gestational Diabetes Mellitus: a Randomized, Double-Blind, Placebo-Controlled Trial. Probiotics and antimicrobial proteins 11(4): 1227-1235	- Study setting does not meet protocol Study not conducted in a high income country (Iran)

Study	Reason
Badehnoosh, Bita, Karamali, Maryam, Zarrati, Mitra et al. (2018) The effects of probiotic supplementation on biomarkers of inflammation, oxidative stress and pregnancy outcomes in gestational diabetes. The journal of maternal-foetal & neonatal medicine : the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians 31(9): 1128-1136	- Study setting does not meet protocol Study is included in Okesene-Gafa 2020 Cochrane review but is not conducted in a high income country (Iran) and therefore does not meet protocol inclusion criteria
Baek, ES and Park, HJ (2013) Effects of a Case Management Program on Self-efficacy, Depression and Anxiety in Pregnant Women with Gestational Diabetes Mellitus. Korean journal of women health nursing 19(2): 88-98	- Study not reported in English Article reported in Korean
Bahado-Singh, Ray O, Mele, Lisa, Landon, Mark B et al. (2012) Fetal male gender and the benefits of treatment of mild gestational diabetes mellitus. American journal of obstetrics and gynecology 206(5): 422e1-5	- Study does not contain an intervention relevant to this review protocol Secondary analysis of Landon 2009 which was excluded due to inappropriate intervention
Bao, Hongdan, Yu, Pingxiang, Song, Xiaoxiao et al. (2020) The influence of home-based exercise on gestational diabetes: a meta-analysis of randomized controlled trials. The journal of maternal-foetal & neonatal medicine: the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians 33(13): 2300-2305	- Systematic review used as source of primary studies Systematic review included studies that did not meet the protocol inclusion criteria (inappropriate population) or overlapped with articles included in Brown 2017 Cochrane review included in this review
Barati, Z., Iravani, M., Karandish, M. et al. (2021) The effect of oat bran consumption on gestational diabetes: a randomized controlled clinical trial. BMC Endocrine Disorders 21(1): 67	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Behboudi-Gandevani, Samira, Bidhendi-Yarandi, Razieh, Panahi, Mohammad	- Systematic review used as source of primary studies

Study	Reason
Hossein et al. (2021) The Effect of Mild Gestational Diabetes Mellitus Treatment on Adverse Pregnancy Outcomes: A Systemic Review and Meta-Analysis. Frontiers in endocrinology 12: 640004	Systematic review includes studies that do not meet the protocol inclusion criteria (inappropriate intervention of insulin therapy treatment to intervention arm only, inappropriate retrospective study design, inappropriate population of borderline glucose intolerance, secondary study long term follow-up outcomes for 5-10 year old children) or studies overlapping with Brown 2017 Cochrane review included in this review. Additional studies have been checked
Bennett, C J, Walker, R E, Blumfield, M L et al. (2019) Attenuation of maternal weight gain impacts infant birthweight: systematic review and meta-analysis. Journal of developmental origins of health and disease 10(4): 387-405	- Systematic review used as source of primary studies Systematic review looks at interventions for both gestational diabetes and those without gestational diabetes. Relevant included studies have been checked and either overlapped with Han 2017 and Brown 2017 Cochrane systematic reviews included in this review or was not conducted in a high income country (China)
Bernadette, N.T., Prasetyo, B., Wibisono, S. et al. (2022) Comparison of the Effect of Glycemic Control on the Incidence of Fetal Macrosomia and Large for Gestational Age in Gestational Diabetes Mellitus Patients; A Systematic Review. Indian Journal of Forensic Medicine and Toxicology 16(2): 273-281	- Systematic review used as source of primary studies Included studies in the systematic review did not meet the protocol inclusion criteria as they were either not randomised controlled trials or included inappropriate intervention of pharmacological therapy
Berry, Diane C, Hall, Emily G, Neal, Madeline N et al. (2016) Results of the Optimizing Outcomes in Women with Gestational Diabetes Mellitus and Their Infants, a Cluster Randomized, Controlled Pilot Study: Lessons Learned. Journal of National Black Nurses' Association : JNBNA 27(2): 1-10	- Study design or type not relevant to this review protocol Paper discusses Berry 2013 that has been assessed and does not meet protocol as intervention of interest starts 6 weeks postpartum
Berry, Diane C, Neal, Madeline, Hall, Emily G et al. (2013) Rationale, design, and methodology for the optimizing outcomes in women with gestational diabetes mellitus	- Study design or type not relevant to this review protocol

Study	Reason
and their infants study. BMC pregnancy and childbirth 13: 184	Protocol for trial that does not meet protocol inclusion criteria (interventions of interest begin 6 weeks postpartum)
Bertini, AM (2009) Up to date treatment of gestational diabetes mellitus. Journal of perinatal medicine 37(suppl1): 3	- Study design or type not relevant to this review protocol Abstract of study with interventions that do not meet protocol inclusion criteria (glibenclamide or metformin).
Bertini, Ayleen, Garate, Barbara, Pardo, Fabian et al. (2022) Impact of Remote Monitoring Technologies for Assisting Patients With Gestational Diabetes Mellitus: A Systematic Review. Frontiers in bioengineering and biotechnology 10: 819697	- Systematic review used as source of primary studies Systematic review included studies that did not meet the protocol inclusion criteria (study design not RCT, intervention is delivered during postnatal period, no outcomes of interest, focus of intervention on blood glucose monitoring, study conducted in country that is not high income status). Additional studies were checked
Bgeginski, Roberta, Ribeiro, Paula A B, Mottola, Michelle F et al. (2017) Effects of weekly supervised exercise or physical activity counseling on fasting blood glucose in women diagnosed with gestational diabetes mellitus: A systematic review and meta-analysis of randomized trials. Journal of diabetes 9(11): 1023-1032	- Systematic review used as source of primary studies All included studies overlap with Han 2017 and Brown 2017 Cochrane systematic reviews included in this review or are included in the Brown 2017 lifestyle Cochrane systematic review which did not meet the protocol for this review with included studies checked
Bhavya Swetha, R.V.; Samal, R.; George, C.E. (2020) The Effect of Vitamin D Supplementation on Improving Glycaemic Control in Diabetic Vitamin D-Deficient Pregnant Women: A Single-Blinded Randomized Control Trial. Journal of Obstetrics and Gynecology of India 70(2): 119-125	- Study setting does not meet protocol Study not conducted in a high income country (India)
Bielefeld, Dale; Grafenauer, Sara; Rangan, Anna (2020) The Effects of Legume Consumption on Markers of Glycaemic Control in Individuals with and without Diabetes Mellitus: A Systematic Literature	- Systematic review used as source of primary studies

Study	Reason
Review of Randomised Controlled Trials. Nutrients 12(7)	The systematic review did not find any studies examining this intervention in women with gestational diabetes
Blackwell, Sean C, Landon, Mark B, Mele, Lisa et al. (2016) Relationship Between Excessive Gestational Weight Gain and Neonatal Adiposity in Women With Mild Gestational Diabetes Mellitus. Obstetrics and gynecology 128(6): 1325-1332	- Study does not contain an intervention relevant to this review protocol Secondary analysis of Landon 2009 which contained an intervention that did not meet the protocol inclusion criteria
Brislane, Aine, Reid, Ly-Anh, Bains, Gyan et al. (2023) Optimizing Blood Glucose Control through the Timing of Exercise in Pregnant Individuals Diagnosed with Gestational Diabetes Mellitus. International journal of environmental research and public health 20(8)	- Study does not contain an intervention relevant to this review protocol Women with gestational diabetes were prescribed other interventions such as pharmacological therapy (insulin or metformin) or diet without exercise or diet with exercise along with the exercise intervention
Brooten, D., Youngblut, J.A.M., Brown, L. et al. (2001) A randomized trial of nurse specialist home care for women with high-risk pregnancies: Outcomes and costs. American Journal of Managed Care 7(8): 793-803	- Population not relevant to this review protocol Population includes women with gestational diabetes, pregestational diabetes, chronic hypertension, or high risk for preterm labour. Data for women with gestational diabetes was not reported separately
Brown, J., Alwan, N.A., West, J. et al. (2017) Lifestyle interventions for the treatment of women with gestational diabetes. Cochrane Database of Systematic Reviews 2017(5): cd011970	- Systematic review includes studies that does not meet protocol Systematic review includes studies with pharmacological interventions (insulin) which do not meet the protocol inclusion criteria
Bung, P, Artal, R, Khodiguian, N et al. (1991) Exercise in gestational diabetes. An optional therapeutic approach?. Diabetes 40suppl2: 182-5	- Comparator in study does not match that specified in this review protocol This study is included in Brown 2017 Cochrane review but does not meet protocol inclusion criteria as only the control arm were given insulin in addition to diet while the intervention was physical activity and diet without insulin

Study	Reason
Bung, P, Bung, C, Artal, R et al. (1993) Therapeutic exercise for insulin-requiring gestational diabetics: effects on the fetus--results of a randomized prospective longitudinal study. Journal of perinatal medicine 21(2): 125-37	- Study does not contain an intervention relevant to this review protocol Comparison includes pharmacological intervention of insulin (exercise and diet vs insulin and diet)
Caballero-Ruiz, Estefania, Garcia-Saez, Gema, Rigla, Mercedes et al. (2017) A web-based clinical decision support system for gestational diabetes: Automatic diet prescription and detection of insulin needs. International journal of medical informatics 102: 35-49	- Study does not contain an intervention relevant to this review protocol The study focuses on glucose monitoring which is outside the remit of this review
Cai, Q., Xiao, C., Zhou, Y. et al. (2020) Effect of comprehensive nursing on blood glucose level, unhealthy emotion, and pregnancy outcome of patients with gestational diabetes mellitus. International Journal of Clinical and Experimental Medicine 13(10): 8158-8166	- Study setting does not meet protocol Study not conducted in a high income country (China)
Camarena Pulido, E.E., Mora Gonzalez, S., Corona Gutierrez, A.A. et al. (2022) Effect of supplementation with 5,000 IU of vitamin D on the glycemic profile of women with gestational diabetes mellitus. Journal of Perinatal Medicine 50(9): 1225-1229	- Study setting does not meet protocol Study not conducted in a high income country (Mexico)
Cao, Diana X, Wong, Eva Y, Vela, Melanie N et al. (2021) Effect of Probiotic Supplementation on Glycemic Outcomes in Patients with Abnormal Glucose Metabolism: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Annals of nutrition & metabolism 77(5): 251-261	- Comparator in study does not match that specified in this review protocol Comparison includes pharmacological intervention of insulin (exercise and diet vs insulin and diet)
Cao, Yan-Min, Wang, Wei, Cai, Na-Na et al. (2021) The Impact of the One-Day Clinic Diabetes Mellitus Management Model on Perinatal Outcomes in Patients with Gestational Diabetes Mellitus. Diabetes, metabolic syndrome and obesity : targets and therapy 14: 3533-3540	- Study setting does not meet protocol Study not conducted in a high income country (China)

Study	Reason
Carolan-Olah, Mary C (2016) Educational and intervention programmes for gestational diabetes mellitus (GDM) management: An integrative review. Collegian (Royal College of Nursing, Australia) 23(1): 103-14	- Review article but not a systematic review Integrative review containing non-RCTs and some overlapping studies from the included Cochrane reviews. Included RCTs have been checked
Carolan-Olah, Mary; Duarte-Gardea, Maria; Lechuga, Julia (2017) A systematic review of interventions for Hispanic women with or at risk of Gestational diabetes mellitus (GDM). Sexual & reproductive healthcare : official journal of the Swedish Association of Midwives 13: 14-22	- Systematic review used as source of primary studies The systematic review examined both gestational diabetes and non gestational diabetes population. Studies in women with gestational diabetes were checked and most did not meet the protocol inclusion criteria as they were not conducted in high income countries or did not include intervention of interest (pharmacological). One eligible study has already been assessed in this review
Carter, Ebony B, Barbier, Kate, Hill, Pamela K et al. (2022) Pilot Randomized Controlled Trial of Diabetes Group Prenatal Care. American journal of perinatology 39(1): 45-53	- No outcomes of interest Study included women with type 2 diabetes or gestational diabetes diagnosed ≤32 weeks but does not report outcomes separately for women with gestational diabetes
Casey, Brian M, Mele, Lisa, Landon, Mark B et al. (2015) Does maternal body mass index influence treatment effect in women with mild gestational diabetes?. American journal of perinatology 32(1): 93-100	- Study does not contain an intervention relevant to this review protocol Secondary analysis of Landon 2009 which has been assessed and excluded as intervention does not meet the protocol inclusion criteria (insulin use part of intervention)
Casey, Brian M, Rice, Madeline Murguia, Landon, Mark B et al. (2020) Effect of Treatment of Mild Gestational Diabetes on Long-Term Maternal Outcomes. American journal of perinatology 37(5): 475-482	- Population not relevant to this review protocol Follow-up study with focus on postpartum findings. Original study Landon 2009 has been assessed and excluded as intervention does not meet the protocol
Cetinkaya Ozdemir, Serap, Kucukturkmen Pasa, Busra, Metin, Tuba et al. (2022) The	- Systematic review used as source of primary studies

Study	Reason
effect of probiotic and synbiotic use on glycemic control in women with gestational diabetes: A systematic review and meta-analysis. Diabetes research and clinical practice 194: 110162	Systematic review contains studies that either do not meet protocol inclusion criteria (not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Ceysens, G.; Rouiller, D.; Boulvain, M. (2006) Exercise for diabetic pregnant women. Cochrane Database of Systematic Reviews 2010(1): cd004225	- More recent systematic review included that covers the same topic Earlier Cochrane systematic review to Brown 2017 and all included studies are also included in Brown 2017
Chao, H., Chen, G., Wen, X. et al. (2019) Dietary control plus nutrition guidance for blood glucose and pregnancy outcomes in women with gestational diabetes. International Journal of Clinical and Experimental Medicine 12(3): 2773-2778	- Study setting does not meet protocol Study not conducted in a high income country (China)
Chen, H, Liu, X, Zou, Z et al. (2018) Effects of low glycemic index cereals on metabolomics and pregnancy outcomes in women with gestational diabetes mellitus. Chinese journal of clinical nutrition 26(6): 331-337	- Study not reported in English Full text article not in English
Chen, Yuan, Yue, Rensong, Zhang, Boxun et al. (2020) Effects of probiotics on blood glucose, biomarkers of inflammation and oxidative stress in pregnant women with gestational diabetes mellitus: A meta-analysis of randomized controlled trials. Medicina clinica 154(6): 199-206	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Chollet, M.B. and Pettitt, D.J. (2006) Treatment of gestational diabetes mellitus. Clinical Diabetes 24(1): 35-36	- Study design or type not relevant to this review protocol Review of Crowther 2005 study captured in search and excluded due to inappropriate intervention/comparator.
Cilar Budler, L. and Budler, M. (2022) Physical activity during pregnancy: a systematic review for the assessment of current evidence with future	- Systematic review used as source of primary studies

Study	Reason
recommendations. BMC Sports Science, Medicine and Rehabilitation 14(1): 133	The systematic review did not focus on gestational diabetes as population. Relevant articles were checked
Coe, Dawn P, Conger, Scott A, Kendrick, Jo M et al. (2018) Postprandial walking reduces glucose levels in women with gestational diabetes mellitus. Applied physiology, nutrition, and metabolism = Physiologie appliquee, nutrition et metabolisme 43(5): 531-534	- Study design or type not relevant to this review protocol Randomised cross-over design which is not considered to be appropriate for the review question
Cremona, A, O'Gorman, C, Cotter, A et al. (2018) Effect of exercise modality on markers of insulin sensitivity and blood glucose control in pregnancies complicated with gestational diabetes mellitus: a systematic review. Obesity science & practice 4(5): 455-467	- Systematic review used as source of primary studies Systematic includes studies that do not meet the protocol inclusion criteria (inappropriate population without gestational diabetes, not conducted in high income countries) or overlap with included studies in Brown 2017 Cochrane systematic review. Additional studies were checked
Crowther, Caroline A, Hiller, Janet E, Moss, John R et al. (2005) Effect of treatment of gestational diabetes mellitus on pregnancy outcomes. The New England journal of medicine 352(24): 2477-86	- Study does not contain an intervention relevant to this review protocol Component of intervention arm included pharmacological intervention of insulin if required by the participant.
Dallanora, Suelen, Medeiros de Souza, Yasmin, Deon, Rubia Garcia et al. (2018) Do probiotics effectively ameliorate glycemic control during gestational diabetes? A systematic review. Archives of gynecology and obstetrics 298(3): 477-485	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (population at risk of gestational diabetes, not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Davenport, Margie H, Sobierajski, Frances, Mottola, Michelle F et al. (2018) Glucose responses to acute and chronic exercise during pregnancy: a systematic review and meta-analysis. British journal of sports medicine 52(21): 1357-1366	- Systematic review used as source of primary studies The systematic review included studies that did not meet the protocol inclusion criteria (inappropriate study design, population not gestational diabetes, not high income country) or studies that overlapped with

Study	Reason
	included studies in Brown 2017 Cochrane systematic review included in this review. Additional studies were checked
de Barros, Marcelo C, Lopes, Marco A B, Francisco, Rossana P V et al. (2010) Resistance exercise and glycemic control in women with gestational diabetes mellitus. American journal of obstetrics and gynecology 203(6): 556e1-6	- Study setting does not meet protocol Study is included in Brown 2017 Cochrane review but is not conducted in a high income country (Brazil) and therefore does not meet protocol inclusion criteria
di Biase, N, Napoli, A, Sabbatini, A et al. (1997) Telemedicine in the treatment of diabetic pregnancy. Annali dell'Istituto superiore di sanita 33(3): 347-51	- Population not relevant to this review protocol Population does not meet protocol inclusion criteria - insulin dependent diabetic women
Dingena, Cassy F, Arofikina, Daria, Campbell, Matthew D et al. (2023) Nutritional and Exercise-Focused Lifestyle Interventions and Glycemic Control in Women with Diabetes in Pregnancy: A Systematic Review and Meta-Analysis of Randomized Clinical Trials. Nutrients 15(2)	- Systematic review used as source of primary studies Systematic review included studies with interventions that do not meet protocol inclusion criteria (co-supplements). Relevant studies were checked and did not meet protocol or overlapped with studies in included Cochrane reviews.
Dolatkhah, N, Hajifaraji, M, Abbasalizadeh, F et al. (2015) Is there a value for probiotic supplements in gestational diabetes mellitus? A randomized clinical trial. Journal of health, population, and nutrition 33: 25	- No outcomes of interest Study not conducted in a high income country (Iran)
Draffin, Claire R, Alderdice, Fiona A, McCance, David R et al. (2017) Impact of an educational DVD on anxiety and glycaemic control in women diagnosed with gestational diabetes mellitus (GDM): A randomised controlled trial. Diabetes research and clinical practice 126: 164-171	- Study does not contain an intervention relevant to this review protocol The educational intervention contained multiple components that were not in scope of the review (administering insulin, guide to blood glucose self-monitoring)
Durnwald, C.P., Downes, K., Leite, R. et al. (2018) Predicting persistent impaired glucose tolerance in patients with gestational diabetes: The role of high sensitivity CRP and adiponectin.	- Population not relevant to this review protocol Secondary study reporting postpartum outcomes. Original trial was Durnwald 2016 which was captured in the search and assessed

Study	Reason
Diabetes/Metabolism Research and Reviews 34(2): e2958	
Durnwald, Celeste P, Mele, Lisa, Spong, Catherine Y et al. (2011) Glycemic characteristics and neonatal outcomes of women treated for mild gestational diabetes. Obstetrics and gynecology 117(4): 819-827	- Study does not contain an intervention relevant to this review protocol Secondary study to Landon 2009 which was excluded due to inappropriate intervention
Eberle, Claudia; Loehnert, Maxine; Stichling, Stefanie (2021) Effectivness of specific mobile health applications (mHealth-apps) in gestational diabtetes mellitus: a systematic review. BMC pregnancy and childbirth 21(1): 808	- Systematic review used as source of primary studies Systematic review contains studies that do not meet protocol inclusion criteria (focus is on blood glucose monitoring, not high income). Additional studies were checked
Eberle, Claudia and Stichling, Stefanie (2021) Effects of Telemetric Interventions on Maternal and Fetal or Neonatal Outcomes in Gestational Diabetes: Systematic Meta-Review. JMIR diabetes 6(3): e24284	- Systematic review used as source of primary studies Systematic review contains studies that do not meet protocol inclusion criteria (study design not randomised). Additional studies were checked
Ehrlich, S F, Hedderson, M M, Quesenberry, C P Jr et al. (2014) Post-partum weight loss and glucose metabolism in women with gestational diabetes: the DEBI Study. Diabetic medicine : a journal of the British Diabetic Association 31(7): 862-7	- Secondary publication of an included study that does not provide any additional relevant information Substudy from Ferrara 2011 DEBI study focusing on the postpartum period. The original study has been assessed and is included in the review.
Ehrlich, S.F., Rand, B., Zite, N.B. et al. (2023) Exploring the relationship between regular physical activity and the 24-hour glucose cycle in gestational glucose intolerance and gestational diabetes mellitus. American Journal of Obstetrics and Gynecology 228(1): 100-102	- Population not relevant to this review protocol Study includes women with gestational diabetes as well as gestational glucose intolerance and does not report gestational diabetes results separately
Ehrlich, Samantha F, Maples, Jill M, Barroso, Cristina S et al. (2021) Using a consumer-based wearable activity tracker for physical activity goal setting and measuring steps in pregnant women with	- No outcomes of interest No outcomes of interest reported with a focus on acceptance and validity of intervention

Study	Reason
gestational diabetes mellitus: exploring acceptance and validity. BMC pregnancy and childbirth 21(1): 420	
El-Gamasy, B.S.M., Hassan, S.A., Ghonemy, G.E. et al. (2022) Effect of Lifestyle Modification on Pregnancy Outcomes among Women with Gestational Diabetes: Quasi Randomized Controlled Trail (QRCT). NeuroQuantology 20(6): 6068-6080	- Study setting does not meet protocol Study not conducted in a high income country (Egypt)
Falavigna, Maicon, Schmidt, Maria I, Trujillo, Janet et al. (2012) Effectiveness of gestational diabetes treatment: a systematic review with quality of evidence assessment. Diabetes research and clinical practice 98(3): 396-405	- Systematic review used as source of primary studies Systematic review contains studies that do not meet protocol inclusion criteria (pharmacological intervention of insulin). Additional studies were checked
Farrar, Diane, Simmonds, Mark, Bryant, Maria et al. (2017) Treatments for gestational diabetes: a systematic review and meta-analysis. BMJ open 7(6): e015557	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (pharmacological interventions or comparators or population not gestational diabetes) or overlap with studies included in Han 2017 Cochrane systematic review included in this review. Additional studies were checked
Fatemeh, K; Mahin, B; Mehrbanoo, A (2019) The Effect Of Counseling on Health Promotion Behaviors in Diabetic Mothers; Zabol 2018. Journal of diabetic nursing 7(4): 983-991	- Study not reported in English Full text paper not in English
Fei, Bei-bei, Ling, Li, Hua, Chen et al. (2014) Effects of soybean oligosaccharides on antioxidant enzyme activities and insulin resistance in pregnant women with gestational diabetes mellitus. Food chemistry 158: 429-32	- Study setting does not meet protocol Study not conducted in a high income country (China)
Feng, Yaofang, Zhao, Zengcai, Fu, Dayin et al. (2021) Maternal and neonatal outcomes	- Systematic review includes studies that does not meet protocol

Study	Reason
after energy-restricted diet for women with gestational diabetes mellitus: A systematic review and meta-analysis of randomized controlled trials. Medicine 100(14): e25279	Systematic review includes studies that are not conducted in high income countries or overlap with Han 2017 Cochrane systematic review included in this review
Fiskin, Gamze and Sahin, Nevin (2021) Nonpharmacological Management of Gestational Diabetes Mellitus: Diaphragmatic Breathing Exercise. Alternative therapies in health and medicine 27(s1): 90-96	- Study setting does not meet protocol Study not conducted in a high income country (Turkey)
Frank, R.W.; Gopal, K.R.; Rodrigues, D.E. (2021) Effectiveness of exercises in glycaemic control and maternal outcome among women with gestational diabetes mellitus- A pilot study. Journal of Clinical and Diagnostic Research 15(5): qc06-qc10	- Study setting does not meet protocol Study not conducted in a high income country (India)
Gao, Li, Lin, Liyuan, Shan, Nan et al. (2020) The impact of omega-3 fatty acid supplementation on glycemic control in patients with gestational diabetes: a systematic review and meta-analysis of randomized controlled studies. The journal of maternal-foetal & neonatal medicine : the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians 33(10): 1767-1773	- Systematic review includes studies that does not meet protocol Systematic review contains intervention that does not meet protocol inclusion criteria (omega-3 supplements)
Garcia-Patterson, A, Martin, E, Ubeda, J et al. (2001) Evaluation of light exercise in the treatment of gestational diabetes. Diabetes care 24(11): 2006-7	- Study design or type not relevant to this review protocol Letter describing a cross-over study
Garcia-Patterson, Apolonia, Balsells, Montserrat, Sola, Ivan et al. (2023) Impact of gestational diabetes mellitus treatment on medium/long-term outcomes after pregnancy: A systematic review and meta-analysis. Diabetic medicine : a journal of the British Diabetic Association 40(1): e14998	- Systematic review used as source of primary studies Systematic review contains with interventions not meeting the protocol inclusion criteria (insulin as needed in intervention arm only). Other studies were checked

