# p-GDm: Prevention of gestational diabetes. A qualitative study of pregnant women's attitudes and willingness to engage with interventions to prevent gestational diabetes

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
27/03/2020		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
01/04/2020		[X] Results		
<b>Last Edited</b> 09/04/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	[] Individual participant data		
UJ/U4/2U24	NULLILIONAL MELADONC, ENGOCHNE			

## Plain English summary of protocol

Background and study aims

Gestational diabetes (GDM) is a common pregnancy-related condition which causes high blood glucose (sugar) levels and increases the risk of damaging effects for both mother and baby. The prevalence of GDM has increased by about a third over the past decade, and this is mainly explained by an increase in obesity. GDM is usually diagnosed at 24-28 weeks of pregnancy and little is known about blood glucose levels in early pregnancy. Although preventing GDM is recognised as a priority by Diabetes UK, the most effective strategies have yet to be identified. In Oxford, a remote monitoring digital application called GDm-Health™ has been developed. GDm-HealthTM supports management of GDM by a smart phone app that automatically transmits blood glucose measurements to a secure web site and allows for communication between healthcare professionals and women with GDM via texts. This system is clinically reliable and highly satisfactory to women with GDM, but has only been proven in women in later pregnancy with a confirmed diagnosis of GDM. The researchers are interested in applying this technology earlier in pregnancy to investigate its usefulness for prevention or earlier detection and management of GDM. However, asking women to test blood glucose levels before a formal diagnosis may be challenging and for this reason the researchers intend to conduct a qualitative study asking women for their opinions about this.

## Who can participate?

Female, aged 18 years or above, in the first trimester of pregnancy, and at risk of GDM.

## What does the study involve?

The researchers intend to recruit 40 women at risk of developing GDM at their routine 12-week nuchal scan and invite them to take part in a recorded interview that lasts approximately 30 minutes. The researchers will ask a series of open questions about blood testing and strategies for GDM prevention, including diet and physical activity, transcribe the interviews and apply thematic analysis.

What are the possible benefits and risks of participating?

It is likely that there is little apparent benefit for women taking part in this study, although some may feel better knowing they are contributing to other women's well-being in the future. Women may also appreciate being able to discuss their personal challenges and having their opinions sought. Some women may feel distress when asked to discuss personal feelings and opinions.

Where is the study run from? John Radcliffe Hospital (UK)

When is the study starting and how long is it expected to run for? April 2020 to March 2022

Who is funding the study? NIHR Oxford Biomedical Research Centre (UK)

Who is the main contact?

Dr Pamela Dyson (public), pamela.dyson@ocdem.ox.ac.uk

Dr Lucy MacKillop (scientific), Lucy.Mackillop@ouh.nhs.uk

## Contact information

## Type(s)

Public

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#### Type(s)

Scientific

#### Contact name

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## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

270870

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

1.3, IRAS 270870

# Study information

#### Scientific Title

p-GDm: A qualitative study of pregnant women's attitudes and willingness to engage with interventions to prevent gestational diabetes

## Acronym

p-GDm

## **Study objectives**

Women at risk of gestational diabetes would be willing to engage with preventative measures, including blood glucose monitoring, dietary and physical activity interventions in early pregnancy and before a formal diagnosis of gestational diabetes

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 27/02/2020, West of Scotland REC 5 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 20/WS/0054

## Study design

Qualitative study

## Primary study design

Other

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Gestational diabetes

#### **Interventions**

Women at risk of gestational diabetes will be recruited from the nuchal screening clinic and invited to take part in a recorded face-to-face structured interview. Each interview will take 30-40 minutes.

#### **Intervention Type**

Other

## Primary outcome(s)

Women's willingness to engage with blood glucose monitoring and dietary and physical activity interventions in early pregnancy assessed using qualitative interviews analysed with thematic analysis

## Key secondary outcome(s))

Assessed by qualitative interview analysed with thematic analysis:

- 1. Acceptability of:
- 1.1. Being informed they are a high risk of GDM
- 1.2. Testing blood glucose levels before a formal diagnosis of GDM
- 1.3. Different interventions to reduce the risk of GDM
- 2. Use of technology:
- 2.2. Blood glucose meters
- 2.3. App
- 3. Feedback:
- 3.1. Blood glucose levels
- 3.2. Text messages

## Completion date

31/03/2022

# Eligibility

#### Kev inclusion criteria

- 1. Participant is willing and able to give informed consent for participation in the study.
- 2. Female, aged 18 years or above
- 3. First trimester of pregnancy
- 4. At risk of GDM, assessed by one of the following:
- 4.1. Pre-pregnancy obesity (BMI>30kg/m²)
- 4.2. Previous diagnosis of GDM
- 4.3. Previous large baby (birth weight >4.5kg)
- 4.4. A first-degree relative with diabetes
- 4.5. Belonging to a high-risk ethnic group (South Asian, Chinese, Afro-Caribbean or Middle Eastern)

## Participant type(s)

#### Healthy volunteer

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

#### Sex

Female

#### Total final enrolment

18

## Key exclusion criteria

- 1. Severe congenital anomaly found on ultrasound
- 2. Planned termination
- 3. Significant pre-pregnancy comorbidity including renal failure, severe liver disease, organ transplant, cardiac failure, psychiatric conditions requiring in-patient admission, history of eating disorder
- 4. Diagnosed diabetes or gestational diabetes
- 5. Hyperemesis gravidarum
- 6. Unable to understand English

#### Date of first enrolment

01/04/2020

## Date of final enrolment

28/02/2022

## Locations

#### Countries of recruitment

United Kingdom

England

## Study participating centre John Radcliffe Hospital

Women's Centre Oxford United Kingdom OX3 9DU

# Sponsor information

#### Organisation

Oxford University Hospitals NHS Trust

#### **ROR**

https://ror.org/03h2bh287

# Funder(s)

## Funder type

Government

#### **Funder Name**

NIHR Oxford Biomedical Research Centre

## Alternative Name(s)

NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

## **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Research institutes and centers

#### Location

**United Kingdom** 

# **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other unpublished results	version 1		09/04/2024	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes