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Baby Steps - Walking Away from Gestational Diabetes

Submission date
20/03/2017

Recruitment status
No longer recruiting

Registration date
05/04/2017

Overall study status
Completed

Last Edited
29/08/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Up to 15% of pregnant women develop a temporary type of diabetes during pregnancy called gestational diabetes mellitus (GDM). In GDM, women develop high blood sugar levels as the body is unable to produce enough insulin (a hormone that helps convert sugar into stored energy). GDM is associated with increased risks for mother and baby including increased risk of later life diabetes for the mother. Research shows that structured education programmes can help people to lower their risk of developing cardiovascular disease (disease of the heart and blood vessels) and so can be beneficial for a patient's future health and for health care professionals. The aim of the study is to develop and implement face-to-face and online lifestyle education programme to meet the needs of women with a history of gestational diabetes.

Who can participate?
Women who are up to 36 weeks into their pregnancy who have been diagnosed with gestational diabetes.

What does the study involve?
All participants attend an initial study visit where blood pressure, body measurements and blood samples are taken to measure cholesterol and to find out whether they have diabetes or are likely to develop type 2 diabetes, as well as completing questionnaires about diet and exercise. Participants are then randomly allocated to one of two groups. Those in the first group are given an information leaflet after the birth of the baby. Those in the second group attend two three-hour education sessions spaced approximately two weeks apart. These participants are also given access to an interactive website, which encourages healthy lifestyle choices, such as through diet and exercise advice. All women are asked to wear an activity monitor for eight days before, during (six months) and after the study (12 months) to record their activity levels. At the start of the study and then again after six and 12 months participants complete a number of questionnaires to measure their wellbeing and provide blood samples to assess blood sugar and cholesterol.

What are the possible benefits and risks of participating?
All women taking part will benefit from a free health assessment and physical activity advice as well as information on general fitness levels. There is a small risk of pain or bruising when blood samples are taken.

Where is the study run from?
1. Leicester General Hospital (UK)
2. Leicester Royal Infirmary (UK)
3. George Eliot Hospital NHS Trust (UK)

When is the study starting and how long is it expected to run for?
March 2015 to December 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Helen Dallosso
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
210608

Protocol serial number
32982

Study information

Scientific Title
A randomised controlled trial to investigate the effect of a structured education programme on women who have had gestational diabetes and are at risk of developing type 2 diabetes

Acronym
BABY STEPS

Study objectives
The aim of the study is to implement and evaluate a structured education programme with additional support (wrist-worn activity monitor linked to an interactive website).

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands- Derby Research Ethics Committee, 01/03/2017, ref: 16/EM/0488

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Prevention, Complex Intervention

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Reproductive health and childbirth, Primary sub-specialty: Maternal/ Fetal medicine; UKCRC code/ Disease: Reproductive Health and Childbirth/ Other maternal disorders predominantly related to pregnancy

Interventions
An invitation pack (letter, short information leaflet and prepaid envelope) will be sent to patients identified as eligible on a register maintained by the maternity department. Expressions of interest will be sent to the research team who will contact the responder, check their eligibility and if the responder is interested in taking part they will book them to attend a recruitment clinic. The potential participant will be sent a full Patient Information Leaflet to read before they attend. At the recruitment clinic written informed consent will be obtained by a trained member of the research team after which the various outcome measures will be made and the participant will be asked to complete a questionnaire. The participant will be given an accelerometer and asked to wear it continuously for 8 days and then return it by post to the research team.

After the baseline clinic participants will be randomised using a block design by an independent researcher. Randomisation will be stratified by age (<30; ≥30) and ethnicity (White European; other) and will dictate the pathway each participant will take in the study (control group or intervention group). The stratified randomisation lists will be prepared by an independent statistician, for allocation and concealment. A researcher independent of the study team will follow a standard operating procedure to reveal the randomisation as requested.

Intervention participants will attend the Baby Steps Programme and control participants will be sent an information leaflet about the prevention of diabetes.

The Baby Steps Programme comprises two group education sessions (3 hours each and one week apart) which are delivered by two trained Facilitators. Participants attending will be given a Fit-Bit to help them monitor their physical activity level during the study period and will be given access to a website containing information on how to attain a healthy lifestyle and be more active.

Follow-up data will be collected at 6 months and 12 months. At 6 months the participants will be sent an accelerometer to wear for 8 days and a questionnaire to complete. Both will returned to the research team in a prepaid envelope. At 12 months the participants will be contacted and booked to attend a follow-up clinic. The baseline measures will be repeated and participants will be given an accelerometer to wear for 8 days.

Intervention Type
Other

Primary outcome(s)
Physical activity is measured using an accelerometer, worn for 8 days at baseline, 6 months and 12 months.

Key secondary outcome(s)
1. Lipid profile (high density lipoproteins, low density lipoproteins, triglycerides, total cholesterol) is measured using a venous blood sample at baseline and 12 months
2. Glycated haemoglobin (HbA1c) is measured is measured using a venous blood sample at baseline and 12 months
3. Resting heart rate and blood pressure are measured using an automated BP device at baseline and 12 months
4. Body mass, BMI, waist circumference and hip circumference are measured using a height scale, weight scales, and tape measure at baseline and 12 months
5. Self-reported physical activity is measured using the validated Recent Physical Activity Questionnaire (RPAQ) at baseline, 6 and 12 months
6. Health related quality of Life is measured using the EQ-5D-5L questionnaire at baseline, 6 and 12 months
7. Anxiety and Depression is measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 6 and 12 months
8. Exercise self efficacy is measured using the Jenkins Self-Efficacy for Exercise Expectations Scale at baseline, 6 and 12 months
9. Fruit and vegetable intake is measured using the 5-A-Day Consumption and Evaluation Tool (FACET) at baseline, 6 and 12 months

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. A diagnosis of gestational diabetes in most recent pregnancy
2. Up to 36 months postnatal
3. Willing and able to attend the education sessions and clinic
4. Willing and able to give informed consent
5. Able to speak and read English to a sufficient level to understand the study and education programme

6. Telephone access
7. Aged 18 years and older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
293

Key exclusion criteria
1. Currently has gestational diabetes
2. Currently pregnant at present
3. Type 1 or type 2 diabetes
4. Cancer (not in remission)
5. Severe diagnosed mental illness (e.g. Schizophrenia, bipolar)
6. Previous surgical or medical intervention to treat obesity
7. No access to internet
8. Does not have capacity to give informed consent
9. Participants who are currently participating or who have participated in another clinical intervention study in the previous 12 weeks
10. Unable to speak and read English to a sufficient level to understand the study and education programme

Date of first enrolment
01/05/2017

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
George Eliot Hospital NHS Trust
College Street
Nuneaton
United Kingdom
CV10 7DJ

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
There will not be open access to the data online. However please contact the PI (Prof Kamlesh Khunti, kk22@leicester.ac.uk) if you are interested in accessing the data for further analysis. Please provide a summary of the analysis plans you have and a list of the data you would require. All applications will be considered.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/04/2023	31/05/2023	Yes	No
Protocol article	protocol	12/12/2018		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Participants' experiences of using the app	05/08/2021	31/10/2022	Yes	No
Participant information sheet	version V3	03/01/2017	05/04/2017	No	Yes
Participant information sheet	version V3	03/01/2017	05/04/2017	No	Yes
Statistical Analysis Plan		30/09/2019	24/04/2020	No	No