Study	Reason
Garcia-Patterson, Apolonia, Balsells, Montserrat, Yamamoto, Jennifer M et al. (2019) Usual dietary treatment of gestational diabetes mellitus assessed after control diet in randomized controlled trials: subanalysis of a systematic review and meta-analysis. Acta diabetologica 56(2): 237-240	- Systematic review used as source of primary studies Post-hoc subanalysis of studies included in Garcia-Patterson et al 2023 which has been assessed and studies checked
Garnweidner-Holme, Lisa, Henriksen, Lena, Torheim, Liv Elin et al. (2020) Effect of the Pregnant+ Smartphone App on the Dietary Behavior of Women With Gestational Diabetes Mellitus: Secondary Analysis of a Randomized Controlled Trial. JMIR mHealth and uHealth 8(11): e18614	- No outcomes of interest Secondary study to Borgen 2019 (captured in search and assessed) with no additional outcomes of interest.
Ghasemi, F.; Vakilian, K.; Khalajinia, Z. (2021) Comparing the effect of individual counseling with counseling on social application on self-care and quality of life of women with gestational diabetes. Primary Care Diabetes 15(5): 842-847	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Gillen, Lynda J and Tapsell, Linda C (2004) Advice that includes food sources of unsaturated fat supports future risk management of gestational diabetes mellitus. Journal of the American Dietetic Association 104(12): 1863-7	- Data not reported in an extractable format or a format that can be analysed Study does not report the data for outcomes of interest.
Gillman, Matthew W, Oakey, Helena, Baghurst, Peter A et al. (2010) Effect of treatment of gestational diabetes mellitus on obesity in the next generation. Diabetes care 33(5): 964-8	- Population not relevant to this review protocol Secondary study to Crowther 2005 focusing on offspring. Original trial has been assessed and does not meet the protocol due to inappropriate intervention (pharmacological components).
Gillmer, M D, Maresh, M, Beard, R W et al. (1986) Low energy diets in the treatment of gestational diabetes. Acta endocrinologica. Supplementum 277: 44-9	- Study does not contain an intervention relevant to this review protocol Study contains pharmacological comparator of insulin therapy and does not meet protocol inclusion criteria

Study	Reason
Given, Joanne E, Bunting, Brendan P, O'Kane, Maurice J et al. (2015) Tele-Mum: A Feasibility Study for a Randomized Controlled Trial Exploring the Potential for Telemedicine in the Diabetes Care of Those with Gestational Diabetes. Diabetes technology & therapeutics 17(12): 880-8	- Study does not contain an intervention relevant to this review protocol Intervention group received blood glucose meter and blood pressure monitor both interventions are not within the scope of this review
Gomez Ribot, Dalmiro, Diaz, Esteban, Fazio, Maria Victoria et al. (2020) An extra virgin olive oil-enriched diet improves maternal, placental, and cord blood parameters in GDM pregnancies. Diabetes/metabolism research and reviews 36(8): e3349	- Study setting does not meet protocol Study not conducted in a high income country (China)
Greenawald, M.H. and Jeremiah, M.P. (1997) Management of gestational diabetes. The Journal of family practice 45(5): 377	- Study design or type not relevant to this review protocol Summary and commentary of study included in this review (Garner 1997)
Gunes Ozturk, G.; Akyildiz, D.; Karacam, Z. (2022) The impact of telehealth applications on pregnancy outcomes and costs in high-risk pregnancy: A systematic review and meta-analysis. Journal of telemedicine and telecare: 1357633x221087867	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (not randomised, inappropriate population or not from high income countries). Additional studies have been checked
Guo, H, Zhang, Y, Li, P et al. (2019) Evaluating the effects of mobile health intervention on weight management, glycemic control and pregnancy outcomes in patients with gestational diabetes mellitus. Journal of endocrinological investigation 42(6): 709-714	- Study setting does not meet protocol Study not conducted in a high income country (China)
Guo, Pingping, Chen, Dandan, Xu, Ping et al. (2023) Web-Based Interventions for Pregnant Women With Gestational Diabetes Mellitus: Systematic Review and Meta-analysis. Journal of medical Internet research 25: e36922	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (not conducted in high income countries, inappropriate pharmacological intervention, intervention focus on glucose monitoring). Additional studies were checked

Study	Reason
Guo, W.; Zhang, B.; Wang, X. (2018) Lifestyle interventions for gestational diabetes mellitus to control blood glucose: a meta-analysis of randomized studies. International Journal of Diabetes in Developing Countries 38(1): 26-35	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (not in high income countries, inappropriate pharmacological intervention). Additional studies were checked
Guo, Ying, Zhou, Ling, Sun, Bei et al. (2021) Application of online-offline integrated medical care management in patients with gestational diabetes. Ginekologia polska 92(10): 720-725	- Study setting does not meet protocol Study not conducted in a high income country (China)
Ha, Vanessa, Bonner, Ashley J, Jadoo, Jaynendr K et al. (2017) The effects of various diets on glycemic outcomes during pregnancy: A systematic review and network meta-analysis. PloS one 12(8): e0182095	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (population not gestational diabetes, study not conducted in high income country) or are included in Han 2017 Cochrane systematic review included in this review
Hajifaraji, Majid, Jahanjou, Fatemeh, Abbasalizadeh, Fatemeh et al. (2018) Effect of probiotic supplements in women with gestational diabetes mellitus on inflammation and oxidative stress biomarkers: a randomized clinical trial. Asia Pacific journal of clinical nutrition 27(3): 581-591	- Study setting does not meet protocol Study is included in Okesene-Gafa 2020 Cochrane review but is not conducted in a high income country (Iran) and therefore does not meet protocol inclusion criteria
Han, Shanshan, Crowther, Caroline A, Middleton, Philippa et al. (2013) Different types of dietary advice for women with gestational diabetes mellitus. The Cochrane database of systematic reviews: cd009275	- More recent systematic review included that covers the same topic Later version of the Cochrane systematic review by Han 2017 included in the review. Han 2017 includes all studies that were included in Han 2013
Han, Shanshan, Middleton, Philippa F, Tran, Thach S et al. (2016) Assessing use of a printed lifestyle intervention tool by women with borderline gestational diabetes and their achievement of diet and exercise	- Population not relevant to this review protocol Descriptive nested study within an RCT including women that do not meet the

Study	Reason
goals: a descriptive study. BMC pregnancy and childbirth 16: 44	protocol inclusion criteria as they have borderline gestational diabetes
HANGAARD, Stine, LAURSEN, Sisse H., UDSEN, Flemming W. et al. (2020) Telemedicine Interventions for the Management of Diabetes: A Systematic Review and Meta-Analysis...30th Medical Informatics Europe Conference. Studies in Health Technology & Informatics 270: 1403-1404	- Study design or type not relevant to this review protocol Conference abstract for a systematic review and meta-analysis on telemedicine interventions for diabetes (including gestational diabetes). Included studies references are not provided and is not yet published
Harrison, Anne L, Shields, Nora, Taylor, Nicholas F et al. (2016) Exercise improves glycaemic control in women diagnosed with gestational diabetes mellitus: a systematic review. Journal of physiotherapy 62(4): 188-96	- More recent systematic review included that covers the same topic Systematic review included studies are also included in Brown 2017 Cochrane systematic review included in this review
Hartling, Lisa, Dryden, Donna M, Guthrie, Alyssa et al. (2013) Benefits and harms of treating gestational diabetes mellitus: a systematic review and meta-analysis for the U.S. Preventive Services Task Force and the National Institutes of Health Office of Medical Applications of Research. Annals of internal medicine 159(2): 123-9	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (inappropriate study design, inappropriate population or pharmacological therapy of insulin as intervention). Additional studies have been checked
Hasain, Zubaidah, Che Roos, Nur Aishah, Rahmat, Frhana et al. (2021) Diet and Pre-Intervention Washout Modifies the Effects of Probiotics on Gestational Diabetes Mellitus: A Comprehensive Systematic Review and Meta-Analysis of Randomized Controlled Trials. Nutrients 13(9)	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
He, Xiufang, Geng, Xiaqing, Sha, Manting et al. (2022) Effect of Targeted Care plus Exercise Intervention on Blood Glucose Levels and Maternal and Newborn Outcomes in Patients with Gestational Diabetes Mellitus. Disease markers 2022: 7584936	- Study design or type not relevant to this review protocol Study has been retracted and therefore does not meet protocol inclusion criteria

Study	Reason
Henze, Meg, Burbidge, Hanna, Nathan, Elizabeth et al. (2022) The effect of bedtime snacks on fasting blood glucose levels in gestational diabetes mellitus. Diabetic medicine : a journal of the British Diabetic Association 39(3): e14718	- Study design or type not relevant to this review protocol Randomised cross-over trial design which is not considered to be appropriate for the review question
Hernandez, Teri L. (2015) 9. A Higher Complex Carbohydrate Diet in Gestational Diabetes Improves Maternal Metabolic Outcomes and Infant Adiposity: A Randomized Study. Nursing Outlook 63(1): 104-104	- Study design or type not relevant to this review protocol Abstract to randomised cross-over trial design which is not considered to be appropriate for the review question
Hernandez, Teri L, Van Pelt, Rachael E, Anderson, Molly A et al. (2014) A higher-complex carbohydrate diet in gestational diabetes mellitus achieves glucose targets and lowers postprandial lipids: a randomized crossover study. Diabetes care 37(5): 1254-62	- Study design or type not relevant to this review protocol Study was excluded by Han 2017 Cochrane review as design is randomised cross-over trial which was not considered to be appropriate for the review question
Hernandez, Teri L, Van Pelt, Rachael E, Anderson, Molly A et al. (2016) Women With Gestational Diabetes Mellitus Randomized to a Higher-Complex Carbohydrate/Low-Fat Diet Manifest Lower Adipose Tissue Insulin Resistance, Inflammation, Glucose, and Free Fatty Acids: A Pilot Study. Diabetes care 39(1): 39-42	- Study design or type not relevant to this review protocol Study was excluded by Han 2017 Cochrane review as design is randomised cross-over trial which was not considered to be appropriate for the review question
Hillyard, Medbh, Casson, Karen, Sinclair, Marlene et al. (2018) Can physical activity and dietary interventions improve maternal and foetal outcomes in women with gestational diabetes mellitus? A systematic review and meta-analysis. Evidence Based Midwifery 16(3): 76-83	- Systematic review used as source of primary studies Systematic review includes studies that don't meet the protocol inclusion criteria (not high income countries) or overlap with studies included in Han 2017 and Brown 2017 Cochrane systematic reviews included in this review
Honarvar, B., Salehi, F., Shaygani, F. et al. (2019) Opportunities and threats of electronic health in management of diabetes mellitus: An umbrella review of systematic review and meta-analysis	- Systematic review used as source of primary studies Systematic review of systematic reviews which include all diabetes populations. The

Study	Reason
studies. Shiraz E Medical Journal 20(1): e81794	four systematic reviews that include gestational diabetes (among other diabetes populations) have been checked
Horsch, Antje, Gilbert, Leah, Lanzi, Stefano et al. (2018) Improving cardiometabolic and mental health in women with gestational diabetes mellitus and their offspring: study protocol for MySweetHeart Trial, a randomised controlled trial. BMJ open 8(2): e020462	- Study design or type not relevant to this review protocol Protocol with no results yet reported
Horvath, Karl, Koch, Klaus, Jeitler, Klaus et al. (2010) Effects of treatment in women with gestational diabetes mellitus: systematic review and meta-analysis. BMJ (Clinical research ed.) 340: c1395	- Systematic review includes studies that does not meet protocol Systematic review includes studies that do not meet the protocol inclusion criteria which include pharmacological intervention. Additional studies were checked
Hu, Zhi-Geng, Tan, Rong-Shao, Jin, Di et al. (2014) A low glycemic index staple diet reduces postprandial glucose values in Asian women with gestational diabetes mellitus. Journal of investigative medicine : the official publication of the American Federation for Clinical Research 62(8): 975-9	- Study setting does not meet protocol Study not conducted in a high income country (China)
Huang, FL, Hu, HY, Zhang, SH et al. (2021) Effect of Mobile Health for Standardized Management on Women with Gestational Diabetes Mellitus. Zhongguo yi xue ke xue yuan xue bao. Acta Academiae Medicinae Sinicae 43(4): 551-557	- Study setting does not meet protocol Study not conducted in a high income country (China)
Huang, Shuyuan, Magny-Normilus, Cherlie, McMahon, Erin et al. (2022) Systematic Review of Lifestyle Interventions for Gestational Diabetes Mellitus in Pregnancy and the Postpartum Period. Journal of obstetric, gynecologic, and neonatal nursing : JOGNN 51(2): 115-125	- Systematic review used as source of primary studies Systematic review included studies that did not meet the protocol inclusion criteria(inappropriate population of women without gestational diabetes, intervention delivered in postpartum period or non randomised study design). Additional studies were checked

Study	Reason
Huang, Xiaoyi, Huang, Jingxing, Wu, Jiezhu et al. (2020) Different exercises for pregnant women with gestational diabetes: a meta-analysis of randomized controlled trials. The Journal of sports medicine and physical fitness 60(3): 464-471	- Systematic review used as source of primary studies Included studies do not meet the protocol inclusion criteria (control arm received insulin or not conducted in high income country) or overlap with included studies in Brown 2017 Cochrane systematic review included in review
Huifen, Zhao, Yaping, Xie, Meijing, Zhao et al. (2022) Effects of moderate-intensity resistance exercise on blood glucose and pregnancy outcome in patients with gestational diabetes mellitus: A randomized controlled trial. Journal of diabetes and its complications 36(5): 108186	- Study setting does not meet protocol Study not conducted in a high income country (China)
Igwesi-Chidobe, Chinonso Nwamaka, Okechi, Peace Chioma, Emmanuel, Grace Nneoma et al. (2022) Community-based non-pharmacological interventions for pregnant women with gestational diabetes mellitus: a systematic review. BMC women's health 22(1): 482	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (non randomised studies, studies not from high income countries) and include studies that overlap with Han 2017 Cochrane systematic review included in this review. Additional studies were checked
Ilic, S; Jovanovic, L; Pettitt, D J (1999) Comparison of the effect of saturated and monounsaturated fat on postprandial plasma glucose and insulin concentration in women with gestational diabetes mellitus. American journal of perinatology 16(9): 489-95	- Study design or type not relevant to this review protocol Study was excluded by Han 2017 cochrane review as design is randomised cross-over trial which was not considered to be for the review question
Iyawa, G.E.; Dansharif, A.R.; Khan, A. (2021) Mobile apps for self-management in pregnancy: a systematic review. Health and Technology 11(2): 283-294	- Systematic review used as source of primary studies Systematic review included studies not meeting the protocol inclusion criteria (population other than gestational diabetes). Studies including women with gestational diabetes were checked
Jacqueminet, S and Jannot-Lamotte, M-F (2010) Therapeutic management of	- Review article but not a systematic review

