Preconception care and its effect on the prevention of gestational diabetes in Bangladesh (PCPGDB)

Center for Global Health Research (CGHR)

Diabetic Association of Bangladesh

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1. Abstract:

Background: It is well known that women with undiagnosed or poorly managed gestational diabetes (GDM), as well as their infants, are at increased risk of developing type 2 diabetes (T2DM) and other cardiometabolic diseases including obesity, hypertension, and coronary artery diseases if GDM is not addressed and therefore good sense to do preconception counseling and care earlier.

Objectives: To assess the effects of preconception care on the prevention of GDM in Bangladesh.

Design: Prospective randomized intervention which will be fully quantitative in nature.

Study areas: Out of 54 preconception care centers (PCC) of the Diabetic Association of Bangladesh (BADAS), this proposed study will be undertaken at ten (10) centers having 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.

Study duration: 38 months (June 2023 to August 2026).

Target population: 624 randomly selected women.

Main inclusion criteria: Women aged 18-40 years and planning pregnancy within 6 months to 1-year, permanent residents, and willing to participate and be available for the whole period of the study.

Statistical analysis: Mean and standard deviation will be reported for continuous variables and inter-group comparisons will be tested by two-tailed ANOVA. The proportion of subjects developing GDM in each group and their comparison will also be done by chi-square analysis. For the intervention measures, the absolute and relative risk reductions and 95% CIs of the estimates and the number needed to treat to prevent GDM in one person will be calculated. A p-value <0.05 is considered significant. The statistical package SPSS (PASW Statistics 20) will be used for analyses.

Main Outcome: To observe the rate of incidence of GDM between the intervention and control groups.

Conclusion: This proposed study will fill up the gap in our existing knowledge by testing the effectiveness of preconception care intervention for the prevention of GDM.

Study Coordination: Diabetic Association of Bangladesh.

Funding agency: 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

Keywords: preconception care, prevention, gestational diabetes, Bangladesh.

2. Background of the study

It is estimated that about 50 percent of conceptions are unplanned and almost 25 percent of pregnancies are unwanted in Bangladesh. Nearly three-quarters of mothers in Bangladesh do not receive antenatal care during pregnancy. The urban-rural differential in antenatal care is quite significant. Like other South-Asian countries, the prevalence of gestational diabetes mellitus (GDM) has also been progressively increasing in Bangladesh. It is well known that women with undiagnosed or poorly managed GDM as well as their infants are at increased risk of developing type 2 diabetes (T2DM) and other cardio-metabolic diseases in the future if GDM is not addressed and therefore good sense to do pre-conception counseling and care earlier.

The majority of people (89%) in Bangladesh are Muslims. Muslim marriage is a solemn covenant between a man and a woman which must be registered by the Marriage Registrar (Kazi in the local language). Religion plays an important role in the conception of Bangladesh family values. For the prevention of GDM, we need to intervene prior to conception. Therefore, there is an excellent opportunity to seek the influence of Kazis in creating individual and community awareness in helping people to take proactive action and change their attitudes about preconception care, proper pregnancy planning, and prevention of NCDs, particularly GDM.

Considering the influence of religious leaders and the positive impact of preconception care, the Diabetic Association of Bangladesh (BADAS) has been running a project named "Preconception Care through Religious Leaders" since May 2016. It is a joint initiative of BADAS, the Ministry of Law, Justice and Parliamentary Affairs, and the Noncommunicable Disease Control Program of the Directorate General of Health Services of the Ministry of Health and Family Welfare of the Government of the People's Republic of Bangladesh. It was initially funded by World Diabetes Foundation, Denmark. The goal of this program is to improve community awareness of preconception care and prevention of non-communicable diseases (NCDs) particularly GDM among newly married couples in Bangladesh. This program assured a healthier start in life and hopes that future generations will not have to fight the same difficulties as the current adult population.

BADAS has already trained 400 Marriage Registers and 300 Health Professionals and established 54 preconception care corners in 54 centers/ hospitals of BADAS throughout the country. In this program, the trained Kazis discuss the positive impact of preconception care and planned the pregnancy for the couples during the actual wedding ceremony, and distribute a booklet containing information on pre-conception care and prevention of GDM. They also advise the couples to visit the nearest preconception care corners of BADAS for receiving targeted healthy lifestyle advice and routine check-ups including screening for diabetes, hypertension, anemia, nutritional status, and urinary infection before planning the pregnancy. BADAS has also launched a pre-conception counseling package at a minimum cost (600 BDT). In the last week of July 2018, an order has been circulated by the Ministry of Law, Justice and Parliamentary Affairs which states that all the marriage registrars are now included in the preconception care program and the slogan of the program must be imprinted by the seal in the marriage contract (Kabin Nama).

A total of 30,000 couples have already been provided counseling by trained religious leaders and 15,000 'at risk women' have visited conception/antenatal care and training regarding GDM prevention and care. A total of 7000 women have screened for GDM. Appropriate advice and treatment have been provided to

women diagnosed with GDM. From our preliminary findings, 70 to 75% of newly married women usually visit the preconception care centers after getting the initial information from the Kazis.

The rate of IFG, IGT, and DM among women of reproductive age seeking preconception care were 2.7, 16.2, and 10.8% respectively. The rate of general obesity, central obesity, anemia, hypertension, albuminuria, and UTI were 41.9, 70.8, 54.1, 9.8%, 6.8, and 13.5% respectively.

The National Council of BADAS has because of the enormous needs, and this successful project decided to take pre-conception care as one of the core programs of the Association. BADAS has also launched a national campaign "Healthy Mother- Health Children- Healthy National: All Pregnancy Should be Planned."

A cohort of 60,000 women will be followed from pre-conception to 5 years after delivery through this scheme. One-page information on pre-conception care included in the general guidebook of BADAS has already been circulated to 4.5 million registered patients of BADAS. It has created a massive impact on creating community awareness among people with diabetes and their family members. This project has also developed a website (www.pcc-badas.org) and a free mobile helpline (10614). Half a million people have already got information about preconception care through the Facebook campaign.

The project has also launched an online education program (both in Bangla and English) on pre-conception care for health professionals and general people. The International Diabetes Federation (IDF) and the South Asian Federation of Endocrine Societies (SAFES) have endorsed our education program on preconception care. Now anyone from any part of the world can take part in our online certificate program. About 4000 health professionals have already taken part in this online certificate course.

It is a matter of pride that the Honourable President, Honourable Prime Minister, and Honourable Minister of Health and Family Welfare of Govt. of Bangladesh have endorsed preconception care and planned pregnancy.

To date, we have not estimated the value that could be gained from investing in preconception care intervention targeting reproductive-age women (18-40 years) in Bangladesh. To address this gap in the evidence and inform decision-making for the prevention of GDM and future T2DM among Bangladeshi women, this study will evaluate the effect of preconception care to prevent GDM and future T2DM using a prospective randomized control study design.

3. Rationale of the study

Bangladesh's demographic profile in 2020 shows a high birth rate (17.71 births/1,000 population in 2020 est.) and an increased prevalence of multiparity (2 children born/woman in 2020 est.) (1). Not only that, infant mortality (24.73 deaths/1,000 live births) and frequency of congenital malformations (1.41%) are also common while low birth weight (20%) appears to be widely prevalent (1-4) in Bangladesh. Increased morbidity and mortality among mothers and newborns in Bangladesh may, in part, be because of the increased prevalence of T2DM including GDM. Like other South-Asian countries, the prevalence of GDM has also been progressively increasing in Bangladesh. Some population-based studies conducted in Bangladesh at different time points have revealed an increasing trend of GDM prevalence ranging from 6% to 14% based on using different diagnostic criteria (5, 6). Our finding is comparable to other populations

with a high prevalence of GDM. Higher prevalence was observed in the higher age group, higher gravidity, higher BMI, and those with hypertension and a family history of diabetes. The history of abortion, neonatal death, and stillbirth were found higher among GDM mothers than among non-GDM mothers (5). A study has found a high rate of cesarean section, pre-eclampsia, fetal distress, and obstructed labor in GDM mothers. Maternal mortality and perinatal mortality are also high in our population (7). The low socio-economic condition, social discrimination, social and religious barriers, lack of adequate nutritional knowledge, myths and misbelieves related to diabetes with pregnancy, and lack of knowledge related to proper pregnancy planning and care are the possible barriers to effective pregnancy outcomes.

It is estimated that about 50 percent of conceptions are unplanned and almost 25 percent of pregnancies are unwanted in Bangladesh (8). Many mothers in Bangladesh do not receive antenatal care. Nearly three-quarters of mothers received no antenatal care during pregnancy. The urban-rural differential in receiving antenatal care is quite significant. Fifty-eight percent of urban births had received antenatal care from a medically trained person, compared with only 23 percent in rural areas (8).

It is well known that women with undiagnosed or poorly managed GDM, as well as their infants, are at increased risk of developing T2DM and other cardiometabolic diseases including obesity, hypertension, and coronary artery diseases (9, 10) if GDM is not addressed and therefore good sense to do preconception counseling and care earlier. Based on the physiological mechanisms, screening of GDM has been advocated between 24-28 weeks. However, this has the potential to miss many cases of diabetes predating pregnancy and early onset GDM. By knowing the insulin insensitivity at the beginning of pregnancy, strategies should be devised to aim for the early normalization of the intrauterine metabolic environment at a critical period for fetal metabolic imprinting. Shreds of evidence also show that in the modern era achieving healthy maternal and child outcomes is possible in all pregnancies if someone plans it correctly and uses the current management facilities including preconception care, antenatal care, and regular check-ups throughout pregnancy. International Diabetes Federation has given particular importance to the ‘‘Life Cycle” approach to the prevention and care of diabetes—a continuum beginning from preconception, pregnancy, infancy, and childhood to adult life in an integrated manner. However, still, a care gap exists between "desired" and "real" prepregnancy care. The suggested reasons for this gap include socioeconomic deprivation, ethnic differences in the risks and lack of competencies within the health system, use of the health care system, or difficulties with health literacy. These findings should be given particular importance to developing capacity concerning human resources, well-formulated policies, standardized protocols, and culturally sensitive awareness/advocacy campaigns to initiate screening programs before and during the antenatal period and also to prevent NCDs, particularly GDM.

Therefore, it is vital to assess the effect of preconception care intervention to prevent GDM and future T2DM.

4. Hypothesis

Preconception care intervention has an effect on the prevention of GDM in Bangladesh.

5. Research Question

Has preconception care intervention effect on the prevention of GDM in Bangladesh?

6. Objectives

General objective

- To assess the effects of preconception care on the prevention of GDM in Bangladesh.

Specific objectives

1. To observe the rate of GDM between the intervention (preconception care) and control group.
2. To observe the rate of conversion from GDM to glucose dysregulation (Prediabetes and DM) after 6 weeks and 1 year of delivery between the intervention and control group.
3. To evaluate the impact of preconception care intervention with healthy lifestyle modification (including prescribed dietary and exercise advice) on glycemic and cardiometabolic parameters, including obesity (general and abdominal), HTN, and dyslipidemia.
4. To observe pregnancy outcomes (both maternal and fetal) in the intervention and control groups.
5. To assess the knowledge, attitude, and practice (KAP) related to preconception care and GDM at baseline and end line.
6. To examine the potential costs and benefits of preconception care intervention.

7. Outcomes Indicators

Primary outcome

- Incidence of GDM between intervention and control group.

Secondary outcomes

- Rate of conversion from GDM to T2DM among the study population.
- Rate of cardiometabolic parameters including obesity (general and abdominal), HTN, and dyslipidemia between intervention and control groups.
- Changes in body weight, physical activity, and dietary habits between the intervention and control groups.
- Changes in knowledge, attitude, and practice about preconception care and GDM among the study participants at baseline and end line.
- Direct (medical and non-medical) and indirect costs related to intervention will be calculated.

8. Research Methodology

8.1 Study Design and Participants

This study will be a prospective multicenter randomized controlled trial. It will be the part of PCC (preconception care) program, a joint community awareness program of BADAS, the Ministry of Law, Justice and Parliamentary Affairs, and the Non-Communicable Disease Control (NCDC) program of DGHS of the Ministry of Health and Family Welfare.

Out of 54 PCC centers of BADAS, a total of ten (10) centers having both outdoor and indoor (including gynae and obstetric facilities) have been selected following a simple random procedure. These centers

include BIRDEM General Hospital, BIHS General Hospital, Uttara Women and Child Hospital, Shaheed Khalek Ibrahim General Hospital, Wari; Chittagong Diabetic Association, Rajshahi Diabetic Association, Bogra Diabetic Association, Dinajpur Diabetic Association, Barisal Diabetic Association, and Chandpur Diabetic Association. A total of 624 women aged 18-40 years will be recruited (63 participants/at each center) during their preconception care visit following both inclusion and exclusion criteria. They will be then followed during pregnancy, at delivery, 6 weeks after delivery, and for 1 year after delivery. A total of 312 participants will be in the intervention and 312 in the control group following a simple randomization procedure. Considering the 30% prevalence rate of glucose dysregulation (combine DM and Prediabetes) among reproductive-age women (unpublished data of existing preconception care program), 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, urine RME, and ultrasonogram (USG). It assumes that the required 624 participants with normal blood glucose will find out after glucose tests.

8.2 Study Duration

Total duration: 38 months

- **Overall trial date:** 01/06/2023 to 30/08/2023
- **Recruitment data:** 20/08/2023 to 20/08/2024

8.3 Inclusion Criteria

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

8.4 Exclusion Criteria

- Known case of T2DM, prediabetes
- Previous history of GDM.
- Women diagnosed with any physical or mental illness at the time of screening.

8.5 Study Variables

- **Socio-demographic variables:** age, economic status, education status, smoking habit, lifestyle (physical activity and food habit).
- **Anthropometric variables:** height, weight, body mass index (BMI), waist circumferences (WC), and waist-height ratio (WHR).
- **Clinical & Biochemical variables:** blood pressure, fasting plasma glucose (FPG), 2-hour plasma glucose, HbA1c, fasting lipid profile, Hb%, Blood group, Urine RME, and USG.
- knowledge, attitude, and self-care practice and participant's lifestyle (food intake pattern, physical activity, smoking, etc.)

- **Economic Variables:** employment status, productivity loss (income and days/hours of work lost), out-of-pocket payments (OPP), the opportunity cost of time (average wage and time), borrowing/selling assets, expenditure.

8.6 Size of the Study Population and Power Calculation

We have finalized the sample size based on the recent prevalence of GDM (21.1%) in the urban and semi-urban areas of Dhaka as it gave us the most variance (11). It assumes that the risk reduction of GDM in the Bangladeshi trial will achieve a 50% risk reduction. To achieve a 50% risk reduction at 80% power, 5% Type I error with 50% lost to follow-up needs at least 312 participants in each arm and 624 participants in total.

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. sampsi 0.211 0.106, power (0.8) alpha (0.05)

Estimated sample size for two-sample comparison of proportions

Test Ho: p1 = p2, where p1 is the proportion in population 1
                    and p2 is the proportion in population 2
Assumptions:

         alpha =   0.0500  (two-sided)
         power =   0.8000
            p1 =   0.2110
            p2 =   0.1060
         n2/n1 =   1.00

Estimated required sample sizes:

            n1 =      208
            n2 =      208
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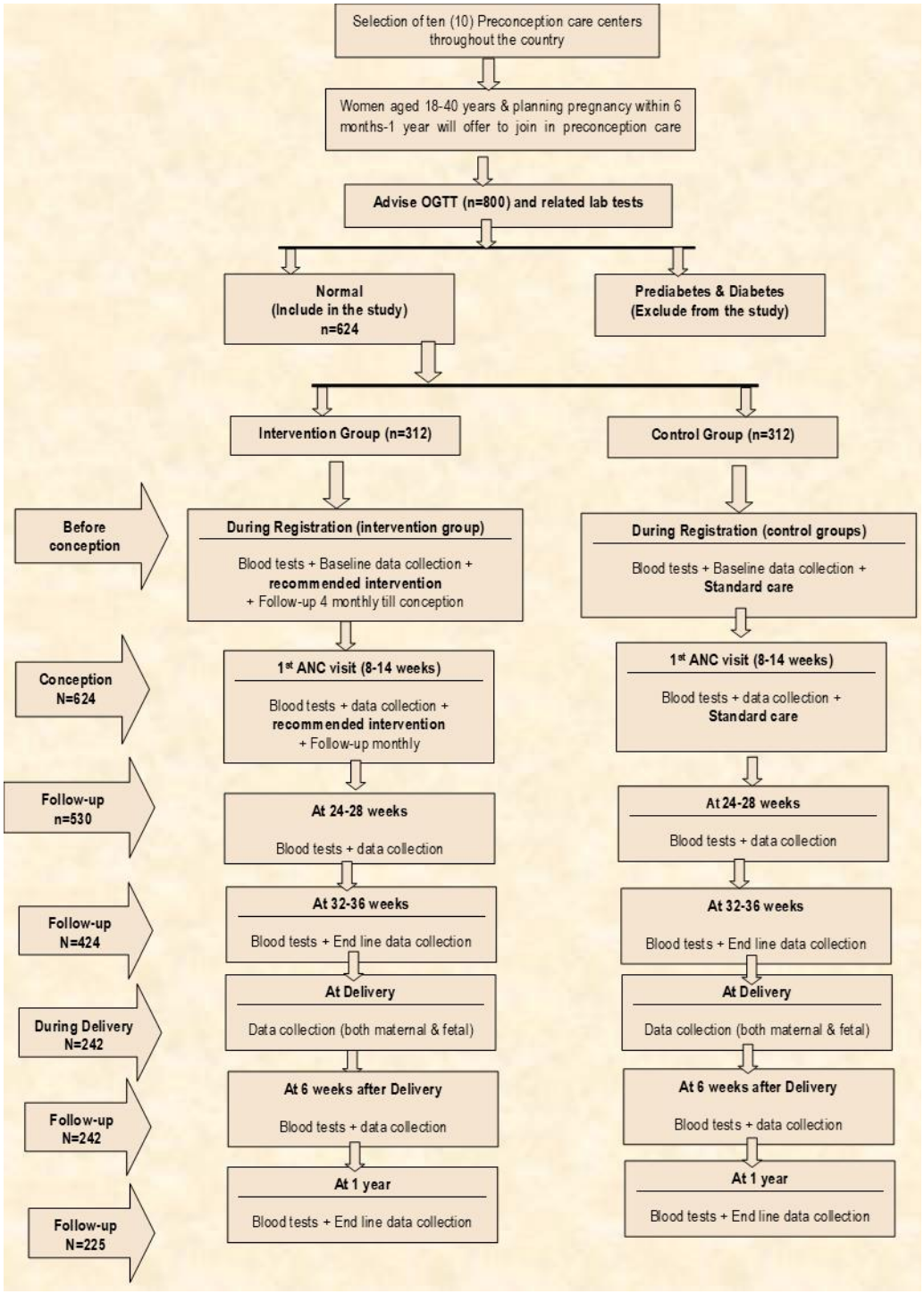
8.7 Randomization and Masking

Participants will be randomized after the project research team determined that they:

1. Will demonstrate a satisfactory interest in joining lifestyle intervention during the run-in.
2. Will express willingness to continue in the trial.
3. Will meet all inclusion/exclusion criteria.
4. Will provide all baseline data.

After exclusions, 624 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 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.

8.9 Flow Chart



8.10 Intervention

8.10.1 Intervention Tool Development

The following interpersonal education and communication (IEC) materials developed by the Preconception Care Program of BADAS will be used for this purpose-

- Guidebook including dietary and exercise diary
- Flip chart
- Poster & leaflets
- Software (Preconception and GDM Registry App)

8.10.2 Intervention (Lifestyle) Group

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/m^2 through the reduction of at least 10% of total calories of their normal meals, and no weight loss for women with BMI <23 kg/m^2, using the WHO BMI classification for Asian population (12); (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.

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.

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.

8.10.3 Control Group

We will only collect data (including both physical and laboratory) at the given time periods of our study.

8.10.4 Structured Interview

The structural interview tool will be used for the subjects. Trained interviewers will conduct interviews through an interview guide. Both at the training stage and in formulating the guides, adequate emphasis will be given to in-depth probing. Responses will be recorded and noted down by interviewers.

Instrument: Pre-formulated questionnaires will be used for this purpose. We will also use a digital App (Preconception and GDM Registry App) for capturing all the information.

Changes in lifestyle: A questionnaire on changes in major dietary and physical activity habits from the last visit, 3-day 24-h food records, and a self-administered questionnaire will be completed at each annual visit.

Body weight, height, waist and hip circumferences, and blood pressure will be measured for all women using the standardized protocol.

9. Data Collection

9.1 Phase 1: Pre-screening Contact

Any interested women aged 18-40 years will be invited for participating in this study. A group of trained personnel of BADAS including a gynecologist and a health educator (dietician by training) will assess the participants. Participants will be advised to fast overnight for at least 8-14h before the screening visit.

