sacn
Scientific Advisory Committee on Nutrition

Nutrition and maternal weight outcomes: annex 5 - data extraction from primary studies

Contents

Abbreviations

AHEI: Alternative Healthy Eating Index

ANC: antenatal care

ASA24: Automated Self-administered 24-hour Dietary Recall

BB-12: Bifidobacterium animalis subspecies lactis

BF%: body fat per cent

BGGI: borderline gestational glucose intolerance

BMI: body mass index

CASI: computer-assisted self-interviewing

CHO: carbohydrate

CI: confidence interval

DP: dietary patterns

DNCT: Diabetes Nutrition and Complications Trial

DRI: Dietary Reference Intake

EC: enhanced care

EVOO: extra virgin olive oil

FFM: fat free mass

FM: fat mass

FPG: fasting plasma glucose

GCT: Glucose Challenge Test

GDM: gestational diabetes mellitus

GI: glycaemic index

GL: glycaemic load

GTT: glucose tolerance test

GW: gestational weeks

GWDCF: Gestational Weight Data Collection Form

GWG: gestational weight gain

HEI: Healthy Eating Index

HOMA-IR: homoeostasis model of assessment of insulin resistance

IG: intervention group

IOM: Institute of Medicine

LGA: large for gestational age

MBRN: Medical Birth Registry of Norway

MDA: Mediterranean diet adherence

MDQS: Maternal Diet Quality Score

MEDAS: Mediterranean Diet Adherence Screener

MET: metabolic equivalent task

NND: New Nordic Diet

OGTT: Oral Glucose Tolerance Test

PRINCESA: Pregnancy Research on Inflammation, Nutrition and City Environments: Systematic Analyses

RCT: randomised controlled trial

RGWG: rate of gestational weight gain

RDA: recommended dietary allowance

rMED: relative Mediterranean diet score

RRR: reduced rank regression

RS: resistant starch

SC: supported care

SFFQ: Semiquantitative Food Frequency Questionnaire

SGA: small for gestational age

SMD: standardised mean difference

SR: systematic review

SRs: systematic reviews

TER: total energy requirement

USDA: US Department of Agriculture

WDDS: Women’s Dietary Diversity Score

Data extracted from primary studies

This annex provides details of the primary studies included in the systematic reviews (SRs) prioritised for description in the main body of the report and for grading and drawing conclusions. Chapter 3 (Methods) provides information on the process of the primary data extraction.

The sections below provide data extracted from relevant primary studies that were included in each systematic review (SR). The evidence on energy and macronutrient intake during pregnancy and GWG was provided by one SR (Tielemans and others, 2016). Details of the primary studies from this SR are not provided in this annex - these are available in Tielemans and others (2016) and its supplementary material.

The terminology used to describe the primary studies included in the SRs reflects the wording used by the study authors. This includes the terms 'adequate' and 'excess' gestational weight gain (GWG).

Foods, dietary patterns and dietary components and GWG

The sections below provide extracted data of the primary studies included in the prioritised SRs providing evidence on:

- dietary interventions during pregnancy (Walker and others, 2018; i-WIP, 2017)
- dietary interventions and weight postpartum (Dalrymple and others, 2018; Dodd and others, 2018)
- maternal dietary patterns during pregnancy (Zhang and others, 2022; Abdollahi and others, 2021; USDA, 2020)
- low glycaemic load (GL) diet during pregnancy (Muktabhant and others, 2015)
- milk and dairy intake during pregnancy (Achón and others, 2019)
- probiotic dietary supplementation during pregnancy (Chatzakis and others, 2019)

Dietary interventions during pregnancy

Walker and others (2018) Attenuating pregnancy weight gain - what works and why: a systematic review and meta-analysis

The characteristics and findings of this SR and meta-analysis are provided in annex 3.

The sections below provide data extracted from relevant primary studies that were included in the systematic review by Walker and others (2018).

Bonomo and others (2005)

Exposure and outcome
Dietary advice and maternal weight gain.

Study design, number of participants and country
A randomized clinical trial recruiting women (n = 450) through a screening procedure at the Diabetic and Pregnancy Centre of Niguarda Ca'Granda Hospital in Milan, Italy, from 1997 to 2002.

Baseline age
Intervention group: age (years) 31.1 (± 4.7).

Control group: age (years) 31.1 (± 4.4).

BMI status
Intervention group: BMI (kg/m^2) 23.1 (± 4.4).

Control group: BMI (kg/m^2) 23.0 (± 4.1).

Ethnicity
All participants were Caucasian.

Recruitment
The trial recruited women of Caucasian origin and with Borderline Gestational Glucose Intolerance (BGGI) (determined by having an elevated Glucose Challenge Test (GCT) (plasma glucose 60 minutes after challenge of equal to or more than 7.8mmol/l), followed by a normal Oral Glucose Tolerance Test (OGTT). Women with a normal GCT were classified as having normal glucose tolerance and excluded from the study, apart from those enrolled as control subjects (Group C). Women with only one abnormal value at the OGTT, and women fulfilling Carpenter and Coustan's diagnostic criteria for gestational diabetes mellitus (GDM) were also excluded.

Randomisation
Participants were randomly assigned to one of 2 study groups.

Intervention
Women were immediately given dietary advice providing 24kcal to 30kcal per kg per day, based on prepregnancy body weight; caloric intake was divided into 3 meals and 2or 3 snacks, and distributed as 50% to 55% carbohydrate, 25% to 30% protein, 20% to 25% fat.

Intervention delivery
Following dietary advice, the participants then entered an out-patient management protocol, which involved visits every 2 weeks, when the main clinical parameters (weight, blood pressure) were recorded, discussion of dietary habits with evaluation of therapeutic compliance, and measurement of fasting and 2 hour postprandial blood glucose, of HbA1c and fructosamine.

Intervention adherence
Discussion of dietary habits with evaluation of therapeutic compliance occurred at visits every 2 weeks.

Control group
Not reported.

Follow-up
Every 2 weeks, the main clinical parameters (weight, blood pressure) were recorded, participants discussed dietary habits with evaluation of therapeutic compliance, and measurements of fasting and 2 hour postprandial blood glucose, of HbA1c and fructosamine were taken.

Diet assessment
Discussion of dietary habits with evaluation of therapeutic compliance occurred at visits every 2 weeks.

Outcome measures
Outcomes were measures of metabolic control, maternal weight gain and pregnancy outcomes (frequency of caesarean sections, Large for Gestational Age (LGA) neonates, Small for Gestational Age (SGA) neonates, neonatal ponderal index, neonatal morbidities and admission to Neonatal Intensive Care Unit (NICU).

Measure of association/effect, 95% CI, p-value
Maternal weight gain was similar in all 3 groups, with no difference between Group A (standard management) (12.6 ± 3.9kg) and Group B (dietary treatment group) (13.1 ± 4.3kg), and between the 22 BGGI group and control subjects (Group C) (13.6 ± 4.4kg).

Variables adjusted for
Not reported.

Deveer and others (2013)

Exposure and outcome
A tailored caloric diet and maternal weight gain.

Study design, number of participants and country
A prospective randomised controlled trial, recruiting women (n = 100) in Turkey.

Baseline age
Mean maternal age (years ± SD) intervention: 29.46 ± 5.82, control: 31.22 ± 5.58 (p = 0.126).

BMI status
Mean BMI (kg/m^2 ± SD) intervention: 28.01 ± 3.60, control: 29.10 ± 4.83 (p = 0.203).

Ethnicity
No information provided.

Disease status
Patients with positive 50g GCT and negative 100g OGTT.

Recruitment
No information provided.

Randomisation
Randomisation was performed with the use of days of a week; women who referred to antenatal polyclinic on Monday, Wednesday and Friday were assigned to the intervention group (n=50) and received individualised dietary advice from a qualified dietitian. Patients who were seen on Tuesday and Thursday constituted control group and received routine antenatal-care (n=50).

Intervention
Individualised prescribed medical nutrition therapy by a dietitian experienced in GDM management. Total daily calories were calculated for each patient by taking into consideration the women's pre-pregnancy weight, activity level, dietary intake, and weight gain. The diet was tailored for women of different body mass index (BMI) by recommending a normocaloric intake in the range of 1,800kcal to 2,500cal per day. Approximately for BMI of 20kg/m^2 to 25kg/m^2, 30kcal per kg per day; for BMI of 25kg/m^2 to 30kg/m^2, 25kcal per kg per day; for BMI of 30kg/m^2 and more, 15kcal to 20kcal per kg per day were given. Calories were divided over 3 meals and 3 snacks. Carbohydrate intake was restricted to 45 percent of calories, with the remainder divided between protein (about 20%) and fat (about 35%). Vegetables and foods high in fibre were encouraged.

Intervention delivery
No information provided.

Intervention adherence
No information on adherence provided.

Control group
Women randomised to the control group were not given dietary advice and routine antenatal care was performed.

Follow-up
Intervention was delivered 24 to 28 weeks to birth. In the study group, patients were followed weekly for the first month after diagnosis and in every 2 weeks until delivery.

Physical activity
Activity level was taken into consideration when calculating total daily calories for the intervention group. No other information on physical activity was given.

Diet assessment
No information provided.

Outcome measures
Total maternal weight gain.

Measure of association/effect, 95% CI, p-value
Total maternal weight gain (kg ±SD) intervention group: 12.62 ± 3.85; control group: 16.10 ± 4.09 (p=0.001).

Variables adjusted for
No information provided.

Di Carlo and others (2014)

Exposure and outcome
A personalised diet plan and gestational weight gain.

Study design, number of participants and country
A prospective controlled study (not randomised) recruiting low-risk pregnant women (n=120) in Italy.

Baseline age
Age (years ± SD) intervention group: 31.3 ± 4.7, control group: 28.2 ± 5.3 (p=0.002).

BMI status
Pre-pregnancy BMI (kg/m^2 ± SD) intervention group: 26.5 ± 6.3, control group: 25.0 ± 4.2 (p=0.3).

Ethnicity
All patients were Caucasian.

Recruitment
No information provided.

Randomisation
Random allocation: women were randomly allocated with a 1:1 ratio into 2 groups. The allocation sequence was concealed from the researchers who enrolled the participants and attached a sequentially numbered, opaque sealed and stapled envelope containing the allocated treatment to the patient clinical record. The dietician opened the envelopes at the time of the first visit.

Intervention
Personalised diet plan meeting both personal preferences and specific gestational needs. The plan took into account the energetic surplus needed by pregnant women. Individualised diet plans were elaborated in agreement with the recommended dietary allowance (RDA) for the Italian population with the average daily caloric intake being 1,916kcal. A typical weekly diet plan included 5 meals per day, distributed throughout the day as follows: breakfast (milk or yoghurt, biscuits or toasted bread), snack (fruits or crackers), lunch (pasta or rice with vegetables, limiting the association of potatoes and tomato sauce, and a side-dish with vegetables), snack (fruits), and dinner (white meat or

fish, limiting to once a week dairy products, cheese, eggs, and ham, associated with a side-dish of vegetables and bread). The only fat allowed, as a preparation or dressing for all meals, was olive oil. Women in this group were scheduled for monthly follow-up appointments with a dietician who monitored their weight gain, discussed any potential issues, gave further suggestions and answered questions, as needed.

Intervention delivery
At baseline, a thorough medical and obstetric history was taken from all participants. Gestational age and anthropometric parameters including pre-pregnancy weight (as reported by the patient) current weight, height, and BMI were recorded for all patients at the first visit as well. Maternal weight at term (as measured at last follow-up visit scheduled beyond 37 weeks gestation), gestational age at delivery and newborn weight were also registered for all participants. Women allocated to the intervention group underwent a dietary interview using a food frequency questionnaire (FFQ) validated for use in Italian subjects, to evaluate their dietary habits and to generate a personalized diet plan meeting both personal preferences and specific gestational needs. Women in the intervention group were scheduled for monthly follow-up appointments with a dietician who monitored their weight gain, discussed any potential issues, gave further suggestions and answered questions, as needed.

Intervention adherence
Information on adherence and compliance were not provided.

Control group
Women allocated to the control group, at first visit, received a standard brochure containing dietary suggestions to be followed during pregnancy and breastfeeding. The brochure provided information on healthy eating during pregnancy, including how to eat a balanced diet, eating a variety of foods, healthy weight gain during pregnancy, and food safety concerns specific to pregnant women. In addition, it included a frequently asked questions (FAQs) section, with an answer to the most frequent questions that may rise during pregnancy and breastfeeding regarding diet and weight gain.

Follow-up
6 to 13 weeks to birth.

Physical activity
No information provided.

Diet assessment
Women allocated to the intervention group underwent a dietary interview using a FFQ validated for use in Italian subjects to evaluate their dietary habits.

Outcome measures
Maternal weight gain.

Measure of association/effect, 95% CI, p-value
Maternal weight gain at term was significantly lower both as compared to pre-pregnancy weight (8.2 ± 4.0kg versus 13.4 ± 4.2kg; p<0.001) and to weight at baseline (7.7 ± 3.8kg versus. 13.7 ± 4.3kg; p<0.001) in the intervention group as compared to controls. Assuming that a pregnancy weight gain up to 12kg is considered healthy in patients with pre-pregnancy BMI within the normal range (BMI 18.5kg/m^2 to 24.9kg/m^2), authors stratified the population from both groups in 2 subgroups: women with a healthy pregnancy weight gain (equal or lower than 12kg) and women with an excessive pregnancy weight gain (greater than 12kg). This analysis showed that 95.1% (58) of patients from the intervention group and only 41% (25) from the control group had a healthy pregnancy weight gain (relative risk 2.4; 95 % CI 1.9 to 2.5; p<0.001).

Variables adjusted for
No information provided.

Ilmonen and others (2011)

Exposure and outcome
Probiotic supplemented dietary counselling and anthropometric measurements.

Study design, number of participants and country
A randomised placebo-controlled trial of 256 women in Finland.

Baseline age
Age (years ± SD) probiotics and diet counselling group: 29.7 ± 4.1, placebo and diet counselling group: 30.1 ± 5.2, placebo and control group: 30.2 ± 5.0 (p=0.813).

BMI status
Baseline BMI status not reported.

Ethnicity
Not reported

Recruitment
Women were informed of the study by leaflets distributed during their first visit to a maternal welfare clinic. Interested recipients contacted the research nurse for information and an appointment at the study clinic.

Randomisation
Performed by an independent statistician according to computer-generated block randomisation of 6 women. assigning participants to diet/probiotics, diet/placebo, or control/placebo groups. Allocation was concealed with sealed envelopes in a double-blind manner for probiotics or placebo in the dietary counselling groups and a single blind manner for those not receiving dietary counselling. Envelopes were not opened until the first study visit.

Intervention
Dietary counselling given by a nutritionist aimed to modify dietary intake to conform with dietary recommendations, providing a 55% to 60% of energy from carbohydrates, 10% to 15% of energy from protein and 30% of energy from fat, with a focus on the amount and type of fat in the diet. Mothers were provided with conventional food products with favourable fat content to be used at home, including spreads and salad dressing. Recommendations on energy intake were made with reference to weight gain. In cases where excessive weight gain occurred, dietary advice was given on regular meal frequency, smaller portion sizes and reduction in consumption of sweet or savoury delicacies. Women were also encouraged to undertake regular physical activity and exercise according to their capabilities, making allowance for the stage of pregnancy. Women receiving probiotics were administered one capsule per day, containing 10 billion colony forming units each of Lactobacillus rhamnosus GG and Bifidobacterium lactis.

Intervention delivery
After baseline, study visits took place at each trimester of pregnancy, and at one, 6 and 12 months postpartum. At each visit, the intervention groups received dietary counselling, supported by provision of food products for use at home and probiotics or placebo capsules. Food products and capsules were consumed from the first trimester of pregnancy until the end of exclusive breastfeeding, a maximum of 6 months postpartum. All pregnant women participating in the study also attended municipal well-women clinics.

Intervention adherence
Compliance in consumption of capsules was good, more than 95% of the subjects consuming the capsules and tolerating them well. Good compliance in attendance at study visits was reported to be most likely attributable to recurring contacts with the same study personnel and immediate feedback to the subjects.

Control group
Received placebo capsules and no additional dietary counselling beyond that provided though the municipal well-women clinics.

Follow-up
Study visits took place at each trimester of pregnancy, and at one, 6 and 12 months postpartum

Physical activity
Participants were encouraged to undertake regular physical activity and exercise according to their capabilities, and were asked to report the weekly frequency of at least 30 minute sessions of exercise causing perspiration and breathlessness.

Diet assessment
Dietary intake was assessed at each visit with 3-day food diaries. A healthy eating index was also calculated based on guidelines given by the European Health Monitoring Program including the intakes of vegetables, fruits and berries, fish and bread and intakes of saturated fatty acids and salt.

Outcome measures
Primary outcome measures were BMI, adiposity defined as waist circumference of 80 cm or more, and proportion of body fat over the 12 months' postpartum period. Secondary outcomes were dietary intakes of foods and nutrients and a healthy eating index during the postpartum period. Gestational weight gain was also assessed.

Measure of association/effect, 95% CI, p-value
The mean total weight gain over pregnancy was 14.8kg (SD 4.8kg), with no significant differences amongst the study groups; diet/probiotics 14.8kg (SD 4.4kg), diet/placebo 14.7kg (SD 5.0kg) and control/placebo 14.8kg (SD 5.2kg) (p = 0.981).

The proportion showing a pregnancy weight gain exceeding that recommended was lowest in the diet/probiotics group and highest in the control/placebo group, although the difference was not statistically significant; 31.9% in the diet/probiotics, 39.7% in the diet/placebo and 45.7% in the control group; (p=0.246). Overall, 39.2% of the women showed a weight gain exceeding that recommended during pregnancy.

The risk of central adiposity defined as waist circumference 80 cm or more was lowered in women in the diet/probiotics group compared with the control/placebo group (OR 0.30, 95%CI 0.11 to 0.85, p=0.023 adjusted for baseline BMI), whilst the diet/placebo group did not differ from the controls (OR 1.00, 95% CI 0.38 to 2.68, p=0.994) at 6 months postpartum. The difference remained at 12 months postpartum, albeit not statistically significant (p=0.489 adjusted for baseline BMI).

Variables adjusted for
Results for anthropometric measurements and other continuous outcome variables were presented as adjusted for baseline (visit 1) or pre pregnancy values.

Korpi-Hyövälti and others (2012)

Exposure and outcome
Dietary counselling and weight gain.

Study design, number of participants and country
An open, randomised and controlled study recruiting women (n=54) from Finnish rural municipalities in South Ostrobothnia: Kauhajoki and Lapua.

Baseline age
No information provided.

BMI status
BMI (kg/m^2 SD) intervention group: 27.3 (6.0), close follow-up group 25.5 (3.4) (not significant).

Ethnicity
No information was provided on ethnicity other than the study was conducted in Finnish rural municipalities.

Recruitment
Women with risk factors for GDM were recruited (high-risk women). A 2 hour oral glucose tolerance test was offered to all women in the first contact with maternal healthcare units during gestational weeks 8 to 12. If the women had one or more risk factors (BMI greater than 25kg/m^2, previous history of GDM or birth of child greater than 4.5kg, age over 40 years, family history of diabetes, that is parents, children, siblings or grandparents) or if the venous plasma glucose concentration after 12 hour overnight fasting was 4.8 mmol/l to 5.5mmol/l and the 2 hour oral glucose tolerance test plasma glucose less than 7.8 mmol/l, they were recruited to the intervention.

Randomisation
Women were randomly assigned to the lifestyle intervention group (n= 27) or to the close follow-up group (n= 27) by the study physician in the Central Hospital with the use of a computed randomisation list. The healthcare nurses who scheduled the study visits did not have access to the randomisation list.

Intervention
A clinical nutritionist gave dietary advice tailored to each subject in the lifestyle intervention group individually 4 times in the first and second trimesters and 2 times in the third trimester. Briefly, the dietary goals in the study were: carbohydrate 50 to 55 energy percent (E%), fat 30 E%, saturated fat 10 E% and protein 15 E% to 20 E%. The aim regarding the intake of dietary fibre was at least 15g per 4,184kJ (1,000 kcal). Women were encouraged to eat a diet rich in vegetables, berries and fruits, and to use fat-free and low-fat dairy products, low-fat meat, soft margarines and vegetable oils (primarily low-erucic acid rapeseed oil) and whole-grain products. Recommendation for energy intake was 126kJ per kg per day for normal-weight women and 105kJ per kg per day for overweight women. The goal of a during-pregnancy weight gain was 12.5kg to 18kg for underweight women, 11.5kg to 16.0kg for normal-weight women and 7kg to 11.5kg for overweight women. The women received information about the goals of eating, demands of pregnancy, meals and snacks, amount of food, supply of fibre, and amount and quality of fats by the nutritionist.

Intervention delivery
The intervention took place between 8 to 12 gestational weeks and birth.

Intervention adherence
Info on adherence and/or compliance was not provided.

Control group
The women were given general information by a nurse on diet and physical activity in a single session to decrease the risk of GDM during pregnancy. The advice was provided both verbally and in writing. The women returned the Three Factor Eating Questionnaire in the beginning of pregnancy and at weeks 36 to 40. The 4 day food record was completed in the beginning of pregnancy and at weeks 26 to 28 and 36 to 40. Otherwise, the women were followed up in the prenatal clinic of the municipal health centre at 1-month intervals according to standard care in Finland.

Follow-up
In the intervention group, the Three-Factor Eating Questionnaire was used in the beginning of pregnancy and at weeks 36 to 40. The baseline 4 day (4 consecutive days, 1 weekend day) food record was completed before the first appointment at weeks 8 to 12, checked by the nutritionist, and formed the basis for dietary advice during the first session. The food record procedure was repeated before the fifth appointment at weeks 26 to 28 and the sixth appointment at weeks 36 to 40. In the close-follow up group, the 4 day food record was completed in the beginning of pregnancy and at weeks 26 to 28 and 36 to 40. Otherwise, the women were followed up in the prenatal clinic of the municipal health centre at 1-month intervals according to standard care in Finland.

Physical activity
The close-follow up group received general information from a nurse on diet and physical activity in a single session to decrease the risk of GDM during pregnancy. No information was provided on what the intervention group received in relation to physical activity.

Diet assessment
Dietary intake was recorded 3 times during pregnancy using 4 day food records.

Outcome measures
Weight gain (kg).

Measure of association/effect, 95% CI, p-value
The weight gain tended to be lower in the lifestyle intervention group: Weight gain (kg SD) gestational weeks 36 to 40 intervention group: 11.4 (6.0), close follow-up group: 13.9 (5.1) (not significant).

Variables adjusted for
Pre-pregnancy weight.

McCarthy and others (2016)

Exposure and outcome
Dietary advice and self-weighing for the reduction in obstetric complications and GWG.

Study design, number of participants and country
Randomised controlled clinical trial involving 382 participants, conducted in Australia.

Baseline age
The mean age of participants was 31.8 years in the standard care group (SD = 4.6 years) and 31.9 years in the intervention group (SD = 4.6 years).

BMI status
Participants had a BMI of at least 25kg/m². The median BMI was 30.1kg/m² in the standard care group and 30.5kg/m² in the intervention group.

Ethnicity
The majority of participants were born in Australia (74% of the standard care group and 77% of the intervention group). No further information given.

Recruitment
Women were recruited from the antenatal clinic area of a large Australian tertiary level maternity hospital. A research midwife approached women at the time of their first or second antenatal visit, offered written information and invited them to participate.

Randomisation
Randomised using a computer-generated random number table with balanced variable blocks of 4, 6, or 8. Allocation was parallel, 1:1, and stratified as overweight (BMI 25kg/m² to 29.9kg/m²) or obese (BMI at least 30kg/m²). Opaque, sequentially numbered sealed envelopes were filled with allocation to standard care or serial self-weighing, opened after consent obtained and BMI calculated.

Intervention
Encouragement to self-weigh and record regularly, an individual 30 minute dietary advice session, and encouragement for doctors and nurses to talk to them about their weight at antenatal appointments.

Intervention delivery
Women in the intervention group were given a card listing their booking BMI and advising on their target gestational weight gain based on IOM GWG guidelines, with space to chart serial weights. The reverse side listed 7 general points of weight management advice, based on The Australian Guide to Healthy Eating. The research midwife provided an individual session of approximately 30 minutes, which comprised simple dietary advice, encouraged serial weighing and recording, and discussing weight gain with doctors and/or midwives at subsequent antenatal appointments. Women in the standard care group received a card listing their booking BMI and advising their target gestational weight gain. No other changes were made to routine care, which does not include regular weighing.

Intervention adherence
Estimated from self-recalled report at 36 weeks of number of times a participant had weighed herself at home during pregnancy. Full adherence = 0 or 1 time in standard care group or 5 or more times in intervention group. Non-adherence = 5 or more times in standard care group or 0 or 1 time in intervention group. Part adherence = 2 to 4 times in either group. Full adherence by 66 women out of 190 in the standard care group and 82 women out of 190 in the intervention group.

Control group
Received standard antenatal care.

Follow-up
The research midwife recorded participants' weight at their 36-week clinical review.

Physical activity
No information provided

Diet assessment
Diet not assessed.

Outcome measures
Primary outcome was a composite of one or more obstetric complications. Secondary outcomes included a reduction in GWG in each weight category and the percentage of participants with GWG within Institute of Medicine (IOM) guidelines for weight category.

Measure of association/effect, 95% CI, p-value
There was no difference in mean GWG (0.9 kg (95% CI 2.0, 0.25), or adherence to IOM targets according to BMI at entry between the study groups.

