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Preconception care and gestational diabetes prevention in Bangladesh

Submission date
16/07/2023

Recruitment status
No longer recruiting

Registration date
23/08/2023

Overall study status
Completed

Last Edited
07/08/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Gestational diabetes is a type of diabetes that develops during pregnancy. It occurs when a pregnant woman's body cannot produce enough insulin or effectively use the insulin it produces. Insulin is a hormone that helps regulate blood sugar levels.
We know that when women have undiagnosed or poorly managed gestational diabetes (GDM) during pregnancy, they and their babies are more likely to get type 2 diabetes (T2DM) and other heart and metabolic diseases like obesity, high blood pressure, and coronary artery diseases later on. So, it's a good idea to offer counseling and care before getting pregnant to address GDM early.
The goal of this study is to see how preconception care can help prevent GDM in Bangladesh.

Who can participate?
Women aged 18-40 years and planning pregnancy within 6 months to 1 year, without previous history of diabetes, prediabetes, and gestational diabetes; without any physical or mental illness at the time of screening, permanent residents, and willing to participate and be available for the whole period of the study.

What does the study involve?
Over the course of 36 months, this study will involve counseling, biophysical measurement, and laboratory investigations related to the study outcomes. A total of 800 women (80 participants /each center) planning a pregnancy within 6 months to 1 year will be invited to the preconception care program. Any woman with any form of glucose intolerance (IFG, IGT, and DM), previous history of GDM, sub-fertility, and any chronic disease will be excluded from preconception care. All the participants will be offered a free preconception care package. It includes registration, counseling, measurement of nutritional status and blood pressure, and laboratory investigation including fasting and 2h 75-gram oral glucose test, HbA1c, lipid profile, Hb%, blood group, and urine RME. It assumes that the required 624 participants with normal blood glucose will find out after glucose tests.
In the intervention group, participants will be followed before pregnancy (2-4 times based on their conception), during conception (1-3 times based on GDM positivity), 6 weeks after delivery, and 1 year after delivery. The first two appointments before pregnancy will be face-to-face and the next two appointments will be online (if needed). All the participants will be informed about

structured healthy lifestyle education (including diet and physical activity) effective for GDM prevention. For the rest of the visits, participants will come for biophysical measurement, and laboratory investigations related to the study outcomes.
In the control group, participants will be followed before pregnancy (1 time), during conception (1-3 times based on GDM positivity), 6 weeks after delivery, and 1 year after delivery. The subjects in the control group will come only for biophysical measurement, and laboratory investigations.

What are the possible benefits and risks of participating?
Benefits: Maternal (including the rate of GDM) and fetal outcomes will be improved.
Risk: No potential risk.

Where is the study run from?
Centre for Global Health Research of Diabetic Association of Bangladesh and ten preconception care centers (PCC) of the Diabetic Association of Bangladesh (BADAS), have both outdoor and indoor gynae and obstetric facilities. These centers include BIRDEM General Hospital, BIHS General Hospital, Uttara Women and Child Hospital, Shaheed Khalek Ibrahim General Hospital, Wari; Chittagong Diabetic Association Centre, Rajshahi Diabetic Association Centre, Bogra Diabetic Association Centre, Dinajpur Diabetic Association Centre, Sylhet Diabetic Association Centre, and Chandpur Diabetic Association Centre.

When is the study starting and how long is it expected to run for?
June 2023 to August 2026

Who is funding the study?
Non-Communicable Disease Control Program of Directorate General of Health Services, Ministry of Health and Family Welfare, Government of the People's Republic of Bangladesh

Who is the main contact?
Dr Bishwajit Bhowmik, cghr@dab-bd.org, doctorbiplob@yahoo.com

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
BADAS-ERC/EC 1231466

Study information

Scientific Title
Preconception care and its effect on the prevention of gestational diabetes in Bangladesh

Acronym
PCPGDB

Study objectives
Preconception care intervention has an effect on the prevention of gestational diabetes mellitus (GDM) in Bangladesh.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/07/2023, Ethical Review Committee (ERC) of the Diabetic Association of Bangladesh (122 Kazi Nazrul Islam Avenue, Shahbag, Dhaka, 1000, Bangladesh; +880-2-9661551; ERC@dab-bd.org), ref: BADAS-ERC/EC 1231466

Primary study design
Interventional

Study design
Prospective multicenter randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Effects of preconception care on prevention of gestational diabetes

Interventions
Participants will be allocated at random in a 1:1 ratio to an intensive lifestyle intervention to promote increased physical activity and dietary modification or to only standard care to the control group.

Randomization lists will be generated and supplied by the coordinating center, and staff who will perform the baseline measurements will have no access to the randomization lists. Neither staff delivering the intervention nor participants will be masked to the study arm.

Participants will be in the study for 36 months.

a. Dietary intervention (Weeks 1–4): In the 1st week, each participant will meet one-on-one with a dietitian who will instruct the participant on how to achieve the five goals of the intervention, including (1) reduction in 5–10% of initial body weight in women with BMI ≥23 kg/m2 through the reduction of at least 10% of total calories of their normal meals, and no weight loss for women with BMI <23 kg/m2, using the WHO BMI classification for Asian population; (2) total fat intake <30% of the energy consumed; (3) saturated fat intake <10% of the energy consumed; (4) carbohydrate intake 50–60% of the energy consumed; and (5) fiber intake 20–30 g/day. Based on each participant's current status of body weight, and physical activity, along with food and nutrient intakes which have been assessed from the baseline survey, the dietitian will provide them advice on how to modify their diet, which includes (a) intake of appropriate energy, (b) inclusion of appropriate amounts of fish, eggs, low-fat milk, lean meat and reduction in fatty meat, animal fat in the diet, (c) avoidance/reduction of simple sugars and refined carbohydrates, and (d) inclusion of more fiber-rich food, such as whole grains, wheat flour with the standard grade, corn/corn starch, brown rice, vegetables, and fruits.
b. Physical activity intervention (Weeks 1–4): The physical activity goal is to gradually increase the physical activity from 15 to 30 min/day over the first 4 weeks. Participants will be instructed to engage in moderate or vigorous physical activity during commuting (walking to/from work) or leisure time (e.g., walking, jogging, etc.) for at least 15 min/day, 7 days/week during Week 1. The level of physical activity will be increased to at least 30 min/day, 7 days/week in Week 4, and will be maintained there over the whole trial.
c. Diet and physical activity monitoring (Week 5–Onward): Each subject will complete a questionnaire on changes in major dietary habits and physical activity habits from the last visit, and 3-day 24-h food records five times during the assessment by the dietitian. The dietitian will review questionnaires and food records, calculate the nutrient intakes via dietary analysis software developed by the Centre for Global Health Research of the Diabetic Association of Bangladesh, provide an assessment of deviations from the suggested diets and exercise, and then offer specific suggestions at each visit. Body weight will be measured at each visit to monitor compliance.

Intervention Type
Other

Primary outcome(s)
Gestational diabetes (GDM) will be identified according to the IADPSG (International Association of Diabetes and Pregnancy Study) criteria using an oral glucose tolerance test at the first antennal visit, 24-48 weeks (if find normal at ANC visit), and 32-36 weeks (if find normal at 24-28 weeks).

Key secondary outcome(s)
1. Diabetes and prediabetes will be identified according to WHO criteria using an oral glucose tolerance test (including fasting and 2h 75-gram oral glucose test) at the time of registration, 6 weeks after delivery, and 1 year after delivery.
2. HbA1c by using the HPLC method, fasting lipid profile (including total cholesterol, triglycerides, HDL-C, and LDL-C), urine RME, will be at registration, first antennal visit, 6 weeks after delivery, and 1 year after delivery.
3. Hb% and blood grouping will be measured at registration, and an ultrasonogram (USG) will be done at the first antennal visit.
4. Anthropometric measurements including height, weight, hip, and waist circumference (WC) will be taken at registration, first antennal visit, 6 weeks after delivery, and 1 year after delivery.

Completion date
30/08/2026

Eligibility

Key inclusion criteria
1. Women aged 18-40 years and planning pregnancy within 6 months to 1 year.
2. Permanent residents.
3. Willing to participate and be available for the whole period of the study.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Total final enrolment
624

Key exclusion criteria
1. Known case of T2DM, prediabetes
2. Previous history of GDM.
3. Women diagnosed with any physical or mental illness at the time of screening.

Date of first enrolment
20/08/2023

Date of final enrolment
20/08/2024

Locations

Countries of recruitment
Bangladesh

Study participating centre

Centre for Global Health Research, Diabetic Association of Bangladesh
122 Kazi Nazrul Islam Avenue, Shahbag
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Sponsor information

Organisation
Non-Communicable Disease Control Program of Directorate General of Health Services, Ministry of Health and Family Welfare, Government of the People's Republic of Bangladesh

Funder(s)

Funder type
Government

Funder Name
Non-Communicable Disease Control Program of Directorate General of Health Services, Ministry of Health and Family Welfare, Government of the People's Republic of Bangladesh.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
cghr@dab-bd.org

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?
Participant information sheet			26/07/2023	No	Yes
Protocol file		18/07/2023	26/07/2023	No	No