

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

<b>Submission date</b> 30/05/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 13/06/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/01/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> 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

Judith.parsons@kcl.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Ms Judith Parsons

**ORCID ID**

<http://orcid.org/0000-0002-9656-5940>

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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  $\geq 18$  years
2. Diagnosed with GDM (NICE criteria)
3.  $\leq 30$  weeks pregnant
4. Able to speak and understand English
5. Access to the internet
6. Body mass index (BMI) of  $\geq 25$  kg/m<sup>2</sup> (or  $\geq 22$  kg/m<sup>2</sup> 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.  $\geq 31$  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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United Kingdom

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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](mailto: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?
<a href="#">Participant information sheet</a>	version v4	28/02/2018	13/06/2018	No	Yes
<a href="#">Protocol file</a>	version v5	28/02/2018	13/06/2018	No	No
<a href="#">Results article</a>		30/12/2022	03/01/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No