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The Bangladesh D:Clare Project: Mobilising communities to prevent type 2 diabetes

Submission date
18/10/2019

Recruitment status
No longer recruiting

Registration date
31/10/2019

Overall study status
Completed

Last Edited
15/08/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background
More than one third of adults in rural Bangladesh have raised blood glucose levels meeting WHO criteria for intermediate hyperglycaemia (raised blood glucose levels that can lead to diabetes) or type 2 diabetes (T2DM). A previous study called DMagic investigated a community mobilisation intervention, in which paid non-expert volunteers guided residents in villages in Bangladesh through a four-phase Participatory Learning and Action (PLA) cycle. In this process, community members themselves identified, prioritised and took action to raise awareness of and reduce behavioural, social and environmental factors that increase risk of hyperglycaemia and T2DM in their community. That study showed that after 18 months of the PLA process, community awareness and understanding of T2DM was greatly increased and the rate of T2DM and intermediate hyperglycaemia was 64% lower in villages that took part than in villages that did not participate. Further, among people who were identified as having intermediate hyperglycaemia before the study, those living in the villages that participated were much less likely to progress to diabetes that people living in villages that did not take part.
This study aims to further investigate how this process works, again in villages in Bangladesh.

Who can participate?
Adults aged 30 years and over who are permanent residents of the participating upazilla (sub-district) in Faridpur district, Bangladesh.

What does the study involve?
The villages in the area will be grouped into clusters. The clusters will be randomly allocated to one of two groups - one receiving the intervention, and the other acting as controls. The PLA community mobilisation meetings involve participants identifying and addressing factors that may increase their risk of developing intermediate hyperglycaemia or diabetes or to learn about effectively managing their condition if they are already affected.
At the start of the study and before any intervention, the clusters will be tested to find out the proportion of residents who have intermediate hyperglycaemia or diabetes, to understand people's knowledge and awareness of diabetes, and to investigate common risk factors for diabetes in those communities. The survey will be repeated after 18 months when the intervention has been completed.

What are the possible benefits and risks of participating?
There are three main benefits of taking part. All individuals participating in the evaluation surveys will be told their blood glucose results and will receive information on healthy levels and how to access appropriate care-seeking and further testing. Through active community engagement throughout the project, the study will increase individual and collective awareness of diabetes and its causes, which will result in improved understanding of the prevention and treatment of the disease, behaviour change, service use, and effective management of community resources for healthier lives and improved diabetes management. All participants will benefit from initiatives to strengthen the capacity of local health systems to respond to the growing burden of diabetes. There are no risks involved with taking part in the study.

Where is the study run from?
The Diabetic Association of Bangladesh

When is the study starting and how long is it expected to run for?
September 2019 to November 2022

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

Who is the main contact?
Dr Edward Fottrell, e.fottrell@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Edward Fottrell

ORCID ID
https://orcid.org/0000-0003-0518-7161

Contact details
30 Guilford Street
London
United Kingdom
WC1N 1EH
+44 (0)2079052203
e.fottrell@ucl.ac.uk

Type(s)
Scientific

Contact name
Dr Carina King

ORCID ID
https://orcid.org/0000-0002-6885-6716

Contact details
30 Guilford Street
London
United Kingdom
WC1N 1EH
+44 (0)2031082084
c.king@ucl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
N/A

Study information

Scientific Title
The Bangladesh Diabetes: Community-led Awareness, Response and Evaluation (D:Clare) Project

Acronym
D:Clare

Study objectives
Horizontal scale-up of Participatory Learning and Action community mobilisation across Alfadanga upazila will significantly increase population-level awareness of diabetes prevention and control, and reduce the prevalence of intermediate hyperglycaemia and diabetes by at least 30%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 07/11/2019, University College London Research Ethics Committee (c/o Helen Dougal, Research Ethics Co-ordinator, Office of the Vice-Provost (Research), University College London, 2 Taviton St, London WC1E 6BT, UK; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: 4199 /007, revision approved 16/12/2020.
2. Approved 03/12/2019, Ethical Review Committee of the Diabetic Association of Bangladesh (122 Kazi Nazrul Islam Avenue, Shahbagh, Dhaka-1000, Bangladesh; +880 (0)58616641-50, +880 (0)9661551-60; info@dab-bd.org), ref: BADAS-ERC/E/19/00276

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
1. Intermediate hyperglycaemia
2. Type 2 diabetes mellitus

Interventions
Current interventions as of 17/12/2020:
Community mobilisation through male and female community groups using a Participatory Learning and Action Cycle whereby groups themselves identify and prioritise problems associated with diabetes and the risk of developing diabetes, next they plan strategies to address these problems, put these strategies into practice and, finally, evaluate the effectiveness of these strategies. Lay salaried facilitators will convene the groups on a monthly basis over a period of 18 months. Approximately 108 participatory groups will be established (giving a population coverage of approximately one group per 200 adults aged 30 years and above).

