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The GestatiOnal Diabetes future DiabEteS prevention Study (GODDESS) - feasibility study

Submission date
30/05/2018

Recruitment status
No longer recruiting

Registration date
13/06/2018

Overall study status
Completed

Last Edited
03/01/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Background and study aims
Women who develop a type of diabetes during pregnancy called gestational diabetes mellitus (GDM) are at higher risk of developing type 2 diabetes (T2DM) in the future compared to women without GDM. There are also at risk of further episodes of GDM in subsequent pregnancies. An estimated 1 in 20 pregnancies in the UK are affected by GDM, and the incidence is increasing. The children of mothers with diabetes in pregnancy are more likely to be obese or develop T2DM. T2DM is associated with long-term complications, but can be delayed or prevented in populations at high risk through lifestyle interventions promoting healthy eating, physical activity or weight loss. An intervention has been developed to help prevent T2DM through healthy eating, physical activity and weight loss in women with GDM. The aim of this study is assess the feasibility of conducting a full scale trial of this intervention.

Who can participate?
Pregnant women aged 18 and over who have recently received a diagnosis of GDM

What does the study involve?
Participants are randomly allocated to receive the intervention plus usual care or to receive usual care only. The intervention consists of five one-to-one motivational interviewing sessions, use of a pedometer, access to an information website and participation in a WhatsApp group. The study is conducted over a 12-month period with data collected at the start and after 6 and 12 months to examine the feasibility of conducting a trial through measuring the number of participants recruited and retained. The acceptability of the trial and the intervention from the participants' and healthcare professionals' perspectives is also assessed. Secondly, a number of other factors are measured in both groups including weight loss, diet, physical activity, blood glucose, depression and diabetes risk perception.

What are the possible benefits and risks of participating?
The results of this feasibility trial will be used to inform the full scale trial, which will test the effectiveness of the intervention. There may be benefits for those participants in the intervention group resulting from the receipt of five extra sessions of one-to-one, individualised care, as well as access to a website providing information, a pedometer and a WhatsApp group. Benefits could include increased understanding of GDM, improved emotional wellbeing,

increased social connection, and improved physical health. All participants may benefit from receiving extra blood tests, which will provide the participant with more information on their own health. There are not considered to be any major risks involved in the study. Possible minor risks include added anxiety as a result of the extra blood tests and participants may feel burdened by having to attend more hospital appointments that they otherwise would.

Where is the study run from?
1. King's College Hospital (UK)
2. St Thomas' Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2017 to May 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Ms Judith Parsons
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Contact information

Type(s)
Scientific

Contact name
Ms Judith Parsons

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36423

Study information

Scientific Title
The GestatiOnal Diabetes future DiabEteS prevention Study (GODDESS) - feasibility study

Acronym
GODDESS version 1

Study objectives
Women who develop a type of diabetes during pregnancy called gestational diabetes mellitus (GDM), are at higher risk of developing type 2 diabetes (T2DM) in the future compared to women without GDM. There are also at risk of further episodes of GDM in subsequent pregnancies. An estimated 1 in 20 pregnancies in the UK are affected by GDM, and the incidence is increasing. The children of mothers with diabetes in pregnancy are more likely to be obese or develop T2DM. T2DM is associated with long-term complications, but can be delayed or prevented in populations at high risk, through lifestyle interventions promoting healthy eating, physical activity or weight loss. The trialists have developed an intervention to help prevent T2DM through healthy eating, physical activity and weight loss in women with GDM, and want to undertake a feasibility study before they conduct a full scale trial of this intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Surrey Borders Research Ethics Committee, provisional favourable ethical opinion 22 /05/2018, subject to revising some information on a poster advertising the study, final approval pending, ref: 18/LO/0794

Study design
Randomised; Interventional; Design type: Prevention, Education or Self-Management, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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

Interventions
60 women who have recently received a diagnosis of GDM will be recruited and block randomisation in blocks of 10 will be used to randomly assign 30 women to receive the intervention and 30 to receive usual care. The intervention group will receive five one-to-one motivational interviewing sessions and be supported by use of a pedometer, access to an information website and participation in a WhatsApp group. This will be in addition to usual care. The control group will receive usual care only. The intervention will be conducted over a 12-month period with data collected at baseline, 6 months and 12 months.

