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Dietary intervention in gestational diabetes

Submission date
10/02/2020

Recruitment status
No longer recruiting

Registration date
28/04/2020

Overall study status
Completed

Last Edited
20/08/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Gestational diabetes affects 35,000 pregnancies annually in the UK, causing adverse outcomes to mother and child, such as large-for-gestational age (LGA) (babies are born bigger than usual) and difficult deliveries. Obesity and excessive gestational weight gain are risk factors for gestational diabetes. However, it is unclear if weight gain remains important in women after diagnosis (28 weeks). National guidelines give no calorie or weight targets to guide management. Observational data suggests that women who avoid excessive weight gain during pregnancy, particularly after a diagnosis of gestational diabetes, had improved pregnancy outcomes, needed less medical intervention during labour and gave birth to infants with a healthier birth weight and had lower rates of LGA. Women with a reduced weight gain after diagnosis also had better postnatal glucose tolerance. This raises the exciting possibility that an 8-10 week intervention in late pregnancy could improve pregnancy outcomes and also reduce maternal diabetes risk long-term. The aim of this study is to assess the effects of a reduced-calorie diet in late pregnancy in women with gestational diabetes.

Who can participate?
Overweight or obese women with gestational diabetes

What does the study involve?
Participants are randomly allocated to receive diet boxes (standard calorie vs reduced calorie) containing all meals from 30 weeks to delivery. Food diaries, continuous glucose monitoring, Bluetooth scales and questionnaires will measure compliance, glucose control, weight changes and quality of life. Women will receive standard antenatal gestational diabetes care including regular ultrasound scans and treatment (insulin and/or metformin) as needed. The study will assess if an 8-10 week intervention can reduce maternal weight gain and infant birthweight. Delivery mode, treatment requirements, complications, and maternal glucose levels will also be assessed.

What are the possible benefits and risks of participating?
The information obtained from the study may help improve care for pregnant women with gestational diabetes in the future. Participants receive the best possible diet for women with gestational diabetes through the diet boxes, with minimal time for preparation or cooking (and, during the pandemic, also reduced exposure to shops). The provision of free food over 8 to 10 weeks saves participants' money. Blood test analysis may detect otherwise unknown

abnormalities such as high cholesterol or longer-term risk of diabetes, offering the possibility of having important conditions diagnosed early. The risks of taking part in this study are low. The participants will be hungry on the diet (or feel very full). Some women may have a small weight loss during the study. There is good evidence that in women with gestational diabetes, weight loss can be safe and even beneficial to both mother and baby. Substantial weight loss can cause babies to be born smaller than usual (small-for-gestational-age). The researchers will monitor participants' weights carefully and stop the intervention and arrange appointments/ultrasound scans as needed. Giving blood samples may cause a small amount of discomfort. Wearing a glucose sensor could be inconvenient for some participants but most people do not find this troublesome. For participants consenting to have the DXA scan at Visit 4, there is a very small dose of radiation given. The dose of radiation received during a DXA scan is equivalent to the amount of natural atmospheric radiation received over a few hours and does not pose any substantial risk to participants.

Where is the study run from?
1. Cambridge University Hospitals NHS Foundation Trust (UK)
2. North West Anglia NHS Foundation Trust (UK)
3. Norfolk And Norwich University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2018 to February 2023

Who is funding the study?
Diabetes UK

Who is the main contact?
Prof. Claire Meek
cm881@leicester.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Claire Meek

ORCID ID
https://orcid.org/0000-0002-4176-8329

Contact details
Leicester Diabetes Centre
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW
+44 (0)7504 986426
cm881@leicester.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
242924

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 39156, IRAS 242924

Study information

Scientific Title
DiGest: dietary intervention in gestational diabetes: a randomised controlled trial

Acronym
DiGest

Study objectives
This study is a multicentre, prospective, randomised, controlled, double-blind trial to assess the effects of a reduced-calorie diet in late pregnancy in women with gestational diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/07/2018, West Midlands - Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8106; nrescommittee.westmidlands-blackcountry@nhs.net), REC ref: 18/WM/0191

Study design
Randomized; Interventional; Design type: Treatment, Dietary

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gestational diabetes

Interventions
This study design is a randomised controlled double-blind trial of a nutritional intervention. Overweight or obese women with gestational diabetes will be randomly allocated to receive

either a standard-calorie or reduced-calorie dietbox every week from diagnosis of gestational diabetes until delivery. The study is double-blind as women and their research and clinical teams will not know which dietbox they will be receiving. This is a new way of running a nutritional study.

