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## Protocol of economic evaluation of m-Health and community groups for prevention and control of diabetes in rural Bangladesh: a three-arm cluster randomised controlled trial

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3 **Protocol of economic evaluation of m-Health and community groups for**  
4 **prevention and control of diabetes in rural Bangladesh: a three-arm cluster**  
5 **randomised controlled trial.**  
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## Abstract

*Introduction:* Type 2 Diabetes mellitus (T2DM) is one of the leading causes of death and disability worldwide, generating substantial economic burden for people with diabetes and their families, and to health systems and national economies. Bangladesh has one of the largest numbers of adults with diabetes in the South Asian region. This paper describes the planned economic evaluation of a three-arm cluster randomised control trial of mHealth and community mobilisation interventions to prevent and control T2DM and non-communicable diseases' (NCDs) risk factors in rural Bangladesh (D-Magic trial).

*Methods and Analysis:* The economic evaluation will be conducted as a within-trial analysis to evaluate the incremental costs and health outcomes of mHealth and community mobilisation interventions compared to the status quo. The analyses will be conducted from a societal perspective, assessing the economic impact for all parties affected by the interventions, including implementing agencies (program costs), health care providers, and participants and their households. Incremental cost-effectiveness ratios (ICERs) will be calculated in terms of cost per case of intermediate hyperglycaemia and T2DM prevented and cost per case of diabetes prevented among individuals with intermediate hyperglycaemia at baseline, and cost-per mm Hg reduction in systolic blood pressure. In addition to ICERs, the economic evaluation will be presented as a cost-consequence analysis where the incremental costs and all statistically significant outcomes will be listed separately. Robustness of the results will be assessed through sensitivity analyses.

*Ethics and Dissemination:* The approval to conduct the study was obtained by the University College London Research Ethics Committee (4766/002) and by the Ethical Review Committee of the Diabetic Association of Bangladesh (BADAS-ERC/EC/t5100246). The findings of this study will be disseminated through different means within academia and the wider policy sphere.

*Trial registration:* ISRCTN41083256. Registered 30/03/2016

**Strengths and limitations of this study**

- This protocol paper reports planned data collection and analyses alongside a complex public health trial to ensure transparency.
- The findings of this study will provide valuable evidence for decision-makers when considering the potential implementation of novel mHealth and community mobilisation through a Participatory Learning and Action Approach interventions for the prevention of diabetes and mitigation of NCDs risk factors
- The applicability of the findings may be limited to similar settings, and the interventions may require further adaptation to ensure feasibility and sustainability in similar or other contexts.

## BACKGROUND

### Burden of diabetes mellitus

Diabetes mellitus, mainly type 2, is a one of the leading causes of death and disability worldwide. It is estimated that around 415 million people worldwide, or 9% of adults aged 20-79 have diabetes, with about 75% of people living with diabetes residing in low- and middle-income countries (LMICs) (1). It is predicted that by 2040, one in 10 adults will have diabetes, unless preventive efforts are undertaken (1). Diabetes, if not managed properly, can lead to several complications, such as heart attack, kidney failure, leg amputation, vision loss and several other long-term consequences, that impact significantly on quality of life and cause premature death (1, 2). Diabetes and its complications create a substantial economic burden for people with diabetes and their families, and for health systems and national economies through direct medical costs and productivity loss (2).

Bangladesh has the second largest number of adults with diabetes in the South Asian region, with around 7 million adults aged 20-79 years with diabetes (1). The prevalence of diabetes among adults (20-79 years old) in Bangladesh is estimated to be around 8.5 % (1, 2), with a three to four-fold increase since the 1990s (3, 4). It is predicted that prevalence of diabetes in Bangladesh will reach 23.6% in men and 33.5% in women by 2030, unless preventive efforts are undertaken (3).

Underlying the increasing prevalence of diabetes, globally and in Bangladesh, are complex genetic, environmental and lifestyle factors, including changes in dietary habits and increases in risk factors like smoking and physical inactivity (2). Effective interventions are available to prevent type 2 Diabetes mellitus (T2DM), and to prevent the complications and premature death from diabetes (2). The evidence from LMICs shows that lifestyle and other non-pharmacological interventions can prevent and delay the onset of T2DM and its complications (5). However, there is a lack of cost effective programs designed specifically for Bangladeshi populations, taking into account their contextual needs and resources.

### The Bangladesh D-Magic Trial

The Bangladesh D-magic is a three-arm cluster randomised control trial (cRCT) of mHealth and community mobilisation interventions, conducted in four rural upazilas in Faridpur district, Bangladesh. The trial aims to assess the effectiveness and cost-effectiveness of the interventions in the prevention and control of T2DM and NCD risk factors in rural Bangladesh. In the D-magic trial, the clusters (96 villages) were randomised to receive either the mHealth intervention, the community mobilisation intervention, or be in the control arm (32 in each). In the mHealth intervention, individuals receive voice messages about prevention and control of NCD risk factors and T2DM on their mobile phone. In the community mobilisation intervention, a trained facilitator initiates a series of diabetes and NCD risk-factor focused monthly group meetings for men and women, working through a participatory learning and action (PLA) cycle by which group members themselves identify, prioritise and tackle

1  
2  
3 problems associated with T2DM and its risk factors. In addition, all study areas (both  
4 intervention and control) clusters receive health system strengthening activities,  
5 which include the training/refresher training of health care workers working in the  
6 community and health facilities, in the prevention, diagnosis and treatment of T2DM,  
7 as well as the development of essential equipment inventories.

8  
9 Details of the D-Magic trial are described in detail elsewhere (6). This protocol paper  
10 aims to fully describe the methodology for the economic evaluation of the trial.  
11

## 12 13 **Economic evaluations of community and mHealth interventions for prevention 14 and control of diabetes** 15

16  
17 There is evidence that mHealth programs can have a positive impact on behaviour  
18 change and prevention and control of diabetes and NCDs in high-risk populations (7-  
19 10). However, there is little information on the cost and cost-effectiveness of mHealth  
20 interventions for the prevention and control of NCDs (11-13). Two recent systematic  
21 reviews of the economic evidence of mHealth (12), and mHealth for diabetes  
22 prevention and control (13), have shown that there are a handful of NCD and diabetes  
23 interventions that have reported cost and cost effectiveness evidence. Nearly all of  
24 these studies have been conducted in high-income settings. The majority of these  
25 studies report that mHealth interventions are cost-effective or cost saving, though the  
26 quality of reported evidence was not satisfactory in some of cases (12, 13).  
27  
28

29  
30 Similarly, although there is some evidence on effectiveness of community-based  
31 interventions in the management of T2DM in low-income settings (14-18), there is  
32 little evidence on how cost effective these interventions might be (13). A recent  
33 review (13) has identified 10 community-based interventions on preventing and  
34 controlling diabetes. These interventions, which are largely implemented in high-  
35 income settings, have reported that community-based interventions are cost-effective  
36 or cost-saving approaches in the management of T2DM (13).  
37  
38

39  
40 The current study will be the first to assess the cost-effectiveness of community  
41 mobilisation through PLA in the prevention of T2DM. This approach has previously  
42 been shown to be highly cost-effective in improving maternal and newborn health  
43 (19, 20). This study will also contribute to the evidence on cost-effectiveness of  
44 mHealth interventions for preventing T2DM in LMIC settings.  
45  
46

## 47 **Aim and objectives**

48  
49 The D-Magic economic evaluation aims to measure the cost-effectiveness of mHealth  
50 and participatory community group interventions to prevent and to control T2DM and  
51 NCD risk factors in rural Bangladesh from a societal perspective.

52 The specific objectives of the D-Magic economic evaluation are:

- 53  
54 1. To estimate the costs of setting up and implementing the mHealth and  
55 participatory community group interventions as well as health system  
56 strengthening (HSS) activities;  
57  
58

2. To calculate the costs to the healthcare system, of increased care-seeking (i.e. diagnosis and treatment) for T2DM and other NCDs, as a result of the D-Magic interventions;
3. To measure costs associated to the intervention participants and their households of changes in diabetes or other NCD-related diagnosis and management care-seeking costs as well as any costs associate with changes in diet and other life-style behaviours, as a result of the D-Magic interventions;
4. To present the incremental costs and outcomes of the interventions as a cost-consequence analysis;
5. To calculate the incremental cost-effectiveness of the mHealth and community mobilisation interventions combined with HSS activities, as compared to HSS activities alone, where all new HSS activities are delivered in addition to the existing government programmes.

## METHODS

### Study setting and population

The study setting for the D-Magic trial is Faridpur district, located south of Dhaka. The district has a population of over 1.7 million people in a high-density area of just over 2000 square kilometres. It is primarily an agricultural economy, with the main crops being jute and rice. Like in the rest of Bangladesh, healthcare is provided at three levels: primary care is provided at Community Clinics and at Union Health and Family Welfare Centres; secondary level care providers (both in- and out-patient services) are sub-district (Upazilla) health complexes and hospitals; and tertiary care is provided at district hospitals and medical college hospitals (21). Private and informal service providers are also present in the area, with the informal sector being the main provider in rural areas (21), Faridpur district included. Inadequate and inequitable access to services, shortages of skilled health care providers, short supplies of medicines and poor quality and low responsiveness of services are the main challenges faced by the Bangladesh healthcare system (21), and remains a challenge in Faridpur district too.

The study population for the D-Magic study are men and non-pregnant women who are aged 30 years or more and permanent residents (i.e. lived there for more than 6 month) of 96 villages (clusters) in four rural upazillas – Nagarkanda, Boalmari, Saltha and Madhukhali – in Faridpur district.

### Trial design

The D-Magic trial is a three-arm cRCT which is implemented in four rural upazilas in Faridpur district, Bangladesh. In D-Magic trial, 96 clusters (villages) were randomised to receive either the mHealth intervention, the community mobilisation intervention, or be in the control arm. All three arms receive a number of health system strengthening activities. The interventions will be completed by end of December and all data collection will be ongoing until May 2018. A brief description of the mHealth, community mobilisation and health system strengthening



1  
2  
3 interventions are presented in the following sections; a full description of the  
4 interventions is presented elsewhere (6).  
5

### 6 **mHealth intervention**

7  
8 The mHealth intervention involves free of charge voice messages about the  
9 prevention and control of T2DM and NCD risk factors sent twice-weekly to the  
10 individual's mobile phone during an 18-month period. The intervention and the  
11 messages' content were developed based on findings from baseline formative  
12 research in the study area, and application of a number of behaviour change theories,  
13 such as the COM-B (Capability, Opportunity, Motivation, Behaviour) theory for  
14 understanding behaviour (22) and the Theoretical Domains Framework (TDF) to  
15 encourage change (23, 24). The mHealth intervention is available to all individuals  
16 who have access to a mobile phone and registered to receive the messages by  
17 providing their mobile number to the intervention community recruiters.  
18  
19  
20

### 21 **Community Mobilisation intervention**

22  
23 The community mobilisation intervention involves initiation and facilitation of  
24 separate male and female participatory groups, with approximately 20 members in  
25 each. The intervention is an adaptation of a participatory women's groups  
26 intervention implemented in South Asia (including Bangladesh) and Sub-Saharan  
27 African settings and shown to be effective and cost effective at reducing neonatal  
28 mortality (20, 25). The groups progress through a series of 18 monthly meetings  
29 following the four phases of PLA. During phase 1, participants identify and prioritise  
30 factors that affect their health, particularly those increasing their risk of developing or  
31 failing to manage T2DM; in phase 2, the participants and their community come up  
32 with feasible strategies that can be implemented to address the problems identified in  
33 phase 1; during phase 3, they implement these strategies; in phase 4 they evaluate the  
34 strategies they have implemented. The groups are run by salaried facilitators, who are  
35 recruited from the study areas and have a minimum of higher secondary school  
36 education. The facilitators undertook one week's training on group facilitation and  
37 basic health messages related to NCD prevention and control, in particular T2DM.  
38 They also have received refresher training during the course of the interventions.  
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### 44 **Health Systems Strengthening (HSS)**

45 A series of health system strengthening activities are carried out in all study areas  
46 (both intervention and control clusters). These activities, which are tailored according  
47 to the mapping of health care providers in the project area in the formative phase of  
48 the project, included the training of mainly informal health care workers in the  
49 community and distributing educational materials among formal and informal  
50 providers in prevention, diagnosis and treatment of T2DM, as well as the  
51 development of essential equipment inventories.  
52  
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### 55 **Measurement of health outcomes/effectiveness**

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2  
3 The D-Magic trial will test the effect of the community mobilisation intervention and  
4 mHealth intervention relative to the control and does not directly compare the effects  
5 of each intervention relative to the other. Analysis of the outcomes will be by  
6 intention to treat at the individual and cluster level as appropriate. Moreover,  
7 participants with missing data on the primary outcomes will be excluded from  
8 primary outcome analysis (6).  
9

#### 10 11 Primary outcome

12 The D-Magic trial has two primary outcomes: (1) combined prevalence of  
13 intermediate hyperglycaemia (i.e. impaired fasting glucose or impaired glucose  
14 tolerance) and T2DM, and (2) cumulative two-year incidence of T2DM among  
15 individuals identified with intermediate hyperglycaemia at the start of the trial (6).  
16 Using the prevalence data, the number of intermediate hyperglycaemia and diabetes  
17 mellitus cases prevented, and the number of diabetes cases prevented among  
18 individuals with intermediate hyperglycaemia at baseline will be calculated as the  
19 difference between the expected and the actual number of cases using the adjusted  
20 odds ratio relative to the control population.  
21  
22  
23

#### 24 25 Secondary outcomes

26 The trial has a number of secondary outcomes including diastolic and systolic blood  
27 pressure, prevalence of hypertension, body mass index, prevalence of overweight and  
28 obesity, prevalence of abdominal obesity, health-related quality of life, and  
29 psychological distress among self-reported diabetics (6).  
30

31 Comparison will be made between the interventions (mHealth and community  
32 mobilisation) and control (HSS activities only) to estimate incremental cost-  
33 effectiveness ratios (ICERs) for the primary outcomes; in terms of cost per case of  
34 intermediate hyperglycaemia and diabetes mellitus prevented and cost per case of  
35 diabetes prevented among individuals with intermediate hyperglycaemia at baseline,  
36 and for some of the secondary outcomes such as cost- per mm Hg reduction in  
37 systolic BP. ICER will be conducted if a significant impact on the outcomes is  
38 observed. Moreover, all costs and (statistically significant) outcomes, both primary  
39 and secondary, will be presented separately in a cost-consequence analysis.  
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#### 44 **Willingness to pay/Contingent Valuation study**

45 We will conduct a willingness to pay (WTP) study in order to elicit maximum  
46 monthly amount of money each participant or household would be willing to pay if an  
47 m-Health service on diabetes and NCD risk factors' prevention and management (i.e.  
48 weekly voice messages) was available.  
49

50 WTP studies are widely used in order to elicit monetary value of a service or good not  
51 available in the market (26-29). In the Bangladesh context, Islam et al (2015) in a  
52 recent study estimated WTP of T2DM patients for receiving messages for increasing  
53 adherence to treatment (30). Similar to Islam et al (2015), we will use an open-ended  
54 contingent valuation (CV) method (26, 29, 31), asking participants through an open-  
55 ended question how much they would be willing to pay monthly to receive voice  
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3 messages related to diabetes and NCD risk factors' prevention and management, if  
4 such a service was available. Open-ended CV is a more flexible approach and avoids  
5 starting point bias or range bias introduced by other methods such bidding game and  
6 payment cards (26). The theoretical framework defined by O'Brien and Gafni (27) for  
7 CV studies will be used to design the study.

8  
9 WTP questions will be asked from all the participants at the end-line impact  
10 evaluation survey. WTP values will be compared across different groups, for  
11 example, based on exposure to the interventions (i.e. among those exposed to  
12 mHealth, or exposed to participatory groups, and participants who have not been  
13 exposed to either of these interventions) or health condition (people diagnosed with  
14 diabetes or other NCDs and others). In addition, for each participant, detailed  
15 individual and household level socio-economic characteristics will be collected to  
16 examine the extent to which WTP values will vary by socio-economic status of  
17 participants.  
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### 22 **Equity impact of the D-Magic interventions**

23 In addition to measuring efficiency/cost-effectiveness of the D-Magic interventions,  
24 an analysis of equity impact of the interventions will be conducted to assess whether  
25 impacts/gains from the intervention are equitably shared among the target population.  
26 This will be done through sub-group analyses of the primary and secondary outcomes  
27 based on the socio-economic status of the target population.  
28  
29

### 30 **Identification, measurement and valuation of resource use**

31 The cost-effectiveness and cost-consequence of the D-Magic interventions will be  
32 measured from a societal perspective (32, 33); measuring the economic impact for all  
33 parties affected by the interventions, including implementing agency (or program  
34 costs), public healthcare providers (at both local and national levels) and users, who  
35 are the intervention participants and their households. The following sections provide  
36 a detailed description of the proposed methods for measuring and valuing programme  
37 costs, healthcare provider costs and participants/household costs. Programme costs  
38 include those incurred by the implementing agency or program provider i.e. Diabetic  
39 Association of Bangladesh (BADAS). The healthcare provider costs are those  
40 incurred by the government health facilities in the study area including community  
41 clinics, Health & Family Welfare centres and Upazila Health Complex/hospitals. The  
42 household or user costs include those incurred by participants and their households.  
43 Table 1 provides an overview of the financial and economic costs to be employed in  
44 the economic evaluation of the D-Magic interventions.  
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### 50 **Programme-related costs**

51 Direct and indirect costs of designing and implementing mHealth, community  
52 mobilisation and health system strengthening interventions will be estimated using a  
53 combination of activity-based costing (34) and ingredients approach (35).  
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56 Financial or expenditure data  
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3 Programme costs are mainly financial or accounting costs, which are collected  
4 prospectively from the project accounts or expenditure records of the implementing  
5 partner and entered (generally, on an annual basis) to an MS Excel data capture tool.  
6 The tool contains different sections/worksheets that will allow the categorization of  
7 costs into line items (i.e. staff, materials, capital, and joint costs), start up and  
8 implementation costs of the interventions, and costs associated with the different  
9 programme components, i.e. m-Health, community mobilization, HSS, and  
10 monitoring and evaluation. Key informant interviews with project leads and  
11 monthly/quarterly staff time sheets will be used to allocate joint costs between the  
12 programme components. The summary worksheets in the cost data capture tool  
13 present the costs by programme component (e.g. mHealth, community mobilisation  
14 and HSS), summarise the total cost data per intervention, allows effect data to be  
15 entered and estimates the cost-effectiveness results.  
16  
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#### 20 Donated items and opportunity costs

21 Some items, such as donated items and volunteer time, are not captured in the  
22 accounting system and need to be converted to economic costs using their market  
23 value and then entered into the data capture tool (36-38). Potential donated items are  
24 equipment donated by the implementing agency (i.e. purchased by previous projects  
25 and used in the D-Magic project). The donated items will be identified through key  
26 informant interviews with the project leads.  
27

28 The majority of volunteer time is related to designing messages for the mHealth  
29 intervention, where several meetings were held with experts who were volunteers.  
30 Detailed information regarding these meetings, including the number of meetings,  
31 their duration, and the participants is being documented by the project. The  
32 opportunity cost of the time invested by the experts will be measured as a proportion  
33 of their salary or a salary equivalent using published national/local wage rate reports.  
34  
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37

#### 38 **Public healthcare providers costs**

39 The D-Magic project is likely (at least in the short term) to increase seeking care for  
40 diabetes, other NCDs and NCD risk factors such as hypertension, particularly demand  
41 for services such as testing and treatment for hypertension, diabetes and pre-diabetes,  
42 or seeking advice or treatment for weight control. In addition, there is a time  
43 (opportunity) cost of direct involvement in the HSS activities for the healthcare  
44 providers (Table 1).  
45  
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47

#### 48 Cost of changes in demand for services

49 The costs to public healthcare providers in the project area due to increased (or any  
50 changes in) demand for their services will be estimated. A mapping of the health care  
51 providers in the study area has been completed and 20 functional governmental health  
52 care facilities, at different levels, have been identified. These facilities included 14  
53 Community Clinics, 3 Health & Family Welfare centres and 3 Upazila Health  
54 Complex/Hospitals. A sample of 11 health facilities including 8 community clinics  
55 and 2 Health & Family Welfare centres (with equal numbers in control and  
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3 intervention clusters), as well as one Upazila Health Complex/Hospital (which cover  
4 both control and intervention areas) were selected for baseline audits of diabetes and  
5 NCD services, estimating their resource utilisations and unit costs. Similar audits and  
6 cost data collection will be conducted for the same facilities post-intervention in order  
7 to assess the changes in NCD service utilisation attributable to the D-Magic  
8 interventions. This data will be complemented by health seeking behaviour  
9 information collected from the study participants in control and interventions clusters  
10 at the D-Magic end-line impact evaluation survey. Differences in service utilisation  
11 between intervention and control areas will be attributed to the D-Magic  
12 interventions.

13  
14  
15 A simple audit and cost-capture tool was developed for facility data collection and  
16 piloted with facilities at different levels. Data from the cost-capture tool will be  
17 complemented by the existing data from the facility reports, and published data. Costs  
18 of services provided by the facilities will be estimated using a step-down approach  
19 (39).

20  
21 Any change in demand for services provided in the facilities other than those  
22 mentioned above and the services not covered by them, in intervention areas  
23 compared to the control, will be identified during the trial's routine monitoring and  
24 end-line impact evaluation survey. Any cost of that change in demand will be  
25 calculated using published data on the unit costs of those services.  
26  
27  
28

#### 29 Opportunity cost of HSS activities

30 Moreover, as discussed earlier, HSS activities include several training sessions for  
31 health care providers in prevention, diagnosis and treatment of T2DM. Information on  
32 the number of meetings, their duration and participation is being documented by the  
33 project. The opportunity cost of the time spent by the providers will be measured as a  
34 proportion of their salary for formal providers or as a salary equivalent, for informal  
35 providers.  
36  
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#### 39 **Participants and their household costs**

40 D-Magic interventions may influence participants and their households' costs in a  
41 number of ways. These include changes in health seeking behaviour, and changes in  
42 household lifestyles that might affect food and non-food consumption patterns and  
43 spending as well as time spent engaging in physical activities. It also includes the  
44 time (opportunity) cost of participation in the PLA group meetings and participating  
45 in the actions taken by the groups (Table 1).  
46  
47  
48

#### 49 Health care seeking costs

50 D-Magic may increase the participants and their households' seeking advice and care  
51 from both formal and informal providers for testing and treatment for hypertension,  
52 diabetes, pre-diabetes and other NCDs. Information on costs of care seeking are  
53 collected from all the participants recruited in the project, at the baseline and end-line  
54 evaluation surveys. This information will be complemented by the data collected from  
55 the household consumption expenditure survey. The difference in spending for the  
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2  
3 participants and their households will be calculated and compared between  
4 intervention and control areas.  
5

#### 6 Changes in household food and non-food expenditure

7 Changes in food and non-food expenditure will be captured in a comprehensive  
8 household consumption and expenditure survey. The survey will be conducted on a  
9 random sub-sample of 300 households (100 per trial arm) at the end of intervention  
10 period. The changes in the expenditure will be compared between interventions and  
11 control areas.  
12  
13

#### 14 Opportunity cost of participation in the interventions

15 Participating in the PLA group meetings incur some costs to the participants and their  
16 family. These costs include the direct costs (e.g. cost of getting to the group) and time  
17 cost of group participation (e.g. travel time and time spent in the group) and  
18 participating in the actions taken by the group, or changing health and lifestyle  
19 behaviours. Information on the potential direct and time costs will be collected  
20 through a sub-sample survey of 312 group participants (both male and female),  
21 randomly selected. Sample size for the survey was primarily calculated to give  
22 sufficiently accurate estimate of group participants' characteristics.  
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25  
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#### 28 **Cost-effectiveness and cost-consequence analyses**

29 Economic evaluation will be conducted as a within-trial analysis using the intention-  
30 to-treat results, and will be presented in terms of ICERs, calculated as the difference  
31 in total costs of mHealth and community mobilisation interventions (plus HSS  
32 activities) versus HSS activities only (or control), divided by the difference in mean  
33 effects of each interventions versus control (40) (41). As mentioned previously,  
34 ICERs will be evaluated in terms of cost per case of intermediate hyperglycaemia and  
35 T2DM prevented and cost per case of T2DM prevented among individuals with  
36 intermediate hyperglycaemia at baseline, and for some of the secondary outcomes  
37 such as cost- per mm Hg reduction in systolic BP. In addition to ICERs, the economic  
38 evaluation will be presented as a cost-consequence analysis where the incremental  
39 costs and all statistically significant outcomes will be listed separately, allowing  
40 policymakers to compare the costs and all impacts/gains of the D-Magic  
41 interventions. Cost-consequence analysis has been recommended for complex public  
42 health interventions, such as D-Magic, that have multiple health and non-health  
43 impacts, which are difficult to measure in a common outcome unit (41, 42).  
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45 All costs will be presented in 2017 prices in Bangladeshi Taka and International  
46 Dollars (INT\$). All costs will be adjusted for inflation using the Bangladeshi  
47 Consumer Price Index (CPI) and will be converted to 2017 INT\$ using the  
48 Purchasing Power Parity (PPP) conversion factor for Bangladesh. Moreover, both  
49 costs and outcomes will be discounted using a standard discount rate of 3%, as  
50 recommended by WHO-CHOICE (43) and the Gates Reference Case for Economic  
51 Evaluation (44). The impact of uncertainty in key parameters on the cost-  
52 effectiveness results will be assessed through a series of deterministic and  
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3 probabilistic sensitivity analyses. Reporting of the study design, analytical methods  
4 and findings will follow the Consolidated Health Economic Evaluation Reporting  
5 Standards (CHEERS) statement (45). The D-Magic interventions will be judged to be  
6 cost-effective and affordable (though, indirectly) against the WHO-CHOICE  
7 recommendation (43), as well as recently developed cost-effectiveness thresholds  
8 (46).

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10 The possibility of conducting an extended cost-effectiveness analysis (47) alongside  
11 modeling national scale up of the D-Magic interventions will be explored. Moreover,  
12 we will explore the possibility of running a long-term cost-effectiveness analysis  
13 using decision analytical modelling based on the relevant outcomes such as systolic  
14 blood pressure, body mass index, etc. (if statistically significant) to predict future  
15 economic impacts from implementing the D-Magic interventions on the target  
16 population.  
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## 19 20 **CONCLUSION**

21 In order to increase transparency and minimise bias, publication and peer-review of  
22 economic evaluation protocols is encouraged. The economic evaluation of the D-  
23 Magic interventions will contribute to the scarce cost-effectiveness evidence on  
24 mHealth and community mobilisation interventions for preventing diabetes and  
25 NCDs. The findings from this study will provide decision-makers in Bangladesh and  
26 other similar low-resource settings with valuable information to inform any future  
27 implementation of these innovative interventions.  
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## 30 31 32 **Contributors**

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35 HHB, EF, AK, HJ, JM, CK, JS, NB, JK, RH, AKAK, AC and KA contributed to the  
36 study design; HHB, EF, CK, JM contributed to the statistical analyses; SKS, MARC,  
37 NA, KA, BN and TN contributed to data acquisition; HHB was responsible for the  
38 initial drafting of this manuscript; all authors contributed to the review of this  
39 manuscript and provided comments. All authors read and approved the final  
40 manuscript.  
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46 Global Alliance for Chronic Diseases (GACD) Diabetes Programme.  
47  
48

## 49 50 **Competing interests**

51 The authors declare they have no competing interests.  
52

## 53 54 **Ethics approval**

55 The D-Magic trial has been approved by the University College London Research  
56 Ethics Committee (4766/002) and by the Ethical Review Committee of the Diabetic  
57 Association of Bangladesh (BADAS-ERC/EC/t5100246). The trial has been  
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3 registered and assigned an International Standard Randomised Controlled Trial  
4 Number (ISRCTN41083256).  
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Table 1: Overview of resource use and costs measures included in the economic evaluation of the D-Magic interventions.

Perspective/cost category	Type of costs	Description	Sources	Sample size	
<b>Provider</b>	Program/implementing agency	Direct	Costs of implementing mHealth, community mobilisation and HSS interventions	(1) Project accounts of the implementing agencies (2) Interviews with the project staff	N/A
		Indirect	The opportunity cost of volunteer experts attended the mHealth design meetings, donated items, etc.	(1) Project records on numbers of meeting, attendants etc. (2) Published reports on local wage information based on skill category (3) Field offices' inventory information	(1) All meetings held and number of people attended in the meetings will be recorded (2) The list of all equipment in the field offices
	Public healthcare providers	Direct	Changes in utilisation of T2DM and NCD related services at the public health facilities in the study area	(1) Detailed audit and costing study of the health facilities (2) Baseline and end-line cross-sectional surveys (for information on changes in costs of health seeking)	(1) Random sample of health facilities at different levels in both intervention and control areas (2) All participants in the study
		Indirect	The opportunity cost of the time spent by the health care providers attending HSS meetings	(1) Project records on numbers of meeting, attendants etc. (2) Published reports on local wage information based on skill category	All meetings held and number of people attended in the meetings will be recorded
	<b>Participants/households</b>	Direct	Household expenditure on food and non-food	Household consumption expenditure survey	A random sample of 300 households in the study area
			Costs of health seeking for the participants and their households	Baseline and end-line cross-sectional surveys	All participants in the study
Indirect		Opportunity cost of participation in the groups	Group participants survey	A random sample of 312 group participants (both male and female)	

\* HSS: health system strengthening, T2DM: type 2 Diabetes mellitus, NCD: non-communicable diseases

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## CHEERS Tool

Section/item		Item no.	Recommendation	Response
Title and abstract	Title	1	Identify the study as an economic evaluation, or use more specific terms such as “cost-effectiveness analysis” and describe the interventions compared.	Yes
	Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base-case and uncertainty analyses), and conclusions.	Yes
Introduction	Background and objectives	3a	Provide an explicit statement of the broader context for the study.	Yes
		3b	Present the study question and its relevance for health policy or practice decisions.	Yes
	Target population and subgroups	4	Describe characteristics of the base-case population and subgroups analyzed including why they were chosen.	Yes
	Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	Yes
	Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	Yes
	Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	Yes
	Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	Yes
	Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	Yes
	Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	Yes
	Methods	Measurement of effectiveness	11 a)	Single study–based estimates: Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.
11 b)			Synthesis-based estimates: Describe fully the methods used for the identification of included studies and synthesis of clinical effectiveness data.	n/a
Measurement and valuation of preference based outcomes		12	If applicable, describe the population and methods used to elicit preferences for outcomes.	n/a
Estimating resources and costs		13 a)	Single study–based economic evaluation: Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	Yes
		13 b)	Model-based economic evaluation: Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	n/a

	Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	Yes
	Choice of model	15	Describe and give reasons for the specific type of decision-analytic model used. Providing a figure to show model structure is strongly recommended.	n/a
	Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytic model.	n/a
	Analytical methods	17	Describe all analytic methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (e.g., half-cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	Yes
Results	Study parameters	18	Report the values, ranges, references, and if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	Not possible in the protocol although the process is described
	Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	Not possible in the protocol although the process is described
	Characterising uncertainty	20 a	Single study-based economic evaluation: Describe the effects of sampling uncertainty for estimated incremental cost, incremental effectiveness, and incremental cost-effectiveness, together with the impact of methodological assumptions (such as discount rate, study perspective).	Not possible in the protocol although the process is described
		20 b	Model-based economic evaluation: Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	n/a
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	Not possible in the protocol although the process is described	
Discussion	Study findings, limitations, generalisability, and current knowledge	22	Summarize key study findings and describe how they support the conclusions reached. Discuss limitations and the generalizability of the findings and how the findings fit with current knowledge	Not possible in the protocol although the process is described
	Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other nonmonetary sources of support.	Yes
Other	Conflicts of interest	24	Describe any potential for conflict of interest among study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors' recommendations.	Yes

# BMJ Open

## Protocol of economic evaluation and equity impact of m-Health and community groups for prevention and control of diabetes in rural Bangladesh: a three-arm cluster randomised controlled trial.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-022035.R1
Article Type:	Protocol
Date Submitted by the Author:	16-May-2018
Complete List of Authors:	Haghparsat-Bidgoli, Hassan; University College London, Institute for Global Health Shaha, Sanjit ; Diabetic Association of Bangladesh Kuddus, Abdul; Diabetic Association of Bangladesh, Perinatal Care Project Chowdhury, Md.Alimul Reza ; Diabetic Association of Bangladesh Jennings, Hannah ; University College London, Institute for Global Health Ahmed, Naveed; Diabetic Association of Bangladesh Morrison, Joanna; University College London, Institute for Global Health Aker, Kohenour; Diabetic Association of Bangladesh Nahar, Badrun ; Diabetic Association of Bangladesh Nahar, Tasmin ; Diabetic Association of Bangladesh King, C.; UCL, Institute for Global Health Skordis-Worrall, Jolene; University College London Medical School, Batura, Neha; University College London, Institute for Global Health Khan, Jahangir; Liverpool School of Tropical Medicine, Health Economics Mansaray, Anthony ; ICAP Sierra Leone Hunter, Rachael; University College London, Research Dept of Primary Care and Population Health Azad Khan, A.K. ; Diabetic Association of Bangladesh Costello, Anthony ; University College London, Institute for Global Health; World Health Organisation Azad, Kishwar; Diabetic Association of Bangladesh, Fottrell, Edward; University College London, Institute for Global Health
<b>Primary Subject Heading</b>:	Health economics
Secondary Subject Heading:	Diabetes and endocrinology, Global health, Health policy, Health services research, Public health
Keywords:	HEALTH ECONOMICS, DIABETES & ENDOCRINOLOGY, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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3 **Protocol of economic evaluation and equity impact of m-Health and community**  
4 **groups for prevention and control of diabetes in rural Bangladesh: a three-arm**  
5 **cluster randomised controlled trial.**  
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**Abstract**

*Introduction:* Type 2 Diabetes mellitus (T2DM) is one of the leading causes of death and disability worldwide, generating substantial economic burden for people with diabetes and their families, and to health systems and national economies. Bangladesh has one of the largest numbers of adults with diabetes in the South Asian region. This paper describes the planned economic evaluation of a three-arm cluster randomised control trial of mHealth and community mobilisation interventions to prevent and control T2DM and non-communicable diseases' risk factors in rural Bangladesh (D-Magic trial).

*Methods and Analysis:* The economic evaluation will be conducted as a within-trial analysis to evaluate the incremental costs and health outcomes of mHealth and community mobilisation interventions compared to the status quo. The analyses will be conducted from a societal perspective, assessing the economic impact for all parties affected by the interventions, including implementing agencies (program costs), health care providers, and participants and their households. Incremental cost-effectiveness ratios (ICERs) will be calculated in terms of cost per case of intermediate hyperglycaemia and T2DM prevented and cost per case of diabetes prevented among individuals with intermediate hyperglycaemia at baseline, and cost-per mm Hg reduction in systolic blood pressure. In addition to ICERs, the economic evaluation will be presented as a cost-consequence analysis where the incremental costs and all statistically significant outcomes will be listed separately. Robustness of the results will be assessed through sensitivity analyses. In addition, an analysis of equity impact of the interventions will be conducted.

*Ethics and Dissemination:* The approval to conduct the study was obtained by the University College London Research Ethics Committee (4766/002) and by the Ethical Review Committee of the Diabetic Association of Bangladesh (BADAS-ERC/EC/t5100246). The findings of this study will be disseminated through different means within academia and the wider policy sphere.

*Trial registration:* ISRCTN41083256. Registered 30/03/2016

### Strengths and limitations of this study

- This protocol paper reports planned data collection and analyses alongside a complex public health trial to ensure transparency.
- This protocol can assist in designing mHealth and community mobilisation through Participatory Learning and Action Approach interventions for the prevention of diabetes and mitigation of NCDs risk factors.
- The protocol, and planned analysis and reporting follow recommended guidelines to design and report economic evaluations.
- An equity impact analysis and contingent valuation study will be conducted alongside the study.
- The study is powered to assess the cost-effectiveness of each intervention against control only. The study is not powered to test the differences between the mHealth and community mobilisation interventions. Therefore, it will be possible to estimate incremental cost and effect of each intervention compared to the control only.

## BACKGROUND

### Burden of diabetes mellitus

Diabetes mellitus, mainly type 2, is a one of the leading causes of death and disability worldwide. It is estimated that around 415 million people worldwide, or 9% of adults aged 20-79 have diabetes, with about 75% of people living with diabetes residing in low- and middle-income countries (LMICs) (1). It is predicted that by 2040, one in 10 adults will have diabetes, unless preventive efforts are undertaken (1). Diabetes, if not managed properly, can lead to several complications, such as heart attack, kidney failure, leg amputation, vision loss and several other long-term consequences, that impact significantly on quality of life and cause premature death (1, 2). Diabetes and its complications create a substantial economic burden for people with diabetes and their families, and for health systems and national economies through direct medical costs and productivity loss (2). It is reported that in many countries between 5% and 20% of total health expenditure are spent on diabetes (1). This is in addition to the large financial burden on individuals and their families due to the cost of seeking care.

Bangladesh has the second largest number of adults with diabetes in the South Asian region, with around 7 million adults aged 20-79 years with diabetes (1). The prevalence of diabetes among adults (20-79 years old) in Bangladesh is estimated to be around 8.5 % (1, 2), with a three to four-fold increase since the 1990s (3, 4). It is predicted that prevalence of diabetes in Bangladesh will reach 23.6% in men and 33.5% in women by 2030, unless preventive efforts are undertaken (3). The increasingly high incidence of diabetes in Bangladesh has had a significant economic burden, in particular for people with diabetes, their families and the country's health care system. It is estimated that the annual health expenditure for diabetes is around US\$218 million, where most of the costs born by the families (5).

Underlying the increasing prevalence of diabetes, globally and in Bangladesh, are complex genetic, environmental and lifestyle factors, including changes in dietary habits and increases in risk factors like smoking and physical inactivity (2). Effective interventions are available to prevent type 2 Diabetes mellitus (T2DM), and to prevent the complications and premature death from diabetes (2). The evidence from LMICs shows that lifestyle and other non-pharmacological interventions can prevent and delay the onset of T2DM and its complications (6). However, there is a lack of cost effective programs designed specifically for Bangladeshi populations, taking into account their contextual needs and resources.

### The Bangladesh D-Magic Trial

The Bangladesh D-magic is a three-arm cluster randomised control trial (cRCT) of mHealth and community mobilisation interventions, conducted in four rural upazilas in Faridpur district, Bangladesh. The trial aims to assess the effectiveness and cost-effectiveness of the interventions in the prevention and control of T2DM and NCD risk factors in rural Bangladesh. In the D-magic trial, the clusters (96 villages) were

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3 randomised to receive either the mHealth intervention, the community mobilisation  
4 intervention, or be in the control arm (32 in each). In the mHealth intervention,  
5 individuals receive voice messages about prevention and control of NCD risk factors  
6 and T2DM on their mobile phone. In the community mobilisation intervention, a  
7 trained facilitator initiates a series of diabetes and NCD risk-factor focused monthly  
8 group meetings for men and women, working through a participatory learning and  
9 action (PLA) cycle by which group members themselves identify, prioritise and tackle  
10 problems associated with T2DM and its risk factors. In addition, all study areas (both  
11 intervention and control) clusters receive health system strengthening activities,  
12 which include the training/refresher training of health care workers working in the  
13 community and health facilities, in the prevention, diagnosis and treatment of T2DM,  
14 as well as the development of essential equipment inventories.

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18 Details of the D-Magic trial are described in detail elsewhere (7). This protocol paper  
19 aims to fully describe the methodology for the economic evaluation of the trial.  
20

### 21 **Economic evaluations of community and mHealth interventions for prevention** 22 **and control of diabetes** 23

24  
25 There is evidence that mHealth programs can have a positive impact on behaviour  
26 change and prevention and control of diabetes and NCDs in high-risk populations (8-  
27 11). However, there is little information on the cost and cost-effectiveness of mHealth  
28 interventions for the prevention and control of NCDs (12-14). Two recent systematic  
29 reviews of the economic evidence of mHealth (13), and mHealth for diabetes  
30 prevention and control (14), have shown that there are a handful of NCD and diabetes  
31 interventions that have reported cost and cost effectiveness evidence. Nearly all of  
32 these studies have been conducted in high-income settings. The majority of these  
33 studies report that mHealth interventions are cost-effective or cost saving, though the  
34 quality of reported evidence was not satisfactory in some of cases (13, 14).  
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39 Similarly, although there is some evidence on effectiveness of community-based  
40 interventions in the management of T2DM in low-income settings (15-19), there is  
41 little evidence on how cost effective these interventions might be (14). A recent  
42 review (14) has identified 10 community-based interventions on preventing and  
43 controlling diabetes. These interventions, which are largely implemented in high-  
44 income settings, have reported that community-based interventions are cost-effective  
45 or cost-saving approaches in the management of T2DM (14).  
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49 The current study will be the first to assess the cost-effectiveness of community  
50 mobilisation through PLA in the prevention of T2DM. This approach has previously  
51 been shown to be highly cost-effective in improving maternal and newborn health  
52 (20, 21). This study will also contribute to the evidence on cost-effectiveness of  
53 mHealth interventions for preventing T2DM in LMIC settings.  
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### 56 **Aim and objectives** 57 58 59

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3 The D-Magic economic evaluation aims to measure the cost-effectiveness of mHealth  
4 and participatory community group interventions to prevent and to control T2DM and  
5 NCD risk factors in rural Bangladesh from a societal perspective.

6 The specific objectives of the D-Magic economic evaluation are:

- 7 1. To estimate the costs of setting up and implementing the mHealth and  
8 participatory community group interventions as well as health system  
9 strengthening (HSS) activities;
- 10 2. To calculate the costs to the healthcare system, of increased care-seeking (i.e.  
11 diagnosis and treatment) for T2DM and other NCDs, as a result of the D-  
12 Magic interventions;
- 13 3. To measure costs associated to the intervention participants and their  
14 households of changes in diabetes or other NCD-related diagnosis and  
15 management care-seeking costs as well as any costs associate with changes in  
16 diet and other life-style behaviours, as a result of the D-Magic interventions;
- 17 4. To present the incremental costs and outcomes of the interventions as a cost-  
18 consequence analysis;
- 19 5. To calculate the incremental cost-effectiveness of the mHealth and community  
20 mobilisation interventions combined with HSS activities, as compared to HSS  
21 activities alone, where all new HSS activities are delivered in addition to the  
22 existing government programmes.

23  
24 In addition to the above-mentioned objectives, the equity impact of the mHealth and  
25 community mobilisation interventions will be assessed.  
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## 28 **METHODS**

### 29 **Study setting and population**

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31 The study setting for the D-Magic trial is Faridpur district, located south of Dhaka.  
32 The district has a population of over 1.7 million people in a high-density area of just  
33 over 2000 square kilometres. It is primarily an agricultural economy, with the main  
34 crops being jute and rice. Like in the rest of Bangladesh, healthcare is provided at  
35 three levels: primary care is provided at Community Clinics and at Union Health and  
36 Family Welfare Centres; secondary level care providers (both in- and out-patient  
37 services) are sub-district (Upazilla) health complexes and hospitals; and tertiary care  
38 is provided at district hospitals and medical college hospitals (22). Private and  
39 informal service providers are also present in the area, with the informal sector being  
40 the main provider in rural areas (22), Faridpur district included. Inadequate and  
41 inequitable access to services, shortages of skilled health care providers, short  
42 supplies of medicines and poor quality and low responsiveness of services are the  
43 main challenges faced by the Bangladesh healthcare system (22), and remains a  
44 challenge in Faridpur district too.  
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52 The study population for the D-Magic study are men and non-pregnant women who  
53 are aged 30 years or more and permanent residents (i.e. lived there for more than 6  
54 month) of 96 villages (clusters) in four rural upazillas – Nagarkanda, Boalmari, Saltha  
55 and Madhukhali – in Faridpur district.  
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### **Trial design**

The D-Magic trial is a three-arm cRCT which is implemented in four rural upazilas in Faridpur district, Bangladesh. In D-Magic trial, 96 clusters (villages) were randomised to receive either the mHealth intervention, the community mobilisation intervention, or be in the control arm. All three arms receive a number of health system strengthening activities. The interventions implementation was started in July 2016 and will be completed by end of December 2017 and all data collection will be ongoing until June 2018.

Detailed information on the randomisation and participants recruitment process, trial time-line, and a full description of the interventions is presented elsewhere (7). A brief description of the mHealth, community mobilisation and health system strengthening interventions are presented in the following sections.

### **mHealth intervention**

The mHealth intervention involves free of charge voice messages about the prevention and control of T2DM and NCD risk factors sent twice-weekly to the individual's mobile phone during a 14-month period. The intervention and the messages' content were developed based on findings from baseline formative research in the study area, and application of the behaviour change theories the COM-B (Capability, Opportunity, Motivation, Behaviour) model for understanding behaviour (23) and the Theoretical Domains Framework (TDF) to encourage change (24, 25). The mHealth intervention is available to all individuals who have access to a mobile phone and registered to receive the messages by providing their mobile number to the intervention community recruiters.

### **Community Mobilisation intervention**

The community mobilisation intervention involves initiation and facilitation of separate male and female participatory groups, with approximately 20 members in each. The intervention is an adaptation of a participatory women's groups intervention implemented in South Asia (including Bangladesh) and Sub-Saharan African settings and shown to be effective and cost effective at reducing neonatal mortality (21, 26). The groups progress through a series of 18 monthly meetings following the four phases of PLA. During phase 1, participants identify and prioritise factors that affect their health, particularly those increasing their risk of developing or failing to manage T2DM; in phase 2, the participants and their community come up with feasible strategies that can be implemented to address the problems identified in phase 1; during phase 3, they implement these strategies; in phase 4 they evaluate the strategies they have implemented. The groups are run by salaried facilitators, who are recruited from the study areas and have a minimum of higher secondary school education. The facilitators undertook one week's training on group facilitation and basic health messages related to NCD prevention and control, in particular T2DM. They also have received refresher training during the course of the interventions.

### **Health Systems Strengthening (HSS)**



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3 A series of health system strengthening activities are carried out in all study areas  
4 (both intervention and control clusters). These activities, which are tailored according  
5 to the mapping of health care providers in the project area in the formative phase of  
6 the project, included the training of mainly informal health care workers in the  
7 community and distributing educational materials among formal and informal  
8 providers in prevention, diagnosis and treatment of T2DM, as well as the  
9 development of essential equipment inventories.  
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### 12 **Measurement of health outcomes/effectiveness**

13 The D-Magic trial will test the effect of the community mobilisation intervention and  
14 mHealth intervention relative to the control and does not directly compare the effects  
15 of each intervention relative to the other. As this is a cluster-randomised trial, the  
16 outcomes will be measured among individuals (permanent residents) who live in the  
17 intervention clusters, irrespective of whether they took part in groups or received  
18 mHealth messages. Analysis of the outcomes will be by intention to treat at the  
19 individual and cluster level as appropriate. Moreover, participants with missing data  
20 on the primary outcomes will be excluded from primary outcome analysis (7).  
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#### 25 **Primary outcome**

26 The D-Magic trial has two primary outcomes: (1) combined prevalence of  
27 intermediate hyperglycaemia (i.e. impaired fasting glucose or impaired glucose  
28 tolerance) and T2DM, and (2) cumulative two-year incidence of T2DM among  
29 individuals identified with intermediate hyperglycaemia at the start of the trial (7).  
30 Using the prevalence data, the number of intermediate hyperglycaemia and diabetes  
31 mellitus cases prevented, and the number of diabetes cases prevented among  
32 individuals with intermediate hyperglycaemia at baseline will be calculated as the  
33 difference between the expected and the actual number of cases using the adjusted  
34 odds ratio relative to the control population.  
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#### 39 **Secondary outcomes**

40 The trial has a number of secondary outcomes including diastolic and systolic blood  
41 pressure, prevalence of hypertension, body mass index, prevalence of overweight and  
42 obesity, prevalence of abdominal obesity, health-related quality of life, and  
43 psychological distress among self-reported diabetics (7).  
44

45 Comparison will be made between the interventions (mHealth and community  
46 mobilisation) and control (HSS activities only) to estimate incremental cost-  
47 effectiveness ratios (ICERs) for the primary outcomes; in terms of cost per case of  
48 intermediate hyperglycaemia and diabetes mellitus prevented and cost per case of  
49 diabetes prevented among individuals with intermediate hyperglycaemia at baseline,  
50 and for some of the secondary outcomes such as cost- per mm Hg reduction in  
51 systolic BP. ICER will be conducted if a significant impact on the outcomes is  
52 observed. Moreover, all costs and (statistically significant) outcomes, both primary  
53 and secondary, will be presented separately in a cost-consequence analysis.  
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### **Willingness to pay/Contingent Valuation study**

We will conduct a willingness to pay (WTP) study in order to elicit maximum monthly amount of money each participant or household would be willing to pay if an m-Health service on diabetes and NCD risk factors' prevention and management (i.e. weekly voice messages) was available.

WTP studies are widely used in order to elicit monetary value of a service or good not available in the market (27-30). In the Bangladesh context, Islam et al (2015) in a recent study estimated WTP of T2DM patients for receiving messages for increasing adherence to treatment (31). Similar to Islam et al (2015), we will use an open-ended contingent valuation (CV) method (27, 30, 32), asking participants through an open-ended question how much they would be willing to pay monthly to receive voice messages related to diabetes and NCD risk factors' prevention and management, if such a service was available. Open-ended CV is a more flexible approach and avoids starting point bias or range bias introduced by other methods such bidding game and payment cards (27). The theoretical framework defined by O'Brien and Gafni (28) for CV studies will be used to design the study.

WTP questions will be asked from all the participants at the end-line impact evaluation survey. WTP values will be compared across different groups, for example, based on exposure to the interventions (i.e. among those exposed to mHealth, or exposed to participatory groups, and participants who have not been exposed to either of these interventions) or health condition (people diagnosed with diabetes or other NCDs and others). In addition, for each participant, detailed individual and household level socio-economic characteristics will be collected to examine the extent to which WTP values will vary by socio-economic status of participants.

### **Equity impact of the D-Magic interventions**

In addition to measuring efficiency/cost-effectiveness of the D-Magic interventions, an analysis of equity impact of the interventions will be conducted to assess whether impacts/gains from the intervention are equitably shared among the target population. This will be done through sub-group analyses of the primary and secondary outcomes based on the socio-economic status of the target population.

### **Identification, measurement and valuation of resource use**

The cost-effectiveness and cost-consequence of the D-Magic interventions will be measured from a societal perspective (33, 34); measuring the economic impact for all parties affected by the interventions, including implementing agency (or program costs), public healthcare providers (at both local and national levels) and users, who are the intervention participants and their households. The following sections provide a detailed description of the proposed methods for measuring and valuing programme costs, healthcare provider costs and participants/household costs. Programme costs include those incurred by the implementing agency or program provider i.e. Diabetic Association of Bangladesh (BADAS). The healthcare provider costs are those incurred by the government health facilities in the study area including community

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3 clinics, Health & Family Welfare centres and Upazila Health Complex/hospitals. The  
4 household or user costs include those incurred by participants and their households.  
5 Table 1 provides an overview of the financial and economic costs to be employed in  
6 the economic evaluation of the D-Magic interventions.  
7

### 8 9 **Programme-related costs**

10 Direct and indirect costs of designing and implementing mHealth, community  
11 mobilisation and health system strengthening interventions will be estimated using a  
12 combination of activity-based costing (35) and ingredients approach (36).  
13

#### 14 15 **Financial or expenditure data**

16 Programme costs are mainly financial or accounting costs, which are collected  
17 prospectively from the project accounts or expenditure records of the implementing  
18 partner and entered (generally, on an annual basis) to an MS Excel data capture tool.  
19 The tool contains different sections/worksheets that will allow the categorization of  
20 costs into line items (i.e. staff, materials, capital, and joint costs), start up and  
21 implementation costs of the interventions, and costs associated with the different  
22 programme components, i.e. m-Health, community mobilization, HSS, and  
23 monitoring and evaluation. Key informant interviews with project leads and  
24 monthly/quarterly staff time sheets will be used to allocate joint costs between the  
25 programme components. The summary worksheets in the cost data capture tool  
26 present the costs by programme component (e.g. mHealth, community mobilisation  
27 and HSS), summarise the total cost data per intervention, allows effect data to be  
28 entered and estimates the cost-effectiveness results.  
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#### 34 35 **Donated items and opportunity costs**

36 Some items, such as donated items and volunteer time, are not captured in the  
37 accounting system and need to be converted to economic costs using their market  
38 value and then entered into the data capture tool (37-39). Potential donated items are  
39 equipment donated by the implementing agency (i.e. purchased by previous projects  
40 and used in the D-Magic project). The donated items will be identified through key  
41 informant interviews with the project leads.  
42

43 The majority of volunteer time is related to designing messages for the mHealth  
44 intervention, where several meetings were held with experts who were volunteers.  
45 Detailed information regarding these meetings, including the number of meetings,  
46 their duration, and the participants is being documented by the project. The  
47 opportunity cost of the time invested by the experts will be measured as a proportion  
48 of their salary or a salary equivalent using published national/local wage rate reports.  
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#### 51 52 **Public healthcare providers costs**

53 The D-Magic project is likely (at least in the short term) to increase seeking care for  
54 diabetes, other NCDs and NCD risk factors such as hypertension, particularly demand  
55 for services such as testing and treatment for hypertension, diabetes and pre-diabetes,  
56 or seeking advice or treatment for weight control. In addition, there is a time  
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(opportunity) cost of direct involvement in the HSS activities for the healthcare providers (Table 1).

#### Cost of changes in demand for services

The costs to public healthcare providers in the project area due to increased (or any changes in) demand for their services will be estimated. A mapping of the health care providers in the study area has been completed and 20 functional governmental health care facilities, at different levels, have been identified. These facilities included 14 Community Clinics, 3 Health & Family Welfare centres and 3 Upazila Health Complex/Hospitals. A sample of 11 health facilities including 8 community clinics and 2 Health & Family Welfare centres (with equal numbers in control and intervention clusters), as well as one Upazila Health Complex/Hospital (which cover both control and intervention areas) were selected for baseline audits of diabetes and NCD services, estimating their resource utilisations and unit costs. Similar audits and cost data collection will be conducted for the same facilities post-intervention in order to assess the changes in NCD service utilisation attributable to the D-Magic interventions. This data will be complemented by health seeking behaviour information collected from the study participants in control and interventions clusters at the D-Magic end-line impact evaluation survey. Differences in service utilisation between intervention and control areas will be attributed to the D-Magic interventions.

A simple audit and cost-capture tool was developed for facility data collection and piloted with facilities at different levels. Data from the cost-capture tool will be complemented by the existing data from the facility reports, and published data. Costs of services provided by the facilities will be estimated using a step-down approach (40).

Any change in demand for services provided in the facilities other than those mentioned above and the services not covered by them, in intervention areas compared to the control, will be identified during the trial's routine monitoring and end-line impact evaluation survey. Any cost of that change in demand will be calculated using published data on the unit costs of those services.

#### Opportunity cost of HSS activities

Moreover, as discussed earlier, HSS activities include several training sessions for health care providers in prevention, diagnosis and treatment of T2DM. Information on the number of meetings, their duration and participation is being documented by the project. The opportunity cost of the time spent by the providers will be measured as a proportion of their salary for formal providers or as a salary equivalent, for informal providers.

#### **Participants and their household costs**

D-Magic interventions may influence participants and their households' costs in a number of ways. These include changes in health seeking behaviour, and changes in household lifestyles that might affect food and non-food consumption patterns and

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3 spending as well as time spent engaging in physical activities. It also includes the  
4 time (opportunity) cost of participation in the PLA group meetings and participating  
5 in the actions taken by the groups (Table 1).  
6

#### 7 8 Health care seeking costs

9 D-Magic may increase the participants and their households' seeking advice and care  
10 from both formal and informal providers for testing and treatment for hypertension,  
11 diabetes, pre-diabetes and other NCDs. Information on costs of care seeking are  
12 collected from all the participants recruited in the project, at the baseline and end-line  
13 evaluation surveys. This information will be complemented by the data collected from  
14 the household consumption expenditure survey. The difference in spending for the  
15 participants and their households will be calculated and compared between  
16 intervention and control areas.  
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#### 19 20 Changes in household food and non-food expenditure

21 Changes in food and non-food expenditure will be captured in a comprehensive  
22 household consumption and expenditure survey. The survey will be conducted on a  
23 random sub-sample of 300 households (100 per trial arm) at the end of intervention  
24 period. The changes in the expenditure will be compared between interventions and  
25 control areas.  
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#### 28 29 Opportunity cost of participation in the interventions

30 Participating in the PLA group meetings incur some costs to the participants and their  
31 family. These costs include the direct costs (e.g. cost of getting to the group) and time  
32 cost of group participation (e.g. travel time and time spent in the group) and  
33 participating in the actions taken by the group, or changing health and lifestyle  
34 behaviours. Information on the potential direct and time costs will be collected  
35 through a sub-sample survey of 312 group participants (both male and female),  
36 randomly selected. Sample size for the survey was primarily calculated to give  
37 sufficiently accurate estimate of group participants' characteristics.  
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#### 41 42 **Cost-effectiveness and cost-consequence analyses**

43 Economic evaluation will be conducted as a within-trial analysis using the intention-  
44 to-treat results, and will be presented in terms of ICERs, calculated as the difference  
45 in total costs of mHealth and community mobilisation interventions (plus HSS  
46 activities) versus HSS activities only (or control), divided by the difference in mean  
47 effects of each interventions versus control (41) (42). As mentioned previously,  
48 ICERs will be evaluated in terms of cost per case of intermediate hyperglycaemia and  
49 T2DM prevented and cost per case of T2DM prevented among individuals with  
50 intermediate hyperglycaemia at baseline, and for some of the secondary outcomes  
51 such as cost- per mm Hg reduction in systolic BP. In addition to ICERs, the economic  
52 evaluation will be presented as a cost-consequence analysis where the incremental  
53 costs and all statistically significant outcomes will be listed separately, allowing  
54 policymakers to compare the costs and all impacts/gains of the D-Magic  
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3 interventions. Cost-consequence analysis has been recommended for complex public  
4 health interventions, such as D-Magic, that have multiple health and non-health  
5 impacts, which are difficult to measure in a common outcome unit (42, 43).

6 All costs will be presented in 2017 prices in Bangladeshi Taka and International  
7 Dollars (INT\$). All costs will be adjusted for inflation using the Bangladeshi  
8 Consumer Price Index (CPI) and will be converted to 2017 INT\$ using the  
9 Purchasing Power Parity (PPP) conversion factor for Bangladesh. Moreover, both  
10 costs and outcomes will be discounted using a standard discount rate of 3%, as  
11 recommended by WHO-CHOICE (44) and the Gates Reference Case for Economic  
12 Evaluation (45). The impact of uncertainty in key parameters on the cost-  
13 effectiveness results will be assessed through a series of deterministic and  
14 probabilistic sensitivity analyses. Reporting of the study design, analytical methods  
15 and findings will follow the Consolidated Health Economic Evaluation Reporting  
16 Standards (CHEERS) statement (46). The D-Magic interventions will be judged to be  
17 cost-effective and affordable (though, indirectly) against the WHO-CHOICE  
18 recommendation (44), as well as recently developed cost-effectiveness thresholds  
19 (47).

20 The possibility of conducting an extended cost-effectiveness analysis (48) alongside  
21 modeling national scale up of the D-Magic interventions will be explored. Moreover,  
22 we will explore the possibility of running a long-term cost-effectiveness analysis  
23 using decision analytical modelling based on the relevant outcomes such as systolic  
24 blood pressure, body mass index, etc. (if statistically significant) to predict future  
25 economic impacts from implementing the D-Magic interventions on the target  
26 population.

### 27 28 29 30 31 32 33 34 **Strengths and limitations of the study**

35 In order to increase transparency and minimize bias, publication and peer-review of  
36 economic evaluation protocols is encouraged. This study reports planned data  
37 collection and analyses alongside a complex public health trial. The study will  
38 contribute to the scarce cost-effectiveness evidence on mHealth and community  
39 mobilisation interventions for preventing diabetes and NCDs.

40 Furthermore, adopting a cost-consequence analysis approach makes it possible to  
41 report all health and non-health impacts of the D-Magic interventions, in addition to  
42 ICERs, which can assist policy makers to make informed decisions in designing or  
43 implementing similar complex interventions. Incorporating equity impact analysis  
44 and contingent valuation are other strengths of this study, which provide useful  
45 information for future scale-up of the interventions.

46 The study design has one limitation. The D-Magic trial is not powered to test the  
47 differences between the mHealth and community mobilisation interventions due to  
48 the large sample size required and the resources available for the trial. However, the  
49 possibility of a direct comparison between the two interventions will be explored.

### 50 51 52 53 54 55 **Patient and public involvement**

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3 Patients and public were not involved in the process of this study. Patients and public  
4 will be informed of the study results via peer-reviewed journals, conference and local  
5 dissemination meetings.  
6

### 7 **Contributors**

8 HHB, EF, AK, HJ, JM, CK, JS, NB, JK, RH, AKAK, AC and KA contributed to the  
9 study design; HHB, EF, CK contributed to the statistical analyses; SKS, MARC, NA,  
10 KA, BN and TN contributed to data acquisition; AM has contributed to the literature  
11 review and drafting the paper; HHB was responsible for the initial drafting of this  
12 manuscript; all authors contributed to the review of this manuscript and provided  
13 comments. All authors read and approved the final manuscript.  
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19 Global Alliance for Chronic Diseases (GACD) Diabetes Programme.  
20

### 21 **Competing interests**

22 The authors declare they have no competing interests.  
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### 25 **Ethics approval**

26 The D-Magic trial has been approved by the University College London Research  
27 Ethics Committee (4766/002) and by the Ethical Review Committee of the Diabetic  
28 Association of Bangladesh (BADAS-ERC/EC/t5100246). The trial has been  
29 registered and assigned an International Standard Randomised Controlled Trial  
30 Number (ISRCTN41083256). Informed cluster-level consent from village/community  
31 leaders, and individual informed consent was obtained from all participants in the trial  
32 prior to their participation in the study.  
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Table 1: Overview of resource use and costs measures included in the economic evaluation of the D-Magic interventions.

Perspective/cost category	Type of costs	Description	Sources	Sample size	
<b>Provider</b>	Program/implementing agency	Direct	Costs of implementing mHealth, community mobilisation and HSS interventions	(1) Project accounts of the implementing agencies (2) Interviews with the project staff	N/A
		Indirect	The opportunity cost of volunteer experts attended the mHealth design meetings, donated items, etc.	(1) Project records on numbers of meeting, attendants etc. (2) Published reports on local wage information based on skill category (3) Field offices' inventory information	(1) All meetings held and number of people attended in the meetings will be recorded (2) The list of all equipment in the field offices
	Public healthcare providers	Direct	Changes in utilisation of T2DM and NCD related services at the public health facilities in the study area	(1) Detailed audit and costing study of the health facilities (2) Baseline and end-line cross-sectional surveys (for information on changes in costs of health seeking)	(1) Random sample of health facilities at different levels in both intervention and control areas (2) All participants in the study
		Indirect	The opportunity cost of the time spent by the health care providers attending HSS meetings	(1) Project records on numbers of meeting, attendants etc. (2) Published reports on local wage information based on skill category	All meetings held and number of people attended in the meetings will be recorded
	<b>Participants/households</b>	Direct	Household expenditure on food and non-food	Household consumption expenditure survey	A random sample of 300 households in the study area
			Costs of health seeking for the participants and their households	Baseline and end-line cross-sectional surveys	All participants in the study
Indirect		Opportunity cost of participation in the groups	Group participants survey	A random sample of 312 group participants (both male and female)	

\* HSS: health system strengthening, T2DM: type 2 Diabetes mellitus, NCD: non-communicable diseases

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## CHEERS Tool

Section/item		Item no.	Recommendation	Response
Title and abstract	Title	1	Identify the study as an economic evaluation, or use more specific terms such as “cost-effectiveness analysis” and describe the interventions compared.	Yes
	Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base-case and uncertainty analyses), and conclusions.	Yes
Introduction	Background and objectives	3a	Provide an explicit statement of the broader context for the study.	Yes
		3b	Present the study question and its relevance for health policy or practice decisions.	Yes
	Target population and subgroups	4	Describe characteristics of the base-case population and subgroups analyzed including why they were chosen.	Yes
	Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	Yes
	Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	Yes
	Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	Yes
	Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	Yes
	Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	Yes
	Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	Yes
	Methods	Measurement of effectiveness	11 a)	Single study–based estimates: Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.
11 b)			Synthesis-based estimates: Describe fully the methods used for the identification of included studies and synthesis of clinical effectiveness data.	n/a
Measurement and valuation of preference based outcomes		12	If applicable, describe the population and methods used to elicit preferences for outcomes.	n/a
Estimating resources and costs		13 a)	Single study–based economic evaluation: Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	Yes
		13 b)	Model-based economic evaluation: Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	n/a

	Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	Yes
	Choice of model	15	Describe and give reasons for the specific type of decision-analytic model used. Providing a figure to show model structure is strongly recommended.	n/a
	Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytic model.	n/a
	Analytical methods	17	Describe all analytic methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (e.g., half-cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	Yes
Results	Study parameters	18	Report the values, ranges, references, and if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	Not possible in the protocol although the process is described
	Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	Not possible in the protocol although the process is described
	Characterising uncertainty	20 a	Single study-based economic evaluation: Describe the effects of sampling uncertainty for estimated incremental cost, incremental effectiveness, and incremental cost-effectiveness, together with the impact of methodological assumptions (such as discount rate, study perspective).	Not possible in the protocol although the process is described
		20 b	Model-based economic evaluation: Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	n/a
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	Not possible in the protocol although the process is described	
Discussion	Study findings, limitations, generalisability, and current knowledge	22	Summarize key study findings and describe how they support the conclusions reached. Discuss limitations and the generalizability of the findings and how the findings fit with current knowledge	Not possible in the protocol although the process is described
	Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other nonmonetary sources of support.	Yes
Other	Conflicts of interest	24	Describe any potential for conflict of interest among study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors' recommendations.	Yes

# BMJ Open

## Protocol of economic evaluation and equity impact of m-Health and community groups for prevention and control of diabetes in rural Bangladesh in a three-arm cluster randomised controlled trial

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Keywords:	HEALTH ECONOMICS, DIABETES & ENDOCRINOLOGY, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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## Abstract

*Introduction:* Type 2 Diabetes mellitus (T2DM) is one of the leading causes of death and disability worldwide, generating substantial economic burden for people with diabetes and their families, and to health systems and national economies. Bangladesh has one of the largest numbers of adults with diabetes in the South Asian region. This paper describes the planned economic evaluation of a three-arm cluster randomised control trial of mHealth and community mobilisation interventions to prevent and control T2DM and non-communicable diseases' risk factors in rural Bangladesh (D-Magic trial).

*Methods and Analysis:* The economic evaluation will be conducted as a within-trial analysis to evaluate the incremental costs and health outcomes of mHealth and community mobilisation interventions compared to the status quo. The analyses will be conducted from a societal perspective, assessing the economic impact for all parties affected by the interventions, including implementing agencies (program costs), health care providers, and participants and their households. Incremental cost-effectiveness ratios (ICERs) will be calculated in terms of cost per case of intermediate hyperglycaemia and T2DM prevented and cost per case of diabetes prevented among individuals with intermediate hyperglycaemia at baseline, and cost-per mm Hg reduction in systolic blood pressure. In addition to ICERs, the economic evaluation will be presented as a cost-consequence analysis where the incremental costs and all statistically significant outcomes will be listed separately. Robustness of the results will be assessed through sensitivity analyses. In addition, an analysis of equity impact of the interventions will be conducted.

*Ethics and Dissemination:* The approval to conduct the study was obtained by the University College London Research Ethics Committee (4766/002) and by the Ethical Review Committee of the Diabetic Association of Bangladesh (BADAS-ERC/EC/t5100246). The findings of this study will be disseminated through different means within academia and the wider policy sphere.

*Trial registration:* ISRCTN41083256. Registered 30/03/2016

#### Strengths and limitations of this study

- This protocol paper reports planned data collection and analyses alongside a complex public health trial to ensure transparency.
- This protocol can assist in designing mHealth and community mobilisation through Participatory Learning and Action Approach interventions for the prevention of diabetes and mitigation of NCDs risk factors.
- The protocol, and planned analysis and reporting follow recommended guidelines to design and report economic evaluations.
- An equity impact analysis and contingent valuation study will be conducted alongside the study.
- The study is powered to assess the cost-effectiveness of each intervention against control only. The study is not powered to test the differences between the mHealth and community mobilisation interventions. Therefore, it will be possible to estimate incremental cost and effect of each intervention compared to the control only.

## BACKGROUND

### Burden of diabetes mellitus

Diabetes mellitus, mainly type 2, is a one of the leading causes of death and disability worldwide. It is estimated that around 415 million people worldwide, or 9% of adults aged 20-79 have diabetes, with about 75% of people living with diabetes residing in low- and middle-income countries (LMICs) (1). It is predicted that by 2040, one in 10 adults will have diabetes, unless preventive efforts are undertaken (1). Diabetes, if not managed properly, can lead to several complications, such as heart attack, kidney failure, leg amputation, vision loss and several other long-term consequences, that impact significantly on quality of life and cause premature death (1, 2). Diabetes and its complications create a substantial economic burden for people with diabetes and their families, and for health systems and national economies through direct medical costs and productivity loss (2). It is reported that in many countries between 5% and 20% of total health expenditure are spent on diabetes (1). This is in addition to the large financial burden on individuals and their families due to the cost of seeking care.

Bangladesh has the second largest number of adults with diabetes in the South Asian region, with around 7 million adults aged 20-79 years with diabetes (1). The prevalence of diabetes among adults (20-79 years old) in Bangladesh is estimated to be around 8.5 % (1, 2), with a three to four-fold increase since the 1990s (3, 4). It is predicted that prevalence of diabetes in Bangladesh will reach 23.6% in men and 33.5% in women by 2030, unless preventive efforts are undertaken (3). The increasingly high incidence of diabetes in Bangladesh has had a significant economic burden, in particular for people with diabetes, their families and the country's health care system. It is estimated that the annual health expenditure for diabetes is around US\$218 million, where most of the costs born by the families (5).

Underlying the increasing prevalence of diabetes, globally and in Bangladesh, are complex genetic, environmental and lifestyle factors, including changes in dietary habits and increases in risk factors like smoking and physical inactivity (2). Effective interventions are available to prevent type 2 Diabetes mellitus (T2DM), and to prevent the complications and premature death from diabetes (2). The evidence from LMICs shows that lifestyle and other non-pharmacological interventions can prevent and delay the onset of T2DM and its complications (6). However, there is a lack of cost effective programs designed specifically for Bangladeshi populations, taking into account their contextual needs and resources.

### The Bangladesh D-Magic Trial

The Bangladesh D-magic is a three-arm cluster randomised control trial (cRCT) of mHealth and community mobilisation interventions, conducted in four rural upazilas in Faridpur district, Bangladesh. The trial aims to assess the effectiveness and cost-effectiveness of the interventions in the prevention and control of T2DM and NCD risk factors in rural Bangladesh. In the D-magic trial, the clusters (96 villages) were

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3 randomised to receive either the mHealth intervention, the community mobilisation  
4 intervention, or be in the control arm (32 in each). In the mHealth intervention,  
5 individuals receive voice messages about prevention and control of NCD risk factors  
6 and T2DM on their mobile phone. In the community mobilisation intervention, a  
7 trained facilitator initiates a series of diabetes and NCD risk-factor focused monthly  
8 group meetings for men and women, working through a participatory learning and  
9 action (PLA) cycle by which group members themselves identify, prioritise and tackle  
10 problems associated with T2DM and its risk factors. In addition, all study areas (both  
11 intervention and control) clusters receive health system strengthening activities,  
12 which include the training/refresher training of health care workers working in the  
13 community and health facilities, in the prevention, diagnosis and treatment of T2DM,  
14 as well as the development of essential equipment inventories.  
15 Details of the D-Magic trial are described elsewhere (7). This protocol paper aims to  
16 fully describe the methodology for the economic evaluation of the trial.  
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### 21 **Economic evaluations of community and mHealth interventions for prevention** 22 **and control of diabetes** 23 24

25 There is evidence that mHealth programs can have a positive impact on behaviour  
26 change and prevention and control of diabetes and NCDs in high-risk populations (8-  
27 11). However, there is little information on the cost and cost-effectiveness of mHealth  
28 interventions for the prevention and control of NCDs (12-14). Two recent systematic  
29 reviews of the economic evidence of mHealth (13), and mHealth for diabetes  
30 prevention and control (14), have shown that there are a handful of NCD and diabetes  
31 interventions that have reported cost and cost effectiveness evidence. Nearly all of  
32 these studies have been conducted in high-income settings. The majority of these  
33 studies report that mHealth interventions are cost-effective or cost saving, though the  
34 quality of reported evidence was not satisfactory in some of cases (13, 14).  
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39 Similarly, although there is some evidence on effectiveness of community-based  
40 interventions in the management of T2DM in low-income settings (15-19), there is  
41 little evidence on how cost effective these interventions might be (14). A recent  
42 review (14) has identified 10 community-based interventions on preventing and  
43 controlling diabetes. These interventions, which are largely implemented in high-  
44 income settings, have reported that community-based interventions are cost-effective  
45 or cost-saving approaches in the management of T2DM (14).  
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49 The current study will be the first to assess the cost-effectiveness of community  
50 mobilisation through PLA in the prevention of T2DM. This approach has previously  
51 been shown to be highly cost-effective in improving maternal and newborn health  
52 (20, 21). This study will also contribute to the evidence on cost-effectiveness of  
53 mHealth interventions for preventing T2DM in LMIC settings.  
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### 56 **Aim and objectives** 57 58 59 60

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3 The D-Magic economic evaluation aims to measure the cost-effectiveness of mHealth  
4 and participatory community group interventions to prevent and to control T2DM and  
5 NCD risk factors in rural Bangladesh from a societal perspective.

6 The specific objectives of the D-Magic economic evaluation are:

- 7 1. To estimate the costs of setting up and implementing the mHealth and  
8 participatory community group interventions as well as health system  
9 strengthening (HSS) activities;
- 10 2. To calculate the costs to the healthcare system, of increased care-seeking (i.e.  
11 diagnosis and treatment) for T2DM and other NCDs, as a result of the D-  
12 Magic interventions;
- 13 3. To measure costs associated to the intervention participants and their  
14 households of changes in diabetes or other NCD-related diagnosis and  
15 management care-seeking costs as well as any costs associate with changes in  
16 diet and other life-style behaviours, as a result of the D-Magic interventions;
- 17 4. To present the incremental costs and outcomes of the interventions as a cost-  
18 consequence analysis;
- 19 5. To calculate the incremental cost-effectiveness of the mHealth and community  
20 mobilisation interventions combined with HSS activities, as compared to HSS  
21 activities alone, where all new HSS activities are delivered in addition to the  
22 existing government programmes.

23  
24 In addition to the above-mentioned objectives, the equity impact of the mHealth and  
25 community mobilisation interventions will be assessed.  
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## 28 **METHODS**

### 29 **Study setting and population**

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31 The study setting for the D-Magic trial is Faridpur district, located south of Dhaka.  
32 The district has a population of over 1.7 million people in a high-density area of just  
33 over 2000 square kilometres. It is primarily an agricultural economy, with the main  
34 crops being jute and rice. Like in the rest of Bangladesh, healthcare is provided at  
35 three levels: primary care is provided at Community Clinics and at Union Health and  
36 Family Welfare Centres; secondary level care providers (both in- and out-patient  
37 services) are sub-district (Upazilla) health complexes and hospitals; and tertiary care  
38 is provided at district hospitals and medical college hospitals (22). Private and  
39 informal service providers are also present in the area, with the informal sector being  
40 the main provider in rural areas (22), Faridpur district included. Inadequate and  
41 inequitable access to services, shortages of skilled health care providers, short  
42 supplies of medicines and poor quality and low responsiveness of services are the  
43 main challenges faced by the Bangladesh healthcare system (22), and remains a  
44 challenge in Faridpur district too.  
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52 The study population for the D-Magic study are men and non-pregnant women who  
53 are aged 30 years or more and permanent residents (i.e. lived there for more than 6  
54 month) of 96 villages (clusters) in four rural upazillas – Nagarkanda, Boalmari, Saltha  
55 and Madhukhali – in Faridpur district.  
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### **Trial design**

The D-Magic trial is a three-arm cRCT which is implemented in four rural upazilas in Faridpur district, Bangladesh. In D-Magic trial, 96 clusters (villages) were randomised to receive either the mHealth intervention, the community mobilisation intervention, or be in the control arm. All three arms receive a number of health system strengthening activities. The interventions implementation was started in July 2016 and was completed by end of December 2017 and all data collection was completed in June 2018.

Detailed information on the randomisation and participants recruitment process, trial time-line, and a full description of the interventions is presented elsewhere (7). A brief description of the mHealth, community mobilisation and health system strengthening interventions are presented in the following sections.

### **mHealth intervention**

The mHealth intervention involves free of charge voice messages about the prevention and control of T2DM and NCD risk factors sent twice-weekly to the individual's mobile phone during a 14-month period. The intervention and the messages' content were developed based on findings from baseline formative research in the study area, and application of the behaviour change theories the COM-B (Capability, Opportunity, Motivation, Behaviour) model for understanding behaviour (23) and the Theoretical Domains Framework (TDF) to encourage change (24, 25). The mHealth intervention is available to all individuals who have access to a mobile phone and registered to receive the messages by providing their mobile number to the intervention community recruiters.

### **Community Mobilisation intervention**

The community mobilisation intervention involves initiation and facilitation of separate male and female participatory groups, with approximately 20 members in each. The intervention is an adaptation of a participatory women's groups intervention implemented in South Asia (including Bangladesh) and Sub-Saharan African settings and shown to be effective and cost effective at reducing neonatal mortality (21, 26). The groups progress through a series of 18 monthly meetings following the four phases of PLA. During phase 1, participants identify and prioritise factors that affect their health, particularly those increasing their risk of developing or failing to manage T2DM; in phase 2, the participants and their community come up with feasible strategies that can be implemented to address the problems identified in phase 1; during phase 3, they implement these strategies; in phase 4 they evaluate the strategies they have implemented. The groups are run by salaried facilitators, who are recruited from the study areas and have a minimum of higher secondary school education. The facilitators undertook one week's training on group facilitation and basic health messages related to NCD prevention and control, in particular T2DM. They also have received refresher training during the course of the interventions.

### **Health Systems Strengthening (HSS)**



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3 A series of health system strengthening activities are carried out in all study areas  
4 (both intervention and control clusters). These activities, which are tailored according  
5 to the mapping of health care providers in the project area in the formative phase of  
6 the project, included the training of mainly informal health care workers in the  
7 community and distributing educational materials among formal and informal  
8 providers in prevention, diagnosis and treatment of T2DM, as well as the  
9 development of essential equipment inventories.  
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### 12 **Measurement of health outcomes/effectiveness**

13 The D-Magic trial will test the effect of the community mobilisation intervention and  
14 mHealth intervention relative to the control and does not directly compare the effects  
15 of each intervention relative to the other. As this is a cluster-randomised trial, the  
16 outcomes will be measured among individuals (permanent residents) who live in the  
17 intervention clusters, irrespective of whether they took part in groups or received  
18 mHealth messages. Analysis of the outcomes will be by intention to treat at the  
19 individual and cluster level as appropriate. Moreover, participants with missing data  
20 on the primary outcomes will be excluded from primary outcome analysis (7).  
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#### 25 **Primary outcome**

26 The D-Magic trial has two primary outcomes: (1) combined prevalence of  
27 intermediate hyperglycaemia (i.e. impaired fasting glucose or impaired glucose  
28 tolerance) and T2DM, and (2) cumulative two-year incidence of T2DM among  
29 individuals identified with intermediate hyperglycaemia at the start of the trial (7).  
30 Using the prevalence data, the number of intermediate hyperglycaemia and diabetes  
31 mellitus cases prevented, and the number of diabetes cases prevented among  
32 individuals with intermediate hyperglycaemia at baseline will be calculated as the  
33 difference between the expected and the actual number of cases using the adjusted  
34 odds ratio relative to the control population.  
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#### 39 **Secondary outcomes**

40 The trial has a number of secondary outcomes including diastolic and systolic blood  
41 pressure, prevalence of hypertension, body mass index, prevalence of overweight and  
42 obesity, prevalence of abdominal obesity, health-related quality of life, and  
43 psychological distress among self-reported diabetics (7).  
44

45 Comparison will be made between the interventions (mHealth and community  
46 mobilisation) and control (HSS activities only) to estimate incremental cost-  
47 effectiveness ratios (ICERs) for the primary outcomes; in terms of cost per case of  
48 intermediate hyperglycaemia and diabetes mellitus prevented and cost per case of  
49 diabetes prevented among individuals with intermediate hyperglycaemia at baseline,  
50 and for some of the secondary outcomes such as cost- per mm Hg reduction in  
51 systolic BP. ICER will be conducted if a significant impact on the outcomes is  
52 observed. Moreover, all costs and (statistically significant) outcomes, both primary  
53 and secondary, will be presented separately in a cost-consequence analysis.  
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### **Willingness to pay/Contingent Valuation study**

We will conduct a willingness to pay (WTP) study in order to elicit maximum monthly amount of money each participant or household would be willing to pay if an m-Health service on diabetes and NCD risk factors' prevention and management (i.e. weekly voice messages) was available.

WTP studies are widely used in order to elicit monetary value of a service or good not available in the market (27-30). In the Bangladesh context, Islam et al (2015) in a recent study estimated WTP of T2DM patients for receiving messages for increasing adherence to treatment (31). Similar to Islam et al (2015), we will use an open-ended contingent valuation (CV) method (27, 30, 32), asking participants through an open-ended question how much they would be willing to pay monthly to receive voice messages related to diabetes and NCD risk factors' prevention and management, if such a service was available. Open-ended CV is a more flexible approach and avoids starting point bias or range bias introduced by other methods such bidding game and payment cards (27). The theoretical framework defined by O'Brien and Gafni (28) for CV studies will be used to design the study.

WTP questions will be asked from all the participants at the end-line impact evaluation survey. WTP values will be compared across different groups, for example, based on exposure to the interventions (i.e. among those exposed to mHealth, or exposed to participatory groups, and participants who have not been exposed to either of these interventions) or health condition (people diagnosed with diabetes or other NCDs and others). In addition, for each participant, detailed individual and household level socio-economic characteristics will be collected to examine the extent to which WTP values will vary by socio-economic status of participants.

### **Equity impact of the D-Magic interventions**

In addition to measuring efficiency/cost-effectiveness of the D-Magic interventions, an analysis of equity impact of the interventions will be conducted to assess whether impacts/gains from the intervention are equitably shared among the target population. This will be done through sub-group analyses of the primary and secondary outcomes based on the socio-economic status of the target population.

### **Identification, measurement and valuation of resource use**

The cost-effectiveness and cost-consequence of the D-Magic interventions will be measured from a societal perspective (33, 34); measuring the economic impact for all parties affected by the interventions, including implementing agency (or program costs), public healthcare providers (at both local and national levels) and users, who are the intervention participants and their households. The following sections provide a detailed description of the proposed methods for measuring and valuing programme costs, healthcare provider costs and participants/household costs. Programme costs include those incurred by the implementing agency or program provider i.e. Diabetic Association of Bangladesh (BADAS). The healthcare provider costs are those incurred by the government health facilities in the study area including community

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3 clinics, Health & Family Welfare centres and Upazila Health Complex/hospitals. The  
4 household or user costs include those incurred by participants and their households.  
5 Table 1 provides an overview of the financial and economic costs to be employed in  
6 the economic evaluation of the D-Magic interventions.  
7

### 8 9 **Programme-related costs**

10 Direct and indirect costs of designing and implementing mHealth, community  
11 mobilisation and health system strengthening interventions will be estimated using a  
12 combination of activity-based costing (35) and ingredients approach (36).  
13

#### 14 15 **Financial or expenditure data**

16 Programme costs are mainly financial or accounting costs, which are collected  
17 prospectively from the project accounts or expenditure records of the implementing  
18 partner and entered (generally, on an annual basis) to an MS Excel data capture tool.  
19 The tool contains different sections/worksheets that will allow the categorization of  
20 costs into line items (i.e. staff, materials, capital, and joint costs), start up and  
21 implementation costs of the interventions, and costs associated with the different  
22 programme components, i.e. m-Health, community mobilization, HSS, and  
23 monitoring and evaluation. Key informant interviews with project leads and  
24 monthly/quarterly staff time sheets will be used to allocate joint costs between the  
25 programme components. The summary worksheets in the cost data capture tool  
26 present the costs by programme component (e.g. mHealth, community mobilisation  
27 and HSS), summarise the total cost data per intervention, allows effect data to be  
28 entered and estimates the cost-effectiveness results.  
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#### 34 35 **Donated items and opportunity costs**

36 Some items, such as donated items and volunteer time, are not captured in the  
37 accounting system and need to be converted to economic costs using their market  
38 value and then entered into the data capture tool (37-39). Potential donated items are  
39 equipment donated by the implementing agency (i.e. purchased by previous projects  
40 and used in the D-Magic project). The donated items will be identified through key  
41 informant interviews with the project leads.  
42

43 The majority of volunteer time is related to designing messages for the mHealth  
44 intervention, where several meetings were held with experts who were volunteers.  
45 Detailed information regarding these meetings, including the number of meetings,  
46 their duration, and the participants is being documented by the project. The  
47 opportunity cost of the time invested by the experts will be measured as a proportion  
48 of their salary or a salary equivalent using published national/local wage rate reports.  
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#### 51 52 **Public healthcare providers costs**

53 The D-Magic project is likely (at least in the short term) to increase seeking care for  
54 diabetes, other NCDs and NCD risk factors such as hypertension, particularly demand  
55 for services such as testing and treatment for hypertension, diabetes and pre-diabetes,  
56 or seeking advice or treatment for weight control. In addition, there is a time  
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3 (opportunity) cost of direct involvement in the HSS activities for the healthcare  
4 providers (Table 1).  
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#### 6 Cost of changes in demand for services

7 The costs to public healthcare providers in the project area due to increased (or any  
8 changes in) demand for their services will be estimated. A mapping of the health care  
9 providers in the study area has been completed and 20 functional governmental health  
10 care facilities, at different levels, have been identified. These facilities included 14  
11 Community Clinics, 3 Health & Family Welfare centres and 3 Upazila Health  
12 Complex/Hospitals. A sample of 11 health facilities including 8 community clinics  
13 and 2 Health & Family Welfare centres (with equal numbers in control and  
14 intervention clusters), as well as one Upazila Health Complex/Hospital (which cover  
15 both control and intervention areas) were selected for baseline audits of diabetes and  
16 NCD services, estimating their resource utilisations and unit costs. Similar audits and  
17 cost data collection will be conducted for the same facilities post-intervention in order  
18 to assess the changes in NCD service utilisation attributable to the D-Magic  
19 interventions. This data will be complemented by health seeking behaviour  
20 information collected from the study participants in control and interventions clusters  
21 at the D-Magic end-line impact evaluation survey. Differences in service utilisation  
22 between intervention and control areas will be attributed to the D-Magic  
23 interventions.  
24

25 A simple audit and cost-capture tool was developed for facility data collection and  
26 piloted with facilities at different levels. Data from the cost-capture tool will be  
27 complemented by the existing data from the facility reports, and published data. Costs  
28 of services provided by the facilities will be estimated using a step-down approach  
29 (40).  
30

31 Any change in demand for services provided in the facilities other than those  
32 mentioned above and the services not covered by them, in intervention areas  
33 compared to the control, will be identified during the trial's routine monitoring and  
34 end-line impact evaluation survey. Any cost of that change in demand will be  
35 calculated using published data on the unit costs of those services.  
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#### 38 Opportunity cost of HSS activities

39 Moreover, as discussed earlier, HSS activities include several training sessions for  
40 health care providers in prevention, diagnosis and treatment of T2DM. Information on  
41 the number of meetings, their duration and participation is being documented by the  
42 project. The opportunity cost of the time spent by the providers will be measured as a  
43 proportion of their salary for formal providers or as a salary equivalent, for informal  
44 providers.  
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#### 47 **Participants and their household costs**

48 D-Magic interventions may influence participants and their households' costs in a  
49 number of ways. These include changes in health seeking behaviour, and changes in  
50 household lifestyles that might affect food and non-food consumption patterns and  
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3 spending as well as time spent engaging in physical activities. It also includes the  
4 time (opportunity) cost of participation in the PLA group meetings and participating  
5 in the actions taken by the groups (Table 1).  
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7

#### 8 Health care seeking costs

9 D-Magic may increase the participants and their households' seeking advice and care  
10 from both formal and informal providers for testing and treatment for hypertension,  
11 diabetes, pre-diabetes and other NCDs. Information on costs of care seeking are  
12 collected from all the participants recruited in the project, at the baseline and end-line  
13 evaluation surveys. This information will be complemented by the data collected from  
14 the household consumption expenditure survey. The difference in spending for the  
15 participants and their households will be calculated and compared between  
16 intervention and control areas.  
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#### 20 Changes in household food and non-food expenditure

21 Changes in food and non-food expenditure will be captured in a comprehensive  
22 household consumption and expenditure survey. The survey will be conducted on a  
23 random sub-sample of 300 households (100 per trial arm) at the end of intervention  
24 period. The changes in the expenditure will be compared between interventions and  
25 control areas.  
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#### 29 Opportunity cost of participation in the interventions

30 Participating in the PLA group meetings incur some costs to the participants and their  
31 family. These costs include the direct costs (e.g. cost of getting to the group) and time  
32 cost of group participation (e.g. travel time and time spent in the group) and  
33 participating in the actions taken by the group, or changing health and lifestyle  
34 behaviours. Information on the potential direct and time costs will be collected  
35 through a sub-sample survey of 312 group participants (both male and female),  
36 randomly selected. Sample size for the survey was primarily calculated to give  
37 sufficiently accurate estimate of group participants' characteristics.  
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#### 42 **Cost-effectiveness and cost-consequence analyses**

43 Economic evaluation will be conducted as a within-trial analysis using the intention-  
44 to-treat results, and will be presented in terms of ICERs, calculated as the difference  
45 in total costs of mHealth and community mobilisation interventions (plus HSS  
46 activities) versus HSS activities only (or control), divided by the difference in mean  
47 effects of each interventions versus control (41) (42). As mentioned previously,  
48 ICERs will be evaluated in terms of cost per case of intermediate hyperglycaemia and  
49 T2DM prevented and cost per case of T2DM prevented among individuals with  
50 intermediate hyperglycaemia at baseline, and for some of the secondary outcomes  
51 such as cost- per mm Hg reduction in systolic BP. In addition to ICERs, the economic  
52 evaluation will be presented as a cost-consequence analysis where the incremental  
53 costs and all statistically significant outcomes will be listed separately, allowing  
54 policymakers to compare the costs and all impacts/gains of the D-Magic  
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3 interventions. Cost-consequence analysis has been recommended for complex public  
4 health interventions, such as D-Magic, that have multiple health and non-health  
5 impacts, which are difficult to measure in a common outcome unit (42, 43).

6 All costs will be presented in 2017 prices in Bangladeshi Taka and International  
7 Dollars (INT\$). All costs will be adjusted for inflation using the Bangladeshi  
8 Consumer Price Index (CPI) and will be converted to 2017 INT\$ using the  
9 Purchasing Power Parity (PPP) conversion factor for Bangladesh. Moreover, both  
10 costs and outcomes will be discounted using a standard discount rate of 3%, as  
11 recommended by WHO-CHOICE (44) and the Gates Reference Case for Economic  
12 Evaluation (45). The impact of uncertainty in key parameters on the cost-  
13 effectiveness results will be assessed through a series of deterministic and  
14 probabilistic sensitivity analyses. Reporting of the study design, analytical methods  
15 and findings will follow the Consolidated Health Economic Evaluation Reporting  
16 Standards (CHEERS) statement (46). The D-Magic interventions will be judged to be  
17 cost-effective and affordable (though, indirectly) against the WHO-CHOICE  
18 recommendation (44), as well as recently developed cost-effectiveness thresholds  
19 (47).

20 The possibility of conducting an extended cost-effectiveness analysis (48) alongside  
21 modeling national scale up of the D-Magic interventions will be explored. Moreover,  
22 we will explore the possibility of running a long-term cost-effectiveness analysis  
23 using decision analytical modelling based on the relevant outcomes such as systolic  
24 blood pressure, body mass index, etc. (if statistically significant) to predict future  
25 economic impacts from implementing the D-Magic interventions on the target  
26 population.

### 27 28 29 30 31 32 33 34 **Strengths and limitations of the study**

35 In order to increase transparency and minimize bias, publication and peer-review of  
36 economic evaluation protocols is encouraged. This study reports planned data  
37 collection and analyses alongside a complex public health trial. The study will  
38 contribute to the scarce cost-effectiveness evidence on mHealth and community  
39 mobilisation interventions for preventing diabetes and NCDs.

40 Furthermore, adopting a cost-consequence analysis approach makes it possible to  
41 report all health and non-health impacts of the D-Magic interventions, in addition to  
42 ICERs, which can assist policy makers to make informed decisions in designing or  
43 implementing similar complex interventions. Incorporating equity impact analysis  
44 and contingent valuation are other strengths of this study, which provide useful  
45 information for future scale-up of the interventions.

46 The study design has one limitation. The D-Magic trial is not powered to test the  
47 differences between the mHealth and community mobilisation interventions due to  
48 the large sample size required and the resources available for the trial. However, the  
49 possibility of a direct comparison between the two interventions will be explored.

### 50 51 52 53 54 55 **Patient and public involvement**

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3 Patients and public were not involved in the process of this study. Patients and public  
4 will be informed of the study results via peer-reviewed journals, conference and local  
5 dissemination meetings.  
6

### 7 **Contributors**

8 HHB, EF, AK, HJ, JM, CK, JS, NB, JK, RH, AKAK, AC and KA contributed to the  
9 study design; HHB, EF, CK contributed to the statistical analyses; SKS, MARC, NA,  
10 KA, BN and TN contributed to data acquisition; AM has contributed to the literature  
11 review and drafting the paper; HHB was responsible for the initial drafting of this  
12 manuscript; all authors contributed to the review of this manuscript and provided  
13 comments. All authors read and approved the final manuscript.  
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19 Global Alliance for Chronic Diseases (GACD) Diabetes Programme.  
20

### 21 **Competing interests**

22 The authors declare they have no competing interests.  
23

### 24 **Ethics and Dissemination**

25 The D-Magic trial has been approved by the University College London Research  
26 Ethics Committee (4766/002) and by the Ethical Review Committee of the Diabetic  
27 Association of Bangladesh (BADAS-ERC/EC/t5100246). The trial has been  
28 registered and assigned an International Standard Randomised Controlled Trial  
29 Number (ISRCTN41083256). Informed cluster-level consent from village/community  
30 leaders, and individual informed consent was obtained from all participants in the trial  
31 prior to their participation in the study. The findings of this study will be disseminated  
32 through different means within academia and the wider policy sphere.  
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Table 1: Overview of resource use and costs measures included in the economic evaluation of the D-Magic interventions.

Perspective/cost category	Type of costs	Description	Sources	Sample size	
<b>Provider</b>	Program/implementing agency	Direct	Costs of implementing mHealth, community mobilisation and HSS interventions	(1) Project accounts of the implementing agencies (2) Interviews with the project staff	N/A
		Indirect	The opportunity cost of volunteer experts attended the mHealth design meetings, donated items, etc.	(1) Project records on numbers of meeting, attendants etc. (2) Published reports on local wage information based on skill category (3) Field offices' inventory information	(1) All meetings held and number of people attended in the meetings will be recorded (2) The list of all equipment in the field offices
	Public healthcare providers	Direct	Changes in utilisation of T2DM and NCD related services at the public health facilities in the study area	(1) Detailed audit and costing study of the health facilities (2) Baseline and end-line cross-sectional surveys (for information on changes in costs of health seeking)	(1) Random sample of health facilities at different levels in both intervention and control areas (2) All participants in the study
		Indirect	The opportunity cost of the time spent by the health care providers attending HSS meetings	(1) Project records on numbers of meeting, attendants etc. (2) Published reports on local wage information based on skill category	All meetings held and number of people attended in the meetings will be recorded
	<b>Participants/households</b>	Direct	Household expenditure on food and non-food	Household consumption expenditure survey	A random sample of 300 households in the study area
			Costs of health seeking for the participants and their households	Baseline and end-line cross-sectional surveys	All participants in the study
Indirect		Opportunity cost of participation in the groups	Group participants survey	A random sample of 312 group participants (both male and female)	

\* HSS: health system strengthening, T2DM: type 2 Diabetes mellitus, NCD: non-communicable diseases

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## CHEERS Tool

Section/item		Item no.	Recommendation	Response
Title and abstract	Title	1	Identify the study as an economic evaluation, or use more specific terms such as “cost-effectiveness analysis” and describe the interventions compared.	Yes
	Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base-case and uncertainty analyses), and conclusions.	Yes
Introduction	Background and objectives	3a	Provide an explicit statement of the broader context for the study.	Yes
		3b	Present the study question and its relevance for health policy or practice decisions.	Yes
	Target population and subgroups	4	Describe characteristics of the base-case population and subgroups analyzed including why they were chosen.	Yes
	Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	Yes
	Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	Yes
	Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	Yes
	Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	Yes
	Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	Yes
	Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	Yes
	Methods	Measurement of effectiveness	11 a)	Single study–based estimates: Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.
11 b)			Synthesis-based estimates: Describe fully the methods used for the identification of included studies and synthesis of clinical effectiveness data.	n/a
Measurement and valuation of preference based outcomes		12	If applicable, describe the population and methods used to elicit preferences for outcomes.	n/a
Estimating resources and costs		13 a)	Single study–based economic evaluation: Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	Yes
		13 b)	Model-based economic evaluation: Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	n/a

	Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	Yes
	Choice of model	15	Describe and give reasons for the specific type of decision-analytic model used. Providing a figure to show model structure is strongly recommended.	n/a
	Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytic model.	n/a
	Analytical methods	17	Describe all analytic methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (e.g., half-cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	Yes
Results	Study parameters	18	Report the values, ranges, references, and if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	Not possible in the protocol although the process is described
	Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	Not possible in the protocol although the process is described
	Characterising uncertainty	20 a	Single study-based economic evaluation: Describe the effects of sampling uncertainty for estimated incremental cost, incremental effectiveness, and incremental cost-effectiveness, together with the impact of methodological assumptions (such as discount rate, study perspective).	Not possible in the protocol although the process is described
		20 b	Model-based economic evaluation: Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	n/a
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	Not possible in the protocol although the process is described	
Discussion	Study findings, limitations, generalisability, and current knowledge	22	Summarize key study findings and describe how they support the conclusions reached. Discuss limitations and the generalizability of the findings and how the findings fit with current knowledge	Not possible in the protocol although the process is described
	Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other nonmonetary sources of support.	Yes
Other	Conflicts of interest	24	Describe any potential for conflict of interest among study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors' recommendations.	Yes