Variables adjusted for
Baseline weight.

Thornton and others (2009)

Exposure and outcome
A balanced nutritional regimen and gestational weight gain.

Study design, number of participants and country
A randomised parallel-group trial that recruited obese pregnant women (n=232) from the ambulatory obstetric clinics of 3 tertiary care medical centres in the United States ((Morristown Memorial Hospital (1998 to 2000), St Luke's-Roosevelt Hospital Center (2001 to 2002), and Jamaica Hospital Medical Center (2002 to 2005)) between June 1998 and May 2005.

Baseline age
Intervention group (n=116): median age 26.8 years; control group (n=116): median age 27.3 years.

BMI status
All participants were obese.

Baseline BMI (kg/m^2) intervention group: mean BMI 37.41 (SD 7.01); control group: mean BMI 38.22 (SD 7.48).

Ethnicity
Intervention group: African American n= 46 (39.7%); Caucasian n= 25 (21.6%); Latina n= 29 (25%); Indian n= 16 (13.7%).

Control group: African American n= 49 (42.2%); Caucasian n= 27 (23.3%); Latina n= 25 (21.6%); Indian n= 15 (12.9%).

Recruitment
Pregnant women were recruited if they were pregnant with a single fetus between 12 and 28 weeks of gestation and had a BMI greater than or equal to 30kg/m^2. Participants with pre-existing diabetes, hypertension, or chronic renal disease were excluded.

Randomisation
A randomisation system was used to determine the group assignment of participants. Envelopes were prepared and sequentially numbered. A card indicating the assigned group was placed in the envelope, and the envelope was sealed. A random-number table was used to assign each consecutively numbered envelope to either the study or control group in blocks of 10.

Intervention
The intervention was a prescribed balanced nutritional regimen based on their weight at entry into the study and followed dietary guidelines similar to those used in patients with the diagnosis of gestational diabetes. Participants were placed on an 18kcal to 24kcal per kg balanced nutritional regimen, consisting of 40% carbohydrates, 30% protein, and 30% fat. No patient received a diet of fewer than 2,000 calories.

Intervention delivery
All women in the study group were asked to record in a diary all of the foods and beverages consumed during each day. These records were reviewed at each prenatal visit by the physician. Six weeks after delivery, the patient was weighed during her postpartum visit and exited the study. Patients in both groups were weighed at each prenatal visit. The weight of all participants was recorded at the time of entry into the study, before delivery, and at 6 weeks postpartum.

Intervention adherence
Adherence was defined as recording daily food intake and bringing the logbook to the clinic visit for review by the physician. Non-adherence was defined as not recording food intake for more than a week and failing to bring the logbook to clinic for review.

Control group
Participants allocated to the control group were told to eat to appetite following general prenatal dietary guidelines.

Follow-up
Participants weights were recorded at the time of entry into the study (12 to 28 weeks), before delivery and 6 weeks postpartum.

Physical activity
Participants in the intervention and control groups were encouraged to engage in 30 minutes of walking per day.

Diet assessment
Dietary intake of pregnant women was recorded by participants, who were asked to record in a diary all of the foods and beverages consumed during each day. These records were reviewed at each prenatal visit by the physician.

Outcome measures
The primary outcomes were perinatal outcomes, including maternal weight, weight gain, weight loss, gestational diabetes, preeclampsia, ketonuria, gestational hypertension, hemorrhage postpartum, infection postpartum, preterm delivery, post term delivery, labour induction, caesarean delivery, adherence with prescribed nutritional regimen, a composite maternal outcome combining gestational diabetes or preeclampsia and a composite offspring outcome combining stillbirth, small-for-gestational-age fetus, or admission to the neonatal care unit.

The secondary measure was to compare some of the above outcomes in adherent and nonadherent patients to the prescribed nutritional regimen in the study group.

Measure of association/effect, 95% CI, p-value
There were statistically significant differences between the control and intervention groups for: (a) maternal last weight before delivery, $F(1, 232) = 21.22$, $p < .001$; (b) maternal 6-week postpartum weight, $F(1, 232) = 17.42$, $p < .001$; as well as (c) differences from maternal baseline weight to their last weight before delivery, $F(1, 232) = 89.76$, $p < .001$.

There were statistically significant differences between the adherent and nonadherent groups for (a) maternal last weight before delivery, $F(1, 114) = 4.13$, $p<.05$; (b) maternal 6-week postpartum weight, $F(1, 114) = 5.65$, $p<.05$, (c) weight difference between the baseline pregnancy weight and weight before delivery, $F(1, 114) = 4.13$, $p<.001$; and (d) infant birthweight, $F(1, 114) = 24.97$, $p<.001$.

Variables adjusted for
The trial did not report adjusting for confounders.

Walsh and others (2012) (ROLO study)

Exposure and outcome
Low glycaemic index (GI) diet during pregnancy and excessive weight gain; low GI diet during pregnancy and weight gain (kg).

Study design, number of participants and country
RCT; 781 participants; Ireland.

Inclusion criteria: secundigravid women whose first baby was macrosomic (birthweight greater than 4.0kg).

Baseline age
Intervention group mean 32.0 (SD 4.2) years; Control group mean 32.0 (SD 4.2) years.

Enrolment gestational age: intervention group 13.0 (SD 2.3) weeks, control group 12.9 (SD 2.2) weeks.

BMI status
Intervention group mean BMI 26.8 (SD 5.1); Control group mean BMI 26.8 (SD 4.8).

Ethnicity
No information provided.

Recruitment
Women without diabetes, all in their second pregnancy between January 2007 to January 2011, having previously delivered an infant weighing greater than 4kg were identified on first contact with the hospital and recruited at first antenatal consultation. At this visit, women with any underlying medical disorders, including a previous history of gestational diabetes, those on any drugs, and those unable to give full informed consent were excluded. Other exclusion criteria were age less than 18 years, gestation greater than 18 weeks, and multiple pregnancy.

Randomisation
After giving written informed consent, recruited patients were randomised into either the control or the intervention arm of the study. The research midwife did the randomisation by using computer generated allocations in a ratio of one to one contained in sealed opaque envelopes.

Intervention
Women were first advised on general healthy eating guidelines for pregnancy, following the food pyramid. The remainder of the education session focused on the glycaemic index – its definition, concept, and rationale for use in pregnancy. Women were encouraged to choose as many low glycaemic index foods as possible and to exchange high glycaemic index carbohydrates for low glycaemic index alternatives. Women received written resources about low glycaemic index foods after the education session (web appendix). The recommended low glycaemic index diet was eucaloric, and women were not advised to reduce their total caloric intake.

Intervention delivery
Mean gestational age of those attending the dietary session was 15.7 (SD 3.0) weeks.

Initial dietary education session lasting 2 hours. The research dietitian met with the patients at 28 and 34 weeks' gestation for reinforcement of the low glycaemic index diet.

Intervention adherence
To assess adherence to the low glycaemic index diet, patients in the intervention group were given a questionnaire at their 34-week antenatal visit. This was based on a 5 point Likert-type scale (1 = "I followed the recommended diet all of the time"; 5 = "I followed the recommended diet none of the time").

Control group
Routine antenatal care (as standard practice this did not contain any formal dietary advice or specific advice about GWG).

Follow-up
To birth.

Physical activity
No information provided.

Diet assessment
All women completed 3 food diaries of 3 days each – one before dietary intervention and one each in the second and third trimesters of pregnancy. These collected information on typical meal pattern and food choices over 3 days and allowed for estimation of the glycaemic index. The glycaemic load was calculated as the mathematical product of the glycaemic index of a food and its carbohydrate content in grams divided by 100 (glycaemic load=glycaemic index divided by 100 multiplied by the amount of available carbohydrate).

Outcome measures
At their first antenatal consultation, all patients had their weight and height recorded and their body mass index calculated. Maternal weight was recorded at each antenatal consultation.

Measure of association/effect, 95% CI, p-value
From primary study paper: At 40 weeks' gestation, the mean gestational weight gain in the intervention group was 12.2kg compared with 13.7kg in the control group (mean difference -1.3, 95% confidence interval -2.4 to -0.2; P=0.01). Women in the intervention arm of the study were significantly less likely to exceed gestational weight gain recommendations as outlined by the Institute of Medicine (139/368 (38%) v 182/380 (48%); P=0.01). Among women with a normal body mass index (18.5 to 24.9), 40/155 (26%) controls exceeded the guidelines compared with 25/162 (15%) of the intervention arm (P=0.02). In overweight women (body mass index 25 to 29.9), 99/148 (67%) controls and 74/139 (53%) of those receiving the dietary intervention exceeded the guidelines (P=0.02). We found no significant difference between the 2 groups in the proportion of women with a body mass index of greater than 30.0 who exceeded gestational weight gain guidelines (43/75 (57%) v 40/67 (60%); P=0.8).

Variables adjusted for
The authors investigated weight gain both independent samples to test the amount of weight gained and on the basis of a linear model examining total weight with control for starting weight.

Wolff and others (2008)

Exposure and outcome
Dietary counselling and restriction of gestational weight gain.

Study design, number of participants and country
A randomised controlled trial that recruited women (n=50) from the register of newly diagnosed pregnancies. The trial was performed in cooperation between the Department of Clinical Nutrition, Hvidovre Hospital and the Department of Obstetrics and Gynecology, Herlev Hospital, in Denmark.

Baseline age
Intervention group (n=23): mean age 28 (SD 4) years; control group (n=27): mean age 30 (SD 5) years.

BMI status
All participants were obese (BMI at least 30).

BMI (kg/m^2) intervention group: mean BMI 34.9 (SD 4); control group: mean BMI 34.6 (SD 3).

Ethnicity
All participants were Caucasian.

Recruitment
Pregnant women were recruited if they were obese (BMI 30kg/m^2 or above), Caucasian and in their early stages of pregnancy (15±3 weeks of gestation). Participants who smoked, were below 18 or above 45 years of age, having a multiple pregnancy or had medical complications known to affect foetal growth adversely or to contraindicate limitation of weight gain were excluded.

Randomisation
Computerised randomisation of the pregnant women into the intervention and control group took place after the women had given written informed consent in accordance with the Helsinki II Declaration. The physicians and midwives were blinded in regard to the treatment assignment, and the women were asked not to reveal the allocation by the randomisation.

Intervention
Women in the intervention group were instructed to eat a healthy diet according to the official Danish dietary recommendations (fat intake: max 30 energy percent (E%), protein intake: 15 to 20 E%, carbohydrate intake: 50 to 55 E%). The energy intake was restricted based on individually estimated energy requirements and estimated energetic cost of foetal growth. The intervention was designed to restrict the gestational weight gain to 6kg to 7kg.

Intervention delivery
The intervention group received 10 consultations of 1 hour each with a trained dietitian during the pregnancy.

Intervention adherence
The trial does not report on adherence to the intervention.

Control group
The control group had no consultations with the dietitian and had no restrictions on energy intake or gestational weight gain.

Follow-up
Maternal weight was reported at prepregnancy, from 36 weeks of gestation until delivery, and 1, 2, 3 and 4 weeks postpartum. Dietary intake was obtained at inclusion, and at 27 and 36 weeks of gestation in both groups.

Physical activity
The trial did not report on physical activity.

Diet assessment
Dietary intake of pregnant women was recorded using 7-day weighed food records, which were obtained at inclusion, and at 27 and 36 weeks of gestation in both groups. Daily energy intake and diet composition were calculated using Dankost 3000 software. In the intervention group, the food records were used as a tool to identify unhealthy eating patterns and give individualised suggestions of improvements.

Outcome measures
Outcomes of the trial were energy intake, total gestational weight gain, average weekly weight gain from inclusion to 36 weeks of gestation, weight gain from self-reported pregnancy weight to inclusion, spontaneous weight loss by giving birth, weight retention at 4 weeks postpartum, glucose metabolism, birth outcomes (birth weight, infant length, gestational age, placental weight, head circumference and abdominal circumference) and incidence of pregnancy and birth complications (GDM, pregnancy-induced hypertension, preeclampsia, prolonged pregnancy, caesarean delivery).

Total gestational weight gain was categorised as the difference between self-reported prepregnancy weight and weight just before delivery. Furthermore, to avoid a possible influence of bias, rate of weight gain was calculated as the difference between the measured weight at inclusion and 36 weeks of gestation divided by the number of weeks from inclusion to 36 weeks of gestation.

Measure of association/effect, 95% CI, p-value
The women in the intervention group successfully limited their energy intake and restricted the gestational weight gain to 6.6kg vs a gain of 13.3kg in the control group ($p = 0.002$, 95% confidence interval (CI): 2.6kg to 10.8kg).

Variables adjusted for
Mean differences in weight development between the 2 groups and the changes in blood parameters were analysed using analysis of covariance with maternal age and parity included as fixed factors, and height and weight at inclusion included as covariates in the model.

i-WIP (2017) Effect of diet and physical activity-based interventions in pregnancy on gestational weight gain and pregnancy outcomes: meta-analysis of individual participant data from randomised trials

The characteristics and findings of this systematic review and meta-analysis are provided in annex 3.

The sections below provide data extracted from relevant primary studies that were included in the systematic review by i-WIP (2017).

Bechtel-Blackwell (2002) (pilot study)

Exposure and outcome
Computer-Assisted self-interview and nutrition education and gestational weight gain and postpartum weight retention.

Study design, number of participants and country
Randomised controlled trial (RCT); 46 participants (22 participants in the experimental group and 24 participants in the control group); USA.

Baseline age
Baseline age was 13 to 18 years.

BMI status
Not reported.

Ethnicity
African American women.

Recruitment
A convenience sample of all African American adolescent primigravidas aged 13 to 18 years who were receiving prenatal care from an adolescent prenatal clinic were recruited during the first trimester or early second trimester of their pregnancies. The total sample size for this pilot study was 60 participants, with 30 randomly assigned to the nutrition education intervention group (experimental group) and 30 randomly assigned to receive the standard nutritional counselling (control group) on admission to the study.

Randomisation
Participants were randomly assigned to groups by designating a random starting point on the patient list and selecting every other name to be included in the experimental group.

Intervention
A computer-assisted self-interviewing (CASI) nutrition assessment and a group nutrition education intervention. The CASI nutrition assessment was used to describe the nutritional health behaviours. The interview included the following information: a 24 hour dietary recall, questions targeting the dietary recommendations (i.e., What type of vegetables do you eat? How often?), and questions addressing general nutrition such as recent problems with eating, cultural or religious factors influencing diet, likes and dislikes, food allergies, caffeine consumption, food preparation, and nutritional supplements.

The nutrition education intervention consisted of 3 20 minute group sessions that addressed nutritional needs specific to the woman's stage of her pregnancy. For example, the initial class, conducted during the first trimester, included information about eating difficulties associated with nausea and/or vomiting, which is a concern for women in that stage of their pregnancy. Maternal and fetal growth and development issues were targeted for the point during the pregnancy in which the class is taught. This developmentally based approach was vastly different from the standard of care currently offered at the adolescent clinic where the women received one individual, problem-focused nutritional consult during their pregnancy.

Intervention delivery
The nutrition assessment using CASI and the Gestational Weight Data Collection Form (GWDCF) were administered to all participants at 4 separate times: on admission to the study in the first trimester, at 24 to 26 weeks gestation (second trimester), at 32 to 34 weeks (third trimester), and 6 weeks postpartum (after delivery). These data collection points were chosen to correspond with the collection of laboratory data that is related to nutritional status. The GWDCF, a 14-item instrument, was used to obtain background data such as age, parity, height, prenatal health behaviours (i.e., prenatal vitamin supplementation, iron supplementation, exercise, breastfeeding), chronic health problems, and specific data used to evaluate the effectiveness of the intervention, such as gestational weight gain patterns and postpartum weight retention.

Intervention adherence
No information provided.

Control group
Standard of care at the adolescent clinic where the women received one individual, problem-focused nutritional consult during their pregnancy. The information received by the women assigned to the standard of care group was variable as it was dependent on the timing of the individual nutritional consult during the pregnancy.

Follow-up
No information provided.

Physical activity
No information provided.

Diet assessment
24-hour dietary recall.

Outcome measures
Height and weight measurements were obtained from each woman on the clinic's one freestanding weighted scale on admission to the study, with continued measurement of weight only at 24 to 26 weeks, 32 to 34 weeks, 36 to 40 weeks, and 6 weeks postpartum.

Measure of association/effect, 95% CI, p-value
The experimental group gained significantly less weight during the first trimester than the control group (F=6.13, p=.0000). In the second trimester, there was no significant difference in gestational weight gain for the 2 groups (F=2.33, p=.056). During the third trimester, gestational weight gain was significantly higher for the experimental group (F=3.44, p=.0060). For the first trimester weight gain in that the control group had a higher mean weight (6.27lb) than the experimental group (3.20lb). The control group gained slightly more weight (14.88lb) than the experimental group (14.5lb) in the second trimester. In the third trimester, the experimental group (15.14lb) had a higher mean weight gain than the control group (12.29lb).

Variables adjusted for
No information provided.

Briley and others (2002)

Exposure and outcome
In-home prenatal nutrition intervention and weight gain.

Study design, number of participants and country
Randomised trial; 20 participants; USA.

Baseline age
Demographic data for those who completed the study indicated that 7 women in each group (70%) were 21 years of age or younger.

BMI status
Mean (kg/m^2) (±standard deviation) pre-pregnancy body mass index was within the normal range for both groups (intervention, 24.7±3.4; control, 23.2±4.1).

Ethnicity
African-American women.

Recruitment
The women were recruited through the local county health department WIC Program and they were all at 24 weeks gestation or less. They had no pre-existing health conditions and none of them were following prescribed diets.

Randomisation
Women were randomly assigned to either an intervention or a control group.

Intervention
The intervention protocol required a minimum of 6 individualised in-home nutrition assessment and counselling visits.

Visit 1: 24 hour dietary recall, height and weight measurements, prenatal questionnaire, pre-pregnancy questionnaire, 2 24 hour dietary recalls obtained by telephone following this visit.

Visit 2: food frequency, food guide pyramid, recommended weight gain based on the individual's BMI, weight gain graph, Hey Baby and Baby Under Construction documents, Nine-Month Journey document.

Visit 3: discussed calcium, iron, folate, fibre, and protein sources, discussion of dietary intake compared to Food Guide Pyramid, Inside My Mom document, discussed goal setting strategies, individual goal setting.

Visit 4: Healthy Foods, Healthy Baby (teenagers only) document, menu planning, shopping tips, discussed goal achievement.

Visit 5: reassessment of dietary intake, strategies for managing weight gain.

Visit 6: discussed pre and post pregnancy, computer diet analysis, importance of continued good nutrition, special needs for breastfeeding.

Intervention delivery
The intervention protocol required a minimum of 6 individualised in-home nutrition assessment and counselling visits. Visits were scheduled weekly for the first 4 weeks, and

then monthly for 2 more visits. Some clients delivered their babies within the month following the sixth visit. For those who had not delivered, monthly visits continued until parturition. Mean daily energy and nutrient intakes were determined before and after the intervention for both groups. Intakes were analysed and expressed as percent of Recommended Dietary Allowance (RDA) or Dietary Reference Intake (DRI) with 75% RDA or DRI or more considered within normal limits.

Intervention adherence
No information provided.

Control group
Women in the control group were visited twice. The protocols for the 2 visits were the same as visits 2 and 5 for the intervention group: 24 hour dietary recall, plus 2 further dietary recalls obtained by telephone; and then reassessment of dietary intakes. No teaching or counselling was delivered.

Follow-up
No information provided.

Physical activity
No information provided.

Diet assessment
Dietary data collected from both groups included 3 24-hour recalls before and after the intervention. Food models, measuring cups and spoons, and food pictures were used to help clients determine portion sizes. Food Processor Plus computer software was used to analyse all dietary intakes. Mean daily energy and nutrient intakes were determined before and after the intervention for both groups. Intakes were analysed and expressed as percent RDA or DRI with 75% RDA or DRI or more considered within normal limits.

Outcome measures
Mean weight gain.

Measure of association/effect, 95% CI, p-value
Mean weight gain (intervention, 11.9 ± 6.3kg; control, 15.2 ± 5.1kg) for each group was within the recommended range of 11.4kg to 15.9kg.

Variables adjusted for
The authors reported that potential confounding factors were not assessed.

Das and others (2015) (meeting abstract)

Note: the reference in the SR is to a meeting abstract. Information included below is limited due to this.

Exposure and outcome
Behavioural intervention with high-fibre cereal (CF) or resistant starch (RS) on GWG.

Study design, number of participants and country
RCT; 36 participants; USA.

Baseline age
Mean age: 31 ± 0.7 years.

BMI status
Mean BMI: 30 ± 1.1kg/m^2.

Ethnicity
No information provided in the abstract.

Recruitment
No information provided in the abstract.

Randomisation
No information provided in the abstract.

Intervention
From meeting abstract: Recommendations to increase fibre intake with provided fibre sources. Intervention groups provided with either a CF or RS. Support for the intervention groups included weekly emails or phone calls with a weight loss counsellor and regular self-monitoring of body weight.

Intervention delivery
From meeting abstract: Support for the intervention groups included weekly emails or phone calls with a weight loss counsellor and regular self-monitoring of bodyweight.

Intervention adherence
No information provided in the meeting abstract.

Control group
From meeting abstract: Assessment-only control group.

Follow-up
No information provided in the meeting abstract.

Physical activity
No information provided in the meeting abstract.

Diet assessment
No information provided in the meeting abstract.

Outcome measures
No information provided in the meeting abstract.

Measure of association/effect, 95% CI, p-value
All groups gained more than the Institute of Medicine maximum recommendations with the CF group gaining the most (139 plus 10% of maximum recommended weight, mean plus SE), and the RS group gaining the least (119 plus 13%). Weight gain in both intervention groups was neither significantly different from the control group (129 plus 35%, P=.50, main effect) nor from each other (P=.18). Percent weight gain was more variable in the control group (35% vs. CF=10%, RS=13%, SE, P=.02).

Variables adjusted for
No information provided in the meeting abstract.

Deveer and others (2013)

Primary data extraction for this study is included under Walker and others (2018) Attenuating Pregnancy Weight Gain - What Works and Why: A Systematic Review and Meta-Analysis.

Di Carlo and others (2014)

Primary data extraction for this study is included under Walker and others (2018) Attenuating Pregnancy Weight Gain - What Works and Why: A Systematic Review and Meta-Analysis.

Gómez Tabares and others (1994) (abstract)

Note: information included is limited as this is only available in English as an abstract (the full article is available in Spanish only).

Exposure and outcome
Diet for gestational diabetes and maternal morbimortality.

Study design, number of participants and country
No information provided in the abstract; 60 participants; Colombia.

Baseline age
No information provided in the abstract.

BMI status
No information provided in the abstract.

Ethnicity
No information provided in the abstract.

Recruitment
From abstract: Authors studied prospectively 60 obese patients divided in 3 groups of 20 patients each with overweight of 20% to 29%; 30% to 39% and 40%, respectively.

Randomisation
No information provided in abstract.

Intervention
No information provided in abstract.

Intervention delivery
No information on timing or style of delivery given in abstract.

Intervention adherence
No information provided in abstract.

Control group
No information provided in abstract.

Follow-up
No information provided in abstract.

Physical activity
No information provided in abstract.

Diet assessment
No information provided in abstract.

Outcome measures
No information provided in abstract.

Measure of association/effect, 95% CI, p-value
No information provided in abstract.

Variables adjusted for
No information provided in abstract.

Khoury and others (2005)

Exposure and outcome
Cholesterol-lowering diet and maternal weight gain.

Study design, number of participants and country
RCT; 290 participants; Norway.

Baseline age
Intervention group: mean age 29.8 ± 3.4 years; control group: mean age 29.6 ± 3.7 years.

BMI status
BMI (kg/m^2) intervention group: mean BMI 24.3 ± 2.9; control group: mean BMI 24.3 ± 2.7.

Ethnicity
White women.

Recruitment
Potential participants received information about the study enclosed with the ultrasound appointment at the National Hospital, Oslo, from June 1999 to November 2001. The information was sent to 2,238 women, of whom 985 expressed interest in the study. Of these, 670 women were screened for inclusion, 294 met the inclusion criteria, 4 withdrew before randomisation, leaving 290 women that were randomised.

Randomisation
Eligible women were randomly allocated to the usual diet or intervention diet. The randomisation list was generated from a table of random numbers drawn up by the investigator, who had no contact with the pregnant women. The dietician responsible for giving the dietary advice was given sealed, consecutively numbered, opaque envelopes containing the randomisation number and code (control or intervention). The dietician then allocated the next available number to each screened and eligible subject and opened the envelope to determine whether the subject was to follow the usual diet or the intervention

diet. The physicians and midwives caring for the women, the specialist physician, and all laboratory and other personnel were blinded in regard to the treatment assignment. The subjects were asked not to reveal their dietary assignment to any of the study staff or other subjects.

Intervention
The intervention diet aimed to limit dietary cholesterol to 150mg per day and to reduce the intake of saturated fat to 8% of dietary energy by replacing saturated fat by mono- and polyunsaturated fat. Total fat was planned to constitute 32% of total energy intake (with 8% to 9% of energy from polyunsaturated fat and 16% to 17% from monounsaturated fat), protein 16% to 17% of energy, and carbohydrates 50% to 51% of energy. Energy intake aimed at a weight gain of 8kg to 14kg from pre-pregnancy levels. The dietician encouraged the intake of fatty fish, vegetable oils, especially olive oil and rapeseed oil, nuts, nut butters, margarine based on olive- or rapeseed oil, and avocado to replace meat, butter, cream, and fatty dairy products. In addition, the consumption of fresh fruits and vegetables was advised (at least 6 a day). Intake of dairy products in the form of skimmed or low-fat products (skimmed milk, fat-reduced cheese, and yogurt) in place of full fat products was encouraged. Subjects were advised to choose meat for a main meal twice a week and use legumes, vegetable main dishes, fatty fish, or poultry with the fat trimmed off on the other days. Cooking lessons were scheduled to implement special foods (for example legumes, olive oil) in the intervention group. Coffee was limited to 2 cups of filtered coffee a day.

Intervention delivery
Gestational week 17 to 20 to birth. Dietician visits were scheduled at inclusion, and at weeks 24, 30, and 36. Both the intervention and control groups followed the same schedule of physician and dietician visits and assessments. Subjects in both groups were asked to follow the assigned diet until delivery and were reminded to continue the diet after week 36.

Intervention adherence
To assess dietary compliance, weighed dietary records were assigned on a predetermined day weekly throughout pregnancy grouped in 3 periods. The diet was recorded on 4 days during weeks 19 to 24, on 6 days during weeks 24 to 30, and on 6 days during weeks 30 to 36 of gestation.

Control group
The control group was asked to consume their usual diet based on Norwegian foodstuffs, and not to introduce more oils or low-fat meat and dairy products than usual, aiming at 32% of energy from total fat (including 12% from saturated fat), 16% to 17% of energy

from protein, and 50% to 51% of energy from carbohydrate. Energy intake aimed at a weight gain of 8kg to 14kg, as in the intervention group.

Follow-up
Gestational week 17 to 20 to birth.

Physical activity
No physical activity was prescribed by the trial, but reported its cohort contained women with above average level of physical activity.

Diet assessment
48 hour dietary recall at inclusion then the diet was recorded (via weighed dietary records) on 4 days during weeks 19 to 24, on 6 days during weeks 24 to 30, and on 6 days during weeks 30 to 36 of gestation.

Outcome measures
No information provided.

Measure of association/effect, 95% CI, p-value
Weight gain between inclusion and week 30 was higher in the control than in the intervention group (mean 6.0kg SD 2.2kg vs 5.4kg SD 2.3kg), difference 0.6kg (95% CI 0.05 to 1.1, P = .03). At week 36, the difference was not statistically significant (9.4kg SD 3.0 in the control group vs 8.9kg SD 3.1 in the intervention group), difference 0.5kg (95% CI 0.2 to 1.3; P = .2).

Variables adjusted for
No information provided.

Korpi-Hyövälti and others (2012)

Primary data extraction for this study is included under Walker and others (2018) Attenuating Pregnancy Weight Gain - What Works and Why: A Systematic Review and Meta-Analysis.

Mujsindi and others (2014) (poster)

Note: the reference in the SR is to a poster. Information included below is limited due to this.

Exposure and outcome
Nutrition education and gestational weight gain.

Study design, number of participants and country
RCT; 79 participants; USA.

Baseline age
No information provided in the poster.

BMI status
Obese women – no further information provided in the poster.

Ethnicity
No information provided in the poster.

Recruitment
No information provided in the poster.

Randomisation
No information provided in the poster.

Intervention
The intervention consisted of 5 dietary and nutrition consultation sessions during the pregnancy and at 3 months postpartum, food records, pedometers and logs, pregnancy activity questionnaire and food frequency questionnaire. Anthropometric measures were collected at 20, 24, 30 and 36 weeks and at 3 and 6 months postpartum.

Intervention delivery
No information provided in the poster.

Intervention adherence
No information provided in the poster.

Control group
No information provided in the poster.

Follow-up
The intervention consisted of 5 dietary and nutrition consultation sessions during the pregnancy and at 3 months postpartum, food records, pedometers and logs, pregnancy activity questionnaire and food frequency questionnaire. Anthropometric measures were collected at 20, 24, 30 and 36 weeks and at 3 and 6 months postpartum.

Physical activity
No information provided in the poster.

Diet assessment
No information provided in the poster.

Outcome measures
No information provided in the poster.

Measure of association/effect, 95% CI, p-value
There was no difference in mean gestational weight gain between the intervention and control at 20 weeks, 24, 30 and 36 weeks.

Variables adjusted for
No information provided in the poster.

Parat and others (2015) (poster)

Note: the reference in the SR is to a poster. Information included below is limited due to this.

Exposure and outcome
Patient therapeutic education with dietary counselling sessions and excess weight gain.

Study design, number of participants and country
RCT; 268 participants; France.

Baseline age
Intervention group: 30.3 ± 5.1 years, control group 30.4 ± 5.0 years.

BMI status
Intervention group: 32.5 ± 5.4kg/m^2, control group 32.5 ± 5.4kg/m^2.

Ethnicity
No information provided in the poster.

Recruitment
No information provided in the poster.

Randomisation
No information provided in the poster.

Intervention
Patient therapeutic education with 2 individual and 4 collective dietary counselling sessions – no further information provided in the poster.

Intervention delivery
Patient therapeutic education with 2 individual and 4 collective dietary counselling sessions at 18, 26, 33 weeks of gestation and 2 months after delivery - no further information provided in the poster.

Intervention adherence
Patient therapeutic education with 2 individual and 4 collective dietary counselling sessions at 18, 26, 33 weeks of gestation and 2 months after delivery.

Control group
Routine care including at least one dietary consultation - no further information provided in the poster.

Follow-up
Pre 20 weeks to 2 months after delivery.

Physical activity
No information provided in the poster.

Diet assessment
No information provided in the poster.

Outcome measures
Excess weight gain.

Measure of association/effect, 95% CI, p-value
No information provided in the poster for our outcome of interest.

Variables adjusted for
No information provided in the poster.

Quinlivan and others (2011)

Exposure and outcome
A 4-step multidisciplinary protocol of antenatal care (including a brief intervention by a food technologist before each visit) and the incidence of gestational diabetes.

Study design, number of participants and country
A randomised trial that recruited women (n=132) from the maternity service of a public general hospital serving a socioeconomically disadvantaged area in Melbourne, Australia.

Baseline age
Intervention group (n=63): mean age 28.3 (SE 0.63); control group (n=61): mean age 29.5 (SE 0.71).

BMI status
All participants had a BMI above 25kg/m^2:

- BMI (kg/m^2) intervention group: pre-obese (25 to 29.9) = 26 (42%); obese I (30.0 to 34.9) = 17 (27%); obese II (35.0 to 39.9) = 11 (18%); obese III (40 or above) = 8 (13%)

- BMI (kg/m^2) control group: pre-obese (25 to 29.9) = 30 (49%); obese I (30.0 to 34.9) = 15 (25%); obese II (35.0 to 39.9) = 9 (15%); obese III (40 or above) = 7 (11%)

Ethnicity
Intervention group: Asian 8 (13%); Caucasian 50 (79%); Other 5 (8%)

Control group: Asian 16 (26%); Caucasian 41 (67%); Other 4 (7%)

Recruitment
Women were recruited if they were pregnant with a fetus with no known anomalies, spoke English, did not intend to relinquish their infant, did not have a multiple gestation, were able to attend hospital for antenatal care and were overweight (BMI 25 to 29.9) or obese (BMI above 29.9) on standard body mass index determination.

Randomisation
Randomisation to the intervention or control groups occurred using computer-generated numbered sealed opaque envelopes, stratified by category (overweight or obese), which were only opened by the midwife after each woman's enrolment was completed.

Intervention
Women in the intervention group attended a study-specific antenatal clinic, which provided a 4-step multidisciplinary approach to the management of obese pregnant women.

Intervention delivery
Women in the intervention group received 4-step multidisciplinary antenatal care, which included:

- continuity of obstetric provider
- weighing on arrival at each visit
- a 5 brief minute intervention by a food technologist who asked about the women's eating habits of the previous day, provided information on reading food labels, shopping lists of affordable foods available from local shops and recipes for a healthy pregnancy diet, at every visit
- clinical psychology management to assess symptoms of depression and anxiety, stressful life events and determine whether psychological factors were involved in eating patterns

Intervention adherence
The trial did not report on adherence to the intervention.

Control group
Participants allocated to the control group received routine public antenatal care. This consisted of midwifery, obstetrician and general practitioner antenatal clinics, with access to high-risk antenatal clinics if indicated on medical grounds.

Follow-up
Weight gain was recorded at the booking session (8 to 12 weeks) and the onset of labour.

Physical activity
The trial did not report on physical activity.

Diet assessment
Dietary intake of pregnant women was assessed using an audit of items consumed in the day before the first and final antenatal visit.

Outcome measures
The primary outcome was the prevalence of the combined diagnoses of decreased gestational glucose tolerance and gestational diabetes mellitus. Secondary outcomes were weight gain in pregnancy defined as the difference between the booking weight and weight at the onset of labour and birthweight, as measured by the attending midwife immediately following birth on neonatal scales which had been calibrated at the start of the study and every month during the study period.

Measure of association/effect, 95% CI, p-value
Significant results were also obtained in the comparisons of weight gain during pregnancy between groups ($t110 = 5.57$, $p < 0.001$). On average, participants in the intervention group gained 7.0kg (SE = 0.65kg) which was significantly less than that gained by the control group with an average of 13.8kg (SE = 0.67kg).

Variables adjusted for
The trial reported that all potential confounding factors identified were adjusted for the outcome of GDM but does not state whether the comparison of weight gain during pregnancy was adjusted for confounders.

Thornton and others (2009)

Primary data extraction for this study is included under Walker and others (2018) Attenuating Pregnancy Weight Gain—What Works and Why: A Systematic Review and Meta-Analysis.

Vítolo and others (2011) (abstract)

Note: information include is limited as this is only available in English as a meeting abstract (the full article is available in Spanish only)

Exposure and outcome
Dietary counselling according to nutritional status. Outcome not available from abstract.

Study design, number of participants and country
Randomised trial; 315 participants; Brazil.

Baseline age
Above 35 years.

BMI status
All.

Ethnicity
Not available from the abstract.

Recruitment
Not available from the abstract.

Randomisation
Not available from the abstract.

Intervention
The Intervention Group received dietary counselling according to nutritional status.

Intervention delivery
Not available from the abstract.

Intervention adherence
Not available from the abstract.

Control group
The control group did not receive the dietary guidelines but were informed about their nutritional status and were asked to perform the prenatal care.

Follow-up
Not available from the abstract.

Physical activity
Not available from the abstract.

Diet assessment
Not available from the abstract.

Outcome measures
Not available from the abstract.

Measure of association/effect, 95% CI, p-value
Not available from the abstract.

Variables adjusted for
Not available from the abstract.

Comments
Limited information available as full article only available in Spanish and limited information available from the SR.

Walsh and others (2012) (ROLO study)

Primary data extraction for this study is included under Walker and others (2018) Attenuating Pregnancy Weight Gain - What Works and Why: A Systematic Review and Meta-Analysis.

Wolff and others (2008)

Primary data extraction for this study is included under Walker and others (2018) Attenuating Pregnancy Weight Gain - What Works and Why: A Systematic Review and Meta-Analysis.

Dietary interventions and weight postpartum

Dalrymple and others (2018) Lifestyle interventions in overweight and obese pregnant or postpartum women for postpartum weight management: a systematic review of the literature

The characteristics and findings of this SR are provided in annex 3.

The sections below provide data extracted from relevant primary studies that were included in the systematic review by Dalrymple and others (2018).

Falciglia and others (2017)

Exposure and outcome
Dietary intervention to increase target vegetable intake and change in maternal BMI.

Study design, number of participants and country
A randomised controlled dietary intervention that recruited overweight women (n=104) attending their 6-week postpartum follow-up visit at a large obstetrics clinic in the Cincinnati metropolitan area were screened for inclusion between March 2008 and April 2011.

Baseline age
Intervention (n=52): mean age (years): 28.8 (SD 4.8).

Usual care (n=52): mean age (years): 29.3 (SD 4.0).

BMI status
Mean baseline BMI (kg/m^2):

Intervention: 31.3 (SD 4.7).

Usual care: 29.7 (SD 4.5).

Ethnicity
Intervention (n, %): Non-Hispanic White: 39 (75.0%); Other: 13 (25.0%).

Usual care (n, %): Non-Hispanic White: 38 (73.1%); Other: 14 (26.9%).

Recruitment
Inclusion criteria consisted of: BMI of 25kg/m^2 or above with no co-morbidities; 21 to 35 years of age; given birth to a singleton, full-term infant; a target vegetable intake (deep-yellow and dark-green vegetables) less than or equal to 1.5 servings per day (based on current vegetable intake from pilot data); full medical clearance from a physician to participate; no special diet prescribed; limited use of alcohol (one alcoholic drink/day); and no use of illegal drugs or tobacco. Mothers that did not meet those criteria were excluded.

Randomisation
Participants were randomized to either dietary intervention (n= 52) or usual care (n= 52).

Intervention
The dietary intervention focused on consuming a healthy diet, with an emphasis on deep-yellow and dark-green vegetables. Target vegetables included carrots, winter squash, sweet potatoes, broccoli, spinach, and peas. The manual developed for the individualised nutrition education sessions included 3 modules: Maternal diet (calorie level appropriate for gradual weight loss while supporting lactation), Intro to solid foods and Transition into toddler foods. Mothers were encouraged to make gradual dietary changes to comply with the US Department of Agriculture (USDA) food guide MyPyramid and achieve the intervention goal of consuming at least 2 servings of the target vegetables and a total of 5 servings of vegetables daily.

Intervention delivery
Mothers received 4 60 minute education sessions with a nutrition professional and8 monthly follow-up phone calls. Counselling began at the obstetrician office and continued at the regularly scheduled paediatric visits. Dietary counselling was provided by nutrition professionals with graduate level training in nutrition and theory-based nutrition education.

Intervention adherence
Not reported.

Control group
At baseline, standard educational materials were mailed to the mothers on healthy eating according to the USDA food guide MyPyramid recommended for breastfeeding or formula feeding needs. A handout with basic information on starting solid foods and transitioning to toddler foods was also included. Formal dietary counselling sessions or phone calls were not included in the usual care group.

Follow-up
Outcomes were measured at baseline (6-weeks postpartum), 6, 12 (post-intervention), and 18 (follow-up) months.

Diet assessment
Dietary intake for the mother/child dyads was assessed via 3 unannounced, interviewer-administered 24-hour dietary recalls conducted over a one-week time span at each evaluation point. Dietary recalls for the mothers were analysed for daily average energy intake (kcal) and food groups (number of servings) according to the 2010 Dietary Guidelines for Americans.

Outcome measures
The primary study outcome was the change in maternal target vegetable intake. Secondary outcomes included child target vegetable intake and whether child vegetable intake was modified by exposure to breastfeeding. Mother/child energy intake and weight indices were also assessed.

Measure of association/effect, 95% CI, p-value
From baseline there was no difference in BMI for the intervention (dietary counselling) and control group at 6 months (p=0.91), 12 months (p=0.35) and subsequent follow-up (18 months) (p=0.53).

Variables adjusted for
Not reported.

Huseinovic and others (2016)

Exposure and outcome
Diet behaviour modification treatment and weight change in postpartum women.

Study design, number of participants and country
A 2-arm randomized controlled trial recruiting women (n= 110) with a self-reported BMI (kg/m^2) of at least 27 at 6 to 15 weeks postpartum through midwives and flyers at antenatal and childcare clinics, as well as via advertisements in shopping centres, web journals, social media sites, and newspapers in Gothenburg and 7 surrounding municipalities in Sweden, between 2011 to 2014.

Baseline age
Intervention group (n= 54): mean age (years): 31.8 (SD 4.5)

Control group (n= 56): mean age (years): 32.6 (SD 4.7)

BMI status
Prepregnancy BMI (kg/m^2):

Intervention group: median (1st, 3rd quartiles): 27.4 (25.4, 32.3)

Control group: median (1st, 3rd quartiles): 28.8 (26.8, 33.0)

Ethnicity
Not reported.

Recruitment
Women with a BMI of $27kg/m^2$ or above, and at 6 to 15 weeks gestation were eligible for inclusion. The exclusion criteria included serious disease in woman or child, participation in another weight trial, and inability to assimilate written study material in Swedish.

Randomisation
Women were randomly assigned to the diet behaviour modification group (D group) or the control group (C group) through a simple randomisation procedure that used numbered and sealed envelopes generated through a random number table prepared by the project coordinator.

Intervention
The diet treatment aimed to achieve an energy intake reduction of 500kcal per day with a nutrient composition according to the Nordic Nutrition Recommendations 2004. These recommendations emphasize a dietary composition of total fat less than 30% of energy intake, saturated fat 10% of energy intake or less, protein 10% to 20% of energy intake, carbohydrate 50% to 60% of energy intake, and fibre at least 12.5 g per 1,000 kcal. The 4 key dietary principles were: 1) limit consumption of sweets, salty snacks, and caloric drinks to 1 day per week and a maximum of 100g per week; 2) substitute regular foods with low-

fat and/or low-sugar alternatives marked with the “green keyhole”; 3) cover one-half of the plate with vegetables at lunch and dinner by applying the “plate model,” an illustration of the proportions between the meal components; and 4) reduce portion sizes.

Intervention delivery
Women randomly assigned to the diet group (n = 54) were instructed to complete a diet record for 4 consecutive days after the baseline visit. They were asked not to divert from their usual food choices or habits because their diet record would be used to construct the diet plan. Within 1 to 2 weeks of the baseline visit, women in the diet group met for a face-to-face visit with the dietitian for 1.5 hours of structured individual diet behaviour modification treatment at the primary health care clinics. The diet plan was presented in a printed booklet covering the dietary principles, the weekly and final weight-loss goals during the intervention, the instructions to self-weigh at least 3 times per week, and guidance on how to use body weight as a proxy for energy balance to adjust energy intake during the intervention. During the intervention period, women were contacted biweekly by the dietitian with standardised cell phone text messages and asked to report current body weight and provided with personalized reinforcement and feedback on their progress. The text message after 6 weeks of intervention was replaced with a telephone call to allow for questions and more thorough feedback. Women also received routine postnatal care at the maternal health care clinics and were offered the treatment and material of the alternative study group after final follow-up.

During the 9 months after intervention termination, standardized monthly e-mails were sent to women in the diet group to increase the likelihood of establishing sustainable lifestyle changes. Women were also asked to report their current body weight and provided with individualised reinforcement and feedback by the dietitian through e-mail correspondence.

Intervention adherence
Not reported.

Control group
Women randomly assigned to the control group (n = 56) received no diet treatment, text messages, or telephone call but were instead given a brochure on healthy eating at the baseline visit. The brochure included advice on regular meal patterns, the plate model, selecting low-fat alternatives labelled with the green keyhole, reducing energy-containing beverages and a recommendation to aim for a weight loss rate of 0.5kg per week. Both groups received routine postnatal care at the maternal health care clinics and were offered the treatment and material of the alternative study group after final follow-up.

Follow-up
Study measurements were conducted at baseline, intervention termination (indicated as 12 weeks) and 9 months later (indicated as 1 year).

Diet assessment
An unannounced, telephoned 24 hour recall was performed with all women a few days before all 3 study visits to assess dietary intake. Women were asked to recall all foods and beverages consumed from midnight to midnight during the preceding whole 24-hour period and to quantify the amounts by use of weights and volumes, household measures, or a booklet of 2-dimensional photographs of different portion sizes of foods.

Dietary intake was calculated by use of the software Dietist XP, based on the Swedish Food Database 2010 and data from food manufacturers. All dietary data presented excluded supplement intake.

Outcome measures
The primary outcome was change in weight after 12 weeks and 1 year. Other anthropometric and treatment-related secondary outcomes were changes in BMI, waist circumference, hip circumference, percent body fat, dietary intake, and physical activity.

Measure of association/effect, 95% CI, p-value
There was a significant effect of a 12-week postpartum diet only intervention on postpartum weight retention when compared to controls (median (1st, 3rd quartiles)); at the end of the intervention ((intervention: −6.1kg (−8.4, −3.2kg), control: −1.6 kg (−3.5, −0.4kg) ($p < 0.001$)) and at a 1-year follow up ((intervention: −10.0kg (−11.7, −5.9kg, control: −4.3kg (−10.2, −1.0kg) ($p = 0.004$)).

Variables adjusted for
The data were analysed by use of linear mixed models adjusted for baseline values of the outcome variable and lactation status.

Peccei and others (2017)

Exposure and outcome
Intensive prenatal nutrition counselling and gestational weight gain.

Study design, number of participants and country
A randomised controlled trial that recruited women (n=272) from an academically affiliated urban health centre prenatal clinic in Revere, Massachusetts, from 23 December 2009 to 20 August 2014.

Baseline age
Baseline age was not reported by allocation group, but the trial did have an inclusion criteria of between 18 to 49 years of age.

BMI status
The trial did not report baseline BMI status.

Ethnicity
Intervention group (n=180): White (non-Hispanic) n= 65 (36.1%); Black (non-Hispanic) n= 14 (7.8%); Hispanic n= n88 (48.9%); Other (non-Hispanic) n= 13 (7.2%).

Control group (n=92): White (non-Hispanic) n= 42 (45.7%); Black (non-Hispanic) n= 3 (3.3%); Hispanic n= 40 (43.5%); Other (non-Hispanic) n= 7 (7.6%).

Recruitment
Pregnant women were recruited if they were between the ages of 18 to 49 years, less than 16 weeks of gestation, and had a BMI at the initial obstetric visit of at least 25 but less than or equal to 40. Participants with multiple gestations, diabetes before pregnancy, or a history of eating disorders were excluded.

Randomisation
The Study Trax Research Platform randomized the women in a 2:1 ratio of intervention to control. The 2:1 ratio was chosen to provide a higher level of nutrition counselling than provided during usual care to the largest number of patients in hope of maximizing the clinical benefit of the trial.

Intervention
The intervention group were encouraged to increase fruits, vegetables, and whole grains while choosing lean protein, low-fat dairy, and healthy fat sources. They were advised to replace high-calorie sugary drinks with water or other low-calorie beverages and limit “discretionary” calories such as high-calorie desserts. Individualised meal plans were made for intervention patients. Estimated energy needs were calculated and approximate calorie levels ranged between 1,800 and 2,400 calories per day with most women prescribed the lower range. Meal plans were individualised based on the prescribed caloric intake, with an emphasis on relatively low carbohydrate intake (45% carbohydrate, 25% protein, 30% fat).

Intervention delivery
An initial study session with a registered dietitian (60 to 90 minutes) provided counselling on topics such as healthy eating guidelines and IOM gestational weight gain recommendations. After the initial visit, the intervention group had individualised

counselling sessions with the study registered dietitian twice a month throughout pregnancy, each lasting approximately 10 to 30 minutes. During twice-per-month nutrition counselling, weight gain trajectory and exercise level were reviewed and individualised meal plans were adjusted accordingly by the registered dietitian. Postpartum, all study participants were asked to fill out the nutrition and exercise questionnaire and received basic counselling by the registered dietitian about a healthy diet with a goal to return to their baseline prepregnancy weight by 6 months postpartum. The registered dietitian developed individualised meal plans for the postpartum period based on a nutrition assessment at 6 weeks postpartum. Approximate calorie ranges were between 1,600 and 2,200 calories per day depending on breastfeeding energy needs, weight gained during pregnancy, and activity level. Intervention patients who continued through 6 months postpartum stayed in contact by phone or in person every 2 weeks. Patients were advised to keep weight loss to 1.5 pounds or less per week if breastfeeding. The last encounter with the study registered dietitian and clinically confirmed weight was at 6 months postpartum.

Intervention adherence
The trial notes that difficulties with compliance may have biased the findings toward the null.

Control group
Participants allocated to the control group received the same initial study session with a registered dietitian (60 to 90 minutes) as the intervention group and were provided counselling on topics such as healthy eating guidelines, IOM gestational weight gain recommendations, the pregnancy-related risks of being overweight or obese and information on basic nutritional needs. Women were encouraged to increase fruits, vegetables, and whole grains while choosing lean protein, low-fat dairy, and healthy fat sources. They were advised to replace high-calorie sugary drinks with water or other low-calorie beverages and limit “discretionary” calories such as high-calorie desserts. Postpartum, all study participants were asked to fill out the nutrition and exercise questionnaire and received basic counselling by the registered dietitian about a healthy diet with a goal to return to their baseline prepregnancy weight by 6 months postpartum. Both the intervention and control groups had their last encounter with the study registered dietitian and clinically confirmed weight at 6 months postpartum and were offered continued follow-up with the health centre registered dietitian if desired.

Follow-up
Throughout pregnancy, around delivery, 6 weeks and 6 months postpartum.

Physical activity
Patients were encouraged to walk 30 minutes on most days and track steps using a pedometer provided by the study to all patients at the first visit, although formal tracking of steps was not assessed during the study.

Diet assessment
Dietary assessment was made based on diet recall over the phone, in addition to food and nutrition questionnaires.

Outcome measures
The primary outcome was the proportion of women with gestational weight gain within IOM guidelines.

The secondary outcomes included neonatal birth weight and maternal and neonatal complications, including gestational diabetes, hypertensive disorders, caesarean delivery, admission to the neonatal intensive care unit, and weight retention at 6 months postpartum.

Total gestational weight gain was calculated from the patient's first documented prenatal weight (at less than 16 weeks of gestation per study eligibility criteria) to the last documented weight before delivery (95% were obtained within 2 weeks before delivery).

Measure of association/effect, 95% CI, p-value
In treatment assignment group analyses, there was no statistically significant difference in the proportion of women with gestational weight gain within IOM guidelines in the intervention group (34.2%) compared with the control (27.5%) group among the total population (OR 1.4, 95% CI 0.8 to 2.4) nor among the obese (OR 1.2, 95% CI 0.6 to 2.6) or overweight (OR 1.6, 95% CI 0.7 to 3.8) subgroups.

In as-treated analyses, among overweight women, assignment to the intervention group was associated with significantly lower total maternal weight gain (26.1 pounds compared with 31.4 pounds; difference -5.3 pounds, 95% CI - 10.0 to -0.6, p= .034) and lower percent of initial BMI at 6 months (101% compared with 106%; difference -4.9, 95% CI -8.8 to -0.9, p= .026).

Variables adjusted for
The trial did not report adjusting for confounders for the outcome of GWG.

Wilkinson and others (2015)

Exposure and outcome
Dietary counselling and weight loss from pre-pregnancy to 6 months postpartum and from 6 weeks postpartum to 6 months postpartum.

Study design, number of participants and country
A randomised controlled trial that recruited overweight/obese women (n=81) by the research midwife reviewing the hospital clinic lists and hospital database that contained women's BMIs and opportunistic recruitment occurred through clinic obstetricians, midwives, diabetes educators and dietitians who were aware of study eligibility criteria, between 31 August 2010 to 7 July 2011.

Baseline age
Intervention (n=36): mean age (years): 31.8 (SD 5.3).

Standard care (n=35): mean age (years): 29.0 (SD 3.8).

BMI status
Mean pre-pregnancy BMI (kg/m^2):

Intervention: 33.5 (SD 5.9).

Standard care: 33.5 (SD 6.4).

Ethnicity
Not reported.

Recruitment
Women were eligible if they had a prepregnancy BMI above 25 kg/m^2, could read and speak English to a level that allowed completion of intervention worksheets, and were older than 18 years (or younger than 18 years, with the consent of a parent or guardian). Women were ineligible if they lived outside the hospital's catchment area, delivered before 36 weeks of pregnancy, had a prepregnancy diagnosis of type 1 or type 2 diabetes mellitus, had a history of substance use or had a severe medical or psychological diagnosis that prevented participation within the intervention.

Randomisation
Women were randomised to the control ('supported care'; SC) or intervention ('enhanced care'; EC) group, stratified by BMI cohort (25 to 30 kg/m^2; above 30 kg/m^2). The computerised randomisation process was managed by the hospital's research support

unit; allocation was concealed using sealed opaque envelopes and the research midwife was blinded to trial group.

Intervention
Members of the intervention group (EC) received a 6-month correspondence intervention designed according to Social Cognitive Theory (SCT) that involved a 1-h face-to-face nutrition assessment, goal-setting introduction and counselling session regarding nutrition post-pregnancy (delivered antenatally at approximately 36 weeks), which was in line with the Australian Dietary Guidelines, and fortnightly information and goal-setting sheets posted from 6 weeks until 3 months postpartum, and then monthly information and goal-setting sheets posted until 6 months postpartum.

Content combined successful weight loss and behaviour change principles (self-monitoring), a low-intensity delivery format (postal correspondence), with evidence-based postpartum nutrition information, recognising women's needs and interests, to decrease their risk of obesity and chronic disease.

Intervention delivery
The research dietitian delivered the initial programme to both groups and experienced hospital-based dietitians delivered the postal intervention.

Intervention adherence
Not reported.

Control group
At the 36-week hospital visit, members of the control group (SC) were provided with a 'Healthy Eating for Breastfeeding' sheet based on the National Dietary Guidelines for women breastfeeding that were current at the time of the study.

Follow-up
Data collection occurred at 3 time points:

- time 1: 36 weeks of pregnancy
- time 2: 6 weeks postpartum (6/52)
- time 3: 6 months postpartum (6/12)

At time 1, data collected included: weight, height, prepregnancy weight (self-reported) and diet quality [fat and fibre behaviour index (FFB)]. Data collected at times 2 and 3 included weight, body composition (fat free mass (FFM) and fast mass (FM)) and diet quality.

Diet assessment
Valid and reliable self-report measures of the health behaviours of interest were used.

Outcome measures
The primary outcome measure was weight loss and was calculated as the difference in weight change between EC and SC groups from (i) 6 weeks to 6 months postpartum and (ii) prepregnancy weight to 6 months postpartum. Secondary outcome measures were diet quality scores, minutes of health enhancing physical activity (HEPA), proportion of women breastfeeding, fasting glucose and fasting insulin levels, and body composition (FM and FFM).

Measure of association/effect, 95% CI, p-value
No significant differences were observed between the primary outcome measure of weight loss from prepregnancy to 6 months postpartum for either the intervention group or the control group (p=0.81), or from 6 weeks to 6 months postpartum for either group (p=0.97).

Variables adjusted for
For selected outcome measures (not reported), further exploratory analysis was undertaken adjusting for maternal age as there was a significant clinical difference at baseline; however, these analyses did not alter the findings and are not reported.

Wiltheiss and others (2013)

Exposure and outcome
Diet quality during early postpartum period and postpartum weight change (5 to 15 months postpartum).

Study design, number of participants and country
A randomised clinical trial that recruited overweight/obese women (n=276) from 14 countries in the Piedmont region of North Carolina between September 2007 and November 2009.

Baseline age
Intervention group (n=131): mean age 33.3 years (SD 4.6 years); control group (n=145) mean age 33.7 years (SD 4.3 years).

BMI status
All participants were overweight or obese.

BMI (kg/m^2) intervention group: overweight (25.0 to 29.9) = 44% (n=57); obese class I (30.0 to 34.9) = 32% (n=42); obese class II (35 to 39.9) = 12% (n=16); obese call III (40 or above) = 12% (n=16).

BMI (kg/m^2) control group: overweight (25.0 to 29.9) = 39% (n=56); obese class I (30.0 to 34.9) = 30% (n=44); obese class II (35 to 39.9) = 21% (n=30); obese call III (40 or above) = 10% (n=15).

Ethnicity
White or other: intervention (83%, n=120); control group (84%, n=110).

Black: intervention (17%, n=25); control group (16%, n=21).

Recruitment
The eligibility criteria were self-reported pre-pregnancy and baseline BMI 25 kg/m^2 or above, having given birth within the last 6 months, having another child aged 2 to 5 years, English-speaking, at least 18 years old, no medical conditions preventing daily physical activity and access to a telephone and mailing address.

Randomisation
Upon completion of the baseline assessments, women were randomized to the control or intervention arm.

Intervention
Education kits, each mailed monthly; motivational counselling; and one group class.

Participants randomized to the intervention arm received 8 monthly educational kits via mail. The kits focused on stress management and parenting, promoted positive healthy changes in the home, and encouraged healthy behaviours in mothers and children. Three kits focused specifically on making changes related to dietary habits. Information included appropriate portion sizes, ways to increase fruit and vegetable intake, ideas for nutritious snacks, how to read food labels, and sample grocery lists with meal plans.

Intervention delivery
At the baseline visit, research staff obtained informed consent and collected baseline anthropometric measures, including verification of current BMI 25 kg/m^2 or above. Following the baseline visit, 2 24-hour dietary recalls were completed. Participants received a 20-to-30-minute telephone call from a trained health coach to review the kit's content and address women's motivation and barriers to change. Participants were invited to attend one group session during the intervention, led by a Registered Dietitian and the trained health coach, to reinforce information from the kits.

Intervention adherence
The Healthy Eating Index-2005 (HEI-2005) tool was used to determine each participant's diet quality.

Control group
Participants in the control arm also received monthly mailings; however, their information focused on reading skills and enjoyment for the preschooler.

Follow-up
Measurements were done at study entry ("baseline" – 2 to 7 months postpartum) and end-of-intervention ("follow-up" – approximately 10 months post-baseline). The average time of baseline assessments was 160 ± 38 days or approximately 5 months postpartum. Weight was measured at baseline and follow-up using the Tanita BWB-800S digital scale.

Diet assessment
Telephone dietary interviews were conducted by trained research staff using the Nutrition Data System for Research, which uses the multiple pass, 24-hour dietary recall method. Two unannounced recalls were collected at each time point, within 2 weeks of the in person visit. Participants were given food portion visuals to assist them in estimating portion sizes and were asked to verify that their food intake was typical for the day being recalled. To accommodate the busy schedules of new mothers, there was no restriction as to whether the days were weekdays or weekend days. The HEI-2005 tool was used to determine each participant's diet quality.

Outcome measures
Weight change and diet quality.

Participants were asked how much they weighed before pregnancy and how much weight they had gained during their pregnancy. Weight at delivery was estimated as the sum of these 2 weights. Weight loss from birth to baseline was estimated as weight at baseline minus weight at delivery.

Measure of association/effect, 95% CI, p-value
Baseline diet quality was not a significant predictor of weight change postpartum ($p = 0.07$).

Variables adjusted for
The following covariates were included in the model because of their potential influence on weight change: arm assignment, baseline weight, household income, work status, race, parity, education level, age, smoking status, marital status, and depression, as well as energy intake and breastfeeding.

Dodd and others (2018) Targeting the postpartum period to promote weight loss: a systematic review and meta-analysis

The characteristics and findings of this systematic review and meta-analysis are provided in annex 3.

The sections below provide data extracted from relevant primary studies that were included in the systematic review by Dodd and others (2018).

Bertz and others (2012)

Exposure and outcome
Dietary behaviour modification treatment and a reduction in body weight.

Study design, number of participants and country
A randomised trial that recruited women (n=62) from 15 antenatal clinics in Gothenburg, Sweden, between 2007 and 2010.

Baseline age
Diet only group (n=15): mean age 33.7 (SD 4.2); control group (n=15): mean age 23.2 (SD 4.6).

BMI status
All participants were overweight or obese.

Mean baseline BMI (kg/m^2) diet only group: 30.0 (SD 2.6); control group: 30.2 (SD 3.4).

Ethnicity
97% of the women in the trial were white.

Recruitment
Women were recruited at 10 to 14 week postpartum if they had a self-reported prepregnancy BMI (in kg/m^2) of 25 to 35, were a non-smoker, with a singleton term delivery, an intention to breastfeed for 6 months, were providing less than 20% of infant energy intake as complementary foods, with a birth weight of infant above 2500g, and no illness in the mother or infant. Women with mild allergies and stable, medicated hypothyroidism were eligible. Women who become pregnant during the first 8 months of the follow up were excluded from the 1-year follow-up measurements.

Randomisation
Randomisation to the treatment or control groups occurred using a 2 X 2 factorial design. Women were stratified on the basis of pre-pregnancy BMI below 28.0 and 28.0 or above,

respectively. A blocked randomisation (block size of 4) was used within each stratum. All possible permutations within a block were identified and selected for each stratum from random numbers in a random-number table. In all, 16 blocks of 4 (n=64) were completed, and 2 blocks of 4 were partially used until a total of 68 women were randomly assigned. Group allocation was concealed to all until completion of baseline measurements.

Intervention
Women in the intervention group were given a dietary modification plan to achieve a reduction of 500kcal per day (2,092kJ per day) with a nutrient composition according to the Nordic Nutrition Recommendations (carbohydrates: 50% to 60% of energy; fat: less than 30% of energy; and protein: 10% to 20% of energy). The plan consisted of the following 4 key steps: limit sweets and snacks to 100 grams per week, substitute low fat and low-sugar alternatives for regular foods, cover one-half of the plate with vegetables at lunch and dinner, and reduce portion sizes. The dietitian provided the women with a document that offered practical changes from the reported baseline diet in accordance with the 4 key steps and calculations of their potential effect on weight loss.

Intervention delivery
Women in the intervention group received a 12-week intervention, with a total of 2.5 hours of individual behaviour modification counselling as follows: 1.5 hour at the start of the intervention and 1 hour at a follow-up home visit after 6 weeks of intervention. Women received a diet-plan booklet, including a checklist for weekly key step achievements, and an electronic body scale for self-weighing 3 times per week. The women were advised to introduce the key steps one at a time at a pace that facilitated weekly weight loss of 0.5kg but not more than 1kg. Strategies to manage the barriers to change and dietary concerns identified by the woman were established jointly. Between visits, women were contacted biweekly with cell phone text messages to report body weight.

During the 9-month period after the intervention, the women were contacted once after 6 months and asked about their health status and whether they still intended to attend the 1-year follow-up.

Intervention adherence
Women were contacted biweekly with cell phone text messages to encourage to adhere to the program. The trial reported that self-monitoring and at-clinic measurements were important to reinforce adherence to the interventions.

Control group
Participants allocated to the control group received usual care (no counselling, home visit, or text messages).

Follow-up
Measurements were made at baseline, after the intervention, and again at a 1 year follow-up 9 months later.

Physical activity
The diet only intervention did not have an exercise component to it.

Diet assessment
Women were provided with an electronic scale and instructed to weigh and record all foods and beverages consumed for 4 consecutive days that were jointly established to be representative of their habitual diets. Women were interviewed regarding their infants' intakes of complementary foods. Dietary intake was calculated with Dietist XP software by using the 2010 Swedish Food Database and data from food manufacturers.

Outcome measures
The primary outcomes of the study were changes from baseline in body weight and body composition.

Measure of association/effect, 95% CI, p-value
Weight changes after the intervention and 1-year follow-up were -8.3 ± 4.2kg and -10.2 ± 5.7kg, respectively, in the diet only group. The main effects of D treatment, on weight were significant at both times ($P < 0.001$).

Variables adjusted for
The trial did not report adjusting for confounders.

McCrory and others (1999)

Exposure and outcome
Weight loss by dieting and lactation performance.

Study design, number of participants and country
A randomised trial that recruited women (n=67) from local physicians' offices, childbirth classes, and letters to new parents, in the United States.

Baseline age
Diet only group (n=22): mean age 31.7 years (SD 5.2); control group (n=23): mean age 31.3 years (SD 5.7).

BMI status
Mean baseline BMI (kg/m^2) diet only group: 25.3 (SD 4.8); control group: 24.9 (SD 3.8).

Ethnicity
Diet only group: non-Hispanic white: n= 17 (77%); Hispanic: n= 3 (14%); Black: n= 0 (0%); Asian: n= 2 (9%).

Control group: non-Hispanic white: n= 18 (78%); Hispanic: n= 2 (9%); Black: n= 3 (13%); Asian: n= 0 (0%).

Recruitment
Women were recruited if they were exclusively breast-feeding; between 8 and 16 weeks postpartum; with no chronic illnesses; were not taking medication regularly; were non-smokers; had delivered a single, healthy, term infant; and were willing to exercise 3 days per week for at least 1 month before the intervention (to prepare physically in case they were assigned to the group with intensive exercise).

Randomisation
At 12 ± 4 weeks postpartum, subjects were randomly assigned using a computer-based assignment, to 1 of 3 groups (a diet group, a diet plus exercise group and a control group), using the Moses-Oakford algorithm with variable block size.

Intervention
Women assigned to the diet only group had a 35% energy deficit. The amount of energy to be provided during the intervention was calculated as 0.65 X total energy requirement (TER). Diets were designed to keep macronutrient proportions identical to those reported at baseline, provided that the recommended dietary allowance for protein during lactation was met (15 grams per day above that for nonlactating women). If this was not the case, the protein intake was increased to meet this requirement and the carbohydrate intake was decreased to compensate.

Intervention delivery
The intervention lasted for 11 days. Diets were individually tailored and food was provided in reweighed amounts. Meals and snacks were prepared from fresh, pre-packaged, and frozen commercial foods. Subjects were encouraged to drink plenty of water and other non-energy-containing beverages and a daily multivitamin and mineral supplement was provided.

Intervention adherence
The trial does not report on adherence to the intervention.

Control group
The control group was asked to maintain their weight during the intervention by maintaining their usual diet and activity patterns.

Follow-up
Maternal weight was measured at baseline and at the end of the intervention. Dietary intake was measured for 4 days during baseline.

Physical activity
For the control and diet groups, exercise frequency and intensity were held constant between the baseline and intervention periods.

Diet assessment
For 4 days during baseline, subjects weighed and recorded all food items consumed to the nearest 2g (Lume-o-gram Lo-Pro; OHAUS, Florham Park, NJ). Nutrient intake was calculated by using the FOOD PROCESSOR II computer program (ESHA Research, Salem, OR), food-composition tables, and data supplied by food manufacturers.

Outcome measures
Outcomes of the trial were change in maternal weight; dietary intake; energy expenditure; energy deficit; change in fat free mass; change in fat mass; change in % body fat; feeding frequency; total time breast-feeding; change in milk volume; milk composition; milk energy output; infant weight; plasma prolactin concentration.

Measure of association/effect, 95% CI, p-value
Weight loss in the control group (0.2kg) was significantly different from that in the diet only group (1.9kg) ($P<0.0001$).

Variables adjusted for
The differences among groups in changes over time were evaluated with analysis of covariance by using change variables as the outcomes (baseline - intervention) and with baseline values controlled for.

Maternal dietary patterns during pregnancy

Zhang and others (2022) Effect of Mediterranean diet for pregnant women: a meta-analysis of randomized controlled trials

The characteristics and findings of this systematic review and meta-analysis are provided in annex 3.

The sections below provide data extracted from relevant primary studies that were included in the systematic review by Zhang and others (2022).

Al Wattar and others (2019)

Exposure and outcome
Mediterranean-style diet and gestational weight gain.

Study design, number of participants and country
A randomised controlled trial that recruited women (n=1,205) from 5 inner-city maternity units in the UK (4 in London, 1 in Birmingham) between 12 September 2014 and 29 February 2016.

Baseline age
Intervention group: mean age 31.4 years (SD 5.2); control group mean age 30.9 years (SD 5.2).

BMI status
69% (836 out of 1,205) were obese.

BMI (kg/m^2) intervention group: normal (18.5 to 24.9) n= 84 (14.2%); overweight (25.0 to 29.9) n= 99 (16.7%); obese (30.0 to 39.9) n= 410 (69.1%).

BMI (kg/m^2) control group: normal (18.5 to 24.9) n= 84 (13.7%); overweight (25.0 to 29.9) n= 102 (16.7%); obese (30.0 to 39.9) n= 426 (69.6%).

Ethnicity
60% (729 out of 1,205) were of Black or Asian ethnicity.

Intervention group: White n= 217 (36.6%); Asian n= 257 (43.3%); Black n= 97 (16.4%); Other n= 22 (3.7%).

Control group: White n= 217 (35.5%); Asian n= 270 (44.1%); Black n= 105 (17.2%); Other n= 20 (3.3%).

Recruitment
Pregnant women were recruited if they were at least 16 years of age, less than 18 weeks' gestation with a singleton pregnancy, able to consume nuts and olive oil, and proficient in written and spoken English. Participants with a history of pre-existing diabetes, gestational diabetes, chronic renal disease, or autoimmune disease, or if they were taking lipid-altering drugs such as statins at the time of booking were excluded.

Randomisation
Women with at least one of the prespecified metabolic risk factors (obesity - BMI 30kg/m^2 or above), raised serum triglycerides (1.7mmol per litre or higher) or chronic hypertension (140mm Hg or higher systolic blood pressure (BP) or 90mm Hg or higher diastolic BP) were randomised to the 2 arms of the trial in a 1:1 ratio via a password-protected online data management system. Minimisation (with a random element to ensure allocation concealment) was used to balance the groups for maternal BMI, parity, and ethnicity.

Intervention
The intervention was based on a Mediterranean-style diet. The key components of the diet included high intake of nuts, extra virgin olive oil, fruit, vegetables, non-refined grains, and legumes; moderate to high consumption of fish; low to moderate intake of poultry and dairy products such as yoghurt and cheese; low consumption of red meat and processed meat; and avoidance of sugary drinks, fast food, and food rich in animal fat. Participants in the intervention arm were provided with mixed nuts (30 grams per day of walnuts, hazelnuts, and almonds) and extra virgin olive oil (0.5 litres per week) as the main sources of cooking fat.

Intervention delivery
The trial dietitian and trained researchers delivered the intervention over 3 face-to-face sessions, which included a personalised one-on-one session at 18 weeks' gestation, and 2 further group sessions at 20 and 28 weeks using pre-piloted presentations. In between the face-to-face sessions, the women were followed up twice with phone calls at 24 and 32 weeks' gestation to reinforce the dietary goals and to assess their general health.

Intervention adherence
The number of sessions attended (at 18-, 20-, and 28-weeks' gestation) was used as a marker of adherence.

Control group
Participants allocated to the control group received dietary advice as per UK national recommendations for antenatal care and weight management in pregnancy.

Follow-up
18-, 20-, and 28-weeks' gestation.

Physical activity
Both groups completed questionnaires at 36 weeks' gestation or at delivery to assess their level of physical activity (International Physical Activity Questionnaires [IPAQ]).

Diet assessment
Dietary intake of pregnant women was assessed using a validated FFQ for Mediterranean diet and a modified short questionnaire (ESTEEM Q) that was previously validated for adherence to the Mediterranean diet in a nonpregnant population.

Outcome measures
The primary endpoints were a composite maternal outcome combining gestational diabetes or preeclampsia and a composite offspring outcome combining stillbirth, small-for-gestational-age fetus, or admission to the neonatal care unit.

Secondary maternal outcomes included gestational diabetes, preeclampsia, gestational weight gain, maternal admission to high dependency or intensive care unit, antepartum haemorrhage, mode of delivery, preterm delivery, and maternal anaemia.

Secondary offspring outcomes included stillbirths, neonatal deaths, small-for-gestational age fetus (below 10th percentile), admission to the neonatal care unit, birth weight, and hypoxic ischaemic encephalopathy. Research staff recorded outcomes from clinical notes and from hospital electronic records following delivery.

Gestational weight gain was categorised as mean gestational weight gain.

Measure of association/effect, 95% CI, p-value
Pregnant women gained less gestational weight (mean 6.8kg versus 8.3kg; adjusted difference −1.2 Kg, 95% CI −2.2 to −0.2, p = 0.03) with intervention versus control.

Variables adjusted for
Adjusted for the minimisation factors, age, history of previous gestational diabetes, family history of hypertensive disorders (hypertension and/or preeclampsia), family history of diabetes, history of stillbirth and the recruitment centre.

Assaf-Balut and others (2017)

Exposure and outcome
Mediterranean diet reinforced with abundant extra virgin olive oil (EVOO) and nuts on the incidence of GDM.

Study design, number of participants and country
A randomised controlled trial that recruited pregnant women (n=874) followed by the Obstetrics Department of the Hospital Clínico San Carlos (Madrid, Spain) between 2 January 2015 and 27 December 2015.

Baseline age
Intervention group (n=500): mean age 33.2 (SD 5.0); control group (n=500): mean age 32.7 (SD 5.3).

BMI status
Prepregnancy BMI (kg/m^2): intervention group: mean BMI 22.9 (SD 3.6); control group: mean BMI 23.3 (SD 4.0).

Baseline
BMI (kg/m^2) intervention group: mean BMI 23.7 (SD 3.8); control group: mean BMI 24.1 (SD 4.1).

Ethnicity
Intervention group: Caucasian n= 345 (69.0%); Hispanic n= 143 (28.6%); Other n= 12 (2.4%).

Control group: Caucasian n= 339 (67.8%); Hispanic n= 142 (28.4%); Other n= 19 (3.8%).

Recruitment
Pregnant women were recruited if they were at least 18 years of age, attending their first gestational visit at 8 to 12 gestational weeks (GW) (Visit 0), with a fasting blood glucose (FBG) of less than 92mg/dL and with a single gestation pregnancy. Pregnant women with a gestational age at entry above 14 GW, or an intolerance to nuts or EVOO, or with medical conditions or pharmacological therapy that could compromise the effect of the intervention and/or the follow-up were excluded.

Randomisation
Women were randomised to the 2 arms of the trial by a permutated block-randomisation, stratified by age (18 to 29, 30 to 34 and 35 or older), pregestational BMI (below 25, 25 to 29.9 and 30kg/m^2 or above), parity (1 or more than 1), and ethnicity (Caucasian, Hispanic and other), in an allocation ratio of 1:1 in blocks of 4 to 6. The participants, staff and the dietician were aware of the allocation assignments. Allocation to the intervention and control groups remained unknown to the statistician and research assistant.

Intervention
The intervention was based on basic Mediterranean diet recommendations. The recommendations were at least 2 servings per day of vegetables, at least 3 servings per day of fruit (avoiding juices), 3 servings per day of skimmed dairy products, wholegrain cereals, 2 to 3 servings of legumes per week, moderate to high consumption of fish; a low consumption of red and processed meat, avoidance of refined grains, processed baked goods, pre-sliced bread, soft drinks and fresh juices, fast foods and precooked meals. The key recommendation for the intervention group was a daily consumption of at least 40mL of EVOO and a handful (25g to 30g) of pistachios.

Intervention delivery
Participants allocated to the intervention group received lifestyle guidance from dieticians one week after inclusion in a unique 1 hour group session. To ensure the consumption of the minimum amount recommended, women were provided at Visit 1 and 2 with 10 litres of EVOO and 2kg of roasted pistachios each. This way, they had available 1 litre of EVOO and 150g of roasted pistachios weekly, throughout the pregnancy. Women were followed-up taking advantage of their scheduled standard-practice laboratory appointments. This was at first ultrasound visit (visit 1), at 24 to 28 GW (visit 2), third trimester evaluation at 36 to 38 GW (visit 3) and at delivery. Nutritional guidance was reinforced at each visit for both groups. Dietary recommendations were individualised at each visit depending on GWG (according to first trimester BMI), in the context of usual recommendations. These recommendations were given in aims to reduce the caloric content of their diet when GWG exceeded the goal, by the dietician (Intervention Group (IG)).