Working in 12 clusters (groups of villages), each cluster will be randomly allocated to one of two groups. Randomisation will be done publicly, in the presence of community leaders. Each cluster will be assigned a number, from 1 to 12, and these numbers will be written on pieces of paper, folded to look identical. They will then be picked out of a container, with the first six clusters assigned to the intervention, and the next six assigned to control. This will be filmed.

The PLA community mobilisation meetings involve participants identifying and addressing factors that may increase their risk of developing intermediate hyperglycaemia or diabetes or to learn about effectively managing their condition if they are already affected. At the start of the study and before any intervention, a community-based sample survey will be undertaken in each of the study clusters to measure population prevalence of intermediate hyperglycaemia and diabetes, knowledge and awareness of diabetes, and common non-communicable disease risk factors. The survey will be repeated just before the second set of clusters begin intervention and again after the intervention in each cluster.

The random allocation of clusters to the first or second phase of intervention roll-out, the phased roll-out and the carefully designed surveys will enable robust evaluation of intervention impact on the occurrence of intermediate hyperglycaemia and diabetes as well as population levels of risk factors and knowledge of diabetes.

Previous interventions:
Community mobilisation through male and female community groups using a Participatory Learning and Action Cycle whereby groups themselves identify and prioritise problems associated with diabetes and the risk of developing diabetes, next they plan strategies to address these problems, put these strategies into practice and, finally, evaluate the effectiveness of these strategies. Lay salaried facilitators will convene the groups on a monthly basis over a period of 18 months. Approximately 216 participatory groups will be established (giving a population coverage of approximately one group per 200 adults aged 30 years and above).

Working in 12 clusters (groups of villages), each cluster will be randomly allocated to one of two groups. Randomisation will be done publicly, in the presence of community leaders. Each cluster will be assigned a number, from 1 to 12, and these numbers will be written on pieces of paper,

folded to look identical. They will then be picked out of a container, with the first six clusters assigned to the intervention, and the next six assigned to be control clusters at the first step. This will be filmed. Those clusters in the first group will be the first to receive the monthly PLA community over a total period of 18 months. Those clusters in the second group will also receive the intervention, but after approximately 12 months delay. This is known as 'stepped-wedge' cluster randomised controlled trial.

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Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 17/12/2020:
Combined prevalence of intermediate hyperglycaemia and diabetes among adults aged 30 years or older defined according to WHO fasting and 2-hour post ingestion of 75 g glucose load, plasma glucose cut-off categorisations for normoglycaemia, intermediate hyperglycaemia (impaired fasting glucose or impaired glucose tolerance), and type 2 diabetes mellitus. Blood glucose measures will be recorded from fasting and 2-hour post-glucose load whole blood samples obtained from finger prick capillaries among a random sample of adults in each of the study clusters using handheld glucometers. These measurements will be done once for each random sample of individuals. A new random sample will be taken at month 0 (before any intervention), and at month 18 (after intervention completion). Intervention and control data points will be compared.

Previous primary outcome measure:
Combined prevalence of intermediate hyperglycaemia and diabetes among adults aged 30 years or older defined according to WHO fasting and 2-hour post ingestion of 75 g glucose load, plasma glucose cut-off categorisations for normoglycaemia, intermediate hyperglycaemia (impaired fasting glucose or impaired glucose tolerance), and type 2 diabetes mellitus.
Blood glucose measures will be recorded from fasting and 2-hour post-glucose load whole blood samples obtained from finger prick capillaries among a random sample of adults in each of the study clusters using handheld glucometers. These measurements will be done once for each random sample of individuals. A new random sample will be taken at month 0 (before any intervention), at month 12 (50% of clusters have received the intervention), and month 24 (100% of clusters have received the intervention). Intervention and control data points will be compared.

Key secondary outcome(s))

Updated 17/12/2020:
All secondary outcomes will be measured in a random sample of adults in each of the study clusters. The information will be collected by interview once for each random sample of individuals, with a new random sample taken at month 0 (before any intervention), at month 18 (after intervention completion).

Previous:
All secondary outcomes will be measured in a random sample of adults in each of the study clusters. The information will be collected by interview once for each random sample of individuals, with a new random sample taken at month 0 (before any intervention), at month 12 (50% of clusters have received the intervention), and month 24 (100% of clusters have received the intervention).