9.2 Phase 2: Sample Survey and Collection of Other Data

Study Plan/Timetable

The duration of the study will be 36 months. The proposed study will be implemented following the timetable below:

	Preconception (6 months -12 months)				Conception			Delivery	Post Delivery	
Procedure	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**Visit 8**	**Visit 9**	**Visit 10**
Timing	At registration	16 weeks (physical)	32 weeks (online)	48 weeks (online)	6-14 weeks	24-28 weeks	32-36 weeks	Delivery	6 weeks	1 year
Informed consent	X									
Check eligibility criteria	X									
Record basic demographic data	X									
Dietary questionnaire	X	X	X	X	X	X	X		X	X
Health questionnaire	X	X	X	X	X	X	X	X	X	X
Blood pressure	X	X	X	X	X	X	X	X	X	X
Anthropometric measurements	X	X	X	X	X	X	X	X	X	X
Collect blood samples	X				X	X	X		X	X
Randomization	X									
Run-in	X									
Counseling session (intervention group)	X	X	X	X						

Informed Consent

Full informed consent will be obtained. All potential participants will be given adequate time to read participant information sheets and had a chance to ask questions to satisfy any queries they have before consent. Staff members taking consent must assess whether potential participants have fully understood the information they provided before taking consent. Those who are not thought to be fully informed will not be included in the trial. All staff members taking consent will be trained in this procedure.

Registration

This will include informed consent and the completion of a detailed medical eligibility questionnaire. The eligibility screening questionnaire will be based on the inclusion/ exclusion criteria described above. If eligible, subjects have to finish the baseline survey at the same time. At the baseline survey, all participants will complete an interview-administered questionnaire and undergo a physical examination. They will also complete the 3-day 24-h food records using dietary record collections will be taught by trained investigators.

Run-in

A week ''run-in'' period followed the baseline survey during which one class on general principles of lifestyle intervention for the prevention of GDM and future T2DM will be taught. The specific lifestyle intervention program will not begin during this period. If a woman was diagnosed with diabetes & prediabetes in our baseline OGTT test, we would exclude her from the present study at this period.

Follow-up

Reinforcement and counseling will be done every 4 months in the intervention group (Lifestyle) with visits to the respective physicians and dietician. The first 2 visits will be physical and the next 2 visits will be online. The subjects in the control group will be requested to come for evaluation during laboratory tests.

Development of Interviewer-administered Questionnaires

Before the study, a panel of experts will be agreed on a structured questionnaire after thorough discussions and also in the light of surveys conducted in previous studies. The panel will be included an endocrinologist, a diabetologist, a statistician, and a public health expert. The questionnaire will be developed by consulting existing information and clinical practices. The questionnaire will be developed in the local language of Bangla. Before the start of the study, pretesting of the questionnaire will be conducted to test its feasibility and reliability. As a result, a few minor modifications will be made after the pilot testing. Trained investigators will be collected data after face-to-face interviews with the participants. To assuring quality control, intensive training will be provided for the investigators to reduce bias as much as possible.

Sample Survey

Upon arrival at the field sites, different sets of investigations and physical examinations will be done for each of the subjects taking part in the study. At first, an initial venous blood sample (5 ml) will be taken to estimate the fasting plasma glucose (FPG), HbA1c, and fasting lipid profile. Then all the subjects will be given 75-gram oral glucose to drink and requested to wait for 2 hours for a second blood sample collection (2 ml). During this 2-hour waiting time, socioeconomic and demographic information, physical activity, dietary habits, quality of life, parental and personal health histories will be verbally obtained using standardized questionnaires. Knowledge, attitude, and practice related to preconception care and the prevention of GDM will also be collected. After completion of the interview, the anthropometric

measurements including height, weight, hip and waist circumference (WC) will be taken. Also, blood pressure (BP) will be recorded at this time followed by a physical examination. These will be carried out through trained personnel. After 2 hours, a second blood sample for OGTT will be collected.

Anthropometrical Measurements

Anthropometric measurements including height, weight, and waist and hip circumferences will be taken with the subjects wearing light clothes and without shoes. Weight will be recorded to the nearest 0.1 kg using electronic digital LCD weighing machines (Best Deluxe Model; Bathroom, Dhaka, Bangladesh) placed on a flat surface. The scales will be placed on a flat surface and calibrated using a standard (20 kg) each day. Height will be taken while the subjects stood in the erect posture, touching the occiput, back, hip, and heels on a straight measuring wall, while the subjects looked straight ahead. Body mass index (BMI) will be calculated as the weight (Kg) divided by the square of the height (m^2). WC will be measured by placing a plastic tape horizontally midway between the lower border of the ribs and the upper border of the iliac crest on the mid-axillary line. Hip circumference will be measured to the nearest centimeter at the greatest protrusion of the buttocks. Waist-hip ratio (WHR) will then be calculated from WC (cm) and height (cm), respectively.

Measurement of Blood Pressure

Special precautions will be taken to reduce the variation of BP value with resting BP. BP will be measured by 1) ensuring the participant rested for 10 minutes before the BP being measured, 2) using standard cuffs for adults fitted with a standard mercury sphygmomanometer, and 3) placing the stethoscope bell lightly over the pulsatile brachial artery on the right arm. Blood pressure will be recorded to the nearest 2 mmHg from the top of the mercury meniscus. Systolic pressure will be recorded at the first appearance of sounds, and diastolic pressure will be measured at phase V, that is, the disappearance of sounds. BP will be measured in both the sitting and standing position. Two readings will be taken 5 minutes apart, and the mean of the two will be taken as the final BP reading of the individual.

Biochemical Examination

Venous samples will be obtained by trained phlebotomists, who will be given written instructions for biochemical analysis. All samples will be collected & stored at the respected laboratory of BADAS. See the table below for a guide to which samples are being taken at which time point.

- **The time frame of biochemical assessment**

	Preconception	**Conception**			**Post delivery**	
	0 month	6-14 weeks	24-28 weeks	32-36 weeks	6 weeks	12 months
Fasting blood glucose	X	X	X	X	X	X
2h blood glucose	X	X	X	X	X	X
HbA_{1C}	X	X			X	X
Total cholesterol	X	X			X	X
Triglycerides	X	X			X	X
HDL-Cholesterol	X	X			X	X
LDL-Cholesterol	X	X			X	X
Hb%	X					
Blood Grouping	X					
Urine RME	X	X			X	X
Ultrasonogram		X				

- **Methods and Specifications of the Machines for the Various Biological Tests**

Test	Sample	Method	Specification of Machine	
			Measurement Type	**Name of the analyzer**
OGTT • FPG • 2h AG	Venous Plasma	Glucose oxidase	End point	Dimension RxL Max (Siemens AG, Erlangen, Germany)
T-Chol	Serum	CHOD-PAP	End point	Do
Tg	Serum	GPO-PAP	End point	Do
HDL	Serum	Direct Enzymatic	End point	Do
LDL	Serum	Direct Enzymatic/ Precipitation Method	End point	Do
HbA_{1C}	Whole blood	HPLC	Colorimetric/ Turbidimetric	Variant Hemoglobin Testing System
Hb%	Whole Blood	Cyanmethemoglobin method	Colorimetric	Abbott Cell-Dyn 4000/3500 (USA)
Urine RME	Urine	Microscopic Examination for pus cell determination and high-power field (40X) for pus cell reporting. urine dipstick test for detecting urine albumin	Quantitative	Olympus, model No CX21FS1

