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Religious leaders and diabetes prevention in Bangladesh

Submission date
24/04/2022

Recruitment status
No longer recruiting

Registration date
08/05/2022

Overall study status
Completed

Last Edited
09/05/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] 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
Type 2 diabetes is a common condition that causes the level of sugar (glucose) in the blood to become too high.
Type 2 diabetes (T2DM) and related non-communicable diseases (NCDs) are common among the adult population in Bangladesh, which can be prevented through lifestyle modification. Evidence shows that culturally sensitive and behaviorally oriented faith-based intervention by religious leaders affects the prevention of T2DM and related NCDs.
Aim: To assess the outcome of faith-based intervention for the prevention of T2DM in high-risk subjects in Bangladesh.

Who can participate?
All individuals aged 25 years or older with diabetes risk score 9 or above and diagnosed with prediabetes (IFG/IGT) as per WHO recommended diagnostic value, permanent residents and willing to participate and available for 12 months of study.

What does the study involve?
Over the course of 12 months, this study will involve counseling, biophysical measurement, and laboratory investigations related to the study outcomes. In the intervention group, participants will visit twelve times (one each month) for counseling with religious leaders. They will discuss healthy lifestyles based on the religious sermon (khutbah) that benefits T2DM prevention. In addition, they will have three appointments (at the time of registration, 4 months, and 12 months) for structured healthy lifestyle education (including diet and physical activity) effective for T2DM prevention, biophysical measurement, and laboratory investigations with researchers from the Centre for Global Health Research of the Diabetic Association of Bangladesh. They will complete a questionnaire on changes in major nutritional and exercise habits and also the changes in Knowledge, Attitude, and Practice (KAP). All these appointments will be face-to-face. The subjects in the control group will be informed about a healthy lifestyle based on the religious sermon (khutbah). After the inclusion and collection of baseline data, they will visit the study site at 4 months and 12 months for the collection of anthropometric, clinical, and laboratory investigations. They will also complete a questionnaire on changes in major nutritional and exercise habits and also the changes in KAP.

What are the possible benefits and risks of participating?
This proposed study will fill up the gap in our existing knowledge by testing the effectiveness of faith-based intervention by religious leaders for the prevention of T2DM and related NCDs. No risk will be involved in this study.

Where is the study run from?
Centre for Global Health Research, Diabetic Association of Bangladesh

When is the study starting and how long is it expected to run for?
April 2022 to April 2023

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, doctorbiplob@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Bishwajit Bhowmik

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
BADAS-ERC/EC 122100330

Study information

Scientific Title
Prevention of diabetes and related NCDs through religious leaders

Acronym
DPRL

Study objectives
Faith-based intervention by religious leaders can affect the prevention of T2DM and related NCD risk factors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/04/2022, The Ethical Review Committee (ERC) of the Diabetic Association of Bangladesh (BADAS, 122 Kazi Nazrul Islam Avenue, Shahbag, Dhaka-1000, Bangladesh; +880-2-9661551; ERC@dab-bd.org), ref: BADAS-ERC/EC 122100330

Study design
Multicenter Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

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
Prevention of diabetes

Interventions
Participants will be allocated at random in a 1:1 ratio.
Intervention arm: provide healthy lifestyle information through religious sermon (khutbah) plus person-specific dietary and physical activity advice;
Control arm: only provide healthy lifestyle information through religious sermon (khutbah)
Follow up is for 12 months

Intervention Type

Behavioural

Primary outcome measure
Rate of conversion from prediabetes to T2DM using blood glucose (both fasting and 2 hours after 75-gram blood glucose drink) among the study population at 4 months and 12 months

Secondary outcome measures
1. Rate of T2DM between intervention and control group using blood glucose at 4 months and 12 months
2. Rate of cardiometabolic parameters including obesity (general and abdominal) by measuring anthropometric parameters, HTN by measuring blood pressure, and dyslipidemia by measuring fasting lipid profile between intervention and control group at 4 months and 12 months
3. Changes in physical activity, and dietary habits between intervention and control group using face-to-face interview (control group) and both face to face interview and guidebook at 4 months and 12 months
4. Level of changes in knowledge, attitude, and practice about T2DM and related cardiometabolic parameters among the study participants using the questionnaire at 4 months and 12 months

Overall study start date
19/04/2022

Completion date
06/04/2023

Eligibility

Key inclusion criteria
1. All individuals aged ≥25 years with diabetes risk score ≥9 and diagnosed with prediabetes (IFG /IGT) as per WHO recommended diagnostic value.
2. Both genders
3. Permanent residents
4. Willing to participate and available for 12 months of study

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
824 (intervention arm:412 & control arm: 412); equal number in all 8 centers.

Key exclusion criteria
1. Pregnant women or planned pregnancy and lactating mothers
2. Known case of T2DM
3. Individuals diagnosed with acute physical or mental illness at the time of screening

Date of first enrolment
07/05/2022

Date of final enrolment
07/06/2022

Locations

Countries of recruitment
Bangladesh

Study participating centre
Centre for Global Health Research, Diabetic Association of Bangladesh
122, Kazi Nazrul Islam Avenue Shahbag
Dhaka
Bangladesh
1000

Sponsor information

Organisation
Ministry of Health and Family Welfare

Sponsor details
Non-Communicable Disease Control Program of Directorate General of Health Services
Government of the People's Republic of Bangladesh
Mohakhali
Dhaka
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Sponsor type
Government

Website
http://www.mohfw.gov.bd/

ROR
https://ror.org/05256fm24

Funder(s)

Funder type
Government

Funder Name
Ministry of Health and Family Welfare, Bangladesh

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/10/2023

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
doctorbiplob@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			04/05/2022	No	No
Other files			04/05/2022	No	Yes
Participant information sheet			04/05/2022	No	Yes
Protocol file		12/04/2022	04/05/2022	No	No