Intervention adherence
A MEDAS questionnaire (a 14-point Mediterranean Diet Adherence Screener) was used to evaluate adherence to the Mediterranean diet at each follow-up visit (baseline, 24 to 28 GW and 36 to 38 GW).

Control group
Women allocated to the control group were advised by midwives to restrict consumption of dietary fat, including EVOO and nuts. These recommendations were provided in local antenatal clinics as part of the available guidelines in pregnancy standard care. Dietary recommendations were individualised at each visit depending on GWG (according to first trimester BMI), in the context of usual recommendations. These recommendations were given in aims to reduce the caloric content of their diet when GWG exceeded the goal, by the midwife.

Follow-up
24 to 28 gestational weeks, 36 to 39 gestational weeks and at delivery.

Physical activity
As part of the intervention, pregnant women were recommended to walk 30 minutes per day. At each follow-up visit, physical activity was evaluated using the Diabetes Nutrition and Complications Trial (DNCT) questionnaire.

Diet assessment
Dietary intake of pregnant women was assessed using a semi-quantitative frequency questionnaire, based on the DNCT study and a 14-point MEDAS at each follow-up visit.

Outcome measures
The primary outcome was to compare the effect of a standard diet versus a Mediterranean diet, supplemented with EVOO and pistachios, on GDM incidence at 24 to 28 GW, in pregnant women with a prior normal fasting glucose (below 96mg/dL) at the first gestational visit (8 to 12 GW).

Secondary maternal outcomes were to assess the effect of the dietary intervention on the percent of diabetic women requiring insulin therapy, gestational weight gain (GWG), pregnancy-induced hypertension, caesarean section (CS), perineal trauma, shoulder dystocia, preterm delivery (before 37 GW), neonates SGA (small for gestational age, above 90 percentile) according to national charts, and admissions to the Neonatal Intensive Care Unit (NICU).

Measure of association/effect, 95% CI, p-value
The intervention group overall GWG was significantly lower at 24 to 28 GW and at 36 to 38 GW (p= 0.022 and 0.037, respectively). At 24 to 28 GW the GWG was significantly lower in all the 3 groups of women stratified by BMI (below 25kg/m^2, 25 to 29.9kg/m^2 and 30kg/m^2 or higher).

Variables adjusted for
Crude and adjusted models were fitted for age (continuous), ethnicity and parity (model 1); for BMI (continuous) in visit 1 (model 2); and for gestational, personal and family history, and smoker status (model 3). In the combined adjusted models, model 1 and 2 (model 4), and 1, 2 and 3 (model 5) were only fitted for the primary outcome due to the small number of events in the secondary outcome variables.

Sewell and others (2017) (pilot study)

Exposure and outcome
Mediterranean diet and gestational weight gain.

Study design, number of participants and country
A 2-arm pilot parallel group randomised controlled trial that recruited women (n=30) from 2 maternity service sites in Scotland between June and December 2012, at an age of approximately 12 gestational weeks.

Baseline age
Intervention group (n=14): mean age 32.2 years (SD 5.2).

Control group (n=16): mean age 33.9 years (SD 4.2).

BMI status
Not reported.

Ethnicity
Not reported.

Recruitment
Pregnant women were recruited if they were at least 16 years of age; in their first trimester; had a history of atopic dermatitis or eczema, food allergy, allergic rhinitis (persistent or intermittent) or asthma in the pregnant woman, her partner, or children; and were willing to give informed consent. Participants who were not pregnant; under 16 years of age; with no history of atopic dermatitis/eczema, food allergy, allergic rhinitis (persistent or intermittent) or asthma in the pregnant woman, her partner, or children; whom had had recent (within the last 3 months) or current involvement in a dietary or supplementation trial; and unable or unwilling to give informed consent were excluded.

Randomisation
Participating women were randomised 1:1 to the intervention (diet advice and support, with a supporting Mediterranean diet resource booklet, in addition to standard care) or control arm. Allocation was stratified by site, using pre-randomised sealed envelopes, based on a predetermined random number allocation, prepared by an independent statistician.

Intervention
The intervention was a 15-minute structured dietary advice session encouraging the consumption of particular foods that are consistent with the Mediterranean diet, administered by a researcher or hospital dietitian using a booklet. No energy restrictions were suggested, and the target of at least 5 portions of fruit and vegetables per day was emphasised.

Intervention delivery
The initial session was directed at increasing consumption of MD foods, with subsequent supportive telephone calls from the dietitian/researcher at 4-, 8- and 18-weeks post enrolment, to review and revise Mediterranean diet goals. Participants were given a shopping voucher (£10) at baseline and 12 weeks post baseline that could be used for purchasing olive oil.

Intervention adherence
Mediterranean diet adherence scores taken at 12 and at 24 weeks post-randomisation using an FFQ.

Control group
Control group participants followed the same protocol as the intervention arm, except they did not receive the structured dietary advice session or supportive follow-up telephone calls. Control arm participants, like intervention arm participants also received supermarket vouchers, but without accompanying advice about how to spend them.

Follow-up
Baseline, 24 and 36 gestational weeks.

Physical activity
No physical activity component is reported.

Diet assessment
The Mediterranean diet score was measured at baseline (around 12 weeks of pregnancy) and at 12- and 24-weeks post randomisation (approximately weeks 24 and 36 of pregnancy). The Scottish Collaborative Group FFQ (version 6.6), a self-administered, 169-item FFQ, was used to estimate nutrient intake and to compare the intervention and control arms.

Outcome measures
Outcomes of the trial were change in mediterranean diet score, urinary nitrate, urinary ferric reducing antioxidant potential (FRAP; a measure of total antioxidant activity), urinary 8-OHdG, creatinine, nutrient intake (total energy, saturated fatty acids, monounsaturated and polyunsaturated fatty acids, vitamin C, A, D or E) weight gain and birth weight.

Measure of association/effect, 95% CI, p-value
No p values or CI reported for the outcome of GWG.

Weight gain from baseline (around 12 weeks of pregnancy) to 36 weeks of pregnancy was 11.6 ± 4.1kg (range 5kg to 19kg) in the intervention arm (n=11) and 11.3 ± 4.0kg (range 3kg to 18kg) in the control arm (n=14).

Variables adjusted for
Data relating to potential confounders were collected: eczema, food allergy, allergic rhino-conjunctivitis and asthma in the mother, father and siblings as reported by the participant; exposure to smoking during pregnancy (by the mother, partner, or in the household); mothers' dietary pattern; folic acid and vitamin D supplementation; maternal education; maternal and paternal employment; body mass at booking-in and at end of trial; the baby's birth weight, and gender. Given the small sample size of this pilot trial, it was not possible to adjust for these confounders in the analysis.

Abdollahi and others (2021) Associations between Maternal Dietary Patterns and Perinatal Outcomes: A Systematic Review and Meta-Analysis of Cohort Studies

The characteristics and findings of this systematic review and meta-analysis are provided in annex 3.

The sections below provide data extracted from relevant primary studies that were included in the systematic review by Abdollahi and others (2021).

Information on the 'measure of association' and 'variables adjusted for' have been extracted from the systematic review and associated supplementary material.

Abreu and others (2017)

Exposure and outcome
Dairy product intake and gestational weight gain.

Study design, number of participants and country
A prospective study of pregnant women (n=98) attending outpatient obstetrics clinics at São João Hospital in Porto, Portugal, between July 2010 to May 2012.

Baseline age
Age (years): 18 to 30 years n=46, 46.9%; 31 to 40 years: n=52, 53.1%.

BMI status
Pre-pregnancy weight status: non-overweight n=59, 58.2%; overweight or obese: n=39, 39.8%.

Ethnicity
The study did not report on the ethnicity of participants.

Recruitment
Pregnant women attending the outpatient obstetrics clinics at São João Hospital in Porto, Portugal were recruited. Women were invited to participate when they came in for their first ultrasound evaluation screening. The recruitment was made consecutively from July 2010 to May 2012.

Randomisation
Not applicable.

Intervention
Dairy product consumption was assessed using a 3-day food diary completed during the first and second trimesters. Weight gain during pregnancy was measured as the difference between the self-reported weight before pregnancy and the last weight recorded prior to delivery and was classified as insufficient, adequate, and excessive, based on NAM (formerly IOM) guidelines.

Intervention delivery
Oral and written instructions on how to complete the food diary were given by a trained nutritionist.

Intervention adherence
A Mediterranean diet score was used as an indicator of diet quality. Based on a total score, each woman was categorised into one of 2 groups for each trimester: low adherence (0 to 4 points) or high adherence (5 to 8 points).

Control group
Not applicable.

Follow-up
Data was collected in the first trimester between the 10th and 12th weeks of gestation (at the time of baseline assessment), in the second trimester between the 20th and 22nd weeks (at the time of the second ultrasound) and again in the immediate post-partum (24 to 48 hours after delivery).

3-day food diaries were completed for each trimester.

Physical activity
No information provided.

Diet assessment
Dietary intake was assessed by a 3-day food diary that included 2 weekdays plus 1 weekend day and was completed for each trimester. Food portion sizes and beverages consumed were estimated using household measures as an aid in determining serving sizes. A description of each food and beverage consumed was recorded, including the method of preparation, the time it was eaten (to the nearest 5 minutes), location, and, if appropriate, the brand name of the product. The nutrient analysis was performed using the software Food Processor SQL. The nutrient and food means of the 3 days were used in the analysis. The amounts of milk (whole, reduced-fat, and fat-free), yogurt, and cheese (including cottage and cream cheese) were presented in term of grams per day (grams per day). In this study, total dairy included milk, yogurt, and cheese. Additionally, change in dairy product intake was computed as the difference between the second and first trimesters.

Outcome measures
Neonatal outcomes were birth weight, length, head circumference, and placental weight.

The maternal outcome was weight gain during pregnancy.

Weight gain during pregnancy corresponded to the difference between the self-reported weight before pregnancy and the last weight recorded prior to delivery. Weight gain was then classified as insufficient, adequate, and excessive.

Maternal outcomes (weight gain during pregnancy) were obtained from hospital records.

Measure of association/effect, 95% CI, p-value
GWG and MED dietary pattern. Highest vs lowest standardised mean difference (SMD) (95% CI): 0.04 (-0.39, 0.42).

Variables adjusted for
Not adjusted.

Alves-Santos and others (2018)

Exposure and outcome
Maternal dietary patterns and GWG (low or normal and excessive).

Study design, number of participants and country
A prospective cohort study of pregnant women (n= 173) at a public healthcare centre located in Rio de Janeiro, Brazil, between November 2009 and October 2011.

Baseline age
Mean age (years): 26.7 (SD 5.5).

BMI status
Pre-pregnancy BMI (kg/m^2): 24.9 (SD 4.2).

Ethnicity
The study did not report on the ethnicity of participants.

Recruitment
Pregnant women were invited to participate in this study if they were between 5 and 13 weeks of gestation at baseline, aged 20 to 40 years and free from infectious and chronic diseases (except obesity). Criteria for exclusions after the baseline clinical evaluation consisted of the following: confirmed pre-gestational diagnosis of infectious or chronic non-communicable diseases (except obesity), gestational week 14 or beyond at the first visit, multiple gestation, miscarriage or stillborn and missing the baseline interview.

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
Tertiles of adherence to the dietary patterns was recorded.

Control group
Not applicable.

Follow-up
Women were followed up at the 5th to 13th, 20th to 26th and 30th to 36th gestational weeks and 30 to 40 days postpartum.

Physical activity
First trimester leisure physical activity was assessed at baseline using a structured questionnaire (yes or no).

Diet assessment
A FFQ was administered in the third trimester (30th to 36th gestational weeks) to obtain information on the habitual diet of pregnant women during the gestational period (last 6 months of pregnancy). The questionnaire composed of 82 food items, including non-alcoholic and alcoholic beverages, with 8 frequency options (more than 3 times per day, 2 to 3 times per day, 1 time per day, 5 to 6 times per week, 2 to 4 times per week, 1 time per week, 1 to 3 times per month and never or hardly ever) and portion sizes (described in household measures). 77 foods items were aggregated into 18 food groups on the basis of similarities in their nutritional composition and the particular dietary habits of these women.

The FFQ data were summarised to dietary patterns (DP) among pregnant women; that is the frequency of intake was transformed into daily frequency, and portion sizes into grams or millilitres.

The study applied the Reduced Rank Regression (RRR) procedure to identify DP related to indicators of maternal adiposity (postpartum weight retention and GWG adequacy). The RRR statistical procedure was used to maximise the explained variation in 2 response variables in the data set, representing a so-called a priori component, as well as the variation in 19 predefined food groups (predictive variables), which composed the a posteriori component.

Outcome measures
Outcome measures were maternal adiposity indicators (excessive GWG, postpartum overweight/obesity and higher postpartum weight retention), leptin, adiponectin and insulin concentrations during pregnancy.

Measure of association/effect, 95% CI, p-value
Western dietary pattern and excessive GWG: Highest vs lowest OR (95% CI): 1.33 (0.56, 3.10).

Common Brazilians dietary pattern and excessive GWG: Highest vs lowest OR (95% CI): 0.74 (0.31, 1.71).

Variables adjusted for
Adjusted for pre-pregnancy BMI, parity number of parturition and the homoeostasis model of assessment of insulin resistance (HOMA-IR).

Ancira-Moreno and others (2019)

Exposure and outcome
Maternal diet quality and gestational weight gain.

Study design, number of participants and country
A prospective study who recruited pregnant women (n=660) who were participating in the Pregnancy Research on Inflammation, Nutrition and City Environments: Systematic Analyses (PRINCESA) cohort in Mexico City, between February 2009 to November 2014.

Baseline age
Inadequate Rate of Gestational Weight Gain (RGWG) (n=196): mean maternal age 25.72 years (SD 5.89).

Adequate RGWG (n=194): mean maternal age: 24.83 years (SD 5.76).

Excessive RGWG (n=270): mean maternal age: 24.89 years (SD 5.76).

BMI status
Pre-pregnancy BMI (kg/m^2) inadequate RGWG: mean BMI 25.59 (SD 6.10); adequate RGWG: mean BMI 24.17 (SD 4.56); excessive RGWG: mean BMI 26.91 (SD 5.23).

Ethnicity
The study did not report on the ethnicity of participants.

Recruitment
Pregnant women were recruited it they had a reliable recall of last menstruation, agreed to prenatal visits every 4 weeks throughout their current pregnancy, provided written consent for their inclusion in the study, had at least one complete dietary recall in both the second and third trimesters of pregnancy and at least 2 measurements of gestational weight during pregnancy. Participants with a previous presence of any medical or obstetric complication in the current pregnancy, had the presence of multiple fetuses or who developed pregnancy complications such as gestational diabetes and preeclampsia were excluded.

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
A Maternal Diet Quality Score (MDQS) was used to define 3 categories of adherence: low (0 to 2 points), medium (3 to 4 points) and high (above 5 points).

Control group
Not applicable.

Follow-up
Women were followed up monthly over the course of their pregnancies. Information on clinical, anthropometric, and biochemical parameters and maternal diet was collected at each visit. Data on maternal diet were collected through a multiple-step 24-hour dietary recall (24HDR) in each prenatal visit (median time between visits: 5 weeks).

Physical activity
Physical activity was assessed at each visit and categorized into whether the women met or did not meet the American College of Obstetricians and Gynaecologists recommendations (at least 150 minutes per week versus less than 150 minutes per week).

Diet assessment
Data on maternal diet were collected through a multiple-step 24-hour dietary recall (24HDR) in each prenatal visit (median time between visits: 5 weeks) by a dietitian with standardized training. To evaluate diet quality, a MDQS was built based on the Mexican Dietary Guidelines and international recommendations for specific foods and nutrients. The following recommendations regarding nutrients and food groups were included: polyunsaturated fats (PUFAS, more than 6% of energy intake), added sugars (400 grams per day), red meat (less than 500 grams per week), low fat dairy products (2 servings per day), legumes (2 servings per day) and foods high in saturated fat and/or added sugar (less than 10% of energy intake). The scores for each recommendation were then summed with a maximum score of 7 if all recommendations were met and a minimum of 0 if no recommendations were met. There were 3 categories of adherence: low (0 to 2 points), medium (3 to 4 points) and high (above 5 points).

Outcome measures
Outcome measures were gestational weight gain trajectories, association between MDQS and GWG trajectories during early-mid pregnancy, middle pregnancy, late pregnancy and prolonged pregnancy and the association between MDQS and adequacy of GWG throughout pregnancy.

RGWG (kg per week) was calculated at each visit throughout the whole pregnancy as weight at the current visit minus weight from the previous visit, divided by follow-up duration (grams per week). We categorized RGWG according to whether IOM

recommendations were met (insufficient, adequate and excessive) based on ranges of the mother's pre-pregnancy BMI.

The total weight gain was not used as an outcome since the timing of the final measurement of weight gain varied between the mothers.

Measure of association/effect, 95% CI, p-value
Excessive GWG and MDQS dietary pattern. Highest vs lowest OR (95% CI): 0.62 (0.41, 0.94).

Variables adjusted for
Adjusted for pre-pregnancy BMI, energy intake, gestational age, maternal age, educational level, parity, fetal sex, marital status and physical activity.

Emond and others (2018)

Exposure and outcome
Maternal diet quality and gestational weight gain.

Study design, number of participants and country
An analysis of the prospective New Hampshire birth cohort study (NHBCS) that recruited pregnant women (n=862) from prenatal clinics in New Hampshire beginning in January 2009.

Baseline age
Alternative Healthy Eating Index 2010 (AHEI-2010) diet quality score (Q1) group (n=215): mean age 28.9 years (SD 5.0).

AHEI-2010 diet quality score (Q2) group (n=215): mean age 30.8 years (SD 4.5).

AHEI-2010 diet quality score (Q3) group (n=216): mean age 32.0 years (SD 4.3).

AHEI-2010 diet quality score (Q4) group (n=216): mean age 33.2 years (SD 4.4).

BMI status
AHEI-2010 diet quality score (Q1) group (n, %): healthy weight (BMI 18.5 to 24.9kg/m^2) 100 (46.5%); overweight (BMI 25.0 to 29.9kg/m^2) 59 (27.4%); obese (BMI above 30.0kg/m^2) 56 (26.1%).

AHEI-2010 diet quality score (Q2) group (n, %): healthy weight (BMI 18.5 to 24.9kg/m^2) 120 (55.8%); overweight (BMI 25.0 to 29.9kg/m^2) 53 (24.7%); obese (BMI above 30.0kg/m^2) 42 (19.5%).

AHEI-2010 diet quality score (Q3) group (n, %): healthy weight (BMI 18.5 to 24.9kg/m^2) 123 (56.9%); overweight (BMI 25.0 to 29.9kg/m^2) 55 (25.5%); obese (BMI above 30.0kg/m^2) 38 (17.6%).

AHEI-2010 diet quality score (Q4) group (n, %): healthy weight (BMI 18.5 to 24.9kg/m^2) 126 (58.3%); overweight (BMI 25.0 to 29.9kg/m^2) 60 (27.8%); obese (BMI above 30.0kg/m^2) 30 (13.9%).

Ethnicity
AHEI-2010 diet quality score (Q1) group (n, %): White, non-Hispanic 204 (94.9%).

AHEI-2010 diet quality score (Q2) group (n, %): White, non-Hispanic 208 (96.7%).

AHEI-2010 diet quality score (Q3) group (n, %): White, non-Hispanic 210 (97.2%).

AHEI-2010 diet quality score (Q4) group (n, %): White, non-Hispanic 212 (98.2%).

Recruitment
Pregnant women were enrolled between 24 and 28 weeks of gestation, and inclusion criteria included English literacy, a singleton pregnancy, and not planning to move. Women were also required to use a private, unregulated water system (for example, private well) at home. For this analysis we excluded mother-child dyads with unrealistic or missing maternal dietary intake data (n=64) or missing data on key covariates from the self-reported questionnaires (n=89); women who were underweight prepregnancy (BMI below 18.5) (n=20); incomplete or unrealistic infant birth outcome data (n=62); or missing urinary arsenic concentrations (a covariate) (n=43).

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
Adherence to the AHEI-2010 was recorded.

Control group
Not applicable.

Follow-up
Maternal weight at each prenatal visit were abstracted from prenatal medical records. Women completed a baseline questionnaire and a validated FFQ at enrolment (24 to 28 weeks of gestation) and a questionnaire mailed 2 weeks postpartum.

Physical activity
Women self-reported their exercise habits during pregnancy ("Did you exercise during your recent pregnancy? Yes versus no") on the postpartum questionnaire.

Diet assessment
Women completed a validated FFQ at enrolment (24 to 28 weeks of gestation). Women were asked to complete the questionnaire with respect to their usual dietary intake during pregnancy. Diet quality was assessed as adherence to the AHEI-2010. The AHEI-2010 includes 11 dietary components: 7 healthful components to encourage [fruits, vegetables, whole grains, nuts and legumes, long-chain n–3 FAs from foods and supplements, polyunsaturated fats, and moderate alcohol consumption] and 4 components to reduce (sugary beverages—sugar sweetened beverages and fruit juice, red and processed meats, trans fatty acids, and sodium). All food components were scored from 0 to 10 such that a higher score indicates a healthier intake.

Outcome measures
Outcomes were gestational weight gain, exercise during pregnancy, gestational diabetes, preeclampsia, dietary intake, gestational age, head circumference, birth weight, birth length, weight-for-length z score, SGA, LGA, macrosomia.

Gestational weight gain was categorized based on the 2009 Institutes of Medicine recommendations for total weight gain during gestation given prepregnancy BMI. Gestational weight gain was computed using prepregnancy weight and the last recorded prenatal weight.

Measure of association/effect, 95% CI, p-value
Excessive GWG and AHEI dietary pattern. Highest vs lowest OR (95% CI): 1.007 (0.68, 1.48).

Variables adjusted for
Not adjusted.

Eshriqui and others (2017)

Exposure and outcome
Prepregnancy dietary patterns and gestational weight gain

Study design, number of participants and country
A prospective cohort of pregnant women (n=198) were followed from a public health care centre in Rio de Janeiro, Brazil, between November 2009 and July 2012.

Baseline age
Baseline age by adherence to prepregnancy dietary patterns:

Fast food and candies: low adherence group (n=64) mean age 27.4 years (SD 5.7); medium adherence group (n=66) mean age 26.0 years (SD 5.3); high adherence group (n=68) mean age 26.8 years (SD 5.6).

Vegetables and dairy: low adherence group (n=66) mean age 25.3 years (SD 5.6); medium adherence group (n=66) mean age 25.8 years (SD 5.1); high adherence group (n=66) mean age 29.1 years (SD 5.1).

Beans, bread and fat: low adherence group (n=65) mean age 27.0 years (SD 5.5); medium adherence group (n=66) mean age 27.5 years (SD 5.6); high adherence group (n=67) mean age 25.7 years (SD 5.4).

BMI status
Prepregnancy BMI by adherence to prepregnancy dietary patterns:

Fast food and candies: low adherence group (n=64) mean BMI 25.12kg/m^2 (SD 4.9); medium adherence group (n=66) mean BMI 24.9kg/m^2 (SD 4.1); high adherence group (n=68) mean BMI 25.2kg/m^2 (SD 4.6).

Vegetables and dairy: low adherence group (n=66) mean BMI 25.2kg/m^2 (SD 4.7); medium adherence group (n=66) mean BMI 25.2kg/m^2 (SD 4.9); high adherence group (n=66) mean BMI 24.8kg/m^2 (SD 4.0).

Beans, bread and fat: low adherence group (n=65) mean BMI 25.4kg/m^2 (SD 4.3); medium adherence group (n=66) mean BMI 24.9kg/m^2 (SD 4.0); high adherence group (n=67) mean BMI 24.8kg/m^2 (SD 5.2).

Ethnicity
The study did not report on the ethnicity of participants.

Recruitment
Women were recruited if they were between 20 to 40 years of age, at gestational week 5 to 13 at baseline, with a singleton pregnancy, without chronic and/or infectious disease (except obesity), and were planning to carry out prenatal care in the public health care centre. After recruitment, participants were excluded from the analysis if they had a

confirmed pre-pregnancy diagnosis of chronic non-communicable diseases; infectious diseases; an advanced pregnancy; multiple gestation; missed the baseline interview; moved out of the program area; missed 1st trimester food intake data; had an estimated energy intake above 6,000kcal per day.

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
Pattern scores were calculated for each woman in each pattern extracted, as a linear combination of all food group intakes that had the maximum amount of shared variation in all response variables. Each woman's pattern score represented the level of adherence she showed to the respective dietary pattern: that is, increasing intakes of food items with positive factor loadings increases the pattern score, whereas increasing intakes of foods with negative loadings decreases the pattern score.

Control group
Not applicable.

Follow-up
Data collection was at gestational weeks 5 to 13, 20 to 26, and 30 to 36. A food frequency questionnaire was administered at baseline (gestational week 5 to 13).

Body weight was measured at all follow-up visits, using a digital scale.

Physical activity
A structured questionnaire was administered at baseline (gestational week 5 to 13) which asked participants about their leisure time physical activity (LTPA) practice before pregnancy (yes or no).

Diet assessment
A semiquantitative FFQ, previously validated for the adult population of Rio de Janeiro, Brazil, was administered by interviewers during the first gestational trimester, when the women were asked about their usual dietary intake during the 6 months before pregnancy.

The FFQ was composed of 82 food items and8 frequency options with 2 or 3 household measure portion options.

The daily amount consumed (grams per day or millilitres per day) of each food item of the FFQ, calculated by multiplying portion size per daily frequency, was used to identify prepregnancy dietary patterns. Food items that were consumed by 80% or more women or with unique nutrition-related compositions were kept separate (that is rice, beans, bread, sugar, fish, coffee, and tea). Foods consumed by <20% of the sample or alcoholic beverages such as wine, beer, and vodka were excluded because they showed low correlations with the food groups defined. The remaining 77 food items were grouped into 19 food groups, according to their nutrition-related similarities and the eating habits of this population, and then labelled based on the items with higher daily intake frequency. The Brazilian food composition table was used as the main database to calculate nutrient and energy intakes.

Outcome measures
The study outcomes were total cholesterol, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), and triglyceride concentrations at each stage of pregnancy.

Gestational weight gain up to the third trimester was calculated considering the difference between the third trimester weight and the first trimester weight. Next, this variable was divided by the number of weeks between the 2 measurements to obtain the rate of weight gain up to the third trimester (kilograms per number of weeks between the first and third trimester measurements).

Measure of association/effect, 95% CI, p-value
GWG: Highest vs lowest SMD (95% CI):

Vegetables and dairy: 0.28 (-0.05, 0.62).

Fast food and candies: 0.14 (-0.19, 0.48).

Variables adjusted for
Not adjusted.

Fernández-Barrés and others (2019)

Exposure and outcome
Mediterranean diet and gestational weight gain.

Study design, number of participants and country
A cohort study that recruited pregnant women (n=2,127) from the 4 Spanish regions of Asturias, Gipuzkoa, Sabadell, and Valencia as part of the population based Infancia y Medio Ambiente (INMA) birth cohort study, between 2003 and 2008.

Baseline age
Age by tertiles of relative Mediterranean diet score (rMED) score:

T1 (n=925): mean age at delivery 30.2 years (SD 4.4); T2 (n=631): mean age at delivery 31.1 years (SD 4.0); T3 (n=639): mean age at delivery 31.4 years (SD 3.9).

BMI status
Pre-pregnancy BMI (kg/m^2) by tertiles of rMED score:

TI (n=925): mean BMI 23.5kg/m^2 (SD 4.1); T2 (n=631): mean BMI 23.6kg/m^2 (SD 4.1); T3 (n=639): mean BMI 23.5kg/m^2 (SD 4.3).

Ethnicity
The study did not report on the ethnicity of participants.

Recruitment
Pregnant women were included if they were at least 16 years, had an intention to deliver at the reference hospital, an ability to communicate in Spanish or regional languages, had a singleton pregnancy, and no assisted conception.

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
Adherence to the Mediterranean diet was assessed using the rMED. The rMED was constructed with the data obtained from the FFQ during the first and third trimesters. The rMED was constructed taking into account the consumption of vegetables, fruits and nuts, cereals, legumes, fish, olive oil, meat, and dairy products. All the food groups were measured as grams per 1,000kcal per day, and values were divided into tertiles. Values of 0, 1, and 2 were assigned to the intake tertiles, positively scoring higher intakes for the 6

components that fit into the Mediterranean diet. The scoring was reversed for meat and dairy components presumed to not fit into the Mediterranean diet, thus positively scoring lower intakes. Scores were summed for each component, for a total score ranging from 0 to 16. The score was further divided into tertiles to identify those with low (tertile 1), medium (tertile 2), and high (tertile 3) adherence to the Mediterranean diet.

Control group
Not applicable.

Follow-up
Maternal diet was assessed in the first trimester (week 12) and third trimester (week 32) of pregnancy using a 101-item FFQ.

Physical activity
Physical activity was reported using METS (metabolic equivalents) in hours per day.

Diet assessment
Maternal diet was assessed in the first trimester (week 12) and third trimester (week 32) of pregnancy using a 101-item FFQ. At week 12 of pregnancy (first trimester), mothers were asked about their diet during the first trimester of pregnancy, and at week 32 (third trimester), mothers were asked about their diet between weeks 12 and 32 of pregnancy. The FFQ specified standard units and serving sizes for each food item. Nutrient values and total energy intake were calculated based on the US Department of Agriculture's food composition tables and other published national sources

Outcome measures
Outcomes included pregnancy and offspring cardiometabolic risk score, components of the score and related biomarkers, growth trajectories, gestational age and birth weight.

Measure of association/effect, 95% CI, p-value
GWG and rMED dietary pattern: Highest vs lowest SMD (95% CI) -0.01 (-0.17, 0.02).

Variables adjusted for
Not adjusted.

Gesteiro and others (2012)

Exposure and outcome
First trimester diet quality and gestational weight gain.

Study design, number of participants and country
A cohort study that recruited women (n=35) who gave birth at the Mérida Hospital, Spain.

Baseline age
All participants (n=35): mean age 30.4 years (SE 0.9) (95% CI 28.6 to 32.3).

BMI status
All participants: mean pregestational BMI 23.0kg/m^2 (SE 0.6) (95% CI 21.8 to 24.3).

Ethnicity
All participants were Caucasian.

Recruitment
Participants were women who gave birth at the Mérida Hospital.

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
A cut-off point for the mediterranean diet adherence (MDA) score of less than 7 was selected to define low adherence to the Mediterranean diet.

Control group
Not applicable.

Follow-up
Anthropometrical measurements were taken by trained personnel following hospital's standard procedures. Gestational weight gain was obtained from hospital records.

Participants were provided with a survey just before the first ultrasound pregnancy test at 12 to 15 week pregnancy. After delivery, participant mothers were surveyed by telephone on major dietary changes occurring through second and third trimesters.

Physical activity
Data concerning physical activity were obtained from the nutritional survey records.

Diet assessment
Participants completed a FFQ that included 169 items classified according to food groups. The dietician reviewed together the usual consumption frequency of each food (per day, per week, per month), together with the normal food helping size, and specific information for mineral and/or vitamin supplements. Daily energy, nutrient intakes and HEI were calculated using a computer programme to evaluate diet quality consumed during the first pregnancy trimester. Dietary data were adjusted to 1,000kcal to reduce measurement error and to adjust for confounding. Diets with HEI scores of up to 70 were labelled 'inadequate', whereas those with HEI scores of above 70 were considered 'adequate'.

The MDA score of 14 points used in the PREDIMED study was modified to 13-point MDA score taking into account that wine should be not consumed through the whole pregnancy. Each of the 13 components comprising the MDA score contributes a maximum of one point to the final score. An extra survey based on the 13 MDA points was performed to search on major dietary changes occurring during late pregnancy. Based on different studies and considering that the average MDA score of the mothers was 6.87, and about a third of them consumed diets with MDA score less than 7, the cut-off point for the MDA score less than 7 was selected to define low adherence to the Mediterranean diet.

Outcome measures
Outcomes included dietary energy, macronutrient and fatty acid energy contribution in the mother, weight gain, glucose markers, insulinaemia, glycaemia and HOMA-IR.

Measure of association/effect, 95% CI, p-value
GWG and HEI and MED dietary patterns: highest vs lowest SMD (95% CI); HEI 0.38 (-0.27, 1.03); MED 0.78 (0.09, 1.48).

Variables adjusted for
Not adjusted.

Hillesund and others (2014)

Exposure and outcome
New Nordic Diet and gestational weight gain.

Study design, number of participants and country
A prospective, population-based pregnancy cohort study (data from the Norwegian Mother and Child Cohort Study), that recruited pregnant women (n=66,597) from all parts of Norway from 1999 to 2008.

Baseline age
Whole sample (n=66,597) mean age (years): 30.1 (SD 4.6).

BMI status
Whole sample mean BMI (kg/m^2): 24.0 (4.2).

Ethnicity
The study did not report on the ethnicity of participants.

Recruitment
Prerequisites for study eligibility were carrying a single fetus, having completed Q1, Q2 and Q4, and contributing data from the Medical Birth Registry of Norway (MBRN). The exclusion criteria comprised of delivery at 42 weeks of gestation, lack of information on length of gestation, more than one pregnancy contributed by the same mother, biologically implausible energy intakes (up to 4,500kJ or more than 20,000kJ), diabetes mellitus diagnosed prior to pregnancy, maternal height less than 140cm or 193cm or above, lack of information on maternal pre-pregnancy weight or height, lack of information on birth weight and birth weight less than 1000g at up to 37 weeks of pregnancy.

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
A New Nordic Diet (NND) score was constructed to reflect and quantify participant adherence with the fundamental guidelines of the NND. The NND score was divided into ‘low’ (0 to 3 points), ‘medium’ (4 to 5 points) and ‘high’ (6 to 10 points) NND adherence, respectively.

Control group
Not applicable.

Follow-up
Follow-up was conducted by questionnaires at regular intervals and by linkage to national health registries. Data from the MBRN and from 3 separate questionnaires were used: (i) a baseline questionnaire (Q1) that was completed around gestational week 17; (ii) an FFQ that was completed around gestational week 22 (Q2); and (iii) a follow-up questionnaire (Q4) completed 6 months postpartum.

Physical activity
Data regarding exercise in pregnancy were obtained from Q1 (rarely, 1 to 2 times per week, at least 3 times per week).

Diet assessment
Dietary information was collected from a self-administered, semi-quantitative FFQ. The FFQ covered the period from conception until mid-pregnancy and comprises 255 food items that have been converted into daily energy and nutrient intakes. The NND score was constructed to reflect and quantify participant adherence with the fundamental guidelines of the NND, basically being the inclusion in the diet of: (i) more calories from plant foods and fewer from meat; (ii) more calories from the sea and lakes; and (iii) more calories from the wild countryside as compared with current diet. In addition, the score aimed to cover nutritional aspects of importance in attaining healthy balanced diets. Ten dietary indicators (subscales) were chosen to constitute the score, based on a combination of their potential Nordic identity, the possibility of the foods being caught, grown, cultivated or picked locally without extensive use of fertilizers, their tradition or importance as a food source within the Nordic countries, and their favourable nutritional or health-enhancing potential relative to similar foods within the same food group. The NND score was computed by adding the10 dichotomized subscales, yielding a possible scoring range from 0 to 10. For description and analysis, the NND score was divided into ‘low’ (0 to 3 points), ‘medium’ (4 to 5 points) and ‘high’ (6 to 10 points) NND adherence, respectively.

Outcome measures
The pregnancy outcomes investigated were adequacy of GWG and foetal growth.

GWG was calculated as the difference between pre-pregnancy body weight and body weight at birth as reported in Q1 and Q4. Absolute GWG was categorized as inadequate, optimal or excessive according to maternal pre-pregnancy BMI in line with the BMI-specific Institute of Medicine guidelines for weight gain during pregnancy.

Measure of association/effect, 95% CI, p-value
Excessive GWG and NND score: Highest vs lowest OR (95% CI) 0.97 (0.92, 1.03).

Variables adjusted for
Adjusted for parity, pre-pregnancy BMI, educational attainment, energy intake, smoking, exercise during pregnancy, length of gestation, maternal age at delivery and maternal age.

Mantzoros and others (2010)

Exposure and outcome
Total energy intake, variation in macronutrient intake, and adherence to a Mediterranean diet or the Alternate Healthy Eating Index (AHEI) and gestational weight gain.

Study design, number of participants and country
The subjects for this study were participants in Project Viva, a prospective, observational cohort study of gestational factors, pregnancy outcomes, and offspring health. Pregnant women (n=780) were recruited if they were attending their initial prenatal visit at 8 urban and suburban obstetrical offices of a multi-specialty group practice in eastern Massachusetts, during 1999 to 2003.

Baseline age
All participants (n=780): mean 32.2 years (SD 5.0).

BMI status
Pre-pregnancy BMI (kg/m^2):

All participants: mean 24.7 (SD 5.3).

Ethnicity
All participants: Race/ethnicity, white: n=575 (74%).

Recruitment
Women were included if they were fluent in English, had a gestational age of less than 22 weeks at the initial prenatal clinical appointment, and were having a singleton pregnancy. Exclusion criteria included multiple gestation, inability to answer questions in English, plans to move from the area before delivery, and gestational age greater than 22 completed weeks at the initial prenatal clinical appointment.

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
A Mediterranean dietary pattern score ranged from 0 to 9, with higher scores indicating closer adherence to a Mediterranean-type diet.

Control group
Not applicable.

Follow-up
In-person study visits were performed with the mother at the end of the 1st and 2nd trimesters of pregnancy and with both mother and child immediately after delivery.

Physical activity
Physical activity during the 2nd trimester (hours per week) was reported.

Diet assessment
Maternal diet assessment at both the first and second visits was performed using a semiquantitative food frequency questionnaire (SFFQ), slightly modified for use in pregnancy. Using dietary data from the SFFQ, a modified version of the Mediterranean dietary pattern score was developed. The median values of intake of each of 9 food groups that contribute to the score were calculated and participants received a point on the scale if they measured above the median consumption for each of dairy, fish, fruit, legumes, nuts, unsaturated-to-saturated fat ratio, vegetables, and whole grains and if intake of red and processed meats was below the median value. Thus, Mediterranean dietary pattern scores ranged from 0 to 9, with higher scores indicating closer adherence to a Mediterranean-type diet.

The AHEI was also used, slightly modified for pregnancy (AHEI-P), to measure diet quality on a 90-point scale with each of the following 9 components contributing 10 possible points: vegetables, fruit, ratio of white to red meat, fibre, trans fat, ratio of polyunsaturated to saturated fatty acids, and folate, calcium, and iron from foods.

Macronutrient intakes were also assessed, expressed as percent of energy. Nutrient intakes were determined using the Harvard nutrient composition database used for the Nurses' Health Study and other large cohort studies.

Outcome measures
Maternal variables included maternal diet/nutrient intake, GWG, physical activity during 2nd trimester, impaired glucose tolerance or gestational diabetes.

New-born variables included cord blood leptin and adiponectin concentrations, maternal health habits, gestational age at birth, foetal growth z-score.

Gestational weight gain was calculated as the pre-pregnancy weight subtracted from the last clinically recorded weight before delivery.

Measure of association/effect, 95% CI, p-value
GWG and MED dietary pattern: Highest vs lowest SMD (95% CI): 0.05 (-0.11, 0.22).

Variables adjusted for
Not adjusted.

Shapiro and others (2016)

Exposure and outcome
Maternal diet quality and gestational weight gain.

Study design, number of participants and country
Mother-infant pairs included in this analysis were enrolled in the Healthy Start study, an observational, longitudinal pre-birth cohort study of ethnically diverse mothers. The Healthy Start study recruited pregnant women (n=1,410) from the obstetrics clinics at the University of Colorado Hospital between 2010 to 2014.

Baseline age
Age at delivery:

Healthy Eating Index-2010 (HEI-2010) up to 57 (n=647): mean age 26.3 years (SD 5.9); HEI-2010 above 57 (n=432): mean age 30.0 years (SD 5.8).

BMI status
Pre-pregnancy BMI, n (%):

HEI-2010 up to 57: Normal 333 (51.5%); Overweight 174 (26.9%); Obese 140 (21.6%).

HEI-2010 above 57: Normal 272 (63.0%) Overweight 96 (22.2%); Obese 64 (14.8%).

Ethnicity
Race/ethnicity, n (%):

HEI-2010 up to 57: non-Hispanic white 298 (46.1%); Hispanic 174 (26.9%); non-Hispanic black 133 (20.6%); Other 42 (6.5%).

HEI-2010 above 57: non-Hispanic white 290 (67.1%); Hispanic 90 (20.8%); non-Hispanic black 30 (6.9%); Other 22 (5.1%).

Recruitment
Pregnant women aged 16 years and older, prior to 24 weeks gestation were included. Women were excluded if they had prior diabetes, a history of prior premature birth or foetal death, asthma with active steroid management, serious psychiatric illness, or a current multiple pregnancy.

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
The Healthy Eating Index-2010 (HEI-2010) was used, which is a diet quality scoring system designed to assess adherence to the 2010 Dietary Guidelines for Americans.

Control group
Not applicable.

Follow-up
Healthy Start mothers were invited to participate in 2 research visits during pregnancy. The first visit occurred between 8 and 24 weeks of gestation and the second between 24 and 32 weeks of gestation. A third visit occurred in the hospital, after delivery during which women were asked to complete questionnaires identical to those from the second pregnancy visit.

Physical activity
Physical activity in pregnancy was measured using the Pregnancy Physical Activity Questionnaire from which metabolic equivalent task (MET) values were estimated.

Diet assessment
Maternal diet was assessed several times throughout pregnancy using the Automated Self-administered 24-hour Dietary Recall (ASA24). Healthy Start participants were asked to complete up to 6 ASA24 dietary recalls beginning at their first pregnancy visit (approximately one per month). The Healthy Eating Index-2010 (HEI-2010) was used for a diet quality scoring system and consists of 12 components (total fruit, whole fruit, total vegetables, greens and beans, whole grains, dairy, total protein foods, seafood and plant proteins, fatty acids, refined grains, sodium, and empty calories). The 12 components were scored per 1,000kcal to give a maximum possible total HEI-2010 score of 100. Average food group servings were calculated across the multiple ASA24 recalls for each participant for use in calculating the HEI-2010 component and total scores. Average intakes of total energy, saturated fat, mono- and polyunsaturated fats, and sodium across the repeated recalls were also used for calculation of the HEI-2010 scores.

Outcome measures
Offspring outcomes included fat mass, % fat mass, fat-free mass, length, head circumference, birth weight.

Maternal outcomes included IOM recommended GWG, caesarean section, energy expenditure, dietary intake.

Measure of association/effect, 95% CI, p-value
Excessive GWG and HEI-2010: Highest vs lowest OR (95% CI): 8.83 (6.64, 11.74).

Variables adjusted for
Not adjusted.

Starling and others (2017)

Exposure and outcome
Maternal dietary patterns and gestational weight gain.

Study design, number of participants and country
Participants were enrolled in Healthy Start, a prospective cohort study that recruited pregnant women (n=1,410) from outpatient prenatal clinics at the University of Colorado Hospital between 2009 to 2014.

Baseline age
Maternal age by dietary pattern:

Dietary pattern 1: tertile 1 (n=239) mean age 27.9 years (SD 6.4); tertile 2 (n=258) mean age 29.4 years (SD 5.6); tertile 3 (n=267) mean age 28.5 years (SD 5.5).

Dietary pattern 2: tertile 1 (n=238) mean age 29.5 years (SD 5.3); tertile 2 (n=267) mean age 29.1 years (SD 5.8); tertile 3 (n=259) mean age 27.4 years (SD 6.2).

BMI status
Pre-pregnancy BMI (kg/m^2) by dietary pattern:

Dietary pattern 1: tertile 1 (n=239) mean BMI 26.7kg/m^2 (SD 6.6); tertile 2 (n=258) mean BMI 24.7kg/m^2 (SD 5.9); tertile 3 (n=267) mean BMI 25.0kg/m^2 (SD 5.1).

Dietary pattern 2: tertile 1 (n=238) mean BMI 25.0kg/m^2 (SD 5.8); tertile 2 (n=267) mean BMI 25.3kg/m^2 (SD 6.1); tertile 3 (n=259) mean BMI 25.9kg/m^2 (SD 5.8).

Ethnicity
Race/ethnicity, n (%):

Dietary pattern 1: tertile 1 (n=239) Non-Hispanic white 104 (44%); tertile 2 (n=258) Non-Hispanic white 170 (66%); tertile 3 (n=267) Non-Hispanic white 184 (69%).

Dietary pattern 2: tertile 1 (n=238) Non-Hispanic white 176 (74%); tertile 2 (n=267) Non-Hispanic white 160 (60%); tertile 3 (n=259) Non-Hispanic white 122 (47%).

Recruitment
Pregnant women were included if they were at least 16 years old with a singleton pregnancy, had completed less than 24 weeks of gestation at the time of enrolment, had no previous history of stillbirth or preterm birth at less than 25 weeks of gestation and had no pre-existing diabetes, cancer, psychiatric illness or asthma treated with steroid medications.

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
A dietary pattern score was used to indicate adherence, with a higher pattern score (and thus higher tertile) indicating a greater degree of adherence to that dietary pattern.

Control group
Not applicable.

Follow-up
Participants completed 2 in-person visits during pregnancy, between 10 to 24 weeks and 24 to 32 weeks of gestation, and 1 visit at delivery. Maternal weight during pregnancy was measured at each in-person study visit, and all weights measured at clinic visits were abstracted from the prenatal medical record by study personnel.

Physical activity
Physical activity during pregnancy was reported at each study visit for the preceding 3 months of pregnancy. Physical activity was reported by using the validated Pregnancy Physical Activity Questionnaire.

Diet assessment
At the first study visit, participants received instruction from trained study staff on how to complete monthly web based dietary recalls using the National Cancer Institutes Automated Self-Administered 24-h Recall (ASA24). The ASA24 software calculated quantities consumed per day from each of the USDAs MyPyramid Equivalent food groups by using the dietary intake data. Two dietary patterns were obtained by using reduced-rank regression. Pattern 1 was characterized by a higher consumption of poultry, nuts, cheese, fruits, whole grains, added sugars, and solid fats. Pattern 2 was characterized by a higher consumption of eggs, starchy vegetables, solid fats, fruits, and nonwhole grains and a lower consumption of dairy foods, dark-green vegetables, and whole grains.

Outcome measures
Offspring outcomes included fat mass, % adiposity, fat-free mass, birth weight.

Maternal outcomes included energy intake, physical activity, gestational age at birth, preterm, gestational weight gain, fasting glucose.

GWG was calculated by subtracting the prepregnancy weight from the last recorded maternal weight during pregnancy.

Measure of association/effect, 95% CI, p-value
GWG and Dietary pattern 1 (Healthy): highest vs lowest SMD (95% CI) 0.53 (0.36, 0.71).

Variables adjusted for
Not adjusted.

Tahir and others (2019)

Exposure and outcome
Maternal diet quality during pregnancy and gestational weight gain.

Study design, number of participants and country
Mother–infant dyads included in these analyses were enrolled in the mothers and Infants LinKed for Health (MILK) study, an ongoing prospective cohort study (n=329). Mothers and their infants were recruited from Minneapolis, MN, and Oklahoma City, OK.

Baseline age
All participants (all HEI-2015 Tertiles) (n=329): mean age 30.9 years (SD 4.1).

BMI status
Pre-pregnancy BMI (kg/m^2)

All participants: mean BMI 26.4kg/m^2 (SD 5.4).

Ethnicity
Race, n (%):

All participants: White 299 (86%); Other 49 (14%).

Recruitment
Pregnant women aged 21 to 45 years, with a pre-pregnancy BMI of 18.5kg/m^2 to 40.0kg/m^2, an intention to exclusively breastfeed for at least 3 months, a healthy delivery (defined as less than 3 days in the hospital for vaginal deliveries and less than 5 days in hospital for caesarean section deliveries) and who delivered singleton infants born at-term with a birth weight of 2500g to 4500g was included. The exclusion criteria for the study were as follows: (1) mothers consumed tobacco or more than 1 alcoholic drink per week during pregnancy/lactation; (2) mothers had a history of Type 1 or Type 2 diabetes or current gestational diabetes; (3) mothers had a congenital illness affecting infant feeding or growth; and/or (4) mothers were unable to speak or understand English.

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
A higher HEI–2015 total score (out of 100) represented greater consistency of the diet with the 2015–2020 Dietary Guidelines for Americans.

Control group
Not applicable.

Follow-up
Maternal dietary intake data was collected during the third trimester of pregnancy and at one and 3 months postpartum.

Physical activity
Physical activity during pregnancy were reported at each study visit for the preceding 3 months of pregnancy. Physical activity was reported by using the validated Pregnancy Physical Activity Questionnaire.

Diet assessment
Maternal dietary intake data was collected using the Diet History Questionnaire II (DHQ II), a FFQ designed to assess frequency of intake and portion sizes for 134 food and beverage items and 8 dietary supplement items over the previous month. Maternal diet quality during pregnancy and lactation was estimated using the HEI–2015, a scoring system designed to measure adherence to the 2015 to 2020 Dietary Guidelines for Americans. The HEI–2015 total score is the sum of 13 subcomponent scores that measure adequacy (Total Fruits, Whole Fruits, Total Vegetables, Greens and Beans, Whole Grains, Dairy Products, Total Protein Foods, Seafood and Plant Proteins, and Unsaturated: Saturated fats) and moderation (Refined Grains, Sodium, Added Sugars, and Saturated Fats).

Outcome measures
Infant outcomes included measures of infant growth (length-for-age (LAZ), weight-for-age (WAZ), and weight-for-length (WLZ) Z-scores from birth to 6 months of age) and body composition (body fat percent (BF%)), fat mass (FM), and fat-free mass (FFM) at 6 months of age).

Maternal outcomes included GWG, energy intake during pregnancy, mode of delivery, HEI-2015 score during pregnancy and postpartum, duration of exclusive breastfeeding.

Measure of association/effect, 95% CI, p-value
Excessive GWG and HEI-2015 score, highest vs. lowest OR (95% CI): 0.78 (0.46, 1.34).

Variables adjusted for
Not adjusted.

Tielemans and others (2015)

Exposure and outcome
A posteriori-derived and a priori-defined dietary patterns and gestational weight gain, adequacy of GWG and weight development during pregnancy.

Study design, number of participants and country
This study was embedded in the Generation R Study, a population-based prospective cohort from foetal life onwards in Rotterdam (The Netherlands). Pregnant women (n=3,374) with an expected delivery date between April 2002 and January 2006, living in the urban area around Rotterdam were approached to participate.

Baseline age
Normal weight women (n=2,544): mean age 31.6 years (SD 4.3).

Overweight women (n=830): mean age 31.0 years (SD 4.4).

BMI status
Pre-pregnancy BMI (kg/m^2).

Normal weight women: median BMI 21.6kg/m^2 (IQR 20.4 to 23.0).

Overweight women: median BMI 27.7kg/m^2 (IQR 26.0 to 30.5).

Ethnicity
The study included women of Dutch ancestry.

Recruitment
The study included women of Dutch ancestry, who entered the Generation R Study during pregnancy, with singleton live births. Women with missing dietary information, whose weight was not measured during pregnancy and who were underweight before pregnancy (body mass index (BMI) less than 18.5 kg/m^2) were excluded.

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
Factor scores were determined from FFQs (that is adherence scores) for each participant and each pattern, with a higher factor score indicating that a woman's diet was closer to that dietary pattern.

The Dutch Healthy Diet Index scores provided scores of adherence to the 2006 Dutch healthy diet guidelines, with a higher score corresponding with higher adherence, and thus reflected a healthier diet.

Control group
Not applicable.

Follow-up
Dietary intake in early pregnancy was assessed at enrolment (median 13.4 weeks of gestation (IQR 12.2 to 15.5) using a 293-item semi-quantitative FFQ that covered dietary intake over the previous 3 months.

Women visited the research centre 3 times at median (IQR) gestational ages of 12.9 (12.1 to 14.4) weeks (first visit), 20.4 (19.9 to 21.1) weeks (second visit), and 30.2 (29.9 to 30.8) weeks (third visit). During each visit, maternal weight was measured.

Six weeks after childbirth, women were asked to report their highest weight during pregnancy using a questionnaire, which was used as maximum weight in pregnancy.

To evaluate long-term maternal weight gain, maternal weight was measured 6 years after childbirth.

Physical activity
The components of physical activity were omitted from the Dutch Healthy Diet Index.

Diet assessment
Dietary intake in early pregnancy was assessed at enrolment (median 13.4 weeks of gestation (IQR 12.2 to 15.5)) using a 293-item semi-quantitative FFQ that covered dietary intake over the previous 3 months. The average daily intake of energy and nutrients was calculated using the Dutch food-composition table.

Principal component analysis with Varimax rotation was used to identify a posteriori-derived dietary patterns. The 293 individual food items from the FFQ were aggregated into 23 food groups. Factor scores were determined (that is adherence scores) for each participant and each pattern, by calculating the individual sum of the intake of the food groups, weighted with their factor loadings and standardizing those weighted sums to have mean zero and standard deviation one (standard deviation score). A higher factor score indicated that a woman's diet was closer to that dietary pattern.

Three a posteriori-derived dietary patterns were identified, namely a "Vegetable, oil and fish" pattern, a "Nuts, high-fibre cereals and soy" pattern and a "Margarine, sugar and snacks" pattern.

The a priori-defined dietary pattern was based on the Dutch Healthy Diet Index. This index was developed to measure adherence to the Dutch guidelines for a healthy diet and consisted of10 components: physical activity, vegetable, fruit, dietary fibre, fish, saturated fatty acids, trans-fatty acids, consumption of acidic drinks and foods, sodium, and alcohol. Physical activity, trans-fatty acids, and the consumption of acidic drinks and foods were omitted. The score of each component ranged between 0 and 10 points, resulting in a total score ranging from 0 to 60 points. A higher score on the Dutch Healthy Diet Index corresponded with a higher adherence to the 2006 Dutch healthy diet guidelines and thus reflected a healthier diet. Finally, to facilitate comparison between all dietary patterns, we standardized the "Dutch Healthy Diet Index" pattern to a standard deviation score.

Outcome measures
Gestational weight gain in early, mid and late pregnancy, gestational weight gain adequacy and trajectories of gestational weight.

Measure of association/effect, 95% CI, p-value
GWG and dietary patterns: highest vs lowest SMD (95% CI): vegetable, oil and fish 0.02 (-0.07, 0.11); nuts, high-fibre cereals and soy -0.001 (-0.07, 0.07); Dutch Healthy Eating Index -0.004 (-0.14, 0.13); margarine, sugar and snacks -0.01 (-0.10, 0.08).

Excessive GWG and dietary patterns: highest vs lowest OR (95% CI): vegetable, oil and fish 1.06 (0.76, 1.47); nuts, high-fibre cereals and soy 1.09 (0.77, 1.53); Dutch Healthy Eating Index 1.11 (0.80, 1.53); margarine, sugar and snacks 1.45 (1.05, 1.96).

Variables adjusted for
Adjusted for pre-pregnancy BMI, median gestational age at follow-up, age, educational level, household income, parity, smoking during pregnancy and alcohol consumption.

Zerfu and others (2016)

Exposure and outcome
Dietary diversity during pregnancy and gestational weight gain.

Study design, number of participants and country
A longitudinal, prospective cohort study with 2 arms at a ratio of 1:1 adequate (unexposed) and inadequate (exposed) Women's Dietary Diversity Score (WDDS) that recruited pregnant women (n=373) from 8 randomly selected health centres in 4 rural districts of Ethiopia.

Baseline age
Normal weight women (n=2,544): mean age 31.6 years (SD 4.3).

Overweight women (n=830): mean age 31.0 years (SD 4.4).

BMI status
Pre-pregnancy BMI (kg/m^2).

Normal weight women: median BMI 21.6kg/m^2 (IQR 20.4 to 23.0).

Overweight women: median BMI 27.7kg/m^2 (IQR 26.0 to 30.5).

Ethnicity
The study included women of Dutch ancestry.

Recruitment
The inclusion criteria for the study were as follows: pregnant women who are permanent residents of the study area, with no known medical, surgical, or obstetric problems and who were willing to attend routine antenatal care (ANC) visits. The study enrolled women attending their first antenatal care visit, but all women were already in their second trimester (24 to 28 gestational weeks).

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
Factor scores were determined from FFQs (that is adherence scores) for each participant and each pattern, with a higher factor score indicating that a woman's diet was closer to that dietary pattern.

The Dutch Healthy Diet Index scores provided scores of adherence to the 2006 Dutch healthy diet guidelines, with a higher score corresponding with higher adherence, and thus reflected a healthier diet.

Control group
Not applicable.

Follow-up
The pregnant women were weighed at each visit from enrolment to delivery following the standardized procedures recommended by the World Health Organization (WHO).

Four 24-hour WDDSs from a typical day were collected each month from enrolment to delivery, meaning data were also collected in the preharvest (August to October) and postharvest (November to January) seasons.

Physical activity
The study does not report on physical activity.

Diet assessment
At enrolment, a 24-hour WDDS was collected from the pregnant women by use of the FAO guidelines, and subjects were then divided into "adequate" (WDDS less than 4) or "inadequate" (WDDS at least 4) groups. Briefly, the pregnant women were asked to recall the foods they had consumed in the previous 24 hours. A detailed list of all the ingredients of the dishes, snacks, or other foods consumed was generated to enable better classification of mixed dishes. The foods were then categorized into 9 food groups: 1) cereals, roots and tubers; 2) vitamin A-rich fruit and vegetables; 3) other fruit; 4) other vegetables; 5) legumes and nuts; 6) meat, poultry, and fish; 7) fats and oils; 8) dairy; and 9) eggs.

Overall, 4 24 hour WDDSs from a typical day were collected each month from enrolment to delivery. A pregnant woman was assigned and remained in the adequate or inadequate group if her WDDS remained in that category for at least 3 of the 4 visits. Otherwise, the woman was excluded from the analysis.

Outcome measures
Pregnancy and birth outcomes included birth weight (low birth weight, normal weight), weight, gestational age, duration of follow-up, haemoglobin, number of iron folic acid

tablets taken, iron folic acid proportion taking, anaemia (anaemic, nonanemic), term delivery (PTB, term birth), birth (stillbirth, live birth), weight gain.

Measure of association/effect, 95% CI, p-value
Gestational weight gain and WDDS.

Highest vs lowest SMD (95% CI): 0.33 (0.13, 0.54).

Variables adjusted for
Not adjusted.

Zhu and others (2019)

Exposure and outcome
Diet quality during pregnancy and gestational weight gain.

Study design, number of participants and country
This study used pregnant women (n=2,481) from the Pregnancy Environment and Lifestyle Study (PETALS), a contemporary multi-racial/ethnic prospective cohort study. Pregnant women were identified from the Kaiser Permanente Northern California (KPNC) membership, an integrated health care delivery system, between April 2014 and October 2017.

Baseline age
Age, years, n (%) by quartile of HEI-2010 during pregnancy.

Quartile 1 (n=567): 18 to 24 years 138 (24.3%); 25 to 29 years 164 (28.9%); 30 to 34 years 164 (28.9%); 35 years or older 101 (17.8%).

Quartile 2 (n=567): 18 to 24 years 110 (19.4%); 25 to 29 years 157 (27.7%); 30 to 34 years 191 (33.7%); 35 years or older 109 (19.2%).

Quartile 3 (n=568): 18 to 24 years 66 (11.6%); 25 to 29 years 132 (23.2%); 30 to 34 years 241 (42.2%); 35 years or older 129 (22.7%).

Quartile 4 (n=567): 18 to 24 years 51 (9.0%); 25 to 29 years 148 (26.1%); 30 to 34 years 217 (38.3%); 35 years or older 151 (26.6%).

BMI status
Prepregnancy BMI, (kg/m^2), n (%) by quartile of HEI-2010 during pregnancy.

Quartile 1 (n=567): less than 18.5kg/m^2 22 (3.9%); 18.5 to 24.9kg/m^2 199 (35.1%); 25.0 to 29.9kg/m^2 171 (30.2%); 30kg/m^2 or higher 175 (30.9%).

Quartile 2 (n=567): less than 18.5kg/m^2 13 (2.3%); 18.5 to 24.9kg/m^2 198 (34.9%); 25.0 to 29.9kg/m^2 176 (31.0%); 30kg/m^2 or higher 180 (31.7%).

Quartile 3 (n=568): less than 18.5kg/m^2 11 (1.9%); 18.5 to 24.9kg/m^2 256 (45.1%); 25.0 to 29.9kg/m^2 152 (26.8%); 30kg/m^2 or higher 149 (26.2%).

Quartile 4 (n=567): less than 18.5kg/m^2 16 (2.8%); 18.5 to 24.9kg/m^2 261 (46.0%); 25.0 to 29.9kg/m^2 156 (27.5%); 30kg/m^2 or higher 134 (23.6%).

Ethnicity
Quartile 1 (n=567): Non-Hispanic White 98 (17.3%); Hispanic 245 (43.2%); African American 77 (13.6%); Asian/Pacific Islander 124 (21.9%); Other 23 (4.1%).

Quartile 2 (n=567): Non-Hispanic White 108 (19.0%); Hispanic 254 (44.8%); African American 63 (11.1%); Asian/Pacific Islander 124 (21.9%); Other 18 (3.2%).

Quartile 3 (n=568): Non-Hispanic White 138 (24.3%); Hispanic 218 (38.4%); African American 45 (7.9%); Asian/Pacific Islander 149 (26.2%); Other 18 (3.2%).

Quartile 4 (n=567): Non-Hispanic White 161 (28.4%); Hispanic 220 (38.8%); African American 28 (4.9%); Asian/Pacific Islander 138 (24.3%); Other 20 (3.5%).

Recruitment
Pregnant women aged 18 to 45 years of all races and ethnicities, carrying singleton infants and without recognized pre-existing diseases (such as diabetes, cancer, hepatitis C or liver cirrhosis) were recruited before gestational week 11 at 5 participating medical centres. Women were sequentially excluded if the child had missing data on birthweight from the EHR, missing data from FFQ, implausible daily energy intake (less than 400 or more than 6,000 kcal/day) or had a FFQ completed after the diagnosis of GDM.

Randomisation
Not applicable.

Intervention
Not applicable.

Intervention delivery
Not applicable.

Intervention adherence
An HEI-2010 score was calculated, which assesses adherence to the 2010 Dietary Guidelines for Americans.

Control group
Not applicable.

Follow-up
Survey data were collected at study clinic visit 1 (gestational weeks 10 to 13) and clinic visit 2 (gestational weeks 16 to 19).

Dietary intakes during pregnancy were assessed by the Block FFQ, administered at study clinic visit 1 (gestational weeks 10 to 13).

Physical activity
Physical activity (metabolic equivalent of task or week) was measured using the Pregnancy Physical Activity Questionnaire.

Diet assessment
Dietary intakes during pregnancy were assessed by the Block FFQ, administered at study clinic visit 1 (gestational weeks 10 to 13), that collected information on habitual dietary intake during the previous 3 months. Women reported their usual intake and portion sizes of foods and beverages, including items modified to accommodate the diverse dietary habits of the multi-racial/ethnic cohort. Nutrient intakes were adjusted for total energy intake.

To assess the overall diet quality, we calculated the HEI-2010 score. The HEI-2010 consists of 12 components (total fruit, whole fruit, total vegetables, greens and beans, whole grains, dairy, total protein foods, seafood and plant proteins, fatty acids, refined grains, sodium and empty calories from solid fats, alcohol and added sugars), with a maximum possible score of 100. Alcohol intake was excluded from the empty calories component.

Outcome measures
The primary outcome measures were infant birthweight, gestational age at birth, birthweight z-score (BWZ), LGA, SGA. Other outcomes included gestational weight gain, smoking in pregnancy, alcohol in pregnancy, physical activity, hypertensive disorders in pregnancy, gestational diabetes, preterm birth. GWG was calculated as the difference between pre-pregnancy weight (medical record) and prenatal weight (measured).

Measure of association/effect, 95% CI, p-value
Gestational weight gain and HEI-2010:

Highest vs lowest SMD (95% CI): -0.01 (-0.13, 0.1).

Variables adjusted for
Not adjusted.

USDA (2020) Dietary Patterns during Pregnancy and Gestational Weight Gain: A Systematic Review

The characteristics and findings of this systematic review are provided in annex 3.

Low glycaemic load (GL) diet during pregnancy

Muktabhant and others (2015) Diet or exercise, or both, for preventing excessive weight gain in pregnancy

The characteristics and findings of this SR are provided in annex 3.

The sections below provide data extracted from relevant primary studies that were included in the systematic review by Muktabhant and others (2015).

Clapp III (2002)

Exposure and outcome
A low GI diet and maternal weight gain.

Study design, number of participants and country
A prospective randomised design, recruiting 20 healthy women with an uncomplicated pregnancy in the USA.

Baseline age
Not reported.

BMI status
Not reported.

Ethnicity
Not reported.

Recruitment
Not reported.

Randomisation
Randomised to a dietary intervention at baseline and then at 8 weeks.

Intervention
Randomised to diet containing low glycaemic carbohydrate (CHO) sources (n=10). 17% to 19% protein, 20% to 25% fat and 55% to 60% CHO. Total energy was based on fat-free mass (estimated from 5 site skinfolds and weight stability in the nonpregnant state). CHO sources: unprocessed whole grains, fruits, beans, vegetables, dairy products (aboriginal diet). During pregnancy, all women were allowed to increase caloric intake according to appetite with advancing gestation. All continued the same exercise regimen throughout pregnancy.

Intervention delivery

Intervention adherence
Compliance assessed by 24-hour recall conducted by a dietician at random times twice weekly throughout the study. Nutritionist 3 software was used to calculate caloric intake and diet composition and the GI of the CHO portion of the diet were calculated. The 50 grams white bread standard and mathematical approach was used to calculate the overall dietary GI for each day.

Control group
Isocaloric diet containing similar quantities of protein, fat and carbohydrate (CHO has high GIs) (cafeteria CHO diet). CHO sources: highly processed grains, root vegetables, simple sugars. All continued the same exercise regimen throughout pregnancy.

Follow-up
Maternal weight gain was assessed monthly throughout the pregnancy.

Physical activity
No information provided

Diet assessment
The dietary intakes of all subjects were monitored twice weekly, but the assessment method is not provided.

Outcome measures
Maternal weight gain, glucose and insulin levels and infant anthropometric measures.

Measure of association/effect, 95% CI, p-value
Maternal weight gain was significantly higher in the high glycaemic diet group (mean 18.6kg SE 1.1kg) than the low glycaemic diet group (mean 10.4kg SE 1.1kg) ($p < 0.01$).

Variables adjusted for
None stated.

Horan and others (2014), a follow up study to Walsh and others (2012)

Exposure and outcome
Low glycaemic diet during pregnancy and maternal weight 3 months postpartum.

Study design, number of participants and country
Postpartum follow-up study to an RCT (the ROLO study), including 460 participants, conducted in Ireland.

Baseline age
33.0 ± 3.9 years (Intervention: 32.8 ± 4.0; Control: 33.2 ± 3.8)

BMI status
Mean BMI at booking: 26.3 ± 4.7 kg/m² (Intervention: 26.4 ± 4.7; Control: 26.2 ± 4.6)

Ethnicity
There were 415 white Irish, 35 white non-Irish, 4 Chinese and 6 Filipino or South East Asian mothers who returned the questionnaires at 3 months postpartum and ethnicity was not significantly different between the intervention and control groups ($p = 0.068$).

Recruitment
Of the 800 participants of the original RCT (the ROLO study), 749 completed the study and gave birth to eligible infants (healthy singleton births). 61.4% of these women (228 from the intervention group and 232 from the control group) returned the questionnaires at 3 months postpartum.

Randomisation
No further randomisation beyond that described for the original RCT, described in Walsh and others (2012).

Intervention
See details in Walsh and others (2012).

Intervention delivery
See details in Walsh and others (2012).

Intervention adherence
See details in Walsh and others (2012).

Control group
See details in Walsh and others (2012).

Follow-up
3 months post-partum.

Physical activity
Participants reported the number of 20-minute intervals of physical activity per week (strenuous, moderate, mild).

Diet assessment
Dietary intake over the past 3 months was examined using a condensed version of the self-administered 170 item SLAN (Survey of Lifestyle, Attitudes and Nutrition in Ireland) food frequency questionnaire (FFQ). The FFQ was condensed to include only questions on foods which affect dietary GI, that is moderate- to high-carbohydrate content foods and was therefore used only to compare the GI and GL values of the control and intervention groups at 3 months postpartum.

Outcome measures
Maternal weight change from pre-pregnancy to 3 months postpartum.

Measure of association/effect, 95% CI, p-value
The intervention group had significantly greater weight loss from pre-pregnancy to 3 months postpartum than the control group (1.3 vs. 0.1 kg, p = 0.022).

Variables adjusted for
None stated.

Louie and others (2011)

Exposure and outcome
Low GI diet during pregnancy and excessive weight gain; low GI diet during pregnancy and weight gain (kg); low GI diet during pregnancy and low weight gain.

Study design, number of participants and country
Parallel-arm RCT, 99 participants randomised, 92 participants analysed. Conducted in Australia.

Baseline age
Age, mean (SD) for intervention 34 years (4.1), for control 32.4 years (4.5).

Enrolment gestational age (mean, SD) for intervention 26.1 weeks (4), for control 26 weeks (4.3).

BMI status
Prepregnancy BMI (mean, SD) for intervention 23.9kg/m^2 (4.4), for control 24.1kg/m^2 (5.7).

Ethnicity
Ethnicity (%)

Asian Low GI diet (LGI): 59.6%; conventional high-fibre, moderate GI diet (HF): 55.6% (p=0.697).

Caucasian LGI: 31.9%; HF: 40.0% (p=0.419).

Others LGI: 8.5%; HF: 4.4% (p=0.430).

Recruitment
Inclusion criteria: women with GDM diagnosed by glucose tolerance test (GTT) at 20 to 32 weeks' gestation and singleton pregnancy.

99 women (92 analysed) aged 18 to 45 years diagnosed with GDM by a 75 grams oral glucose tolerance test at 20 to 32 weeks' gestation, with an otherwise healthy singleton pregnancy. The enrolled subjects were centrally randomised to study diet by computer-generated random numbers, stratified by BMI (BMI less than 30kg/m^2 versus 30kg/m^2 or higher) and weeks of gestation (less than 28 weeks or at least 28 weeks).

Randomisation
Study was a 2-arm parallel randomized controlled trial. The enrolled subjects were centrally randomized to study diet by computer-generated random numbers, stratified by BMI (BMI less than 30kg/m^2 versus 30kg/m^2 or higher) and weeks of gestation less than 28 weeks or at least 28 weeks). The allocation sequence was unpredictable and concealed from the recruiter.

Intervention
Low GI diet (n=47) vs conventional high-fibre, moderate GI diet (n=45). Subjects were randomized to one of 2 healthy diets of similar protein (15% to 25%), fat (25% to 30%), and carbohydrate (40% to 45%) content done with an LGI (target GI no more than 50) and the other with a high-fibre content and moderate GI, similar to the Australian population average (HF) (target GI around 60). Both study diets provided all essential nutrients for pregnancy other than iron and iodine, which were supplemented as appropriate by the treating endocrinologist. The baseline 3-day food diary provided information on baseline dietary composition and served as the basis of individualised dietary counselling. Subjects attended at least 3 face-to-face visits with the study dietitian, scheduled to coincide with regular antenatal visits. Intervention began after the 29th week.

Intervention delivery
At enrolment, demographic information, family history of diabetes, and ethnicity were recorded. Subjects were asked to recall their prepregnancy weight, were weighed, and were asked to complete a 3-day food record (including 2 weekdays and 1 weekend day) at baseline and again at 36 to 37 weeks' gestation. A 2-dimensional food model booklet was provided to the subjects to assist in portion size estimation. Last recorded weight before delivery was obtained from the medical record. Subjects attended at least 3 face-to-face visits with the study dietitian, scheduled to coincide with regular antenatal visits. A 24 hour recall of all food and drink intake was conducted during each session to assess compliance. In the case of noncompliance, suitable alternative foods were encouraged. Food sample baskets containing key foods for the assigned diet were provided to promote product recognition and dietary adherence.

Intervention adherence
Participants attended at least 3 face-to-face visits with the study dietician for monitoring adherence and encouragement.

A 24 hour recall of all food and drink intake was conducted during each session to assess compliance. In the case of noncompliance, suitable alternative foods were encouraged. Food sample baskets containing key foods for the assigned diet were provided to promote product recognition and dietary adherence. The study dietitian entered the food records into Australian nutrition analysis software. The GI of individual food items was assigned according to a published method. Dietary glycaemic load (GL) was calculated as follows: (the sum of: GI multiplied by the available carbohydrate of each food in a day, divided by 100. Dietary GI was calculated as follows: (dietary GL divided by total daily available carbohydrate) multiplied by 100. Subjects were deemed compliant if their final dietary GI was no more than 50 in the low-GI group and above 50 in the high fibre group.

Control group
Participants received routine GDM care regardless of dietary assignment.

Follow-up
Subjects provided blood samples at baseline and 36 weeks' gestation - the paper does not report on when final GWG was recorded.

Physical activity
Not reported.

Diet assessment
The study dietitian entered the food records into Australian nutrition analysis software. Dietary GL was calculated as follows: sum of: GI multiplied by the available carbohydrate of each food in a day divided by 100. Dietary GI was calculated as follows: (dietary GL divided by total daily available carbohydrate) multiplied by 100. Subjects were deemed compliant if their final dietary GI was no more than 50 in the LGI group and above 50 in the HF group.

Outcome measures
Subjects were asked to recall their prepregnancy weight, were weighed at enrolment – the paper does not mention when final maternal weight was captured.

Measure of association/effect, 95% CI, p-value
From SR:

RR 0.60 (95% CI 0.32, 1.11).

Results from primary study paper:

Maternal weight gain (kg):

Low GI diet (n=44): 11.9kg ± 0.7; High-fibre moderate-GI diet (HF) (n=43): 13.1kg ± 0.9 (p=0.305).

Below target (%) (based on IOM 2009) LGI = 31.8% HF = 25.6% (p = 0.520).

Within target (%) (based on IOM 2009) LGI = 43.2% HF=32.6% (p = 0.307).

Above target (%) (based on IOM 2009) LGI = 25.0% HF = 41.9% (p = 0.095).

Variables adjusted for
The author reported: Additional analyses with adjustments for ethnicity (Asian vs. Caucasian), BMI; oral glucose tolerance test results; baseline characteristics including daily intakes of energy, monounsaturated fatty acid, polyunsaturated fatty acid, and sodium; fasting blood glucose level (BGL); fasting insulin; homeostasis model assessment

of insulin resistance; and total cholesterol did not change the lack of significance of the between-group comparisons.

Moses and others (2014)

Exposure and outcome
Low glycemic index (LGI) diet and mean GWG.

Study design, number of participants and country
A parallel-arm RCT conducted in Australia from February 2010 to September 2012 (n= 576).

Baseline age
Age, mean (Standard Error of the Mean (SEM)) for intervention 29.9 years (0.3) for control 29.9 years (0.3).

BMI status
Prepregnancy BMI, mean (SEM) for intervention 24.3kg/m^2 (0.3) for control 24.7kg/m^2 (0.3).

Ethnicity
Not reported.

