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The Bangladesh D-Magic Trial: Evaluating the effectiveness of community groups and mobile phone messages on the prevention and control of diabetes in rural Bangladesh

Submission date
30/03/2016

Recruitment status
No longer recruiting

Registration date
04/05/2016

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). As survival rates in developing countries improve, the problem of non-infectious diseases, such as diabetes, increases. Currently between 20-30% of the population of Bangladesh have abnormal blood sugar levels resulting in intermediate hyperglycaemia (where a person's blood sugar levels are above the normal range but do not meet the criteria for diabetes) or fully expressed T2DM. The problem of diabetes and its complications is a growing concern among communities, health service providers and policy-makers, yet raw data on the magnitude and underlying causes of the problem are scarce, especially in rural areas. Underlying the increasing occurrence of intermediate hyperglycaemia and diabetes in Bangladesh are patterns of dietary change, changing lifestyles and increases in other risk factors like lack of exercise. Through population based surveys, this study aims to generate data on the prevalence (commonness) of intermediate hyperglycaemia, diabetes, and associated risk factors in rural villages in Bangladesh and to explore the impact of two programs to improve the detection, management and prevention of diabetes in these deprived populations.

Who can participate?
Adults aged 30 and above who are permanent residents of the participating villages.

What does the study involve?
Participating villages are randomly allocated to one of three groups. Those living in villages in the first group take part in monthly community group meetings for 18 months. These 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. Those living in villages in the second group receive weekly messages to their mobile phones for 18 months. The messages are made up of information about diabetes

and advice on prevention and management of the disease. Those living in villages in the third group only receive standard diabetes prevention and care services. At the start of the study, a large community-based survey is undertaken in the study area in order to establish the commonness of intermediate hyperglycaemia and diabetes, high blood pressure and a range of diabetes risk factors and consequences. At the end of the 18 month study period, the survey is repeated in order to find out if the programmes have had any impact on the occurrence of intermediate hyperglycaemia and diabetes as well as population levels of risk factors. Individuals identified as having intermediate hyperglycaemia at the start of the study are followed up at the end of the study in order to find out how many went on to develop diabetes in each study group.

What are the possible benefits and risks of participating?
There are three main benefits of taking part: any individuals identified as having abnormal blood sugar levels or blood pressure by the trial team will be referred for care; 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 understandings 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 notable risks involved with taking part in the study.

Where is the study run from?
The study is run by the Diabetic Association of Bangladesh and takes place in 96 villages (Bangladesh)

When is the study starting and how long is it expected to run for?
June 2015 to June 2018

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The Bangladesh D-Magic Trial: Diabetes Mellitus: Action through community Groups or mHealth Information for better Control of population blood glucose, risk factors, knowledge and care seeking. A three arm cluster randomised trial.

Acronym
D-Magic

Study objectives
The interventions will lead to a significant reduction in the combined prevalence of intermediate hyperglycaemia and diabetes in adults aged 30 years and over in intervention clusters compared to control clusters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University College London Research Ethics Committee, 20/11/2015, ref: 4766/002
2. Ethical Review Committee of the Diabetic Association of Bangladesh, 31/10/2015, ref: BADAS-ERC/EC / t5100246

Study design
Cluster randomised 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 below to request a participant information sheet.

Health condition(s) or problem(s) studied
1. Intermediate hyperglycaemia
2. Type II Diabetes Mellitus

Interventions
96 villages are randomly allocated to one of three study arms.

Intervention Arm 1: 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 facilitators will convene the groups on a monthly basis over a period of 18 months. 122 participatory groups will be established (giving a population coverage of approximately one group per 450 population).

Intervention Arm 2: mHealth health promotion voice messaging to individual mobile phones. Messages will be sent at least weekly over a period of 18 months.

Control Arm: Control clusters will receive standard diabetes prevention and care in accordance with national guidelines.

All arms: All study clusters, control and intervention, will receive basic health systems strengthening activities.

Intervention Type
Behavioural

Primary outcome measure
1. Combined prevalence of intermediate hyperglycaemia and diabetes among adults aged 30 years or older measured after 18 months of intervention and defined using WHO fasting and two-hour post ingestion of 75g glucose load plasma glucose cut-off categorisations for normoglycaemia, intermediate hyperglycaemia (impaired fasting glucose or impaired glucose tolerance), and type II diabetes mellitus. Blood glucose measures will be recorded from fasting and two-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.
2. Two year cumulative incidence of diabetes among individuals with intermediate hyperglycaemia as defined using WHO diagnostic criteria at baseline.

Secondary outcome measures
The following secondary outcomes will be measured from a random sample of adults aged 30 years or older in each of the study clusters through baseline and endline surveys using trained data collectors:

1. Mean population diastolic and systolic blood pressure derived from the average of two measures or each individual's blood pressure at approximately 5 minute intervals using a digital blood pressure monitor
2. Prevalence of hypertension defined as systolic blood pressure ≥ 140 mmHg or a diastolic blood pressure ≥ 90 mmHg (assessed using digital blood pressure monitor as described above) or self-reported current treatment with antihypertensive medication during the survey questionnaire
3. Mean population body mass index calculated from individual weight and height measures obtained by trained field staff following standard protocols
4. Mean population waist and hip circumference ratio calculated from individual waist and hip measurements obtained by trained field staff following standard protocols
5. Prevalence of overweight and obesity using a cut-off of 23 or more as recommended for South Asian populations
6. Physical activity graded according to the intensity and duration of work (heavy, moderate, mild, and sedentary, based on an equivalent walk of >90 min, 60–90 min, 30–59min, and <30 min /24 h, respectively) based on self-reports in the survey questionnaire
7. Prevalence of inadequate intake of fruit and/or vegetables (< 5 servings/ day), based on self-reports in the survey questionnaire
8. Quality of life measured using the EQ-5D tool in the survey questionnaire
9. Proportion of individuals identified as diabetic by blood glucose testing aware of their diabetic status, based on self-reports in the survey questionnaire
10. Psychological distress among self-reported diabetics measured using the SRQ-20 tool
11. Proportion of population aware of diabetes and able to correctly describe risk factors, symptoms and complications, based on the survey questionnaire
12. Utilisation of diabetic services among individuals with known diabetes, based on self-reports in the survey questionnaire

Overall study start date
27/06/2015

Completion date
28/06/2018

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

Age group
Adult

Sex
Both

Target number of participants
96 clusters; 143 individuals per cluster

Key exclusion criteria
1. Aged less than 30 years
2. Temporary residents in the study clusters
3. Individuals who decline to participate in the survey

Date of first enrolment
13/09/2015

Date of final enrolment
13/09/2015

Locations

Countries of recruitment
Bangladesh

Study participating centre
Diabetic Association of Bangladesh
122 Kazi Nazrul Islam Avenue
Shahbag
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Bangladesh
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Sponsor information

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University College London Institute for Global Health

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ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of study protocol, baseline data and formative research papers and trial results papers, including cost-effectiveness and process evaluation in peer reviewed journals.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019	11/02/2019	Yes	No
Protocol article	protocol	20/08/2018	23/10/2019	Yes	No
Other publications	qualitative process evaluation	04/11/2019	08/11/2019	Yes	No

Results article		11/03/2022	14/03/2022	Yes	No
Other publications	5 year follow up	01/03/2023	14/06/2023	Yes	No
Other publications	cross-sectional survey	23/07/2018	14/06/2023	Yes	No
Other publications	process evaluation	08/05/2021	14/06/2023	Yes	No
Protocol article		19/12/2016	14/06/2023	Yes	No
Results article		22/07/2021	14/06/2023	Yes	No