Definition of Terms

- DM will be defined as if FPG ≥7.0 mmol/L or 2hPG ≥11.1 mmol/L. Prediabetes will be defined as FPG ≥6.1 mmol/l to <7.0 mmol/l (impaired fasting glycemia, IFG) and 2hPG ≥7.8 mmol/l to <11.1 mmol/l (impaired glucose tolerance, IGT). Normal glucose tolerance (NGT) will be defined as FPG <6.1 mmol/l and 2hPG <7.8 mmol/l. For screening of NGT, prediabetes, and DM, diagnostic criteria of WHO in 2006 will be used (13).
- GDM will be defined according to the IADPSG criteria – FPG ≥5.1 mmol/L or 2-h ≥8.5 mmol/L (14).
- Cut off points for general obesity for both sexes will be defined as BMI of ≥25 kg/m^2 (12) and central obesity including WC for men and women will be ≥90 and ≥80 cm (15), and WHR for men ≥0.90 and women for ≥0.80 (15), respectively.
- Hypertension will be defined as systolic blood pressure (SBP) of 140 mm Hg or diastolic blood pressure (DBP) of 90 mm Hg or current treatment with antihypertensive medication (16).
- Cut-off values for serum lipid profiles will be high cholesterol (T-Chol) ≥5.0 mmol/l, high triglycerides (Tg) ≥1.7 mmol/l, high LDL-C ≥3.4 mmol/l and low HDL-C <1.04 mmol/l (for men) and <1.3 mmol/l (for women) (17).
- Dyslipidaemia will be defined as serum triglycerides ≥1.70 mmol/L for both sexes and HDL-C <1.04

mmol/L for men and <1.3 mmol/L for women (16).

- Anaemia will be defined as Hemoglobin <12 g/dl (18).
- Urinary tract infection (UTI) will be defined as symptomatic patients with >5 pus cells/HPF (19) and urine albumin will be reported as the following 6 values: negative, trace (±), 1+, 2+, 3+, and 4+ (corresponding to albumin levels of undetectable or < 10 mg/dL, 10 to 29 mg/dL, 30 to 99 mg/dL, 100 to 299 mg/dL, 300 to 999 mg/dL, and 1000 mg/dL or greater, respectively) (20).
- Socio-economic condition will be classified as low (<5000 Bangladeshi Taka [BDT, 1 USD = 84 BDT]), medium (5000-1000 BDT) and high (>10000 BDT) based on the monthly expenditure.
- Physical activity will be graded on the ordinal scale of 1-3, corresponding to light (<30 minutes walking), moderate (between 30 – 60 minutes), and heavy (>60 minutes), according to the activity level based on their occupation. For data analysis, these results will be transformed into a binary variable - inactive (grade 1: <30 minutes) and active (grade 2 and 3: ≥30 minutes).

10. Data Analysis

Mean and standard deviation will be reported for continuous variables and inter-group comparisons will be tested by two-tailed ANOVA. The proportion of subjects developing GDM in each group and their comparison will also be done by chi-square analysis.

For the intervention measures, the absolute and relative risk reductions and 95% CIs of the estimates and the number needed to treat to prevent GDM in one person will be calculated. A p-value <0.05 is considered significant. The statistical package SPSS (PASW Statistics 20) will be used for analyses.

11. Health Economic Analysis

Economic analyses (cost-efficacy/effectiveness and budget impact analyses) of those interventions implemented will be carried out under a limited societal perspective. Thus, direct (medical and non-medical), as well as indirect costs, will be considered. Direct medical costs will be collected alongside other clinical data generated in the trial. Direct non-medical and indirect costs will be collected by questionnaire.

We will focus on the impact of the intervention on economic outcomes including employment status, productivity loss (lost productivity due to ill health), expenditure, and assets (based on an asset index which will be computed from questions about ownership of assets, housing type and access to services). We will use two-stage models. First, we will evaluate the distributional impact of the intervention using difference-in-differences (DID) analysis to compare outcomes for the intervention group with the control group. In the second part, to evaluate the impact on economic outcomes, we will regress the predicted measure of GDM morbidity from the first stage, on the economic outcome variables (e.g. productivity loss, catastrophic health spending). For each outcome, we will run appropriate regressions. We will take account of socio-demographic and other control variables including gender and will run sensitivity checks to ensure the robustness of our models.

12. Ethical Perspectives

The project will be conducted according to the Helsinki Declaration of medical research. Approval will be sought from the Ethical Review Committee (ERC) of the Diabetic Association of Bangladesh. Written informed consent will be obtained from study participants. All participants will also be informed of their

rights to withdraw from the study at any stage. All participants will be checked for their pregnancy health and will be followed by experienced medical care. This will add to their safety.

Information obtained by the participants will remain confidential and all stored samples will be taken and stored with informed consent. All data files will be anonymous and lists of names will be kept by project leaders in a locked safe. They will inform all participants of abnormal laboratory results and will provide further care for them.

13. Funding of the Study

The total cost of the project will be met by the following sources:

- 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.

14. Organization and Staffing

1. Staff of the study

One (1) Principal Investigator, two (2) CO-PI, four (4) Investigators, ten (10) Filed Officers, ten (10) Volunteers, one (1) Admin and Finance Officer, and one (1) Office Assistant will be recruited to conduct the study.

2. Responsibilities of staff:

Principal investigator (PI): PI, who will be employed for the whole period of study, will be responsible for the following:

- Overall coordination of the project
- Planned the study
- Designed the protocol
- Liaising with the funding agency

CO-Investigator (CO-PI): 2 (two) C)-PI who will be employed for the whole period of study will be responsible for the following:

- Coordination of project staff and investigators
- Planned the study
- Designed the protocol
- Liaising with the funding agency
- Development of education & awareness material
- Data clinging and analysis
- Report writing
- Dissemination

Investigators: Four (4) physicians working in different BADAS, and its AAs will be employed for subject recruitment periods, and will be responsible for the following:

- Coordination of project staff and data collector

- Protocol development,
- Field visits
- Training of data collectors
- Clinical assessment
- Treatment if needed

Volunteers: The data collectors, who will be employed for subject recruitment periods, will be responsible for the following:

- First contact person who will discuss the study with the participants
- Obtaining informed consent
- Conducting structured interviews
- Data entry

Admin and finance officer: The admin and finance officer will be employed for 3 months. He/ She will be responsible for the following:

- Administrative and logistical activities
- Day-to-day finance and accounts-related activities
- Financial reporting
- Supporting other staff

Office assistant (MSLL): The office assistant will be employed for 3 months.

- Messenger
- Photocopying documents
- Posting letters
- Storing papers, equipment

Staff Training

Two weeks of intensive training, including practice sessions, will be conducted separately. An equal number of sessions will be arranged for practical and theoretical purposes. Investigators will train all enumerators to prepare them for quality data collection. The following contents will be included in the training.