Recruitment
Healthy pregnant women at 12 to 16 weeks' gestation who agreed to be randomised were included. Women with pregestational diabetes; multiple birth; assisted reproduction; special diet or referred to a dietitian for other reasons were excluded.

Randomisation
Eligible volunteers who attended for routine antenatal care at less than 20 weeks of gestation were randomly assigned to either a LGI diet or healthy eating diet. Women were randomly assigned by using computer-generated random numbers to 1 of 2 diet groups and stratified by pre-pregnancy BMI (in kg/m^2; less than 30 compared with 30 or higher). The allocation sequence was unpredictable and concealed from the research dietitian.

Intervention
Women were randomly assigned to 1 of 2 dietary groups designated the LGI diet or healthy eating diet. Participants received a detailed dietary education tailored for the assigned diet and their individual requirements for pregnancy (for example, that met energy needs and nutrient requirements). There was no intended difference in the macronutrient distribution in diets. Women in both groups were counselled to adopt diets

that were consistent with the nationally recommended nutritional intake for pregnant women and recommendations of the Australian Guide to Healthy Eating. Participants were provided with 1 of 2 sets of booklets (depending on their allocation) that included information on the choices for and serving sizes of carbohydrate-rich foods. The LGI group received specific information on LGI alternatives for relevant food groups. Specific dietary goals were provided to each participant that focused on differentiating between carbohydrate rich foods) (for example, replace white potato with an LGI potato or change breakfast cereals to rolled oats).

Intervention delivery

Interested patients were provided with a participant information sheet, consent form, and 3 day food record sheet. The first study visit was arranged to coincide with the next obstetric appointment. At the first study visit, the completed 3-day food record was reviewed, and extra details or information (for example, serving sizes and brands, cooking methods, and ingredients) were clarified. Women were asked to estimate portions and quantities on the basis of pictures, food models, and measuring tools (for example, cups and teaspoons). Diet education that was specific to the assigned diet group was given. There were 4 contact points scheduled during the pregnancy. The second contact (phone call) was made around 4 weeks after the initial education and visit to ensure adherence to the prescribed diet and goals set, identify any barriers to adherence, and address any other dietary issues or concerns. At the third visit, dietitians reviewed participants face-to-face at around 28 weeks of gestation before their obstetric appointment to monitor progress and address any new issues. At this visit, participants were also given another 3-day food record and asked to complete the record before their final visit scheduled at around 34 weeks of gestation. At the final visit (at a minimum of 34 weeks of gestation), the dietitian collected and reviewed the final 3 day food record and also measured the final weight of subjects.

Intervention adherence

A phone call was made approximately 4 weeks after the initial education and visit to ensure adherence to the prescribed diet and goals set, identify any barriers to adherence, and address any other dietary issues or concerns. The dietary GI was calculated as the weighted sum of the GI of all carbohydrate foods in the diet, with the weighting proportional to the contribution of each food to total carbohydrate intake.

Control group

Women in the healthy eating group were counselled to follow a conventional healthy diet with recommended foods and serving sizes as noted in the Australian Guide to Healthy Eating and were not given any guidance on the GI. Participants received a detailed dietary education tailored for the assigned diet and their individual requirements for pregnancy (that met energy needs and nutrient requirements). There was no intended difference in the macronutrient distribution in diets. Women in the control group were counselled to

adopt diets that were consistent with the nationally recommended nutritional intake for pregnant women and recommendations of the Australian Guide to Healthy Eating. Participants were provided with 1 of 2 sets of booklets (depending on their allocation) that included information on the choices for and serving sizes of carbohydrate-rich foods.

Follow-up
Outcomes were assessed at baseline, 28 weeks and 34 weeks.

Physical activity
Physical activity was not assessed or controlled for.

Diet assessment
3-day food record.

Outcome measures
Primary outcomes were prevalence of LGA at birth (more than 90th centile); prevalence of childhood obesity as determined by BMI. Secondary outcomes were prevalence of gestational diabetes; ponderal index; prevalence of SGA; GWG.

Measure of association/effect, 95% CI, p-value
A mean difference in weight gain of 0.3kg (95% CI: -0.53, 1.13) between the low GI diet group (mean: 14.1kg (SD 5.2)) and the standard care group (mean: 13.8kg (SD 5)).

Variables adjusted for
No information provided.

Rhodes and others (2010)

Exposure and outcome
Low-GL diet and maternal weight gain.

Study design, number of participants and country
RCT (pilot study), set in Beth Israel Deaconess Medical Center, Boston, Massachusetts and Children's Hospital Boston, Boston, Massachusetts, USA, between January 2007 to June 2009.

Baseline age
Age (p= 0.67): Low-GL diet group: 33.7 years (SD 3.9) and low-fat diet group: 33.2 years (SD 3.7).

BMI status
BMI (kg/m^2) (p= 0.43): Low-GL diet group: 32.1kg/m^2 (SD 4.6) and low-fat diet group: 31.2kg/m^2 (SD 3.1).

Ethnicity
Race-ethnicity (n, %) (p= 0.77)

Low-GL diet group: non-Hispanic white: 14 (56%), Non-Hispanic black: 3 (12%), Hispanic: 5 (20%), Asian: 0 (0%), Non-Hispanic mixed: 2 (8%), Other/unknown: 1 (4%).

Low-fat diet group: non-Hispanic white: 11 (52%), Non-Hispanic black: 2 (10%), Hispanic: 3 (14%), Asian: 1 (5%), Non-Hispanic mixed: 1 (5%), Other/unknown: 3 (14%).

Recruitment
Pregnant women with prepregnancy or 1st trimester BMI equal to or greater than 25kg/m^2 and less than 45kg/m^2, singleton pregnancy, willing to consume the diets for duration of pregnancy, participant to be at week 28 or less of pregnancy at baseline visit were recruited. Women who were smoking during pregnancy, had a major medical illness (e.g., diabetes mellitus, hypertension, thyroid disease), were taking prescription medication known to affect body weight, had alcohol consumption during pregnancy, had intention to deliver infants in the environment outside of Beth Israel Deaconess Medical Center, Boston, a high level of physical activity were excluded.

Randomisation
Random assignment was then performed by the study dietitian. Subjects were randomly assigned to receive either a low-fat or low-GL diet. Random assignment was stratified by history of prior pregnancies (at or beyond 13 weeks gestation) and prepregnancy or first-trimester BMI 30kg/m^2 or higher. Within each of the 4 strata, subjects were assigned to the 2 diet groups in a 1:1 ratio. Separate random assignment envelopes for each stratum were prepared in advance by the Children's Hospital Boston Clinical Research Program in randomly permuted blocks of 2 and 4, preventing anticipation of future assignments.

Intervention
The low-GL diet was designed to be lower in GL, which was achieved by both moderately reducing total carbohydrate and replacing higher GI carbohydrates with lower GI carbohydrates. Target macronutrient composition for the low-GL diet was 45% carbohydrate, 35% fat, and 20% protein. Thus, we aimed to study the potential advantages of decreasing GL from prevailing norms.

Intervention delivery
The dietary intervention was introduced at the baseline visit and further detailed through 2 1 hour in-person counselling sessions. Subjects had in-person maintenance visits at 2 to 4 week intervals. The final visit for measurements was at 36 weeks. One in-person and weekly phone counselling sessions were offered after 36 weeks. Structured written guides were used to ensure differentiation between interventions and consistency in delivery of intervention messages. In addition, we used a patient-centred counselling approach (considering the individual's perspectives, life experiences, circumstances, and resources) to promote dietary behaviour change. Dietary modules available for both groups were developed to address anticipated dietary challenges during pregnancy. To further ensure differentiation in dietary intake between groups, we provided subjects with the majority of their carbohydrate-rich foods, healthful sources of fat and snacks for the low-fat and low-GL diets, respectively, either through monthly delivery from a supermarket to their homes or at in-person visits. Subjects were instructed to eat ad libitum and to consume provided foods to maintain macronutrient balance. All subjects received routine prenatal care and were advised to take a standard prenatal multivitamin.

Intervention adherence
Adherence to intervention diets was discussed at weekly reviews of counselling sessions with the study director.

Control group
The low-fat diet was designed to meet current recommendations for pregnancy from the American Dietetic Association and the Institute of Medicine, which include consumption of a moderately low-fat, low-saturated-fat, high complex carbohydrate diet without consideration of GI. Consequently, such diets tend to be moderately high in GL. The low-fat diet was designed to be similar in GL to prevailing norms, with a target macronutrient composition of 55% carbohydrate, 25% fat, and 20% protein.

Follow-up
Dietary intervention was introduced at the baseline visit and then further detail through 2 1 hour in person counselling sessions. Subjects had in-person maintenance visits at 2 to 4 week intervals. The final visit was at 36 weeks and then one in person and weekly phone counselling sessions were offered after 36 weeks. At each study visit, maternal weight measurements were taken.

Physical activity
There was no formal assessment of physical activity during study participation.

Diet assessment
Adherence to the intervention diets was discussed at weekly reviews of counselling sessions with the study director.

Outcome measures
The primary outcome was birth weight z score. Other endpoints included infant anthropometric measurements, gestational duration, maternal weight gain, and maternal metabolic parameters.

Measure of association/effect, 95% CI, p-value
A mean difference in weight of -0.5kg (95% CI: -3.29, 2.29) between the low GI diet group (mean: 6.4kg (SD 4.5)) and the standard care group (mean: 6.9kg (SD 4.2)).

Walsh and others (2012) (ROLO study)

Primary data extraction for this study is included under Walker and others (2018) Attenuating Pregnancy Weight Gain—What Works and Why: A Systematic Review and Meta-Analysis.

Milk and dairy intake during pregnancy

Achón and others (2019) Effects of milk and dairy product consumption on pregnancy and lactation outcomes: a systematic review

The characteristics and findings of this SR are provided in annex 3.

The sections below provide data extracted from relevant primary studies that were included in the systematic review by Achón and others (2019).

Abreu and others (2017)

Exposure and outcome
Dairy product intake and gestational weight gain.

Study design, number of participants and country
Prospective study; 98 pregnant women; Porto Portugal.

Baseline age
47% (n=46) of the women were aged 18 to 30 years and 53% (n=52) were aged 31 to 40 years.

BMI status
At baseline, 60% (n=59) were non-overweight (BMI below 25) and 40% (n=41) were overweight or obese (BMI 25 or above). Underweight participants (1%) were combined with the normal weight participants in the non-overweight category.

Ethnicity
Not reported.

Recruitment
Pregnant women attending the outpatient obstetrics clinics at São João Hospital in Porto, Portugal were recruited. Women were invited to participate when they came in for their first ultrasound evaluation screening. The recruitment was made consecutively from July 2010 to May 2012.

Randomisation
Not applicable

Intervention
Dairy product consumption was assessed using a 3-day food diary completed during the first and second trimesters. Weight gain during pregnancy was measured as the difference between the self-reported weight before pregnancy and the last weight recorded prior to delivery and was classified as insufficient, adequate, and excessive, based on NAM (formerly IOM) guidelines.

Intervention delivery
Oral and written instructions on how to complete the food diary were given by a trained nutritionist.

Intervention adherence
A Mediterranean diet score was used as an indicator of diet quality. Based on a total score, each woman was categorised into one of 2 groups for each trimester: low adherence (0 to 4 points) or high adherence (5 to 8 points).

Control group
Not applicable.

Follow-up
Data was collected in the first trimester between the 10th and 12th weeks of gestation (at the time of baseline assessment), in the second trimester between the 20th and 22nd weeks (at the time of the second ultrasound) and again in the immediate post-partum (24 to 48 hours after delivery).

The assessment instruments (questionnaires and anthropometric measures) were individually administered on ultrasound evaluation days.

3-day food diaries were completed for each trimester.

Physical activity
No information provided.

Diet assessment
Dietary intake was assessed by a 3-day food diary that included 2 weekdays plus 1 weekend day and was completed for each trimester. Food portion sizes and beverages consumed were estimated using household measures as an aid in determining serving sizes. A description of each food and beverage consumed was recorded, including the method of preparation, the time it was eaten (to the nearest 5 minutes), location, and, if appropriate, the brand name of the product. The nutrient analysis was performed using the software Food Processor SQL. The nutrient and food means of the 3 days were used in the analysis. The amounts of milk (whole, reduced-fat, and fat-free), yogurt, and cheese (including cottage and cream cheese) were presented in term of grams per day (grams per day). In this study, total dairy included milk, yogurt, and cheese. Additionally, change in dairy product intake was computed as the difference between the second and first trimesters.

Outcome measures
Neonatal outcomes were birth weight, length, head circumference, and placental weight.

The maternal outcome was weight gain during pregnancy.

Weight gain during pregnancy corresponded to the difference between the self-reported weight before pregnancy and the last weight recorded prior to delivery. Weight gain was then classified as insufficient, adequate, and excessive.

Maternal outcomes (weight gain during pregnancy) were obtained from hospital records.

Measure of association/effect, 95% CI, p-value
No significant associations between first or second trimester dairy intake and maternal weight gain. However, change in total dairy intake between the second and first trimester was negatively associated with maternal weight gain during pregnancy (Beta =−0.007, p=0.02). No significant difference in second trimester maternal weight gain between groups with the highest (14.6± 5.1kg) or lowest (14.4±5.1kg) adherence to the Mediterranean diet (p=0.839). Similar results for the first trimester.

Variables adjusted for
The study adjusted for mother's weight, height and preconception BMI and weight gain during gestation; smoking status; neonatal sex; gestation age; socio-economic characteristics; educational level; energy intake and compliance to Mediterranean diet (score).

Probiotic dietary supplementation during pregnancy

Chatzakis and others (2019) Prevention of gestational diabetes mellitus in overweight or obese pregnant women: a network meta-analysis

The characteristics and findings of this SR and meta-analysis are provided in annex 3.

The sections below provide data extracted from relevant primary studies that were included in the systematic review by Chatzakis and others (2019).

Asgharian and others (2019)

Exposure and outcome
Probiotic yoghurts and weight gain over pregnancy.

Study design, number of participants and country
Randomised controlled trial of 130 participants, conducted in Iran.

Baseline age
The mean age of the women was 29.5 years in the intervention group (SD 6.2 years) and 29.4 years in the control group (SD 5.5 years).

BMI status
All women had a pre- or early pregnancy BMI of at least 25kg/m^2. The mean BMI was 29.2 (SD 3.3) in the probiotic group and 30.3 (SD 4.1) in the conventional yoghurt group

Ethnicity
No information provided.

Recruitment
Participants were recruited from 5 public health centres in northwest Tabriz, Iran. Potentially eligible women were initially identified using the women's pregnant record books which were available at every health centre. The identified women were called at 17 to 19 weeks of gestation. After explaining the study objectives and methods, those who were willing to participate in the study were asked to attend the administration centre when they were 20 to 22 weeks of gestation for an eligibility assessment and to give consent.

Randomisation
Allocation sequence was generated by a computerized random number generator, stratified by BMI category, and restricted to randomly varying blocks of 4 and 6. Allocation concealment was maintained using consecutively numbered opaque sealed envelopes.

Intervention
Participants received either probiotic or conventional (control) yoghurt packs, 100g per day from 24 weeks of gestation until delivery. The probiotic yoghurt contained 500 million colony forming units per gram of Lactobacillus acidophilus La5 and Bifidobacterium lactis Bb12.

Intervention delivery
The yoghurts were re-supplied on a weekly basis and were collected from the administration centre by participants. They were asked to store the yoghurts in refrigerator and consume them daily by themselves, starting from the same day they received.

Intervention adherence
A daily diary was used for recording the yoghurt consumption which was delivered to the investigator at the weekly visit. The mean days of yoghurt consumption prior the delivery was 99.1 (SD 17.4) for the intervention group and 99.7 (SD 16.6) for the control group.

Control group
Received conventional yoghurts of identical appearance, but without Lactobacillus acidophilus La5 and Bifdobacterium lactis Bb12. Both the intervention and control yoghurts contained Streptococcus thermophilus and Lactobacillus delbrueckii subsp. bulgaricus used for biotransformation of milk (as starter).

Follow-up
Until 30 days after birth for infant outcomes.

Physical activity
No information provided.

Diet assessment
Participants completed a 3-day food diary at 28 weeks of gestation. Dietary intake was quantified by Nutritionist 4 software and a database including tables of contents and nutritional value information inserted on Iranian food products.

Outcome measures
Weight gain over pregnancy was a secondary outcome. Primary outcomes were fasting plasma glucose (FPG) and 1- and 2-hour plasma glucose post 75-g oral glucose tolerance

test (OGTT) measured at 28 weeks of gestation. Other secondary outcomes included gestational diabetes mellitus (GDM), preeclampsia, preterm delivery, delivery mode, and satisfaction with the yoghurts.

Measure of association/effect, 95% CI, p-value
Maternal outcomes pertaining to gestational weight gain did not differ between the groups (p=0.976).

Variables adjusted for
BMI category (overweight or obese).

Callaway and others (2019)

Exposure and outcome
Probiotics and GWG.

Study design, number of participants and country
Randomised controlled trial of 411 participants, conducted in Australia

Baseline age
The mean age of the intervention group was 31.3 years (SD 4.7 years), and for the control group the mean age was 31.7 years (SD 4.8 years).

BMI status
All participants had a BMI of at least 25kg/m^2. The mean BMI for the intervention group was 31.9kg/m^2 (SD 7.5) and for the control group the mean BMI was 31.6kg/m^2 (SD 7.2).

Ethnicity
83.8% of participants in the control group and 89.9% in the intervention group were Caucasian.

Recruitment
Recruitment was conducted at the Royal Brisbane and Women's Hospital, Redcliffe Hospital, and the Mater Mothers' Hospital in Brisbane, Australia.

Randomisation
Participants were randomly assigned to probiotics or placebo prior to 20 weeks' gestation using computer-generated random number codes sealed in opaque envelopes. Participants were stratified by patient centre and by BMI category.

Intervention
Probiotic capsules consisted of a mixture of Lactobacillus rhamnosus (LGG) and Bifidobacterium animalis subspecies lactis (BB-12) at a dose of at least 1 billion colony forming units each per day.

Intervention delivery
Capsules were to be taken once daily from enrolment (prior to 20 weeks gestation) until birth.

Intervention adherence
Compliance to study medication adherence was monitored through interviews with all participants. Compliance with study medication, assessed by participant interview and monthly telephone follow-up, was reported as over 90%. A subset of participants provided faecal samples. Adherence based on faecal analysis was 79%.

Control group
Received matching placebo capsules. Both probiotic and placebo capsules were identically packaged by independent pharmacists.

Follow-up
To 36 weeks' gestation.

Physical activity
No information provided.

Diet assessment
None.

Outcome measures
Weight gain based on self-report at the beginning of pregnancy and measured weight at 36 weeks' gestation was categorized as excessive or inadequate based on the Institute of Medicine guidelines.

Measure of association/effect, 95% CI, p-value
Excessive weight gain occurred in 32.5% of women in the intervention (probiotics) group compared with 46% of women in the placebo (control) group ($p = 0.01$). However, there was no difference in mean weight gain in the 2 groups.

Variables adjusted for
None stated.

Okesene-Gafa and others (2019)

Exposure and outcome
Culturally tailored dietary intervention and/or daily probiotic capsules and excessive GWG.

Study design, number of participants and country
Randomised controlled trial of 230 participants conducted in New Zealand.

Baseline age
The mean age of participants was 28.8 years.

BMI status
Participants had a BMI of 30 kg/m^2 or higher.

Ethnicity
The study included a multiethnic population, with significant representation from Pacific and Māori women.

Recruitment
Women with a singleton pregnancy at 12+0 to 17+6 weeks of gestation and a BMI of 30 kg/m^2 or higher were eligible. Exclusion criteria included preexisting diabetes, known congenital abnormality, and previous bariatric surgery.

Randomisation
Eligible women were randomly allocated using a web-based randomisation program using random permuted blocks of 4 to 8 participants, stratified by BMI (30 to <35 or ≥35 kg/m^2), to either dietary intervention and probiotic or placebo capsules, or routine dietary advice and probiotic or placebo capsules.

Intervention
The dietary intervention included a Healthy Mums and Babies (HUMBA) handbook, 4 home-based education sessions by a community health worker including behaviour change techniques for healthier eating and weight gain monitoring, feedback and positive reinforcement, and motivational text messages. Women allocated to probiotics received capsules containing Lactobacillus rhamnosus GG and Bifidobacterium lactis BB12 (minimum dose 6.5 billion colony forming units).

Intervention delivery
Women were instructed to take 1 capsule (probiotic or placebo) daily until birth. All participants continued routine antenatal care.

Intervention adherence
Compliance with the dietary intervention was defined as completing 3 or 4 dietary intervention visits. Compliance with capsules was defined as taking probiotic or placebo capsules more than 75% of the time and was assessed by participant verbal feedback at 28 weeks, 36 weeks and post-birth. 81% percent of women were compliant with dietary interventions and 76% met the criteria for compliance with probiotic capsules.

Control group
Women allocated to routine dietary advice received the New Zealand Ministry of Health pamphlets “Eating for healthy pregnant women” and “Healthy weight-gain in pregnancy,” with no dietary input from community health workers or text messages. Women in the placebo group received identical capsules to those in the probiotic group, but containing microcrystalline cellulose and dextrose anhydrate.

Follow-up
Until birth.

Physical activity
At 28 weeks gestation women completed New Zealand Physical Activity-Short Form questionnaire.

Diet assessment
Assessed using the New Zealand Food Frequency-Short Form questionnaire at 28 weeks gestation.

Outcome measures
Primary maternal outcome was the proportion of women with excessive GWG, defined as mean weekly weight gain >0.27 kg between recruitment and 36 weeks’ gestation (or closest weight), adjusted for baseline BMI.

Measure of association/effect, 95% CI, p-value
There was no significant difference between intervention groups for the primary outcome of proportion of women with excessive gestational weight gain (dietary intervention vs routine advice: 79/107 [73.8%] vs 90/110 [81.8%], adjusted relative risk [relative risk, 0.92; 95% confidence interval, 0.80 to 1.05, p = 0.22]; probiotics versus placebo: 89/108 [82.4%] and 80/ 109 [73.4%], relative risk, 1.14, 95% confidence interval, 0.99 to 1.31, p = 0.08).

Total maternal weight gain, a secondary outcome, was lower with dietary intervention compared with routine dietary advice (9.7 vs 11.4 kg, adjusted mean difference, -1.76, 95% confidence interval, -3.55 to 0.03, p=0.05).

Variables adjusted for
Maternal baseline BMI (for excessive GWG), gestational age at 36 weeks (for weight change to 36 weeks).

Lindsay and others (2014)

Exposure and outcome
Probiotic supplementation and GWG (secondary outcome).

Study design, number of participants and country
Randomised controlled trial which recruited 175 women, conducted in Ireland.

Baseline age
The mean age of the intervention group was 31.4 years (SD 5.0 years), and for the control group the mean age was 31.0 years (SD 5.2 years).

BMI status
All participants had a BMI of between 30.0kg/m² and 39.9kg/m². The mean BMI for the intervention group was 32.9kg/m² (SD 2.4) and for the control group the mean BMI was 34.1kg/m² (SD 2.7).

Ethnicity
The majority of participants were of Irish ethnicity (84.1% of the intervention group and 79.7% of the control group).

Recruitment
Obese pregnant women were identified at their first antenatal visit to the hospital.

Randomisation
Allocation to either the probiotic or placebo capsules was conducted by an independent researcher by using a computer-generated, simple randomisation process in a ratio of 1:1. The allocation sequence was concealed from the research dietitian who enrolled and assessed participants in sequentially numbered, sealed, opaque envelopes.

Intervention
4 weeks of probiotic capsules containing 100mg Lactobacillus salivarius UCC118 freeze-dried powder to achieve a target dose of a hundred million colony forming units. The women were instructed to take 1 capsule per day after a meal of their choice and keep the bottle refrigerated.

Intervention delivery
Participants were provided with a 2-week supply of probiotics at 24 weeks gestation. When possible, a brief follow-up meeting with the research dietitian was arranged for a fortnight, at which time the participant returned the first capsule bottle for a pill count to monitor compliance and was provided with a second bottle to complete the 4-week intervention period.

Intervention adherence
Poor capsule compliance, as assessed by pill counts, was considered to apply when 3 or more capsules were missed during the 4-week intervention period. 9 women from the intervention group and 12 from the control group were excluded from the analysis due to poor compliance (reflecting 11% and 15% of those allocated to each group respectively).

Control group
The control group received placebo capsules of identical appearance, delivered in an identical way.

Follow-up
Various infant outcomes assessed at birth. Timing of maternal weight measurement not stated.

Physical activity
Subjects were provided with a lifestyle questionnaire that was previously validated for pregnancy and included questions on activity.

Diet assessment
At the 24-week visit, the research dietitian provided and explained a 3-day food diary to each participant. Subjects were instructed to record in detail all food and drink consumed on 3 consecutive days and to include one weekend day within the intervention period. Data from food diaries was entered into the nutritional analysis software (WISP version 3.0; Tinuviel Software) for energy and nutrient intake analysis.

Outcome measures
GWG was a secondary measure. Primary measure was the change in maternal fasting glucose following the intervention.

Measure of association/effect, 95% CI, p-value
No significant difference in GWG between the probiotic and placebo groups. The mean total GWG for the probiotic group was 11.1kg (SD 6.2), and for the placebo group, it was 9.4kg (SD 5.6). The effect size was 0.76kg with a 95% CI of -1.37 to 2.89, and the p-value was 0.479.

Variables adjusted for
Maternal BMI.

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