ISRCTN55443431 https://doi.org/10.1186/ISRCTN55443431

Postnatal intervention for women with a history of gestational diabetes mellitus

Submission date
31/05/2013

Recruitment status
No longer recruiting

Registration date
14/06/2013

Overall study status
Completed

Last Edited
07/01/2019

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Diabetes which first presents during pregnancy [Gestational Diabetes Mellitus (GDM)] is increasingly common and now affects around 15% of pregnant women. It is a condition in which blood sugar levels are higher than normal and is usually diagnosed by an oral glucose tolerance test around 28 weeks gestation. Women with previous GDM have a 50% risk of developing it again in any future pregnancy, and 20% of women will develop type 2 diabetes within the next 10 years. However, there is good evidence that lifestyle changes, including weight management, can prevent or delay the development of type 2 diabetes in people at high risk, such as women with previous GDM. The postnatal period (shortly after pregnancy) is an ideal time for women to make these changes to help prevent weight gain between pregnancies and generally reduce their risk of future type 2 diabetes. Unfortunately, after having a baby, mothers have many demands on their time, often to the neglect of their own health. This study is designed to determine if a postnatal lifestyle intervention to encourage weight loss is both feasible and acceptable among women with previous gestational diabetes.

Who can participate?
Women aged 18 years or older who had a body mass index greater than 25 (overweight or obese) at their pregnancy booking appointment, and who were subsequently diagnosed with GDM.

What does the study involve?
Participants will be asked to attend two study visits 6 months apart. The first of these will coincide with their routine postnatal oral glucose tolerance test (OGTT). Each participant will be asked to complete some questionnaires about their general health, wellbeing and about their levels of physical activity, have a blood test and have some anthropometric measurements (weight, height, waist, hip circumference). Each participant will then be randomly allocated either to the PAIGE lifestyle intervention programme (PAIGE group) or to receive standard lifestyle advice (control group). Those randomised to the PAIGE group, will receive a 1 hour educational session during their routine OGTT clinic visit. In addition, participants will be given a pedometer as a motivational tool to increase physical activity, and offered free referral to a commercial weight management organisation (CWMO) for 12 weeks. The PAIGE team will contact participants from time to time over the 6 months of the study, to provide help and

support as required for successful weight loss and increasing physical activity. Participants allocated to the control group will receive standard lifestyle advice about healthy eating and increasing physical activity). The control group will be offered the free 12 week referral the CWMO at the end of the study.This randomisation will allow us to compare the results of the two different groups to see if the intervention is better at helping women to achieve weight loss than standard care alone.For both groups, Visit 2 will take place at the hospital after 6 months. At this visit we will repeat the weight measurements, and carry out the same blood tests as at the start of the study. Participants will be asked to complete the same questionnaires as at visit 1.

What are the possible benefits and risks of participating?
The study is designed to help women who have a history of GDM, and who are overweight, adopt a healthy lifestyle, lose weight and reduce their risk of diabetes in the future. Those randomised to the PAIGE programme group will receive a 1 hour group education session, a pedometer as a motivational tool to increase physical activity and a free 12 week referral to a CWMO. At the end of the study women in the control group will receive a copy of all the programme materials and will be offered a free 12 week referral to a CWMO. The main disadvantage of taking part in the study is having to give up some spare time. While visit 1 coincides with the participants routine postnatal visits, participants will be asked to attend for one additional study visit, 6 months later. Also, if assigned to the PAIGE group, participants will be asked to attend CWMO sessions to aid weight-loss. The only other disadvantages known are mild discomfort associated with taking a blood test, and that some people may feel a little sick when asked to drink the sweet drink for the oral glucose tolerance test.

Where is the study run from?
The study is being run from the Royal Victoria Hospital Belfast (lead centre) and Craigavon Area Hospital in collaboration with Queens University Belfast.

When is the study starting and how long is it expected to run for?
The study is starting in June 2013 and will run for 18 months.

Who is funding the study?
The Public Health Agency, Northern Ireland.