Recruitment: At the time of referral for glucose (sugar) testing in pregnancy, obese and overweight women will receive an introductory flyer about the study. If gestational diabetes is diagnosed, women will be given a participant information leaflet and an opportunity to discuss study participation with their friends, family and the research team. Women who wish to participate in the study will give written informed consent and will be randomised before 30+6 weeks of pregnancy.

Study visits: This study requires 4 study visits. Study visits will occur at enrolment (28-30 weeks) at 32 weeks and 36 weeks during pregnancy and at 6 weeks postpartum. The timeline for each participant is as follows:

Study visit 1: (approximately 2 hours)
The participant will have a further detailed explanation of the study, and the opportunity to ask any further questions about the study design or the dietboxes. Patients who agree to participate will then give written informed consent and will be enrolled into the study.

At visit 1, the following procedures will be performed:
• Consent form signed
• Baseline weight, height and anthropometry - i.e. measuring the size of the body
• Blood pressure
• Fasting blood tests for sugar levels, hormones, blood count and cholesterol-related tests. Blood will also be stored for specialist tests (metabolomics, lipidomics and genetic testing)
• Case report form will be completed, including information on pre-pregnancy weight, recent weight changes, normal dietary preferences, dietary requirements, medical and obstetric history and infant feeding intentions
• 2 weeks' masked continuous glucose monitoring will commence with detailed explanation to the participant (masked - the participant will not be able to see the readings).
• 3 day food diary will commence
• Urinalysis. A urine sample will be stored for specialist tests (microalbuminuria or metabolomic testing)

• Participants will be given a Bluetooth set of scales on loan
• Questionnaires will be completed:
o Quality of Life (EuroQuol EQ5D)
o Eating behaviour (three factor eating questionnaire; TFEQ-18)
o Breastfeeding opinions and intentions
• Women's dietary preferences will be discussed and the first dietbox will be ordered for delivery to the participant's home
• Women will be randomised to receive either the standard calorie or reduced calorie dietbox
• The first dietbox will be delivered 1-2 weeks after visit 1, to allow at least 7 days of baseline continuous glucose monitoring to be obtained

Monitoring period:
Participants will be in weekly telephone contact with the study team. Participants will weigh themselves regularly using the Bluetooth scales and the information will be assessed by the study team. The study team will also enquire about satisfaction with the dietboxes and adherence and will identify any issues which might arise. Participants will also attend their

standard antenatal GDM appointments and will follow local hospital policies for monitoring. At their clinic appointments, participants will have:
• Regular weight checks
• Regular ultrasound scans for growth
• Urinalysis
If concerns are identified during the monitoring period, further study visits will be arranged by the research team. This might occur in the following circumstances:
• Crossing down >20 percentiles on ultrasound assessment of estimated fetal weight
• Participant has concerns about excessive hunger or other aspects of the diet
• Participant or clinical team identify concerns about weight changes (+/- 5% weight change from pre-pregnancy weight)

Study visit 2: 32 weeks' gestation (45 minutes)
The aim of this visit is to assess weight and to identify any issues with the dietboxes or food delivery. The following procedures will be performed at the 32-week visit:
• Weight, anthropometry and blood pressure
• 2 weeks' masked continuous glucose monitoring will commence
• 3-day food diary will commence to allow a detailed assessment of the continuous glucose monitoring data
• Questionnaires will be completed:
o Satisfaction with the dietbox
o Quality of Life (EuroQuol EQ5D)
o Breastfeeding opinions and intentions
The participant will also be given the participant information leaflets about placental biopsy, cord blood collection, infant anthropometry (body size) examination and infant body composition assessment using the Peapod.

Study visit 3: 36 weeks' gestation (45 minutes)
The aim of this visit is to collect information on glycaemia and weight at the end of the intervention period, but before labour has commenced. The study team will discuss with the participant the possibility of taking cord blood and placental tissue after labour, should appropriate facilities and staff be present at the time. Infant examination for anthropometry and body composition will also be discussed. These investigations are voluntary and a consent form will be signed at 36 weeks if the participant is willing to have these performed.

The following procedures will be performed at the 36-week visit:
• Weight, anthropometry and blood pressure
• Fasting blood tests for sugar levels, hormones, blood count and cholesterol-related tests. Blood will also be stored for specialist testing (metabolomics, lipidomic and genetic testing)
• 2 weeks' masked continuous glucose monitoring will commence
• 3-day food diary will commence
• Questionnaires will be completed:
o Satisfaction with the dietbox
o Quality of Life (EuroQuol EQ5D)
o Breastfeeding opinions and intentions

Delivery
Delivery modality and timing will be determined by local protocols in line with NICE guidance. Where possible, participants will be visited by the study team during their admission to allow the following procedures to be performed:
• Sampling of placental tissue
• Sampling of cord blood and amniotic fluid

• Measurement of neonatal anthropometry
• Measurement of neonatal body composition using a Peapod device

These procedures may not be offered to all participants depending upon availability of equipment and staff at regional sites

Study visit 4: 6 weeks' postpartum (2 hours)
Participants will return at 6 weeks' postpartum for the last study visit. This visit will replace participants' standard postnatal glucose (sugar) testing visit. The following procedures will be performed:
• Weight and anthropometry (body size measurements)
• DXA scan for body composition (at study sites where the relevant equipment and trained staff are available to do this)
• Oral glucose tolerance test (OGTT) with blood testing in the fasting and postprandial state (0, 1 and 2 hours). This test is used to diagnose diabetes and involves having a sugary drink and blood testing before and afterwards. Blood will be tested to assess sugar levels, hormone levels and cholesterol. Some blood will be stored for more specialist tests (metabolomic, lipidomic or genetic testing)
• Urinalysis; a urine sample will be stored for future batch analysis, for example, for microalbuminuria or metabolomic testing
• Questionnaires will be completed:
o Quality of Life (EuroQuol EQ5D)
o Eating behaviour (three factor eating questionnaire; TFEQ-18)
o Infant feeding choice will be documented

Intervention Type
Behavioural

Primary outcome(s)
Neonatal primary outcome measure:
Standardised birth weight (standardised for infant gender and gestational age at delivery);
Timepoint(s): birth/36 weeks gestation - from hospital data at V3 and birth

Maternal primary outcome measure:
Maternal weight change (28-36 weeks), measured using Seca scales at V1 and V3

Key secondary outcome(s))
Neonatal secondary outcome measures:
1. Large for gestational age (using local, national and international centiles and customised centiles) at birth
2. Small for gestational age (using local, national and international centiles and customised centiles) at birth
3. Cord blood C-peptide measured using Diasorin liaison method at birth
4. Cord blood glucose measured using Hexokinase method on Siemen's analyser at birth
5. Amniotic fluid glucose measured using Hexokinase method on Siemen's analyser at birth
6. Neonatal anthropometry (length, weight, abdominal circumference, head circumference, skinfold thickness, mid upper arm circumference) measured using tape measure, Seca scales, Holtain calipers at birth and V4
7. Neonatal body composition measured using Peapod device at birth/V4
8. Neonatal hypoglycaemia (defined as a low blood glucose requiring intravenous dextrose) from hospital data at V4

9. Neonatal admission to the neonatal intensive care unit (NICU) from hospital data at V4
10. Neonatal feeding type on discharge from hospital, from hospital data, maternal questionnaire at V4
11. Neonatal nasogastric feeding from hospital data at V4
12. Duration of neonatal admission from hospital data at V4
13. Neonatal jaundice requiring phototherapy from hospital data at V4
14. Preterm delivery from hospital data at birth
15. Estimated gestational age at birth from hospital data, dataset calculation at birth
16. Apgar scores from hospital data at birth