Study	Reason
gestational diabetes. Diabetes & metabolism 36(6pt2): 658-71	Article was not a systematic review and covered a range of interventions for gestational diabetes using evidence from a range of study designs
Jahanjoo, Fatemeh, Farshbaf-Khalili, Azizeh, Shakouri, Seyed Kazem et al. (2018) Maternal and Neonatal Metabolic Outcomes of Vitamin D Supplementation in Gestational Diabetes Mellitus: A Systematic Review and Meta-Analysis. Annals of nutrition & metabolism 73(2): 145-159	- Systematic review includes studies that does not meet protocol All studies included in the systematic review were not conducted in a high income country (China or Iran)
Jamilian, M., Samimi, M., Kolahdooz, F. et al. (2016) Omega-3 fatty acid supplementation affects pregnancy outcomes in gestational diabetes: A randomized, double-blind, placebo-controlled trial. Journal of Maternal-Fetal and Neonatal Medicine 29(4): 669-675	- Study does not contain an intervention relevant to this review protocol Intervention is omega-3 fatty acid supplementation which does not meet the protocol inclusion criteria
Jamilian, Mehri; Amirani, Elaheh; Asemi, Zatollah (2019) The effects of vitamin D and probiotic co-supplementation on glucose homeostasis, inflammation, oxidative stress and pregnancy outcomes in gestational diabetes: A randomized, double-blind, placebo-controlled trial. Clinical nutrition (Edinburgh, Scotland) 38(5): 2098-2105	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Jamilian, Mehri and Asemi, Zatollah (2015) The Effect of Soy Intake on Metabolic Profiles of Women With Gestational Diabetes Mellitus. The Journal of clinical endocrinology and metabolism 100(12): 4654-61	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Jiang, Ying, Qiu, Chunbo, Wang, Yuanping et al. (2022) Effect of Evidence-Based Diet Nursing on Intestinal Flora and Maternal and Infant Prognosis in Patients with Gestational Diabetes. Evidence-based Complementary & Alternative Medicine (eCAM): 1-7	- Study setting does not meet protocol Study not conducted in a high income country (China)

Study	Reason
Jie, Shen-Qiu, Liang, Xiao, Hong, Pu et al. (2015) Application of seamless care service with multidisciplinary diagnosis and treatment in patients with gestational diabetes. International journal of clinical and experimental medicine 8(9): 16688-93	- Study setting does not meet protocol Application of seamless care service with multidisciplinary diagnosis and treatment in patients with gestational diabetes.
Jin, Shixiao, Sha, Liyan, Dong, Jianli et al. (2020) Effects of Nutritional Strategies on Glucose Homeostasis in Gestational Diabetes Mellitus: A Systematic Review and Network Meta-Analysis. Journal of diabetes research 2020: 6062478	- Systematic review includes studies that does not meet protocol All included studies in the systematic review do not meet the protocol inclusion criteria as they were not conducted in high income studies
Jung, Seulgi, Kim, Yoojin, Park, Jeongok et al. (2021) Psychosocial support interventions for women with gestational diabetes mellitus: a systematic review. Korean journal of women health nursing 27(2): 75-92	- Systematic review used as source of primary studies Systematic review contains studies that do not meet protocol inclusion criteria (population with history of gestational diabetes, not high income, not randomised). Additional studies were checked
Karamali, M, Dadkhah, F, Sadrkhanlou, M et al. (2016) Effects of probiotic supplementation on glycaemic control and lipid profiles in gestational diabetes: A randomized, double-blind, placebo-controlled trial. Diabetes & metabolism 42(4): 234-41	- Study setting does not meet protocol Study is included in Okesene-Gafa 2020 Cochrane review but is not conducted in a high income country (Iran) and therefore does not meet protocol inclusion criteria
Karamali, Maryam, Nasiri, Nabiollah, Taghavi Shavazi, Naemeh et al. (2018) The Effects of Synbiotic Supplementation on Pregnancy Outcomes in Gestational Diabetes. Probiotics and antimicrobial proteins 10(3): 496-503	- Study setting does not meet protocol Study is included in Okesene-Gafa 2020 Cochrane review but is not conducted in a high income country (Iran) and therefore does not meet protocol inclusion criteria
Karlsson, T, Augustin, H, Lindqvist, M et al. (2022) Effect of the New Nordic Diet compared with usual care on glucose control in gestational diabetes mellitus: Study protocol for the randomized controlled trial intervention with new Nordic DIet in women with GestatiOnal diabetes	- Study design or type not relevant to this review protocol Protocol for iNDIGO trial that is still recruiting participants

Study	Reason
mellitus (iNDIGO). Contemporary clinical trials 115: 106706	
Keating, Niamh, Coveney, Ciara, McAuliffe, Fionnuala M et al. (2022) Aerobic or Resistance Exercise for Improved Glycaemic Control and Pregnancy Outcomes in Women with Gestational Diabetes Mellitus: A Systematic Review. International journal of environmental research and public health 19(17)	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (not conducted in high income country, inappropriate study design of conference abstract or inappropriate comparator with insulin) or overlapped with included studies in Brown 2017 Cochrane systematic review included in the review
Keely, Erin J, Malcolm, Janine C, Hadjiyannakis, Stasia et al. (2008) Prevalence of metabolic markers of insulin resistance in offspring of gestational diabetes pregnancies. Pediatric diabetes 9(1): 53-9	- Secondary publication of an included study that does not provide any additional relevant information Follow-up study of offspring to study included in Han 2017 Cochrane systematic review
Kian, Fatemeh Rahimi, Nayeri, Nahid Dehghan, Mehran, Abbas et al. (2016) Comparing the effects of face-to face traninng and booklet-based education on maternal outcoms in gestational diabetes: a randomized controlled clinical trial. Nursing Practice Today 3(2): 1-10	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Kijmanawat, Athasit, Panburana, Panyu, Reutrakul, Sirimon et al. (2019) Effects of probiotic supplements on insulin resistance in gestational diabetes mellitus: A double-blind randomized controlled trial. Journal of diabetes investigation 10(1): 163-170	- Study setting does not meet protocol Study is included in Okesene-Gafa 2020 Cochrane review but is not conducted in a high income country (Thailand) and therefore does not meet protocol inclusion criteria
Kim, Bora, Moon, Jong Youn, Shin, Jae Yong et al. (2022) Effect of smartphone app-based health care intervention for health management of high-risk mothers: a study protocol for a randomized controlled trial. Trials 23(1): 486	- Study design or type not relevant to this review protocol Protocol for trial that is not yet recruiting
Kim, H. and Kim, S. (2013) Effects of an integrated self-management program on	- Study design or type not relevant to this review protocol

Study	Reason
self-management, glycemic control, and maternal identity in women with gestational diabetes mellitus. Journal of Korean Academy of Nursing 43(1): 69-80	Study has been retracted and therefore does not meet protocol inclusion criteria
Kim, J and Chung, C (2021) [Effects of nursing intervention programs for women with gestational diabetes: a systematic review of randomized controlled trials]. Korean journal of women health nursing 27(1): 14-26	- Study not reported in English Systematic review is not published in English
Knopp, R H, Magee, M S, Raisys, V et al. (1991) Hypocaloric diets and ketogenesis in the management of obese gestational diabetic women. Journal of the American College of Nutrition 10(6): 649-67	- Review article but not a systematic review Review article on the management of gestational diabetes
Ko, JM and Lee, JK (2014) Effects of a coaching program on comprehensive lifestyle modification for women with gestational diabetes mellitus. Journal of Korean Academy of Nursing 44(6): 672-681	- Study not reported in English Full text article is not in English
Koch, K.; Horvath, K.; Siebenhofer, A. (2010) What can be expected by treatment of women with gestational diabetes? Systematic review and meta-analysis of treatment trials from 4 decades. Zeitschrift fur Allgemeinmedizin 86(78): 278-289	- Study not reported in English Full text article not in English
Koczarski, M. (2020) The Effect of Probiotic Supplementation on Glycemic Control in Women with Gestational Diabetes Mellitus: A Systematic Review. Topics in Clinical Nutrition 35(3): 270-276	- Systematic review used as source of primary studies Systematic review studies are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Kokic, I.S.; Ivanisevic, M.; Pisot, R. (2015) The role of physical activity and therapeutic exercise in the treatment of gestational diabetes mellitus. Gynaecologia et Perinatologia 24(4): 157-163	- Systematic review used as source of primary studies Includes both randomised and non randomised trials. Relevant included studies have been checked
Kolivand, Mitra, Rahimi, Mehr Ali, Keramat, Afsaneh et al. (2019) Effect of a new self-	- Study setting does not meet protocol

Study	Reason
care guide package on maternal and neonatal outcomes in gestational diabetes: A randomized control trial. Journal of diabetes 11(2): 139-147	Study not conducted in a high income country (Iran)
Kusinski, Laura C, Murphy, Helen R, De Lucia Rolfe, Emanuella et al. (2020) Dietary Intervention in Pregnant Women with Gestational Diabetes; Protocol for the DiGest Randomised Controlled Trial. Nutrients 12(4)	- Study design or type not relevant to this review protocol Protocol to DiGest trial with no published results as of yet
Kyto, Mikko, Markussen, Lisa Torsdatter, Marttinen, Pekka et al. (2022) Comprehensive self-tracking of blood glucose and lifestyle with a mobile application in the management of gestational diabetes: a study protocol for a randomised controlled trial (eMOM GDM study). BMJ open 12(11): e066292	- Study design or type not relevant to this review protocol Protocol for eMOMGDM trial active and not yet recruiting
Lagowska, Karolina, Malinowska, Anna M, Zawieja, Bogna et al. (2020) Improvement of glucose metabolism in pregnant women through probiotic supplementation depends on gestational diabetes status: meta-analysis. Scientific reports 10(1): 17796	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (intervention not of interest, not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Landon, M B, Thom, E, Spong, C Y et al. (2002) A planned randomized clinical trial of treatment for mild gestational diabetes mellitus. The journal of maternal-foetal & neonatal medicine : the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians 11(4): 226-31	- Study design or type not relevant to this review protocol Protocol to study already captured in search Landon 2009
Landon, Mark B, Spong, Catherine Y, Thom, Elizabeth et al. (2009) A multicenter, randomized trial of treatment for mild gestational diabetes. The New England journal of medicine 361(14): 1339-48	- Study does not contain an intervention relevant to this review protocol Component of intervention arm included pharmacological intervention of insulin if required by the participant.

Study	Reason
Landon, MB (2008) A prospective multicenter randomized treatment trial of mild gestational diabetes (GDM). American journal of obstetrics and gynecology 199(6suppl1): 2	- Study design or type not relevant to this review protocol Abstract to study captured in search Landon 2009
Laredo-Aguilera, Jose Alberto, Gallardo-Bravo, Maria, Rabanales-Sotos, Joseba Aingerun et al. (2020) Physical Activity Programs during Pregnancy Are Effective for the Control of Gestational Diabetes Mellitus. International journal of environmental research and public health 17(17)	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (not randomised, not from high income countries). Additional studies have been checked
Latino, Cathy, Gianatti, Emily J, Mehta, Shailender et al. (2022) Does a high dietary intake of resistant starch affect glycaemic control and alter the gut microbiome in women with gestational diabetes? A randomised control trial protocol. BMC pregnancy and childbirth 22(1): 46	- Study design or type not relevant to this review protocol Protocol of trial that is still recruiting with no results available
Lau, Ying, Htun, Tha Pyai, Wong, Suei Nee et al. (2016) Efficacy of Internet-Based Self-Monitoring Interventions on Maternal and Neonatal Outcomes in Perinatal Diabetic Women: A Systematic Review and Meta-Analysis. Journal of medical Internet research 18(8): e220	- Systematic review includes studies that does not meet protocol Systematic review included studies with mixed diabetes populations that do not report data separately for gestational diabetes, non-randomised clinical trials, intervention delivered in postnatal period or focus on glucose monitoring. Additional studies have been checked
Laursen, Sisse H, Boel, Lise, Udsen, Flemming W et al. (2022) Effectiveness of Telemedicine in Managing Diabetes in Pregnancy: A Systematic Review and Meta-Analysis. Journal of diabetes science and technology: 19322968221094626	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (population not gestational diabetes, postpartum outcomes only, intervention focused on blood glucose monitoring or not from high income countries). Additional studies have been checked
Leblalta, Boutheina, Kebaili, Hanane, Sim, Ruth et al. (2022) Digital health	- Systematic review used as source of primary studies

Study	Reason
interventions for gestational diabetes mellitus: A systematic review and meta-analysis of randomised controlled trials. PLOS digital health 1(2): e0000015	Systematic review includes studies that do not meet the protocol inclusion criteria (not conducted in high income countries, inappropriate pharmacological intervention, intervention focus on glucose monitoring). Additional studies were checked
Lemelin, A., Pare, G., Bernard, S. et al. (2019) Demonstrated Cost-effectiveness of a Telehomecare Program for Gestational Diabetes Mellitus Management. Diabetes technology & therapeutics	- Study does not contain an intervention relevant to this review protocol The study focuses on glucose monitoring which is outside the remit of this review
Li, Dandan, Cai, Zixin, Pan, Zhenhong et al. (2021) The effects of vitamin and mineral supplementation on women with gestational diabetes mellitus. BMC endocrine disorders 21(1): 106	- Systematic review includes studies that does not meet protocol Systematic review included studies with interventions that do not meet protocol inclusion criteria. Relevant studies were checked and did not meet protocol as they were not conducted in high income countries
Li, H., Lin, C., Duan, X. et al. (2017) The effect of disease knowledge training on pregnancy outcome in gestational diabetes. Biomedical Research (India) 28(22): 10128-10131	- Study setting does not meet protocol Study not conducted in a high income country (China)
Li, J, Liu, J, Zhang, C et al. (2021) Effects of lifestyle intervention of maternal gestational diabetes mellitus on offspring growth pattern before two years of age. Diabetes care 44(3): e42-e44	- Study setting does not meet protocol Study not conducted in a high income country (China)
Li, Q. and Xing, B. (2016) A phytosterol-enriched spread improves lipid profile and insulin resistance of women with gestational diabetes mellitus: A randomized, placebo-controlled double-blind clinical trial. Diabetes Technology and Therapeutics 18(8): 499-504	- Study setting does not meet protocol Study not conducted in a high income country (China)
Li, Su-Ya, Ouyang, Yan-Qiong, Qiao, Jia et al. (2020) Technology-supported lifestyle interventions to improve maternal-foetal	- Systematic review used as source of primary studies

Study	Reason
outcomes in women with gestational diabetes mellitus: A meta-analysis. Midwifery 85: 102689	Systematic review includes studies that do not meet the protocol inclusion criteria (not from high income countries, the study focuses on glucose monitoring). Additional studies have been checked
Li, Suhua, Gan, Yanqiong, Chen, Min et al. (2020) Effects of the Dietary Approaches to Stop Hypertension (DASH) on Pregnancy/Neonatal Outcomes and Maternal Glycemic Control: A Systematic Review and Meta-analysis of Randomized Clinical Trials. Complementary therapies in medicine 54: 102551	- Systematic review includes studies that does not meet protocol The systematic review includes studies that are not conducted in high income countries or included a population that is not gestational diabetes
Li, Xiaoyan, Luo, Rong, Qiao, Binbin et al. (2022) Exercise Intervention Improves Blood Glucose Levels and Adverse Pregnancy Outcomes in GDM Patients: A Meta-Analysis. Computational and mathematical methods in medicine 2022: 9287737	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (not conducted in high income study or inappropriate population) or are included in Brown 2017 Cochrane systematic review. Additional studies have been checked
Lin, Qiulin, Zhang, Zhiqiang, Meng, Qingchong et al. (2023) Effects of different dietary patterns during pregnancy on birth outcomes and glucose parameters in women with gestational diabetes mellitus: A systematic review and meta-analysis. Primary care diabetes	- Systematic review used as source of primary studies Systematic review included studies that did not meet the protocol inclusion criteria (inappropriate pharmacological intervention, non high income countries, inappropriate study design of non-randomised or randomised crossover trial) or overlapped with included studies in Han 2017 Cochrane systematic review. Additional studies were checked
Lindsay, Karen L, Brennan, Lorraine, Kennelly, Maria A et al. (2015) Impact of probiotics in women with gestational diabetes mellitus on metabolic health: a randomized controlled trial. American journal of obstetrics and gynecology 212(4): 496e1-11	- Population not relevant to this review protocol 51% of the included population were diagnosed with impaired glucose tolerance which do not meet the protocol population criteria. Outcomes are not reported separately for women with gestational diabetes.

Study	Reason
Liu, J.; Xie, X.; Guo, Y. (2017) Effects of health education intervention at gestation period on pregnancy outcome of diabetes mellitus patients. Biomedical Research (India) 28(18): 7950-7954	- Study setting does not meet protocol Study not conducted in a high income country (China)
Long, Mei and Zhang, Xiangchun (2021) The safety and feasibility of comprehensive nutrition care in pregnant women with gestational diabetes mellitus: A protocol for systematic review and meta-analysis. Medicine 100(18): e25505	- study protocol Protocol for systematic review and meta-analysis
Louie, Jimmy Chun Yu, Markovic, Tania P, Ross, Glynis P et al. (2015) Effect of a low glycaemic index diet in gestational diabetes mellitus on post-natal outcomes after 3 months of birth: a pilot follow-up study. Maternal & child nutrition 11(3): 409-14	- Secondary publication of an included study that does not provide any additional relevant information 3 month postpartum follow-up study to study included in Han 2017 Cochrane systematic review (Louie 2011)
Lu, Chao; Zhao, Chenchen; Qu, Guiyu (2018) A meta - analysis of influence of diet and exercise interventions on blood glucose control and pregnancy outcomes in patients with gestational diabetes mellitus. Chinese Nursing Research 32(17): 2753-2758	- Study not reported in English Full text article is not in English
Luo, Xuanhong; Huang, Xiuxian; Deng, Yingying (2015) Influence of Orem self-care model on birth outcomes of gestational diabetes mellitus patients. Chinese nursing research 29(6a): 1954-1956	- Study not reported in English Full text not in English
Lv, Shaofang, Yu, Shanlan, Chi, Rongxiang et al. (2019) Effects of nutritional nursing intervention based on glycemic load for patient with gestational diabetes mellitus. Ginekologia polska 90(1): 46-49	- Study setting does not meet protocol Study not conducted in a high income country (China)
Mahdizade Ari, Marzie, Teymouri, Samane, Fazlalian, Tayebeh et al. (2022) The effect of probiotics on gestational diabetes and its complications in pregnant mother and newborn: A systematic review and meta-analysis during 2010-2020. Journal of clinical laboratory analysis 36(4): e24326	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (not all studies included population of gestational diabetes, not high income) or

Study	Reason
	are included in Okesene-Gafa 2020 Cochrane systematic review included in this review. All studies were checked
Martis, Ruth, Crowther, Caroline A, Shepherd, Emily et al. (2018) Treatments for women with gestational diabetes mellitus: an overview of Cochrane systematic reviews. The Cochrane database of systematic reviews 8: cd012327	- Study design or type not relevant to this review protocol Overview of Cochrane systematic reviews which include Han 2017, Brown 2017 and Okesene-Gafa 2020. Other systematic reviews have been checked and were not relevant due to inappropriate population or interventions
McAuley, Emma, Fleck, Olwen, Cassidy, Laura et al. (2023) A pragmatic lifestyle intervention for overweight and obese women with gestational diabetes mellitus (PAIGE2): A parallel arm, multicenter randomized controlled trial study protocol. Frontiers in clinical diabetes and healthcare 4: 1118509	- Study design or type not relevant to this review protocol Protocol of trial focusing on a postnatal intervention. The pilot study to this trial was checked and also conducted in the postnatal period
McParlin, C, Hodson, K, Barnes, A C et al. (2019) Views, experience and adherence among pregnant women with gestational diabetes participating in a weight loss study (WELLBABE). Diabetic medicine : a journal of the British Diabetic Association 36(2): 195-202	- Study design or type not relevant to this review protocol Secondary qualitative study to the WELLBABE study which is not randomised
Meng, Y. (2021) Effects of comprehensive nursing intervention on maternal and infant outcomes for gestational diabetes mellitus patients. International Journal of Diabetes in Developing Countries 41(4): 650-656	- Study setting does not meet protocol Study not conducted in a high income country (China)
Ming, Wai-Kit, Mackillop, Lucy H, Farmer, Andrew J et al. (2016) Telemedicine Technologies for Diabetes in Pregnancy: A Systematic Review and Meta-Analysis. Journal of medical Internet research 18(11): e290	- Systematic review includes studies that does not meet protocol Systematic review includes studies that do not meet the protocol inclusion criteria (population not gestational diabetes, focus of intervention is glucose monitoring). Additional studies have been checked

Study	Reason
Miremberg, Hadas, Ben-Ari, Tal, Betzer, Tal et al. (2018) The impact of a daily smartphone-based feedback system among women with gestational diabetes on compliance, glycemic control, satisfaction, and pregnancy outcome: a randomized controlled trial. American journal of obstetrics and gynecology 218(4): 453e1-453e7	- Study does not contain an intervention relevant to this review protocol The study focuses on glucose monitoring which is outside the remit of this review
Mirfeizi, Mani, Tourzani, Zahra Mehdizadeh, Jafarabadi, Mohammad Asghari et al. (2017) Health Education in Gestational Diabetes Mellitus and Quality of Life. Journal of Midwifery & Reproductive Health 5(4): 1066-1074	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Mitanchez, Delphine; Ciangura, Cecile; Jacqueminet, Sophie (2020) How Can Maternal Lifestyle Interventions Modify the Effects of Gestational Diabetes in the Neonate and the Offspring? A Systematic Review of Meta-Analyses. Nutrients 12(2)	- Systematic review used as source of primary studies Systematic review includes other systematic reviews which include inappropriate populations such as women without gestational diabetes. Relevant systematic reviews and studies were checked
Miyazaki, Celine, Tanase-Nakao, Kanako, Arata, Naoko et al. (2017) Nonpharmacological interventions to prevent type 2 diabetes in women diagnosed with gestational diabetes mellitus: a systematic overview. Diabetology international 8(2): 160-180	- Systematic review used as source of primary studies Systematic review includes systematic reviews that have been checked and/or included randomised studies do not meet protocol inclusion criteria (inappropriate population, not high income country setting). Additional studies have been checked
Mohd Yusof, Barakatun-Nisak, Firouzi, Somayyeh, Mohd Shariff, Zalilah et al. (2014) Weighing the evidence of low glycemic index dietary intervention for the management of gestational diabetes mellitus: an Asian perspective. International journal of food sciences and nutrition 65(2): 144-50	- More recent systematic review included that covers the same topic Systematic review includes three studies which are also included in Han 2017 Cochrane systematic review

Study	Reason
Mohebbi, Bahram, Tol, Azar, Sadeghi, Roya et al. (2019) Self-management Intervention Program Based on the Health Belief Model (HBM) among Women with Gestational Diabetes Mellitus: A Quazi-Experimental Study. Archives of Iranian medicine 22(4): 168-173	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Mojibian, M, Soheilykhah, S, Zadeh, MAF et al. (2015) The effects of vitamin D supplementation on maternal and neonatal outcome: a randomized clinical trial. International journal of reproductive biomedicine 13(11): 687-696	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Moreira Schmalfuss, Joice, Alende Prates, Lisie, de Azevedo, Melissa et al. (2014) GESTATIONAL DIABETES MELLITUS AND THE IMPLICATIONS FOR THE NURSING CARE IN THE PRENATAL PERIOD. Cogitare Enfermagem 19(4): 754-761	- Review article but not a systematic review Article is a literature review and not a systematic review
Mottola, Michelle F, Davenport, Margie H, Ruchat, Stephanie-May et al. (2018) Ndegree 367-2019 Lignes Directrices Canadiennes Sur L'activite Physique Durant La Grossesse. Journal of obstetrics and gynaecology Canada : JOGC = Journal d'obstetrique et gynecologie du Canada : JOGC 40(11): 1538-1548	- Study not reported in English Full text article is not in English
Movaghar, Rouhina, Farshbaf-Khalili, Azizeh, Hajizade, Khadijeh et al. (2022) The Effect of Probiotics or Synbiotics on the Hypertensive Disorders of Pregnant Women with Gestational Diabetes: A Systematic Review and Meta-analysis. Journal of caring sciences 11(2): 94-104	- Systematic review used as source of primary studies Systematic review contains five studies which all overlap with studies included in Okesene-Gafa 2020 Cochrane systematic review
Mu, Jinhao, Guo, Xian, Zhou, Yanbing et al. (2023) The Effects of Probiotics/Synbiotics on Glucose and Lipid Metabolism in Women with Gestational Diabetes Mellitus: A Meta-Analysis of Randomized Controlled Trials. Nutrients 15(6)	- Systematic review used as source of primary studies Includes studies from Okesene-gafa 2020 Cochrane systematic review with all other studies not conducted in high income countries

Study	Reason
Munda, Ana, Mlinaric, Zala, Jakin, Petra Ana et al. (2023) Effectiveness of a comprehensive telemedicine intervention replacing standard care in gestational diabetes: a randomized controlled trial. Acta diabetologica	- Study does not contain an intervention relevant to this review protocol The study focuses on glucose monitoring which is outside the remit of this review
Nabhani, Zohoor, Hezaveh, Seyed Jamal Ghaemmaghami, Razmpoosh, Elham et al. (2018) The effects of synbiotic supplementation on insulin resistance/sensitivity, lipid profile and total antioxidant capacity in women with gestational diabetes mellitus: A randomized double blind placebo controlled clinical trial. Diabetes research and clinical practice 138: 149-157	- Study setting does not meet protocol Study is included in Okesene-Gafa 2020 Cochrane review but is not conducted in a high income country (Iran) and therefore does not meet protocol inclusion criteria
Namazi, Nazli, Esmaeili, Shahnaz, Ahmadikhatir, Shonaz et al. (2021) Nutrition and Diet Therapy in Diabetes Mellitus: A Roadmap based on available evidence. Journal of diabetes and metabolic disorders 20(2): 1913-1918	- Review article but not a systematic review Article is not a systematic review. Included studies have been checked
Ney, D; Hollingsworth, D R; Cousins, L (1982) Decreased insulin requirement and improved control of diabetes in pregnant women given a high-carbohydrate, high-fiber, low-fat diet. Diabetes care 5(5): 529-33	- Population not relevant to this review protocol Population is type 1 or 2 insulin dependent diabetes.
Nolan, C J (1984) Improved glucose tolerance in gestational diabetic women on a low fat, high unrefined carbohydrate diet. The Australian & New Zealand journal of obstetrics & gynaecology 24(3): 174-7	- Study design or type not relevant to this review protocol Randomised cross-over trial design which is not considered to be appropriate for the review question
North, Sylvia, Crofts, Catherine, Thoma, Christian et al. (2022) The role of maternal diet on offspring hyperinsulinaemia and adiposity after birth: a systematic review of randomised controlled trials. Journal of developmental origins of health and disease 13(5): 527-540	- No outcomes of interest The systematic review did not report any outcomes of interest

Study	Reason
O'Sullivan, JB (1975) Prospective study of gestational diabetes and its treatment. Carbohydrate metabolism in pregnancy and the newborn: 195-204	- Study does not contain an intervention relevant to this review protocol Intervention contains pharmacological therapy of insulin and does not meet the protocol inclusion criteria
Ojo, O., Weldon, S.M., Thompson, T. et al. (2019) The effect of vitamin d supplementation on glycaemic control in women with gestational diabetes mellitus: A systematic review and meta-analysis of randomised controlled trials. International Journal of Environmental Research and Public Health 16(10): 1716	- Systematic review includes studies that does not meet protocol Systematic review only contains studies from non high income countries (Iran or China)
Okesene-Gafa, K.A.M., Brown, J., Mccowan, L. et al. (2018) Probiotics for treating women with gestational diabetes for improving maternal and foetal health and well-being. Cochrane Database of Systematic Reviews 2018(2): cd012970	- Study design or type not relevant to this review protocol Protocol to included Cochrane systematic review by Okesene-Gafa 2020
Okesene-Gafa, Karaponi Am, Moore, Abigail E, Jordan, Vanessa et al. (2020) Probiotic treatment for women with gestational diabetes to improve maternal and infant health and well-being. The Cochrane database of systematic reviews 6: cd012970	- Systematic review includes studies that does not meet protocol Cochrane systematic review does not include any studies that meet the protocol due to studies not from high income countries (8/9 studies) or includes a mixed population and does not report outcomes separately for women with gestational diabetes (1/9 studies; Lindsay 2015).
Palatnik, Anna, Mele, Lisa, Landon, Mark B et al. (2015) Timing of treatment initiation for mild gestational diabetes mellitus and perinatal outcomes. American journal of obstetrics and gynecology 213(4): 560e1-8	- Study does not contain an intervention relevant to this review protocol Secondary study to Landon 2009 which was excluded due to intervention not meeting protocol inclusion criteria
Pan, Jiajia, Pan, Qiangwei, Chen, Yumei et al. (2019) Efficacy of probiotic supplement for gestational diabetes mellitus: a systematic review and meta-analysis. The journal of maternal-foetal & neonatal medicine : the official journal of the European Association of Perinatal	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (population at risk of gestational diabetes, not high income) or are included in

Study	Reason
Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians 32(2): 317-323	Okesene-Gafa 2020 Cochrane systematic review included in this review
Pan, Y.-Q., Zheng, Q.-X., Jiang, X.-M. et al. (2021) Probiotic Supplements Improve Blood Glucose and Insulin Resistance/Sensitivity among Healthy and GDM Pregnant Women: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Evidence-based Complementary and Alternative Medicine 2021: 9830200	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (population other than gestational diabetes, not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Parastou, P, Hossein, S, Ali, M et al. (2017) Effect of Physical Activity Training on Fasting Blood Sugar in Women with Gestational Diabetes. Journal of diabetic nursing 5(1): 1-9	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Park, Seo Jin and Lee, Jina (2020) The effects of health care programs for gestational diabetes mellitus in South Korea: a systematic review. Korean journal of women health nursing 26(4): 274-284	- Systematic review includes studies that does not meet protocol Included studies did not meet the protocol inclusion criteria as they were not randomised
Payne, Ellen, Palmer, Gwendolyn, Rollo, Megan et al. (2022) Rural healthcare delivery and maternal and infant outcomes for diabetes in pregnancy: A systematic review. Nutrition & Dietetics 79(1): 48-58	- Systematic review used as source of primary studies Systematic review did not include randomised controlled studies and was not specific to gestational diabetes
Peng, Tzu-Rong; Wu, Ta-Wei; Chao, You-Chen (2018) Effect of Probiotics on the Glucose Levels of Pregnant Women: A Meta-Analysis of Randomized Controlled Trials. Medicina (Kaunas, Lithuania) 54(5)	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (population at risk of gestational diabetes, not intervention of interest, not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Perez, Alberly, Alos, Victor A, Scanlan, Adam et al. (2015) The rationale, design,	- Population not relevant to this review protocol

Study	Reason
and baseline characteristics of PREVENT-DM: A community-based comparative effectiveness trial of lifestyle intervention and metformin among Latinas with prediabetes. Contemporary clinical trials 45(ptb): 320-327	Includes women with pre-diabetes. Paper reports rationale, design, and baseline characteristics of PREVENT-DM study. The results were reported in O'Brien 2017 which was checked and excluded.
Perez-Ferre, N., Galindo, M., Fernandez, M.D. et al. (2010) A Telemedicine system based on Internet and short message service as a new approach in the follow-up of patients with gestational diabetes. Diabetes Research and Clinical Practice 87(2): e15-e17	- Duplicate reference Duplicate. Brief report to full study from international journal of endocrinology captured in our search.
Perez-Ferre, Natalia, Galindo, Mercedes, Fernandez, M Dolores et al. (2010) The outcomes of gestational diabetes mellitus after a telecare approach are not inferior to traditional outpatient clinic visits. International journal of endocrinology 2010: 386941	- Study does not contain an intervention relevant to this review protocol The study focuses on glucose monitoring which is outside the remit of this review
Perichart-Perera, Otilia, Balas-Nakash, Margie, Rodriguez-Cano, Ameyalli et al. (2012) Low Glycemic Index Carbohydrates versus All Types of Carbohydrates for Treating Diabetes in Pregnancy: A Randomized Clinical Trial to Evaluate the Effect of Glycemic Control. International journal of endocrinology 2012: 296017	- Study setting does not meet protocol Study is included in Han 2017 Cochrane review but is not conducted in a high income country (Mexico) and therefore does not meet protocol inclusion criteria
Phillips, Julie K, Skelly, Joan M, Roberts, Lorinda M et al. (2019) Combined financial incentives and behavioral weight management to enhance adherence with gestational weight gain guidelines: a randomized controlled trial. American journal of obstetrics & gynecology MFM 1(1): 42-49	- Population not relevant to this review protocol Population is not women with gestational diabetes and therefore does not meet the protocol inclusion criteria
Poolsup, Nalinee; Suksomboon, Naeti; Amin, Muhammad (2014) Effect of treatment of gestational diabetes mellitus: a systematic review and meta-analysis. PloS one 9(3): e92485	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (study not conducted in high income country or pharmacological therapy of

Study	Reason
	insulin as intervention). Additional studies have been checked
Qi, S. and Dong, Y. (2022) Effect of Multidisciplinary Team Continuous Nursing on Glucose and Lipid Metabolism, Pregnancy Outcome, and Neonatal Immune Function in Gestational Diabetes Mellitus. Disease Markers 2022: 7285639	- Study setting does not meet protocol Study not conducted in a high income country (China)
Rasekaba, Tshepo M, Furler, John, Blackberry, Irene et al. (2015) Telemedicine interventions for gestational diabetes mellitus: A systematic review and meta-analysis. Diabetes research and clinical practice 110(1): 1-9	- Systematic review includes studies that does not meet protocol Systematic review includes studies that do not meet the protocol inclusion criteria as they focus on glucose monitoring which is outside the remit of this review
Rasekaba, Tshepo M, Furler, John, Young, Doris et al. (2018) Using technology to support care in gestational diabetes mellitus: Quantitative outcomes of an exploratory randomised control trial of adjunct telemedicine for gestational diabetes mellitus (TeleGDM). Diabetes research and clinical practice 142: 276-285	- Population not relevant to this review protocol Only women already taking insulin for gestational diabetes were included
Rasmussen, Louise, Christensen, Maria Lund, Poulsen, Charlotte Wolff et al. (2020) Effect of High Versus Low Carbohydrate Intake in the Morning on Glycemic Variability and Glycemic Control Measured by Continuous Blood Glucose Monitoring in Women with Gestational Diabetes Mellitus-A Randomized Crossover Study. Nutrients 12(2)	- Study design or type not relevant to this review protocol Randomised cross-over trial design which is not considered to be appropriate for the review question
Reader, Diane, Splett, Patricia, Gunderson, Erica P et al. (2006) Impact of gestational diabetes mellitus nutrition practice guidelines implemented by registered dietitians on pregnancy outcomes. Journal of the American Dietetic Association 106(9): 1426-33	- Study does not contain an intervention relevant to this review protocol Component of intervention arm included pharmacological intervention of insulin if required by the participant
Reece, E A, Hagay, Z, Caseria, D et al. (1993) Do fiber-enriched diabetic diets have	- Study design or type not relevant to this review protocol

Study	Reason
glucose-lowering effects in pregnancy?. American journal of perinatology 10(4): 272-4	Study design is not randomised and therefore does not meet protocol inclusion criteria
Rodrigues, Meline Rossetto Kron, Lima, Silvana Andrea Molina, Mazeto, Glaucia Maria Ferreira da Silvia et al. (2019) Efficacy of vitamin D supplementation in gestational diabetes mellitus: Systematic review and meta-analysis of randomized trials. PloS one 14(3): e0213006	- Systematic review includes studies that does not meet protocol Systematic review only contains studies from non high income countries (Iran or China)
Saha, Sumanta (2022) Comparative effectiveness of adjunct non-pharmacological interventions on maternal and neonatal outcomes in gestational diabetes mellitus patients: A systematic review and network meta-analysis protocol of randomized controlled trials. PloS one 17(1): e0263336	- Study design or type not relevant to this review protocol Protocol for a systematic review which is ongoing
Saha, Sumanta and Saha, Sujata (2021) Changes in anthropometric and blood 25-hydroxyvitamin D measurements in antenatal vitamin supplemented gestational diabetes mellitus patients: a systematic review and meta-analysis of randomized controlled trials. Journal of the Turkish German Gynecological Association 22(3): 217-234	- Systematic review includes studies that does not meet protocol Systematic review only contains studies from non high income countries (Iran or China)
Sahhaf Ebrahimi, Farnaz, Homayouni Rad, Aziz, Mosen, Metanat et al. (2019) Effect of L. acidophilus and B. lactis on blood glucose in women with gestational diabetes mellitus: a randomized placebo-controlled trial. Diabetology & metabolic syndrome 11: 75	- Study setting does not meet protocol Study not conducted in a high income country (Iran)
Salazar, FFJ, De Jesus Bastidas Tello, G, Carrera, JEJ et al. (2022) EFFECT OF TREATMENT OF GESTATIONAL DIABETES MELLITUS ON PREGNANCY OUTCOMES. Journal of pharmaceutical negative results 13: 2973-2980	- Full text paper not available Unable to locate full text article

Study	Reason
Saleh, Langeza, Schrier, Nicole L, Bruins, Maaike J et al. (2018) Effect of oral protein hydrolysate on glucose control in patients with gestational diabetes. Clinical nutrition (Edinburgh, Scotland) 37(3): 878-883	- Study does not contain an intervention relevant to this review protocol Specific dietary intervention of oral protein hydrolysate does not meet the protocol listed diet interventions of interest
Sanpawithayakul, Kanokporn, Kaewprasert, Natthapon, Tantiyavarong, Pichaya et al. (2023) Effects of the Consumption of Low to Medium Glycemic Index-based Rice on the Rate of Insulin Initiation in Patients with Gestational Diabetes: A Triple-blind, Randomized, Controlled Trial. Clinical therapeutics 45(4): 347-353	- Study setting does not meet protocol Study not conducted in a high income country (Thailand)
Sarathi, V., Kolly, A., Chaithanya, H.B. et al. (2016) Effect of soya based protein rich diet on glycaemic parameters and thyroid function tests in women with gestational diabetes mellitus. Romanian Journal of Diabetes, Nutrition and Metabolic Diseases 23(2): 201-208	- Study setting does not meet protocol Study not conducted in a high income country (India)
Simmons, David, Immanuel, Jincy, Hague, William M et al. (2023) Treatment of Gestational Diabetes Mellitus Diagnosed Early in Pregnancy. The New England journal of medicine	- Study does not contain an intervention relevant to this review protocol Intervention focus is on immediate compared to delayed or no treatment for gestational diabetes. Both arms undergo standard care and therefore does not meet the protocol inclusion criteria. Both arms also contain "decoy" women without gestational diabetes to mask allocation
Simsek-Cetinkaya, S. and Koc, G. (2022) Effects of a smartphone-based nursing counseling and feedback system for women with gestational diabetes on compliance, glycemic control, and satisfaction: a randomized controlled study. International Journal of Diabetes in Developing Countries	- Study setting does not meet protocol Study not conducted in a high income country (Turkey)
Smits, MW; Paulk, TH; Kee, CC (1995) Assessing the impact of an outpatient education program for patients with	- Study design or type not relevant to this review protocol

Study	Reason
gestational diabetes. Diabetes educator 21(2): 129-134	Study design does not meet protocol inclusion criteria (retrospective analysis of non randomised intervention)
Stevinson, C (2013) Promising evidence for yoga in preventing pregnancy complications. Focus on alternative and complementary therapies 18(3): 162-163	- Study design or type not relevant to this review protocol Commentary on study Rakhshani 2012 that is captured in search and does not meet protocol eligibility criteria (ineligible population high risk not gestational diabetes)
Sugino, Kameron Y, Hernandez, Teri L, Barbour, Linda A et al. (2022) A maternal higher-complex carbohydrate diet increases bifidobacteria and alters early life acquisition of the infant microbiome in women with gestational diabetes mellitus. Frontiers in endocrinology 13: 921464	- No outcomes of interest Secondary study with no relevant outcomes based on a larger randomised trial (Hernandez 2020) which has been checked and is only reported as a conference abstract
Sun, Jihan, Wang, Jinjing, Ma, Wenqing et al. (2022) Effects of Additional Dietary Fiber Supplements on Pregnant Women with Gestational Diabetes: A Systematic Review and Meta-Analysis of Randomized Controlled Studies. Nutrients 14(21)	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (not in English or not in high income countries)
Sung, Ji-Hee, Lee, Da Young, Min, Kyoung Pil et al. (2019) Peripartum Management of Gestational Diabetes Using a Digital Health Care Service: A Pilot, Randomized Controlled Study. Clinical therapeutics 41(11): 2426-2434	- Study does not contain an intervention relevant to this review protocol Sung 2019: Glucose monitoring was a feature of the intervention with the intervention group receiving a blood glucometer and specific training on this. This intervention is outside of the scope of the review
Surendran, Shilpa, Lim, Chang Siang, Koh, Gerald Choon Huat et al. (2021) Women's Usage Behavior and Perceived Usefulness with Using a Mobile Health Application for Gestational Diabetes Mellitus: Mixed-Methods Study. International journal of environmental research and public health 18(12)	- Study design or type not relevant to this review protocol Secondary study using the intervention arm only from Yew 2021 (captured in search and assessed)

Study	Reason
Taghiof, Hamed; Rezai, Shadi; Henderson, Cassandra E (2015) Effect of an Exercise Intervention on Gestational Diabetes Mellitus: A Randomized Controlled Trial. Obstetrics and gynecology 126(3): 676	- Study design or type not relevant to this review protocol Letter about study assessed which does not meet protocol inclusion criteria (outcome is gestational diabetes)
Tan, Yingyao, Huang, Fangying, Wang, Yan et al. (2023) Effects of Exercise Intervention Based on Self-efficacy Theory on Pregnant Women with Gestational Diabetes Mellitus. Zeitschrift fur Geburtshilfe und Neonatologie	- Study setting does not meet protocol Study not conducted in a high income country (China)
Taylor, Bonnie L, Woodfall, Georgia E, Sheedy, Katherine E et al. (2017) Effect of Probiotics on Metabolic Outcomes in Pregnant Women with Gestational Diabetes: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Nutrients 9(5)	- More recent systematic review included that covers the same topic Systematic review contains studies that either do not meet protocol inclusion criteria (not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Thomaz de Lima, Helaine, Lopes Rosado, Eliane, Ribeiro Neves, Paulo Augusto et al. (2013) Systematic review; Nutritional therapy in gestational diabetes mellitus. Nutricion hospitalaria 28(6): 1806-14	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (provide pharmacological therapy of insulin as intervention) or are already included in Han 2017 Cochrane systematic review included in this review. Additional studies were checked
Trout, Kimberly K, Compher, Charlene W, Dolin, Cara et al. (2022) Increased Protein with Decreased Carbohydrate Intake Reduces Postprandial Blood Glucose Levels in Women with Gestational Diabetes: The iPRO Study. Women's health reports (New Rochelle, N.Y.) 3(1): 728-739	- Study design or type not relevant to this review protocol Randomised cross-over trial design which is not considered to be appropriate for the review question
Tsirou, Efrosini, Grammatikopoulou, Maria G, Nigdelis, Meletios P et al. (2021) TIMER: A Clinical Study of Energy Restriction in Women with Gestational Diabetes Mellitus. Nutrients 13(7)	- Study design or type not relevant to this review protocol Non randomised study design

Study	Reason
Ural, Asli and Kizilkaya Beji, Nezihe (2021) The effect of health-promoting lifestyle education program provided to women with gestational diabetes mellitus on maternal and neonatal health: a randomized controlled trial. Psychology, health & medicine 26(6): 657-670	- Study setting does not meet protocol Study not conducted in a high income country (Turkey)
Varner, Michael W, Rice, Madeline Murguia, Landon, Mark B et al. (2017) Pregnancies After the Diagnosis of Mild Gestational Diabetes Mellitus and Risk of Cardiometabolic Disorders. Obstetrics and gynecology 129(2): 273-280	- Study does not contain an intervention relevant to this review protocol Secondary observational follow-up study to Landon 2009 which has been excluded due to inappropriate intervention
Viana, Luciana Vercoza; Gross, Jorge Luiz; Azevedo, Mirela Jobim (2014) Dietary intervention in patients with gestational diabetes mellitus: a systematic review and meta-analysis of randomized clinical trials on maternal and newborn outcomes. Diabetes care 37(12): 3345-55	- More recent systematic review included that covers the same topic Included studies in the systematic review are included in Han 2017 Cochrane systematic review in this review
Walkinshaw, S A (2007) WITHDRAWN: Dietary regulation for 'gestational diabetes'. The Cochrane database of systematic reviews: cd000070	- More recent systematic review included that covers the same topic Cochrane review that is withdrawn as it is currently published in an updated Cochrane review captured by our search (Alwan 2009)
Walkinshaw, S A (2000) Dietary regulation for 'gestational diabetes'. The Cochrane database of systematic reviews: cd000070	- More recent systematic review included that covers the same topic Cochrane review is withdrawn as later versions have been published and have been assessed in this review.
Wan, C.S., Nankervis, A., Teede, H. et al. (2019) Dietary intervention strategies for ethnic Chinese women with gestational diabetes mellitus: A systematic review and meta-analysis. Nutrition & dietetics: the journal of the Dietitians Association of Australia 76(2): 211-232	- Systematic review includes studies that does not meet protocol Systematic review only includes studies that are not conducted in a high income country (China)

Study	Reason
Wang, Chun-Chi, Tung, Yu-Tang, Chang, Hua-Ching et al. (2020) Effect of Probiotic Supplementation on Newborn Birth Weight for Mother with Gestational Diabetes Mellitus or Overweight/Obesity: A Systematic Review and Meta-Analysis. Nutrients 12(11)	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (population not gestational diabetes, not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Wang, Hongjuan, Jiang, Yuanyuan, Wiley, James et al. (2022) Effectiveness of Smartphone-Based Lifestyle Interventions on Women with Gestational Diabetes: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Psychology research and behavior management 15: 3541-3559	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (inappropriate study design, inappropriate postnatal intervention period, focus on blood glucose monitoring, pharmacological intervention, not high income). Additional studies have been checked
Wang, Huiyan, Jiang, Hongyi, Yang, Liping et al. (2015) Impacts of dietary fat changes on pregnant women with gestational diabetes mellitus: a randomized controlled study. Asia Pacific journal of clinical nutrition 24(1): 58-64	- Study setting does not meet protocol Study is included in Han 2017 Cochrane review but is not conducted in a high income country (China) and therefore does not meet protocol inclusion criteria
Wang, Mengmeng, Chen, Zhaojing, Hu, Yan et al. (2021) The effects of vitamin D supplementation on glycemic control and maternal-neonatal outcomes in women with established gestational diabetes mellitus: A systematic review and meta-analysis. Clinical nutrition (Edinburgh, Scotland) 40(5): 3148-3157	- Systematic review includes studies that does not meet protocol Systematic review only contains studies from non high income countries (Iran or China)
Wang, W-B, Jiang, S-M, Li, C-Q et al. (2020) Effects of Science Intervention Service on Advanced Age Patients with Gestational Diabetes Mellitus. Chinese pharmaceutical journal 55(22): 1895-1898	- Study setting does not meet protocol Study not conducted in a high income country (China)
Wang, Wei, Cao, Yan-Min, Cai, Na-Na et al. (2022) Influence of one-day diabetes mellitus clinic management on blood glucose control and prognosis in patients	- Study setting does not meet protocol Study not conducted in a high income country (China)

Study	Reason
with gestational diabetes mellitus. Gynecological endocrinology : the official journal of the International Society of Gynecological Endocrinology 38(4): 324-328	
Wang, X., Juan, Q.-F., He, Y.-W. et al. (2017) Multiple effects of probiotics on different types of diabetes: A systematic review & meta-analysis of randomized, placebo-controlled trials. Journal of Pediatric Endocrinology and Metabolism 30(6): 611-622	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (population other than gestational diabetes, not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Wang, Ya-Hai, Zhou, Huan-Huan, Nie, Zhibin et al. (2022) Lifestyle intervention during pregnancy in patients with gestational diabetes mellitus and the risk of neonatal hypoglycemia: A systematic review and meta-analysis. Frontiers in nutrition 9: 962151	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (inappropriate pharmacological intervention, not high income) or are included in Han 2017 Cochrane systematic review included in this review. Additional studies have been checked
Wang, Z, Li, W, Lyu, Z et al. (2022) Effects of probiotic/prebiotic/synbiotic supplementation on blood glucose profiles: a systematic review and meta-analysis of randomized controlled trials. Public health 210: 149-159	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (population at risk of gestational diabetes, inappropriate intervention, not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Wei, J.; Heng, W.; Gao, J. (2016) Effects of low glycemic index diets on gestational diabetes mellitus. Medicine (United States) 95(22): e3792	- More recent systematic review included that covers the same topic All included studies of the systematic review are also included in Han 2017 Cochrane systematic review included in this review
Wei, Jinhua; Heng, Weijun; Gao, Jianbo (2016) Effects of Low Glycemic Index Diets on Gestational Diabetes Mellitus: A Meta-	- Duplicate reference

Study	Reason
Analysis of Randomized Controlled Clinical Trials. Medicine 95(22): e3792	
Weiler, Hope A, Attar, Atheer, Farahnak, Zahra et al. (2022) Vitamin D Status of Infants of Mothers with Gestational Diabetes: Status at Birth and a Randomized Controlled Trial of Vitamin D Supplementation across Infancy. The Journal of nutrition 152(11): 2441-2450	- Population not relevant to this review protocol Infants of mothers with gestational diabetes during pregnancy were randomised to receive different doses of vitamin D
Wu, Chunfeng; Song, Yang; Wang, Xueying (2023) Vitamin D Supplementation for the Outcomes of Patients with Gestational Diabetes Mellitus and Neonates: A Meta-Analysis and Systematic Review. International journal of clinical practice 2023: 1907222	- Systematic review includes studies that does not meet protocol Systematic review only contains studies from non high income countries (Iran or China)
Xie, Weihua, Dai, Pinyuan, Qin, Yu et al. (2020) Effectiveness of telemedicine for pregnant women with gestational diabetes mellitus: an updated meta-analysis of 32 randomized controlled trials with trial sequential analysis. BMC pregnancy and childbirth 20(1): 198	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (not randomised, focus on glucose monitoring, not high income). Additional studies have been checked
Xie, Yaping, Zhao, Huifen, Zhao, Meijing et al. (2022) Effects of resistance exercise on blood glucose level and pregnancy outcome in patients with gestational diabetes mellitus: a randomized controlled trial. BMJ open diabetes research & care 10(2)	- Study setting does not meet protocol Study not conducted in a high income country (China)
Xu, D., Fu, L., Pan, D. et al. (2022) Role of whole grain consumption in glycaemic control of diabetic patients: A systematic review and meta-analysis of randomized controlled trials. Nutrients 14(1): 109	- Systematic review used as source of primary studies All included studies of the systematic review do not meet the protocol inclusion criteria(inappropriate study design or not conducted in high income country)
Xu, Jiang and Ye, Shandong (2020) Influence of low-glycemic index diet for gestational diabetes: a meta-analysis of randomized controlled trials. The journal of	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (not

Study	Reason
maternal-foetal & neonatal medicine : the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians 33(4): 687-692	from high income countries) or are included in Han 2017 Cochrane systematic review
Xu, Jingqi, Wu, Yuanyuan, Zou, Zhijie et al. (2022) Effect of Dietary Intervention Designed with Behavior Change Wheel on Compliance with Dietary Control in Women with Gestational Diabetes Mellitus: Study Protocol for a Randomized Controlled Trial. International journal of environmental research and public health 19(17)	- Study design or type not relevant to this review protocol Study protocol for trial that is not conducted in a high income country (China)
Yamamoto, Jennifer M, Kellett, Joanne E, Balsells, Montserrat et al. (2018) Gestational Diabetes Mellitus and Diet: A Systematic Review and Meta-analysis of Randomized Controlled Trials Examining the Impact of Modified Dietary Interventions on Maternal Glucose Control and Neonatal Birth Weight. Diabetes care 41(7): 1346-1361	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (not high income) or are included in Han 2017 or Brown 2017 Cochrane systematic reviews included in this review
Yan, Jie; Chen, Xuan; Zhang, Shuguang (2017) Intervention effect of diet education based on blood glucose load on gestational diabetes mellitus patients: a meta analysis. Chinese Nursing Research 31(25): 3144-3148	- Study not reported in English Full text article not in English
Yao, J, Cong, L, Zhu, B et al. (2015) Effect of dietary approaches to stop hypertension diet plan on pregnancy outcome patients with gestational diabetes mellitus. Bangladesh journal of pharmacology 10(4): 732-738	- Study setting does not meet protocol Study not conducted in a high income country (China)
Yaping, Xie, Huifen, Zhao, Chunhong, Liu et al. (2020) A meta-analysis of the effects of resistance training on blood sugar and pregnancy outcomes. Midwifery 91: 102839	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (not from high income countries or is already included in Brown 2017 Cochrane systematic review

Study	Reason
Yaping, Xie, Huifen, Zhao, Meijing, Zhao et al. (2021) Effects of Moderate-Intensity Aerobic Exercise on Blood Glucose Levels and Pregnancy Outcomes in Patients With Gestational Diabetes Mellitus: A Randomized Controlled Trial. Diabetes therapy : research, treatment and education of diabetes and related disorders 12(9): 2585-2598	- Study setting does not meet protocol Study not conducted in a high income country (China)
Yefet, Enav, Bar, Liron, Izhaki, Ido et al. (2023) Effects of Probiotics on Glycemic Control and Metabolic Parameters in Gestational Diabetes Mellitus: Systematic Review and Meta-Analysis. Nutrients 15(7)	- Systematic review includes studies that does not meet protocol Systematic review contains studies that either do not meet protocol inclusion criteria (population at risk of gestational diabetes, not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Yew, T.W., Chi, C., Chan, S.-Y. et al. (2020) A Randomized Controlled Trial to Evaluate the Effects of a Smartphone Application-Based Lifestyle Coaching Program on Gestational Weight Gain, Glycemic Control, Maternal, and Neonatal Outcomes in Women With Gestational Diabetes Mellitus: The SMART-GDM Study. Diabetes care	- Duplicate reference Duplicate to Yew 2021
Yu Louie, J.C., Markovic, T.P., Ross, G.P. et al. (2012) Timing of peak blood glucose after breakfast meals of different glycemic index in women with gestational diabetes. Nutrients 5(1)	- Study design or type not relevant to this review protocol Study was excluded by Han 2017 Cochrane review as design is randomised cross-over trial which was not considered to be appropriate for the review question
Yuan, Kun, Wang, Haoyuan, Chen, Yujia et al. (2020) A 12-hour comprehensive nutrition care benefits blood glucose level and weight gain and improves outcomes in pregnant women with gestational diabetes mellitus. Annals of palliative medicine 9(3): 661-670	- Study setting does not meet protocol Study not conducted in a high income country (China)

Study	Reason
Zahmatkeshan, Maryam, Zakerabasali, Somayyeh, Farjam, Mojtaba et al. (2021) The use of mobile health interventions for gestational diabetes mellitus: a descriptive literature review. Journal of medicine and life 14(2): 131-141	- Review article but not a systematic review The article was not a systematic review and included most study designs. Any relevant articles were checked
Zhang, Jiayue, Ma, Shujuan, Wu, Shilan et al. (2019) Effects of Probiotic Supplement in Pregnant Women with Gestational Diabetes Mellitus: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Journal of diabetes research 2019: 5364730	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Zhang, Ru, Han, Shufen, Chen, Guo-Chong et al. (2018) Effects of low-glycemic-index diets in pregnancy on maternal and newborn outcomes in pregnant women: a meta-analysis of randomized controlled trials. European journal of nutrition 57(1): 167-177	- Systematic review used as source of primary studies Systematic review includes studies that do not meet the protocol inclusion criteria (population not gestational diabetes, not conducted in high income country) or were included in Han 2017 Cochrane systematic review. Additional studies were checked
Zhang, Xinyan, Zhao, Hongxia, Li, Xueyuan et al. (2022) The application of reasonable exercise during pregnancy in gestational diabetes and its influence on pregnancy outcome: a systematic review. Panminerva medica	- Study design or type not relevant to this review protocol Letter to the editor containing a systematic review. References to included studies are not provided
Zhang, Y.; Han, Y.; Dong, Q. (2021) The effect of individualized exercise prescriptions combined with dietary management on blood glucose in the second-and-third trimester of gestational diabetes mellitus. American Journal of Translational Research 13(6): 7388-7393	- Study setting does not meet protocol Study not conducted in a high income country (China)
Zhang, Y, Gong, Y, Xue, H et al. (2018) Vitamin D and gestational diabetes mellitus: a systematic review based on data free of Hawthorne effect. BJOG : an international journal of obstetrics and gynaecology 125(7): 784-793	- Systematic review includes studies that does not meet protocol Systematic review includes studies that do not meet the protocol inclusion criteria (not conducted in a high income country,

Study	Reason
	population not gestational diabetes, non randomised study)
Zheng, Jia, Feng, Qianyun, Zheng, Sheng et al. (2018) The effects of probiotics supplementation on metabolic health in pregnant women: An evidence based meta-analysis. PloS one 13(5): e0197771	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (population at risk of gestational diabetes or healthy women, not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Zhou, Lushan, Ding, Caifei, Wu, Ji et al. (2021) Probiotics and synbiotics show clinical efficacy in treating gestational diabetes mellitus: A meta-analysis. Primary care diabetes 15(6): 937-947	- Systematic review used as source of primary studies Systematic review contains studies that either do not meet protocol inclusion criteria (not high income) or are included in Okesene-Gafa 2020 Cochrane systematic review included in this review
Zhu, Guo-Hong, Xu, Yun, Zou, Li et al. (2021) The effect of interdisciplinary and diversified health education combined with personalized nutrition intervention on FPG, 2hPG, SDS, SAS scores and the pregnancy outcomes of gestational diabetes mellitus. Ginekologia polska	- Study setting does not meet protocol Study not conducted in a high income country (China)
Zou, J. and Huang, J. (2021) Effect of high-quality nursing on blood glucose level, psychological state, and treatment compliance of patients with gestational diabetes mellitus. American Journal of Translational Research 13(11): 13084-13092	- Study setting does not meet protocol Study not conducted in a high income country (China)
فاطمه, دوستی, اعظم, ملکی, حسین, چیتی et al. (2018) تأثیر مشاوره فردی فعالیت فیزیکی مبتنی بر تئوری رفتار برنامه ریزی شده بر شاخص های قندخون در زنان مبتلا به دیابت بارداری: کارآزمایی بالینی تصادفی شده. Qom university of medical sciences journal 12(9): 26-37	- Study not reported in English Full text article is not in English

Study	Reason
官颖, 李锡梅, 王亚丛 et al. (2018) 知识-信念-行为模式对妊娠糖尿病病人自护能力、血糖水平和妊娠结局的影响. Chinese nursing research 32(10): 1585-1587	- Study not reported in English Full text article is not in English
葛艳红, 储静, 张兴 et al. (2017) 个体化医学营养治疗对妊娠糖尿病病人营养行为及血糖的影响. Chinese nursing research 31(14): 1696-1701	- Study not reported in English Full text article is not in English

RCT: randomised controlled trial.

Excluded economic studies

Study	Reason for exclusion
Fitria N, van Asselt ADI, Postma MJ. Cost-effectiveness of controlling gestational diabetes mellitus: a systematic review. Eur J Health Econ. 2019 Apr;20(3):407-417.	Systematic review - individual studies checked for eligibility
Moss JR, Crowther CA, Hiller JE, Willson KJ, Robinson JS; Australian Carbohydrate Intolerance Study in Pregnant Women Group. Costs and consequences of treatment for mild gestational diabetes mellitus - evaluation from the ACHOIS randomised trial. BMC Pregnancy Childbirth. 2007 Oct 28;7:27.	Intervention not relevant (blood glucose monitoring and/or insulin included in intervention)
Ohno MS, Sparks TN, Cheng YW, Caughey AB. Treating mild gestational diabetes mellitus: a cost-effectiveness analysis. Am J Obstet Gynecol. 2011 Sep;205(3):282.e1-7.	Intervention not relevant (blood glucose monitoring and/or insulin included in intervention)
Weile LK, Kahn JG, Marseille E, Jensen DM, Damm P, Lohse N. Global cost-effectiveness of GDM screening and management: current knowledge and future needs. Best Pract Res Clin Obstet Gynaecol. 2015 Feb;29(2):206-24.	Intervention not relevant (screening for Gestational diabetes included in intervention)

Appendix K Research recommendations – full details

Research recommendations for review question: What are the most effective and cost-effective healthy lifestyle interventions for women with gestational diabetes?

Research recommendation

What are the most clinical and cost-effective dietary interventions to improve glycaemic control, maternal and baby outcomes for people with gestational diabetes?

Why this is important

The prevalence of gestational diabetes (GDM) has increased in the United Kingdom (UK), and globally. Gestational diabetes which affects between 10 and 20% of all pregnancies in the UK heightens the risk of delivering a large for gestational age baby, gestational hypertension, pre-eclampsia, stillbirth, delivery by Caesarean section and hypoglycaemia in the newborn. Gestational diabetes also increases the risk of type 2 diabetes in the mother. First line treatment for gestational diabetes is dietary advice, but there is no evidence based 'standard care' protocol for dietary advice in gestational diabetes.

Rationale for research recommendation

Table 17: Research recommendation rationale

Importance to 'patients' or the population	Improved dietary management of gestational diabetes would reduce the risk of complications in pregnancy and the peripartum period, and potentially lower the risk of post-partum Type 2 diabetes in the mother.
Relevance to NICE guidance	NICE guidance NG3 (updated 2020) advises that women with gestational diabetes should eat a healthy diet and to switch from high to low glycaemic index foods, and to exercise regularly. No further advice is provided.
Relevance to the NHS	A standard protocol for evidence based dietary management of gestational diabetes could limit the number of women transitioning to pharmacological management of gestational diabetes, and improve pregnancy outcomes, thus reducing NHS costs.
National priorities	High
Current evidence base	Five studies compared dietary interventions vs standard care to improve glucose control in women with a diagnosis of gestational diabetes, and with a single pregnancy. One study compared high unsaturated fat diet vs low unsaturated fat diet with matching calories against standard care. Four studies compared low-carbohydrate diet vs high-carbohydrate diet against standard care. The committee discussed the evidence of all diet-based comparisons and acknowledged that there was no strong evidence for the benefit of one diet compared to another. Also that there is no accepted definition of standard care, as evidenced by the variation of standard care dietary interventions for GDM across included studies where diet as well as education or counselling components could be included. As a result, it was reasoned that this may be a contributing factor towards the lack of difference in outcomes between arms when compared to

	standard care comparisons. Hence the committee decided to make a research recommendation to address this gap in the evidence for an evidence based standard care dietary intervention for women with a diagnosis of gestational diabetes.
Equality considerations	Ethnicity and socio-economic factors including ethnic and culturally appropriate dietary choices

NHS: National Health Service; NICE: National Institute for Health and Care Excellence.

Modified PICO table

Table 18: Research recommendation modified PICO table

Population	Inclusion: • pregnant women with gestational diabetes with a single pregnancy Exclusion: • women with pre-existing diabetes • women prescribed metformin or insulin for gestational diabetes
Intervention	Diet based interventions should include one or more of the following: • low glycaemic index diet • low carbohydrate diet • energy restricted diet • low unsaturated fat diet • high fibre diet All should have a physical activity component and include/exclude personalised coaching or individual monitoring
Comparator	A different combination of the above
Outcome	Primary outcomes Maternal outcomes: • glycaemic (glucose) control • gestational weight change • mode of delivery: vaginal birth/induction of labour/Caesarean birth Secondary outcomes: Fetal/neonatal outcomes: • large for gestational age (LGA) >90th centile • neonatal hypoglycaemia • neonatal mortality and morbidity (include it as a composite outcome if reported) • cost-effectiveness (including resource use measurements and QALY estimations using a validated preference-based measure such as the EQ-5D or SF-6D).
Study design	RCT
Timeframe	From diagnosis of gestational diabetes until 6 weeks post-partum
Additional information	Sub-group analysis: 1. single vs multiple pregnancy 2. socioeconomic status and deprivation (measured using IMD) 3. ethnicity:

	• White/ White British • Asian/Asian British • Black/African/Caribbean/Black British • mixed/multiple ethnic groups • other ethnic group

QALY: quality adjusted life years; EQ-5D: European Quality of Life Five Dimension; PICO: Population, Intervention, Comparison and Outcome; RCT: randomised controlled trial; SF-6D: six-dimensional health state short form