Who is the main contact?
Professor David R McCance
david.mccance@belfasttrust.hscni.net

Contact information

Type(s)
Scientific

Contact name
Prof David R McCance

Contact details
Consultant Physician
Belfast Health and Social Care Trust
Regional Centre for Endocrinology and Diabetes
Royal Victoria Hospital

Grosvenor Road
Belfast
United Kingdom
BT12 6BA
+44 (0)289 063 3787
david.mccance@belfasttrust.hscni.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12120DMcC-SW

Study information

Scientific Title
PostnAtal lifestyle Intervention programme for overweight women with previous GEstational diabetes mellitus (PAIGE)

Acronym
PAIGE

Study objectives
A pragmatic, postnatal lifestyle intervention, incorporating referral to a commercial weight management organisation (CWMO), developed in partnership with overweight women with a recent history of gestational diabetes mellitus (GDM) and their healthcare professionals, will lead to a reduction in weight after 6 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office of Research Ethics Committees Northern Ireland (ORECNI), 03/04/2013; ref: 13/NI/0026

Study design
Multi-centre non-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Postnatal women with a history of gestational diabetes in a recent pregnancy, and who are overweight

Interventions
The experimental arm will be enrolled in a lifestyle intervention comprising a one hour educational programme delivered during the time they attend for the routine postnatal oral glucose tolerance test (6-12 weeks postpartum), offered a free referral to a three month commercial weight management organisation (Slimming World) scheme, given a pedometer as a motivational tool and will receive intermittent contact via texts and structured phone calls.

The control arm will receive usual care alone and standard post partum lifestyle advice for women with gestational diabetes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Weight at 6 months (taking into account any difference in weight at baseline between the intervention and control groups)

Secondary outcome measures
1. Fasting glucose and 2h OGTT glucose (optional)
2. Waist circumference
3. Pedometer counts, change from baseline at 6 months (intervention group only)
4. Questionnaire data pertaining to physical activity, nutrient intake as estimated by food diary, General Health and Well Being, Motivation to change and Risk Perception Survey for Developing Diabetes (RPS-DD)

Overall study start date
01/06/2013

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. History of gestational diabetes mellitus in last pregnancy. The definition of GDM will be

according to the new International Association of the Diabetes in Pregnancy Study Groups (IADPSG) consensus criteria (7), following a 75g oral glucose tolerance test (OGTT) (fasting glucose ≥5.1 mmol/l or 1h plasma glucose ≥ 10 mmol/l or 2h plasma glucose ≥8.5 mmol/l).
3. Body mass index (BMI) ≥ 25 kg/m2 at booking (if less than 16 weeks, otherwise based on reported pre pregnancy weight) and BMI ≥ 25 kg/m2 at their postnatal OGTT visit. A BMI equivalent to 25 kg/m2 will be used for non Caucasian subjects.
4. Normal or impaired glucose tolerance or impaired fasting glucose (IFG/IGT) on postnatal glucose tolerance testing.
5. Mothers will be encouraged to continue to breast feed. The aim will be to recruit mothers who are not planning a further pregnancy in the next 6 months.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
100

Key exclusion criteria
1. Pregnancy outcome resulting in an anomaly or still birth
2. History of diabetes outside pregnancy or diagnosis of diabetes on the postnatal OGTT
3. Heart, liver, or chronic renal disease
4. Medications that adversely affect glucose tolerance (e.g. steroids)
5. Contraindications to participating in moderate physical activity
6. Moderate/severe depressive illness
7. Excess alcohol consumption
8. Planning another pregnancy in the next 6 months
9. Taking part in another research study
10. Inability to adequately understand verbal explanations or written information given in English, or who have special communication needs
11. Already attending a CWMO

NB: Women will not know if they have a diagnosis of diabetes outside pregnancy until several days after the OGTT appointment (visit 1). Women who are diagnosed with persisting diabetes following the postnatal OGTT will be contacted by their diabetes care team for follow up and will be excluded from the study post randomisation.

Date of first enrolment
01/06/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Consultant Physician
Belfast
United Kingdom
BT12 6BA

Sponsor information

Organisation
Belfast Health and Social Care Trust (UK)

Sponsor details
Research Governance
2nd Floor, King Edward Building
Royal Hospital Site
Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BA
+44 (0)28 9063 6349
alison.murphy@belfasttrust.hscni.net

Sponsor type
Hospital/treatment centre

Website
http://www.belfasttrust.hscni.net/

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
Public Health Agency, Northern Ireland (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2018		Yes	No
HRA research summary			28/06/2023	No	No