- Introduction to the project
- Situation of diabetes especially GDM status and its prevention in Bangladesh
- Instruments to be used for data collection
- Discussion on quantitative tools
- Practical session for data collection methods
- Questionnaire rechecking method
- Quality control of data collection

15. Team Composition and Qualification

National Prof AK Azad Khan will be the Principal Investigator (PI) of the current project. He is the president of the Diabetic Association of Bangladesh and Chair of the International Diabetes Federation South Asia. He is Chairman of the Board of Trustees of Bangladesh University of Health Sciences (BUHS), Honorary President (for life) of the Bangladesh Endocrine Society, Fellow of the Bangladesh Academy of Sciences (BAS), and Honorary Dean, Faculty of Unani & Ayurvedic Medicine, Hamdard University Bangladesh. He has been involved with the Diabetic Association of Bangladesh (BADAS) since 1977 in different capacities and

has been the chief organizer of many healthcare programs including the Primary Prevention Program of Diabetes in Bangladesh. His initiatives on public awareness activities on the prevention of diabetes and other non-communicable diseases through religious leaders have attracted worldwide attention. In Bangladesh, the project of safe motherhood and healthy children for newlyweds through Qazi's (Marriage Registrar) is playing a special role. He was also the PI of the following studies including 1) Assess the Cardiometabolic Risk (DM HTN) among young adult population in Bangladesh, 2) Random Capillary Blood Glucose Predict the Diagnosis of Diabetes and Initiation of Treatment in Adult Bangladeshi Population and 3) Diabetes Prevention through Religious leaders. All these studies were funded by the Non-Communicable Disease Control Program of the Directorate General of Health Services, Ministry of Health and Family Welfare. All these programs are playing special roles in accelerating the "Health Care for All" program of the Honourable Prime Minister of Bangladesh Sheikh Hasina. He initiated the UN Day for Diabetes. On his written request the Govt of Bangladesh raised the issue in the UN in 2006. During his Doctoral study at Oxford, he invented 5ASA based drug for inflammatory bowel disease. He did not patent it so that it becomes easily available to the Public. He received "The Independence Day Award 2018" from the Govt of Bangladesh for Social Services and was nominated as a National Professor in 2021. He was also a Member of the National Committee for the Celebration of the Birth Centenary of the Father of the Nation Bangabandhu Sheikh Mujibur Rahman.

Prof Akhtar Hussain will be the Co-PI of the current project. He is the President of the International Diabetes Federation IDF) and the Past President of the Diabetes in Asia Study Group (DASG). Currently serving as Professor of Chronic Diseases – Diabetes at the NORD University of Norway. He has served as a Professor of Medicine (International Health), at the Faculty of Medicine, the University of Oslo, responsible for International Diabetes and Metabolic Syndrome Research in the Master/Ph.D. program in International Health, at the University of Oslo from 2006 to 2016. He is also the Co-Chair & Professor at Global Health Research Centre, Bangladesh Diabetes Association. Former, Chair, Steering Committee (Diabetes Retinopathy Project) DaAn Health Group, Guangzhou, China. Prof Hussain is also the visiting Professor (Medicine), at the Federal University of Ceara, Brazil. He has contributed to the understanding of differential risk factors for diabetes and metabolic syndrome by ethnicity and migrants in particular. He has maintained a long-term scientific collaboration with Asia as well as Africa and Europe. His other contribution will be to illustrate fetal programming (nutrition, environment, co-morbidity) may contribute to outcomes relevant to metabolic disease in different settings. He has extensive experience in diabetes care, research, and clinical experience. exemplified as co-ordinator for the Preventive trial for Diabetes in IGT cases in Asians (Bangladesh, Pakistan, China, and Norway) with financial support awarded by the Norwegian Research Council (2006 – 2010). In addition, Prof. Hussain was the vice-coordinator for an international consortium for Immigrant Diabetes (IMMIDIAB) financed by the EU FP 6. Prof. Hussain is also the Vice – coordinator of GIFTS (Genomic and lifestyle predictors of fetal outcome relevant to diabetes and obesity and their relevance to prevention strategies in South Asian peoples" study. He was also the Co-PI of the following studies including 1) Assess the Cardiometabolic Risk (DM HTN) among the young adult population in Bangladesh, 2) Random Capillary Blood Glucose Predict the Diagnosis of Diabetes and Initiation of Treatment in Adult Bangladeshi Population, and 3) Diabetes Prevention through Religious leaders. All these studies were funded by the Non-Communicable Disease Control Program of the Directorate General of Health Services, Ministry of Health and Family Welfare.

Dr. Bishwajit Bhowmik will be the Co-PI of the current project. He completed his diploma in diabetology from the UK and his Ph.D. from the University of Oslo, Norway. He took advanced training on diabetology from Newcastle Diabetes Centre, UK, and the Australian Centre for Diabetes Strategies, Prince of Wales Hospital in Sydney' Australia. He has been involved with the Diabetic Association of Bangladesh (BADAS) since 2001 in different capacities. He is now the Consultant Diabetologist & Director, Executive Diabetes Care Centre, Diabetic Association of Bangladesh (BADAS), and Project Director, at the Centre for Global Health Research, BADAS. He is the Assistant Coordinator of the Distance Learning Program of BADAS and General Secretary of Diabetes at Asia Study Group. He worked as Coordinator of a few landmark programs including 1st National Diabetes Guideline, BADAS Diabetes Care Guideline, Nationwide Diabetes Registry, Preconception Care Program, Diabetes Prevention through Religious Leaders, Country Changing Diabetes, Rural Diabetes Care and Research Centres, Mobile Diabetes Care Center, and Online Diabetes School. He was the principal investigator of nationwide screening of diabetes and its related risk factors and nationwide screening of gestational diabetes. He was also the Co-PI of the following studies including 1) Assess the Cardiometabolic Risk (DM HTN) among young adult population in Bangladesh, 2) Random Capillary Blood Glucose Predict the Diagnosis of Diabetes and Initiation of Treatment in Adult Bangladeshi Population, 3) Diabetes Prevention through Religious leaders and 4) National NCD Risk Factor Survey 2022. All these studies were funded by the Non-Communicable Disease Control Program of the Directorate General of Health Services, Ministry of Health and Family Welfare. His research is related to diabetes prevention, obesity, metabolic syndrome, gestational diabetes, maternal nutrition and its link to NCDs, and diabetes education. He is the Fellow of the International Diabetes Federation (IDF) Education Foundation and the Japan Society for the Promotion of Science (JSPS). He is the author of fifty international peer reviewed publications, contributed chapters in two books on medical sciences, and is a member of the editorial board in more than 24 books/guidelines including Diabetes Care BADAS Guideline 2019 and BADAS Diabetes and COVID-19 Guidelines. He is the pioneer in COVID-19 and Diabetes Prevention and Research in Bangladesh. He has developed the largest diabetes and COVID-19 awareness and care platform named COVID-19 and Diabetes – Our initiatives.

Prof Faruque Pathan will be the investigator of the current project. He is now the President of the Bangladesh Endocrinology Society and former President of SAFES (South Asian Federation of Endocrine Societies). He started his career as a diabetologist in BIRDEM in 1984. He obtained MD in Endocrinology in 1993 from Dhaka University and joined as faculty at BIRDEM academy for postgraduate courses, especially endocrine and metabolic disorders. He is working as a professor of Endocrinology since 2008. Now he has taken the responsibility of the head of the department of Endocrinology of BIRDEM since 2014. He has quite a good number of publications (more than 100 publications) in both national and international journals, the editor, and co-author of several books and guidelines in the management of Diabetes. His special interest is in reproductive disorders, short stature, osteoporosis, PCOS, adrenals, and diabetic education. He was honored with a Fellow of the American College of Clinical Endocrinology (AACE) in 2004. He was the founder president of the AACE Bangladesh Chapter, a life member of IDF, a member of EASD, a member of ESE, and a life member of the Bangladesh Medical Association. He is working hard to guide in the Preconception care project, National Registry, and Imam project through religious leaders - unique activities of BADAS. He is involved in upgrading Diabetes for general physicians through a Distance Learning course on Diabetes. He was deeply involved in the DAB care study, Achieve study to evaluate the status of glycaemic control, IO

HAT trial on Hypoglycaemia, Virtue trial on Ramadan by Vildagliptin, Initial trial on Vildagliptin, Phase 3 trial on Linagliptin BI 1218.60 by Boehringer Ingelheim, and Last trial on post -GDM with LSM-Living study. He was also a member of the investigation team of the following studies including 1) Assess the Cardiometabolic Risk (DM HTN) among the young adult population in Bangladesh, 2) Random Capillary Blood Glucose Predict the Diagnosis of Diabetes and Initiation of Treatment in Adult Bangladeshi Population and 3) Diabetes Prevention through Religious leaders. All these studies were funded by the Non-Communicable Disease Control Program of the Directorate General of Health Services, Ministry of Health and Family Welfare.

Dr. Tareen Ahmed will be the investigator of the current project. He is now the Deputy Director of the Health Education Department of BIRDEM (Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine, and Metabolic Disorders) General Hospital and Additional Coordinator, Certificate Course on Diabetology (CCD) under the Distance Learning Program (DLP). He a did Diploma in Endocrinology and Metabolism (DEM) in 2006 and competed in Certificate Course on Diabetology (CCD), Distance Learning Program (DLP) of Diabetic Association of Bangladesh (DAB) in 2004. He is responsible for organizing "Regular Structured Diabetes Education, Re-education and Hands-on Training (on insulin injection, glucometer use, etc.) to patients of BIRDEM", "Structured Training Programs/Courses for Diabetes Educators", "Training on Diabetes Care to Physicians, Nurses and other Medical Personnel" and Clinical management of diabetic patients of BIRDEM OPD. He was the Member of the Panel of Editors of several guidelines including 'Manual for Diabetes Educators: Diabetes Educators Program (DEP), Diabetic Association of Bangladesh (BADAS) and World Diabetes Foundation (WDF), 2009, 'Prevention, Early Detection and Management of Non-communicable Diseases in Bangladesh, A Training Module for Primary Health Care Physicians': NCD Programme- Govt. of Bangladesh, Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine and Metabolic Disorders (BIRDEM) and World Health Organization (WHO), 2009, 'National Guidelines for Management of Diabetes Mellitus in Bangladesh at Primary Care' (in Bengali): NCDC- Directorate General of Health Services, Diabetic Association of Bangladesh (BADAS) and World Health Organization (WHO), 2013. He has been deeply involved in the "Preconception Care through Religious Leaders", "Prevention of Diabetes through Religious Leaders", "Nationwide Screening of Diabetes," and "Nationwide Screening of GDM" program of BADAS. He was also a member of the investigation team of the following studies including 1) Assess the Cardiometabolic Risk (DM HTN) among the young adult population in Bangladesh, 2) Random Capillary Blood Glucose Predict the Diagnosis of Diabetes and Initiation of Treatment in Adult Bangladeshi Population and 3) Diabetes Prevention through Religious leaders. All these studies were funded by the Non-Communicable Disease Control Program of the Directorate General of Health Services, Ministry of Health and Family Welfare.

Dr. Faria Afsana will be the investigator of the current project. She has been working at BIRDEM since 1996 and she is now the Associate Professor at the Department of Endocrinology, BIRDEM. She completed a Diploma in Endocrinology& Metabolism in July 2002 and MD in Endocrinology in July 2009. She is Vice president of the Bangladesh Endocrine Society; President-elect of SAFES (South Asian Federation of Endocrine Societies); Member Secretary of the Research cell, BIRDEM; Member of ACP (American College of Physicians); and Fellow, AACE (Association of American College of Endocrinology). She has been involved as a Coinvestigator in several studies including International Diabetes Management Practice Study, Diabcare

Asia 2008 (Id-INS-3738), Mother and Child Health Study, BADAS and Oslo University Chandra Study (2010), Multi Centre Cost Study (2012), Bangladesh; Randomized control trial of Linagliptin (2012), IOHAT study (2014), INITIAL Study (2015) and Changing Diabetes Barometer project since 2017. She was also a member of the investigation team of the following studies including 1) Assess the Cardiometabolic Risk (DM HTN) among young adult population in Bangladesh, 2) Random Capillary Blood Glucose Predict the Diagnosis of Diabetes and Initiation of Treatment in Adult Bangladeshi Population and 3) Diabetes Prevention through Religious leaders. All these studies were funded by the Non-Communicable Disease Control Program of the Directorate General of Health Services, Ministry of Health and Family Welfare.

Dr. Tasnima Siddiquee will be the investigator of the current project. She has been working as Deputy Coordinator at the Center for Global Health Research of the Diabetic Association of Bangladesh since 2013. Her main research interest is diabetes prevention, lipid disorder, metabolic syndrome, GDM, and maternal health. She has completed a Master of Public Health from the University of Oslo, Norway, and completed a Certificate Course in Diabetology in 2019. She has been deeply involved in "Preconception Care through Religious Leaders" and "Prevention of Diabetes through Religious Leaders," two landmark studies of the Diabetic Association of Bangladesh. She was also part of the "Nationwide Screening of Diabetes," "Nationwide Screening of GDM," and European Funded GIFTS (Genomic and lifestyle predictors of fetal outcome relevant to diabetes and obesity and their relevance to prevention strategies in South Asian peoples) study. She also has experience working with NCDC, DGHS. She was on the Editorial Board of "COVID-19 and Diabetes Guideline" and "Diabetes and HTN Flipchart," the joint initiatives of NCDC, BADAS, and JICA. She was also a member of the investigation team of the following studies including 1) Assess the Cardiometabolic Risk (DM HTN) among young adult population in Bangladesh, 2) Random Capillary Blood Glucose Predict the Diagnosis of Diabetes and Initiation of Treatment in Adult Bangladeshi Population and 3) Diabetes Prevention through Religious leaders. All these studies were funded by the Non-Communicable Disease Control Program of the Directorate General of Health Services, Ministry of Health and Family Welfare.

