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Pakistan prevention programme for gestational diabetes mellitus

Submission date	Recruitment status
20/11/2017	No longer recruiting
Registration date	**Overall study status**
05/12/2017	Completed
Last Edited	**Condition category**
17/06/2024	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The aim of this study is to assess how to deliver a behaviour change strategy to prevent type 2 diabetes in women who developed gestational diabetes mellitus (GDM) in their current pregnancy. Women who developed GDM are at higher risk of developing type 2 diabetes at an early age compared to women with no history of GDM. Lifestyle changes such as exercise, eating fruits and vegetables and low calorie foods can help delay diabetes in these women. This study is assessing in a lower middle income country what is the best way to inform women regarding healthy lifestyle and what type of physical activity is feasible for them.

Who can participate?
Women who delivered at either of the two study sites

What does the study involve?
Participants are randomly allocated to receive either the intervention or standard care. The intervention is centered on equipping individuals with skills, knowledge and confidence so that they feel able to participate in regular physical exercise and eat a healthy diet rich in fruit, vegetables, and low fat dairy products. Exercise in the form of walking is particularly encouraged using a pedometer. The intervention consists of 'face-to-face' consultations at the participant's home by a trained community health worker. Participants have an initial consultation of 1.5 hours followed by a second consultation of 1 hour duration after 4 weeks. This is followed with shorter (30 minutes) reinforcement sessions at 3, 6 and 9 months. Text and voice messaging are also used to reinforce these messages. The participants' weights are measured at the start of the study and after 6 and 12 months.

What are the possible benefits and risks of participating?
The intervention is likely to help study participants to lose weight and become more physically active and adopt balanced eating habits which may reduce their risk of developing type 2 diabetes. At a society level, the results of this study may help to develop a customized program for the prevention of type 2 diabetes for Pakistani women. No direct side effects are anticipated other than the time required for data collection.

Where is the study run from?
1. Aga Khan University (Pakistan)
2. Jinnah Post Graduate Medical Center (Pakistan)

When is the study starting and how long is it expected to run for?
September 2014 to December 2017

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MR/M022048/1

Study information

Scientific Title
Pakistan Prevention Programme for Gestational Diabetes Mellitus (PPP-GDM): a feasibility study

Acronym
PPP-GDM

Study objectives
In women with gestational diabetes mellitus (GDM), is a lifestyle intervention programme focusing on physical activity and weight maintenance feasible in a developing country to decrease the risk of diabetes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Review Committee, The Aga Khan University, 11/09/2015, ref: ERC#3607-CHS-ERC-15

Study design
Pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

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

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

Interventions
A trial feasibility study will be undertaken in Karachi, Pakistan that will establish acceptability and feasibility of the intervention to provide a tailored physical activity and diet programme to reduce weight (up to 5% loss body weight) in women diagnosed with gestational diabetes in their index pregnancy. It will enable the trialists to identify any issues which are needed to be addressed before finalising the design of the full trial.

Block randomization was used to allocate the participants to the trial arms. Allocation was revealed to the researcher via telephone.

The intervention is centered on equipping individuals with skills, knowledge and confidence so that they feel able to participate in regular physical exercise and eat a healthy diet rich in fruit, vegetables, and low fat dairy products. Exercise in the form of walking will be particularly encouraged using a pedometer. Intervention consists of ‘face-to-face’ consultations at the participant’s home by a trained community health worker. Participants will have an initial

consultation of 1.5 hours followed by a second consultation of 1 hour duration after 4 weeks. This will be followed at 3, 6 and 9 months shorter (30 minutes) reinforcement sessions. SMS and voice messaging will also be used to reinforce these messages.

The control group will receive the standard of care.

Intervention Type
Behavioural

Primary outcome measure
Reduction in body weight by 5%; weight was measured at baseline, 6 months and 12 months. Body composition analyzer was used to undertake anthropometry.

Secondary outcome measures
1. Feasibility of sampling strategy, assessed at the time of analysis
2. Proportion of eligible people recruited, assessed at the time of analysis
3. Adherence to the intervention, assessed at the time of analysis
4. Response to randomization, assessed at the time of analysis
5. Contamination: the proportion of participants who increase their physical activity in the usual care arm. Physical activity was measured by Short International Physical Activity Questionnaire at 6 and 12 months
6. Follow-up rate at 6 and 12 months
7. Response at 12 months to Oral Glucose Tolerance Test – this outcome was kept to assess the feasibility of doing OGTT at a woman's home but at the initial phase of the study it was not found to be feasible and NICE guidelines (https://www.nice.org.uk/news/article/new-thresholds-for-diagnosis-of-diabetes-in-pregnancy) also recommend to do fasting blood sugar levels or OGTT to screen for diabetes. Hence the trialists changed their strategy and did FBS on the majority of patients.
8. Duration of moderate or vigorous activity at 12 months follow-up. Physical activity was measured by Short International Physical Activity Questionnaire at 6 months and 12 months
9. Response and completion of the self-reported physical activity (7 day physical activity recall) assessed at the time of analysis
10. Response and completion of abbreviated food frequency questionnaire to estimate frequency of key foods, such as fruit and vegetables – food intake is measured by Food Frequency Questionnaire at 6 months and 12 months
11. Response to blood sampling to measure HbA1c and fasting lipids (LDL, HDL, triglycerides) at baseline and at 12 months. Venous blood samples were collected during fasting at baseline, 6 months and 12 months
12. Blood pressure, BMI, % body fat, waist circumference. Blood pressures are measured by Omron digital blood pressure apparatus at baseline, 6 and 12 months. Rest of the measurements were taken by Tanita body composition analyzer at baseline, 6 and 12 months

Overall study start date
08/09/2014

Completion date
31/12/2017

Eligibility

Key inclusion criteria

1. Women with a history of GDM
2. Delivered at any two of the site hospitals
3. Tested negative on postnatal OGTT at 6 weeks

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200

Key exclusion criteria
Women who are not resident of Karachi or will be migrating out of Karachi within 12 months

Date of first enrolment
23/01/2016

Date of final enrolment
06/12/2016

Locations

Countries of recruitment
Pakistan

Study participating centre
Aga Khan University
Pakistan
74000

Study participating centre
Jinnah Post Graduate Medical Center
Pakistan
75510

Sponsor information

Organisation

Medical Research Council

Sponsor details
Polaris House
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Sponsor type
Research council

Website
https://www.ukri.org/councils/mrc/

ROR
https://ror.org/03x94j517

Organisation
Wellcome Trust

Sponsor details
Gibbs Building
215 Euston Road
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NW1 2BE

Sponsor type
Charity

Website
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Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Additional documents will be available. Protocol is not published but will be shared when it will be published. Planned publication of the study results in a high-impact peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made 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?
Results article		15/06/2024	17/06/2024	Yes	No