Maternal secondary outcome measures:
1. Maternal weight and related measurements at 32 and 36 weeks and postpartum measured using Seca scales, Harpenden calipers, tape measure at V1, V2, V3 and V4
2. Maternal weight measured using Seca scales at V1, V2, V3 and V4
3. Maternal weight change (baseline to 32 weeks and 32 to 36 weeks) using dataset formula calculation at V3
4. Maternal BMI from dataset formula calculation at V1, V3 and V4
5. Maternal weight change (grams per week) from dataset formula calculation at V4
6. Velocity of maternal weight change (baseline to 32, 36 weeks and postpartum, and between each timepoint) from dataset formula calculation at V1, V2, V3, and V4
7. Maternal body composition at 6 weeks postpartum measured using DXA machine, Harpenden calipers, tape measure at V4
8. Maternal glycaemia on biochemical measurement (HbA1c and other biochemical measures of glycaemia) at 32 and 36 weeks and postpartum
9. Maternal glycaemia on continuous glucose monitoring at 32 and 36 weeks measured using Dexcom G6 CGM at V2 and V3:
9.1. Time in target (4.0 - 7.8 mmol/l) from Dexcom Clarity dataset at V1, V2, V3 and V4
9.2. Time below target (<4.0 mmol/l) from Dexcom Clarity dataset at V1, V2, V3 and V4
9.3. Time above target (>7.8 mmol/l) from Dexcom Clarity dataset at V1, V2, V3 and V4
9.4. Area under the curve for blood sugars >7.8 mmol/l from Dexcom Clarity dataset at V1, V2, V3 and V4
9.5. Area under the curve for blood sugars >6.7 mmol/l from Dexcom Clarity dataset at V1, V2, V3 and V4
9.6. Area under the curve for blood sugars <3.5 mmol/L from Dexcom Clarity dataset at V1, V2, V3 and V4
9.7. Area under the curve for blood sugars <2.8 mmol/L from Dexcom Clarity dataset at V1, V2, V3 and V4
9.8. Incidence of hypoglycaemic events from Dexcom Clarity dataset at V1, V2, V3 and V4
9.9. Mild-moderate episodes of hypoglycaemia <3.5mmol/l (mild) and <2.8 mmol/l (moderate) from data for area under the curve <3.5 mmol/l (mild) and <2.8 mmol/l (moderate) and duration of 20 minutes, from Dexcom Clarity dataset at V1, V2, V3 and V4
9.10. Nocturnal hypoglycaemia: glucose <3.5 mmol/l (mild) and <2.8 mmol/l (moderate) between 23.00-07.00 hours, from Dexcom Clarity dataset at V1, V2, V3 and V4
9.11. Time in hypoglycaemic range (<4 mmol/l; <2.5 mmol/l) from Dexcom Clarity dataset at V1, V2, V3 and V4
9.12. Peak and nadir blood glucose from Dexcom Clarity dataset at V1, V2, V3 and V4
9.13. Mean blood glucose from Dexcom Clarity dataset at V1, V2, V3 and V4
9.14. Mean nocturnal blood glucose from Dexcom Clarity dataset at V1, V2, V3 and V4
9.15. Mean postprandial blood glucose for 1, 2 & 4 hours after breakfast, lunch and dinner, from Dexcom Clarity dataset at V1, V2, V3 and V4
9.16. Standard deviation of blood glucose from Dexcom Clarity dataset at V1, V2, V3 and V4
9.17. Coefficient of variation of glucose measurements from Dexcom Clarity dataset at V1, V2,

V3 and V4
9.18. Mean amplitude of glycemic excursions (MAGE) from Dexcom Clarity dataset at V1, V2, V3 and V4
10. Ultrasound measurements at baseline, 32 and 36 weeks, measured in absolute values and as a percentile and where relevant, as a categorical variable (<2.5th, <10th, >90th and >97.5th percentile):
10.1. Abdominal circumference (AC) from hospital data at V1, V2 and V3
10.2. Estimated fetal weight (EFW) from hospital data at V1, V2 and V3
10.3. Head circumference (HC) from hospital data at V1, V2 and V3
10.4. HC/AC ratio from hospital data at V1, V2 and V3
10.5. Umbilical artery flow studies from hospital data at V1, V2 and V3
10.6. Velocity of change of AC, HC, HC/AC and EFW from hospital data at V1, V2 and V3
10.7. Amniotic fluid index from hospital data at V1, V2 and V3
11. Cardiovascular variables at 32 and 36 weeks, and postpartum:
11.1. Blood pressure from Dinamap at V2, V3 and V4
11.2. Mean arterial pressure from Dinamap at V2, V3 and V4
11.3. Heart rate from Dinamap at V2, V3 and V4
11.4. Cardiac output from database formula calculation at V2, V3 and V4
12. Biochemical analysis of maternal blood at 32 and 36 weeks and 6 weeks postpartum:
12.1. Lipids including triglycerides measured using Siemens dimension methods
12.2. Insulin measured using Diasorin liaison method
12.3. Glucose measured using Siemens dimension hexokinase method
12.4. C-peptide measured using Diasorin liaison method
12.5. Liver function tests measured using Siemens dimension methods
12.6. Bile acids measured using Siemens dimension methods
12.7. C-reactive protein (including highly sensitive analyses) measured using Siemens dimension methods
12.8. Metabolomics using Metabolon Ltd or in house method using core facilities
12.9. Nutritional markers - Metabolon Ltd or in house method using core facilities
13. Indices of insulin production or beta-cell function - based on mathematical formulae in literature - for example Stumvoll index and Matsuda index, HOMA-B and HOMA-IR:
13.1. HOMA-IR and HOMA-B scores at 32 and 36 weeks and postpartum as per formulae in the literature
13.2. Matsuda scores (postpartum) - formula described in literature
13.3. Stumvoll index - formula described in literature
14. Maternal complications of pregnancy:
14.1. Pre-eclampsia from hospital data at V4
14.2. Polyhydramnios from hospital data at birth
14.3. Oligohydramnios from hospital data at birth
14.4. Threatened preterm labour from hospital data at birth
14.5. Antepartum haemorrhage from hospital data at birth
14.6. Postpartum haemorrhage from hospital data at V4
14.7. Cholestasis from hospital data at birth
14.8. Abnormal liver function tests in pregnancy from hospital data at birth
14.9. Infections from hospital data at V4
14.10. Maternal antenatal admissions from hospital data at birth
14.11. Pelvic girdle dysfunction from hospital data at birth
14.12. Carpal tunnel syndrome from hospital data at birth
14.13. Reduced fetal movements from hospital data at birth
14.14. Duration of maternal admission at delivery from hospital data at V4
15. Course of gestational diabetes:
15.1. Insulin required (type, dose, time of initiation) from hospital data at birth

15.2. Metformin required (dose, time of initiation) from hospital data at birth
15.3. Other medication required for glucose control from hospital data at birth
16. Delivery modality:
16.1. Delivery type from hospital data at birth
16.2. Timing of labour from hospital data at birth
16.3. Duration of labour from hospital data at birth
16.4. Induction of labour from hospital data at birth
16.5. Pharmacological treatment during induction, labour and delivery from hospital data at birth
16.6. Caesarean section rate from hospital data at birth
16.7. Elective vs emergency Caesarean sections from hospital data at birth
16.8. First vs repeat Caesarean sections from hospital data at birth
17. Maternal quality of life at 32 and 36 weeks and postpartum measured using EQ5D5K at V1, V3 and V4
17.1. Maternal mobility measured using EQ5D5K at V1, V3 and V4
17.2. Maternal self-care measured using EQ5D5K at V1, V3 and V4
17.3. Maternal usual activities measured using EQ5D5K at V1, V3 and V4
17.4. Maternal pain/discomfort measured using EQ5D5K at V1, V3 and V4
17.5. Maternal anxiety and depression measured using EQ5D5K at V1, V3 and V4
17.6. Maternal global health rating measured using EQ5D5K at V1, V3 and V4
17.7. Changes in quality of life measurements (baseline, 32, 36 weeks and 6 weeks postpartum) - database formula calculation
18. Maternal eating behaviour (baseline and postpartum) measured using TFEQ at V1, V3 and V4
18.1. Maternal hunger measured using TFEQ at V1, V3 and V4
18.2. Maternal emotional eating measured using TFEQ at V1, V3 and V4
18.3. Maternal uncontrolled eating measured using TFEQ at V1, V3 and V4
18.4. Maternal restraint measured using TFEQ at V1, V3 and V4
19. Food diary analysis at 32 and 36 weeks and 6 weeks postpartum:
19.1. Reported total calorie input from food diary analysis at V2, V3 and V4
19.2. Intake of carbohydrate, protein and fat (g and % of total) from food diary analysis at V2, V3 and V4
19.3. Glycaemic index of carbohydrate from food diary analysis at V2, V3 and V4
19.4. Saturated vs monounsaturated vs polyunsaturated fat from food diary analysis at V2, V3 and V4
19.5. Number of portions of fruit and vegetables eaten per day from food diary analysis at V2, V3 and V4
19.6. Dietary adherence - number, calorie content and nature of non-dietbox foods eaten at 32 and 36 weeks from food diary analysis at V2 and V3
19.7. Timing of non-adherence to dietboxes from food diary analysis at V2 and V3
19.8. Effects of non-adherence upon CGM measures of glycaemic control (including all the CGM measurements above) - database formula calculation at V2 and V3
19.9. Consistency between reported food intake and CGM glucose concentrations - database formula calculation at V2 and V3
20. Postpartum measurements:
20.1. Postpartum OGTT glucose concentrations and area under the curve from Dexcom Clarity database at V4
20.2. Postpartum maternal anthropometry (height, weight, waist circumference, hip circumference, skinfold thickness, mid upper arm circumference) measured using Seca scales, tape measure, Harpenden calipers at V4
20.3. Postpartum fat mass and fat-free mass measured using DXA machine at V4
21. Infant feeding choices at 6 weeks postpartum measured using maternal questionnaire at V4
22. Infant feeding behaviour measured using maternal questionnaire at V4
23. Additional safety-related analyses:

23.1. Small for gestational age (SGA) and intrauterine growth restriction (IUGR) from hospital data at birth
23.2. Adverse pregnancy outcomes:
23.2.1. Stillbirth from hospital data at birth
23.2.2. Neonatal death from hospital data at V4
23.2.3. Major congenital anomaly from hospital data at V4

Completion date
28/02/2024

Eligibility

Key inclusion criteria
1. Women with GDM diagnosed at 20 to 30+6 weeks' gestation using a standard clinical 75g OGTT in accordance with the guidelines of the National Institute of Health and Care Excellence (NICE)
2. The NICE criteria state that the diagnosis of gestational diabetes will be made with one or more glucose concentrations during the OGTT of:
2.1. >5.6 mmol/l in the fasting state
2.2 >7.8 mmol/l 2 hours after 75 g glucose
3. Pre-pregnancy overweight or obesity (BMI >25 kg/m2)
4. A ultrasound-confirmed viable singleton pregnancy
5. Planned antenatal care at the same centre or a different study centre throughout their pregnancy (ie: not planning to move away from the region before delivery)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
380

Key exclusion criteria
1. Evidence of multiple pregnancy on ultrasound
2. Evidence of severe congenital anomaly on ultrasound
3. Patient planning to terminate the pregnancy for any reason
4. Significant pre-pregnancy diseases or comorbidities which increase risk in pregnancy, for example renal failure, severe liver disease, transplantation, cardiac failure, psychiatric conditions requiring in-patient admission (<1 year)
5. Significant complications in the current pregnancy, such as threatened preterm labour, severe anaemia (Hb<8g/dl) or intra-uterine growth restriction (IUGR)
6. Previous diagnosis of diabetes outside of pregnancy

7. HbA1c at baseline of >48 mmol/mol
8. Medications at the time of the OGTT which may interfere with the results of the OGTT (for example, steroids, immunosuppressants, certain antipsychotics)
9. Estimated fetal weight <10th percentile at diagnosis of GDM
10. Maternal requirement for a highly specialised diet (e.g. vegan)
11. Maternal severe food allergy, for example, a nut allergy causing anaphylaxis
12. Weight loss of >5% pre-pregnancy weight during pregnancy, prior to 28 weeks

Date of first enrolment
01/11/2019

Date of final enrolment
28/07/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
North West Anglia NHS Foundation Trust
Edith Cavell Hospital
Bretton Gate
Bretton
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Kettering General Hospital NHS Foundation Trust
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

Study participating centre
East and North Hertfordshire NHS Trust
Lister Hospital
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Study participating centre
The Princess Alexandra Hospital
Hamstel Road
Harlow
United Kingdom
CM20 1QX

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK; Grant Codes: 17/0005712

Alternative Name(s)
The British Diabetic Association, DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/02/2025	20/02/2025	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Secondary Analysis	19/08/2025	20/08/2025	Yes	No
Participant information sheet	version v6	23/08/2019	28/04/2020	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v9	26/11/2019	28/04/2020	No	No
Statistical Analysis Plan	version 2	18/11/2023	20/11/2023	No	No