The feasibility of conducting a trial will be examined through measuring the number of participants recruited and retained in the study. The acceptability of the trial and intervention from the participants' and healthcare professionals' perspectives will also be assessed. Secondly, a number of other factors will be measured in both groups for indications of preliminary efficacy of the intervention. These include weight loss, diet, physical activity, blood glucose, depression and diabetes risk perception. The results of this feasibility trial will be used to inform the full scale trial to test the effectiveness of the intervention.

Intervention Type
Behavioural

Primary outcome measure
The feasibility of the trial, measured through: acceptability (recruitment, retention, acceptability of intervention and data collection procedures for participants), practicality (fidelity, acceptability for clinic staff and intervention facilitators); Timepoint(s): End of the study

Secondary outcome measures
1. Glucose tolerance is measured using a two hour fasting oral glucose tolerance test (OGTT) at baseline, 6 and 12 months
2. Average plasma glucose concentration is measured using glycated haemoglobin (HbA1c) at baseline, 6 and 12 months
3. Blood pressure is measured using a blood pressure cuff at baseline, 6 and 12 months
4. Weight is measured using digital scales at 6 and 12 months. Baseline weight is taken from pre-existing medical records for weight at pregnancy booking appointment
5. Waist circumference is measured using a tape measure at 6 and 12 months
6. Depression is measured using Patient Health Questionnaire (PHQ) 9 at baseline, 6 and 12 months
7. Postnatal depression is measured using the Edinburgh Postnatal Depression Scale at baseline, 6 and 12 months
8. Quality of life is measured using EuroQol EQ-5D-5L at baseline, 6 and 12 months
9. Body image is measured using the Body Appreciation Scale (BAS) at baseline, 6 months and 12 months
10. Eating behaviour is measured using an adapted version of the Three Factor Eating Questionnaire at baseline, 6 months and 12 months
11. Motivation to change is measured using the Dietary Change Motivation Scale at baseline, 6 and 12 months
12. Diabetes risk perception is measured using the Risk Perception Survey for Developing Diabetes at baseline, 6 and 12 months
13. Dietary intake is measured using the Multiple Pass 24 hour Diet Recall online questionnaire

(INTAKE) at baseline, 6 and 12 months
14. Physical activity is measured using an adapted version of the Global Physical Activity Questionnaire (GPAQ) and 4 day accelerometer at baseline, 6 and 12 months
15. Sleep is measured using 6 questions on sleep at baseline, 6 and 12 months
16. Infant feeding intentions are measured using the Infant Feeding Intentions Scale at baseline
17. Infant feeding is measured using 3 questions at 6 and 12 months

Overall study start date
01/08/2017

Completion date
31/05/2020

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Diagnosed with GDM (NICE criteria)
3. ≤30 weeks pregnant
4. Able to speak and understand English
5. Access to the internet
6. Body mass index (BMI) of ≥ 25 kg/m2 (or ≥22 kg/m2 if Asian)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
60

Key exclusion criteria
1. Unable to consent
2. Under 18 years
3. ≥31 weeks pregnant
4. BMI <24, or <22 in Asian ethnic groups
5. Unable to speak and understand English
6. Serious mental illness
7. No access to the internet

Date of first enrolment
16/07/2018

Date of final enrolment
08/05/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College Hospital (lead centre)
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
St Thomas' Hospital
Westminster Bridge Rd
Lambeth
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Trainees Co-ordinating Centre (TCC); Grant Codes: DRF-2013-06-054

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal intended for May 2021.
Presentation at national and international conferences intended during 2020.

Intention to publish date
01/05/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Judith Parsons (judith.parsons@kcl.ac.uk). The data will be available on request for 5 years after the end date of the study. The researchers will permit access to researchers in recognised academic institutions upon receipt of an explanation for the rationale for accessing the data, its intended use, and an agreement to acknowledge the source of the data. They will provide anonymised data in an Excel spreadsheet. Consent was taken from participants to share anonymous data with other researchers.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v4	28/02/2018	13/06/2018	No	Yes
Protocol file	version v5	28/02/2018	13/06/2018	No	No
Results article		30/12/2022	03/01/2023	Yes	No
HRA research summary			28/06/2023	No	No