

# Pakistan prevention programme for gestational diabetes mellitus

<b>Submission date</b> 20/11/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 05/12/2017	<b>Overall study status</b> Completed	
<b>Last Edited</b> 17/06/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	

## 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?

Dr Romaina Iqbal

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## Contact information

**Type(s)**

Public

**Contact name**

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**Contact details**

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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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Swindon  
United Kingdom  
SN2 1FL  
+44 (0)20 7395 2312  
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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  
London  
United Kingdom  
NW1 2BE

**Sponsor type**

Charity

**Website**

[websupport@headoffice.mrc.ac.uk](mailto:websupport@headoffice.mrc.ac.uk)

**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?
<a href="#">Results article</a>		15/06/2024	17/06/2024	Yes	No