Current secondary outcome measures as of 06/03/2020:
1. Self-awareness of diabetic status. This is the proportion of participants with WHO defined type 2 diabetes according to fasting and 2-hour post ingestion of 75 g glucose load plasma glucose cut-offs or who report having been diagnosed with type 2 diabetes by a healthcare provider during an interviewer administered survey.
2. Physical activity assessed using questions adapted from the WHO Stepwise tool and the 2014 Bangladesh Demographic and Health Survey
3. Mean population diastolic and systolic blood pressure measured by study data collectors using the OMRON HBP 1100 Professional Blood Pressure Monitor (Kyoto, Japan). Two measurements will be taken at approximately 5-min intervals and the respondent’s blood pressure obtained by averaging these measurements.
4. Mean population body mass index calculated from participants' weight and height taken by study data collectors. Weight will be measured using a scale calibrated daily with a known weight. For height, participants will stand in an erect posture vertically touching the occiput, back, hip, and heels on the wall while gazing horizontally in front and keeping the tragus and lateral orbital margin in the same horizontal plane.
5. Mean population waist and hip circumference ratio. The waist to hip circumference ratio will be calculated for study participants using measurements taken by study data collectors. The waist and hip girth will be taken with participants wearing light clothing. Waist girth will be measured by placing a plastic tape horizontally midway between 12th rib and iliac crest on the mid-axillary line. Hip circumference will be measured by taking the extreme end posteriorly and the symphysis pubis anteriorly.
6. Consumption and dietary diversity assessed using questions adapted from the WHO Stepwise tool and the 2014 Bangladesh Demographic and Health Survey
7. Awareness of diabetes symptoms and complications assessed using questions from the WHO Stepwise tool and the 2014 Bangladesh Demographic and Health Survey
8. Utilisation of diabetic services assessed using questions from the WHO Stepwise tool and the 2014 Bangladesh Demographic and Health Survey
9. Psychological distress and ability to self-manage among diabetics assessed using an adapted Appraisal of Diabetes Scale (ADS) tool
10. Depression and anxiety using the PHQ-9 and GAD-7 screening tools
11. Two-year cumulative incidence of diabetes among individuals with intermediate hyperglycaemia as defined using WHO diagnostic criteria at baseline (month 1).

Previous secondary outcome measures:
1. Self-awareness of diabetic status. This is the proportion of participants with WHO defined type 2 diabetes according to fasting and 2-hour post ingestion of 75 g glucose load plasma glucose cut-offs who report having been diagnosed with type 2 diabetes by a healthcare provider during an interviewer-administered survey.

2. Physical activity assessed using questions from the WHO Stepwise tool and the 2014 Bangladesh Demographic and Health Survey
3. Mean population diastolic and systolic blood pressure measured by study data collectors using the OMRON HBP 1100 Professional Blood Pressure Monitor (Kyoto, Japan). Two measurements will be taken at approximately 5-min intervals and the respondent’s blood pressure obtained by averaging these measurements.
4. Mean population body mass index calculated from participants' weight and height taken by study data collectors. Weight will be measured using a scale calibrated daily with a known weight. For height, participants will stand in an erect posture vertically touching the occiput, back, hip, and heels on the wall while gazing horizontally in front and keeping the tragus and lateral orbital margin in the same horizontal plane.
5. Mean population waist and hip circumference ratio. The waist to hip circumference ratio will be calculated for study participants using measurements taken by study data collectors. The waist and hip girth will be taken with participants wearing light clothing. Waist girth will be measured by placing a plastic tape horizontally midway between 12th rib and iliac crest on the mid-axillary line. Hip circumference will be measured by taking the extreme end posteriorly and the symphysis pubis anteriorly.
6. Consumption and dietary diversity assessed using questions from the WHO Stepwise tool and the 2014 Bangladesh Demographic and Health Survey
7. Awareness of diabetes symptoms and complications assessed using questions from the WHO Stepwise tool and the 2014 Bangladesh Demographic and Health Survey
8. Utilisation of diabetic services assessed using questions from the WHO Stepwise tool and the 2014 Bangladesh Demographic and Health Survey
9. Quality of life assessed using the EQ-5D questionnaire
10. Psychological distress among diabetics assessed using the ADS Depression in Diabetes Scale and SRQ-20 mental health screening tools

Completion date
21/11/2022

Eligibility

Key inclusion criteria
1. Aged 30 years and above
2. Permanent residents in one of the study clusters during the study period

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 years

Sex
All

Key exclusion criteria
1. Aged under 30 years
2. Temporary residents in the study clusters
3. Individuals who decline to participate in the survey
4. Individuals who lack the capacity to consent to participate in the study
5. Currently self-reported as pregnant

Date of first enrolment
04/01/2020

Date of final enrolment
15/11/2022

Locations

Countries of recruitment
Bangladesh

Study participating centre
Diabetic Association of Bangladesh
122 Kazi Nazrul Islam Avenue Shahbag
Dhaka
Bangladesh
Dhaka-1000

Sponsor information

Organisation
University College London Institute for Global Health

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

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

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 17/11/2021:
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Ed Fottrell (e.fottrell@ucl.ac.uk) after publication of the main results paper. Fully anonymised, individual-level data will be available for those pursuing research, following the signing of a data sharing agreement.

Previous individual participant data (IPD) sharing statement:
Fully anonymised data will be available for research purposes only, on request to Dr Ed Fottrell. All participants will be asked during informed consent for permission to share anonymised data for the purposes of research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/04/2025	04/04/2025	Yes	No
Results article		14/08/2025	15/08/2025	Yes	No
Protocol article		29/03/2021	17/11/2021	Yes	No
Protocol article		23/03/2023	27/03/2023	Yes	No
Participant information sheet	Participant information sheet version 2	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan		16/09/2022	11/11/2022	No	No