The team also comprises an experienced project research physician, statistician, and field research officer with extensive work experience in relevant fields. The team also comprises an experienced project research physician, statistician, and field research officer with extensive work experience in relevant fields.

16. List of Reports, Schedule of Deliveries, Period of Performance

a. An inception report that will include the initial work plan and a detailed methodological note to carry out the assignment (At the beginning of the study)
b. A final set of data collection tools, including guidance on how to use them in the field along with training strategies for enumerators
c. An interim report with completed activities (2nd week of the study)
d. A final report (Last week of study)
e. A final report on the survey in English including both hard and soft copies with the following sections will be submitted:

i. Executive Summary
ii. Introduction
iii. Methodology
iv. Findings of the baseline survey
v. Analysis of the findings
vi. Conclusions and recommendations as per the project's outcome, outputs, activities, and indicators

f. Raw data used for the analysis

g. Probable schedule
   - Date of commencement: June 2023
   - Date of completion: August 2026

17. Data, Personnel, Facilities, and Local Services

- BADAS will provide full technical assistance and training for all research activities.
- Upon completion of the project, BADAS, and NCDC, DGHS will be the joint owner of all raw data and will have the right to publish the report as long as no conflict of interest with the other party exists.
- NCDC, DGHS, MOHFW will be acknowledged in any reports and publications produced by BADAS.
- The sharing of primary data or reports derived from this assignment will strictly be prohibited without prior concern of NCDC during and within one year period of contract completion.
- The correlation tool will be destroyed after the study by the health documentation destruction policy of the institutional review committee.
- A regulatory binder will be maintained for this study. This will include items such as this protocol, the letter of approval from the IRB, the Waiver of the Authorization form, and all other information pertinent to this study.
- BADAS will provide full support (transport, technical, institutional, and other services relevant to the study) to the members of the three-member Technical Task Team (TTT) for overall monitoring of the research project at any time during the study period.

18. Institutional Arrangement

- BADAS will implement and evaluate the project activities as per the set indicators.
- The Institutional review committee (IRC) of BADAS will review study practice and progress to ensure the study is being conducted to the highest standard, ethically, and is progressing well.
- The study will be indemnified by the Diabetic Association of Bangladesh.
- NCDC, DGHS, MoHFW will monitor and supervise project activities.
- NCDC and DGHS will provide administrative support to explore necessary information from government

health facilities as and when required.

19. Governance

19.1. Governance Committee

- The Institutional review committee (IRC) will review study practice and progress to ensure the study is being conducted to the highest standard, in an ethical manner, and is progressing well.

19.2. Quality Control

A detailed quality control plan (outlined below) will be followed at all stages of the study.

- Extensive supervision and data checking will be provided by the advisory board members.
- Advisor board members will interview selected respondents and will match with the information collected by the enumerators to check the reliability and quality of data.
- The following steps will be followed for quality control of the survey.
    - The investigators and volunteers will be given extensive hands-on training on the technique of interviewing, anthropometric measurements, and keeping records.
    - The data collection instruments will be pre-tested.
    - Spot supervision will be made by a technical advisor.
    - All the staff will be re-interviewed with 20% of randomly selected respondents and will match with the information collected by the interviewers to check the reliability and quality of data.
- Internal quality controls are performed daily by the pathology lab. In addition, the lab is being registered with external quality assurance schemes to ensure the quality of results produced.

19.3. Data Handling and Record Keeping:

The following steps will be followed –

19.3.1. Confidentiality

Information about study subjects will be kept confidential and managed according to the existing rules of the institutional review committee.

19.3.2. Records Retention

The correlation tool will be destroyed at the completion of the study in accordance with the health documentation destruction policy of the institutional review committee.

19.3.3. Regulatory Binder

A regulatory binder will be maintained for this study. This will include items such as this protocol, the letter of approval from the IRB, the Waiver of the Authorization form, and all other information pertinent to this study.

19.4. Reporting Adverse Events (AEs)

Two investigators will be available 24 hours for assistance in case of any adverse events. Subjects will have

24 hours access to emergency inpatient services if related to the study. Records will be kept of any adverse effects occurring during the course of the study and sent to the governance committees.

20. Indemnity

The study will be indemnified by the Diabetic Association of Bangladesh.

21. Future Perspectives

Our findings will help to compile large hospital-based data and create an environment that will be conducive to promoting healthy lifestyles through multi-sectorial, interdisciplinary collaborations.

22. Conflict of Interest

No potential conflict of interest.

23. Report Writing of the Project

A report of the project will be delivered monthly by the investigator. A detailed report writing format will be developed based on the objectives of the study. Moreover, reports including financial reports will be submitted to BADAS and the funding agency at the end of the study.

24. Transfer of Knowledge

Dissemination

- The findings of this study will be nationally disseminated to cater to a larger audience.
- The finding will also be shared in international conferences to cater to an international audience.

Publication in a peer-reviewed journal

- The findings will be published in a peer-reviewed journal to cater to a scientific audience.
- In addition, we will publish summary articles in the Journal of the Bangladesh Medical Association and the Medical Journal of BADAS.

25. Key perspectives and compliance with strategic documents

Relevance and benefit to society

The outcome of this research program will help to develop evidence-based; effective and focused health promotion strategies for the prevention of GDM and future T2DM in those with a history of gestational diabetes. Further, pregnant women and vulnerable children, with special attention to GDM mothers with undernutrition, optimal weight gain, fetal health, GDM, delivery outcomes, and optimal birth weight in the Bangladeshi population relevant for cardiometabolic risk, safe motherhood, and development of policies.

The results of this study will facilitate to development of public health policy for the prevention of diabetes, optimal nutrition, and lifestyle at peri-conception and pregnancy to reduce the prevalence of metabolic disorders in early life that are the forerunners of T2DM and its complications. It will also help to increase awareness among healthcare professionals, policymakers, pregnant women, and their families, of the importance of non-GDM state and prevention of T2DM in those who develop GDM during pregnancies.

Finally, it will help to develop Digital Preconception and GDM Registry very first time in Bangladesh.

Environmental impact

A balanced intake of nutrition (food) will help the natural ecological balance of nature. Therefore, we believe this research and development (R & D) will have a positive impact on the environment.

26. Time Frame:

The duration of the study will be thirty-six months.

Description/ Time in 3 months	1	2	3	4	5	6	7	8	9	10	11	12
Finalize the methodology, field assessment												
Staff recruitment and training												
Development of data collection tool												
Ethical approval												
Screening & patient enrollment												
Intervention tool development												
Baseline assessment												
Baseline data analysis												
Intervention												
Midline assessment												
Midline data analysis												
End line Assessment												
End line and total data analysis												
Report writing												
Dissemination and validation												
Final Report Submission												

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28. Budget

Cost Component	Costs (BDT)
Staff Remuneration	1,498,720.00
Laboratory Investigations	4,092,480.00
Drafting and Printing	105,000.00
Travel and Subsistence:	1,402,600.00
Program Expenditure	1,325,300.00
Computer and Software	340,000.00
Other Administrative Expenses	220,000.00
Grand Total	**8,984,100.00**