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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
27/03/2020

Recruitment status
No longer recruiting

Registration date
01/04/2020

Overall study status
Completed

Last Edited
09/04/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
270870

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/06/2019

Completion date
31/03/2022

Eligibility

Key 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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
40

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
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Women's Centre
Oxford
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Sponsor information

Organisation
Oxford University Hospitals NHS Trust

Sponsor details
Joint Research Office
Second floor OUH Cowley
Unipart House Business Centre
Garsington Road
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OX4 2PG
+44 (0)1865 572386
ouh.sponsorship@ouh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.ouh.nhs.uk/research/contact-us.aspx

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, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
This study is designed to inform our future research into the prevention of gestational diabetes and the results will therefore be published in an internal report.

Intention to publish date

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?
Protocol file	version 1.6	13/10/2020	23/08/2022	No	No
HRA research summary			28/06/2023	No	No
Other unpublished results	version 1		09/04/2024	No	No