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Mediterranean diet to prevent type 2 diabetes in mothers who had diabetes in pregnancy: a feasibility study

Submission date
15/04/2019

Recruitment status
No longer recruiting

Registration date
15/05/2019

Overall study status
Completed

Last Edited
15/01/2020

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Our aim is to evaluate the effects of a Mediterranean diet, in preventing the development of type 2 diabetes after giving birth, in women with gestational diabetes (GDM). Gestational diabetes is high blood sugar that develops during pregnancy. Before we run a large-scale trial to answer this question, we plan to test the feasibility of running the Mediterranean diet intervention in an NHS setting. Additionally, we will look at the acceptability of the study and interventions, particularly in the postnatal period, to women and healthcare professionals.

Who can participate?
Women above the age of 16 who have been diagnosed with gestational diabetes and are taking insulin or metformin during pregnancy are eligible to participate. As the diet intervention involves the intake of nuts, participants must not have nut allergies.

What does the study involve?
Participants will be asked to give consent to join the study during pregnancy, shortly before they are due to give birth. They will begin the diet intervention at 6-13 weeks after childbirth, and continue on the intervention until 1 year after childbirth.

Participants will be invited to attend 3 visits – at 6-13 weeks, 6 months and 1 year after childbirth. The intervention will be explained and started at 6-13 weeks post birth, and will consist of dietary advice and how to follow a Mediterranean diet (reduced red meat and processed sugar, increased fruit and vegetables, oily fish, olive oil and nuts).

We will provide nuts and olive oil, which are part of the intervention, for the duration of their trial participation. During their participation, women will receive regular support and advice from a trained health coach, both face-to-face and via a mobile app to discuss their progress with their diet goals. They can also use the app to interact with other women in the trial through a discussion forum.

Participants will be asked to attend the 3 hospital visits to assess their dietary habits, adverse events and check for type 2 diabetes. There will also be a qualitative part of the study, where acceptability of the study, views of the diet intervention and potential barriers to participation will be explored through interviews with a proportion of participants.

What are the possible benefits and risks of participating?
The anticipated benefit, which can only be confirmed with a subsequent full-scale trial, is that adherence to a Mediterranean diet will reduce the risk of progression to type 2 diabetes in women with previous gestational diabetes if applied in the immediate postnatal period.

There are no foreseen risks to participants through participation in this feasibility study. Women with nut allergies will be excluded from the study. The potential additional financial burden associated with Mediterranean diet ingredients will be avoided as olive oil and nuts will be provided to participants free of charge. There is one additional hospital visit (at 6 months) compared to routine follow-up pathways of women with gestational diabetes.

Where is the study run from?
The study will be organised and conducted at Barts Research Centre for Women's Health (BARC), Queen Mary University of London. Participants will be recruited from maternity units within Barts Health NHS Trust, London.

When is the study starting and how long is it expected to run for?
The study is scheduled to start in May 2019, and is expected to run for 18 months, until November 2020.

Who is funding the study?
The main funder is the Barts and the London Charity. The study receives additional support in the form of dietary supplies free of charge or at a discount from the California Walnut Commission and KTC (Edibles) Limited.

Who is the main contact?
1. Dr Zoe Drymoussi,
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
41072

Study information

Scientific Title
Prevention of progression to type 2 diabetes in women with gestational diabetes: A feasibility study for a randomised trial on a Mediterranean diet

Acronym
MERIT

Study objectives
To evaluate the feasibility of introducing a simple, targeted dietary intervention with a Mediterranean based diet, to prevent the progression to Type 2 Diabetes after childbirth, in women with Gestational Diabetes

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending South Central - Berkshire Research Ethics Committee (Bristol REC Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT; (020) 71048043; nrescommittee.southcentral-berkshire@nhs.net), ref: 19/SC/0064

Study design
Interventional non-randomised study

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Participants will be asked to give consent to join the study during pregnancy, shortly before they are due to give birth. They will begin the diet intervention at 6-13 weeks after childbirth, and continue on the intervention until 1 year after childbirth.

Participants will be invited to attend 3 visits – at 6-13 weeks, 6 months and 1 year after childbirth. The intervention will be explained and started at 6-13 weeks post birth, and will consist of dietary advice and how to follow a Mediterranean diet (reduced red meat and processed sugar, increased fruit and vegetables, oily fish, olive oil and nuts).

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Participants will be asked to attend the 3 hospital visits to assess their dietary habits, adverse events and check for type 2 diabetes. There will also be a qualitative part of the study, where acceptability of the study, views of the diet intervention and potential barriers to participation will be explored through interviews with a proportion of participants.

Intervention Type
Behavioural

Primary outcome(s)
1. Proportion of screened women who are eligible for participation
2. Proportion of eligible women who consent to participate in the study, and who commence the intervention at 6-13 weeks.
3. Rates of follow-up at 6 months and 1 year after delivery.
4. Proportion of recruited women who adhere to the intervention of a Mediterranean based diet. Adherence will be measured as:
4.1 Proportion of women who engage with the coach (in an intervention session, and/or through interaction with the App) – measured continuously from 6-13 weeks postnatally to 12 months

postnatally
4.2 Proportion of women who consume nuts and olive oil as self-reported (daily through the App)
4.3 Mediterranean diet adherence as self-reported through the ESTEEM diet questionnaire at 6 months and 12 months postnatally

Key secondary outcome(s))
1. Proportion of women who engage with the lifestyle App, and frequency of engagement (on the App, engagement is defined as interaction e.g. logging a goal or sending a message), assessed continuously from 6-13 weeks postnatally to 12 months postnatally.
2. Women's views relating to factors influencing their initial participation, the acceptability and adherence to the intervention, and the interaction with the App, through interviews 2-3 months and 5-8 months after the start of the intervention.
3. Robustness of the trial processes (measured as frequency of protocol deviations, data queries, issues with nuts and oil supplies, and major monitoring findings), assessed continuously throughout the trial.
4. Healthcare professionals' views of the acceptability of delivering the intervention and adhering with the study protocol, through interviews during the intervention phase of the trial.
5. Proportion of women with normoglycaemia, and dysglycaemia (impaired glucose tolerance, pre-diabetes, T2D) through blood tests at 6 months and 12 months after delivery.
6. Weight change at 6 months and 1 year after delivery.
7. Preliminary relevant cost data to inform future economic evaluation, through clinical data collection at 6 months and 12 months postnatally.

Completion date
01/03/2021

Eligibility

Key inclusion criteria
1. Women diagnosed with gestational diabetes as per the National Institute for Health and Care Excellence (NICE) criteria at time of consent and who are treated with metformin and/or insulin in pregnancy.
2. Aged 16 years or over at the time of consent.
3. Able and willing to follow a Mediterranean diet until 1 year after childbirth.
4. Smartphone user

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
83

Key exclusion criteria
1. Unable to provide written informed consent in English
2. Diagnosed with pre-existing type 1 or type 2 diabetes
3. Body Mass Index of <= 18.5 kg/m2 or >= 50 kg/m2
4. Allergic to nuts
5. Concomitant participation in:
-another dietary interventional study during pregnancy;
-another interventional study in the postnatal period

Date of first enrolment
31/05/2019

Date of final enrolment
27/12/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Barts Research Centre for Women's Health (BARC)
Queen Mary University of London
Yvonne Carter Building
58 Turner Street
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E1 2AB

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
Whitechapel Rd
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Sponsor information

Organisation

Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Barts and the London Charity and Related Charities; Grant Codes: MGU0373

Funder Name
California Walnut Commission

Funder Name
KTC (Edibles) Limited

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes