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Research in context

Evidence before this study

Added value of this study

Implications of all the available evidence

Introduction

The global prevalence of diabetes was estimated to be 9% among adults in 2016 and about 75% of people living with diabetes were in low-income and middle-income countries (LMICs).[1] Roughly 20–30% of adults in rural areas of Bangladesh have abnormal fasting glucose or impaired glucose tolerance (together termed intermediate hyperglycaemia) and about 10% have diabetes,[2–4] with the prevalence of diabetes (mostly type 2 diabetes) expected to reach 24–34% by 2030.[5] Despite the large burden of diabetes and intermediate hyperglycaemia in Bangladesh, awareness and knowledge is low[6] and e ective strategies to prevent and control diabetes are urgently needed.

Lifestyle and non-pharmacological interventions can prevent or delay the onset of type 2 diabetes.[7] Individual targeted strategies that use mobile phone technology (mHealth) have been shown to reduce the incidence of type 2 diabetes in high-risk individuals,[8] but have not been shown to a ect behaviour change and diabetes status among a general, rural population. Community-based and peer support interventions might be a cost-e ective means of promoting lifestyle changes in LMICs,[9–11] although a recent trial in India showed no e ect on disease outcomes.[12] Participatory learning and action (PLA) is a specific approach to community mobilisation that engages communities to identify and address their own local problems. It has been shown to improve maternal and newborn survival in LMICs[13] and might also improve child health[14,15] and women's reproductive health.[16]

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We aimed to separately assess the e ects of mHealth health messaging and PLA community mobilisation on the prevalence of intermediate hyperglycaemia and diabetes among the general adult population in rural Bangladesh, and to assess the e ect of these interventions on the incidence of diabetes among people with inter-

and kitchen gardening to increase access to healthy food were popular strategies. Facilitators were locally recruited men and women who had completed higher secondary certificate level of education and were recruited by the study team following assessment of their communication skills, motivation, and familiarity with the study areas. Facilitators received a total of 14 days' training about PLA and community entry, group facilitation, and the basics of type 2 diabetes symptoms, prevention, and control. Each facilitator was responsible for running six to nine PLA groups each month. In addition, an equal number of men's and women's groups were established within each village, with a total of 122 groups facilitated by 16 facilitators (eight men, eight women) across 32 villages. Joint meetings of men's and women's groups were encouraged after phase 1 of the PLA cycle (ie, after identification and prioritisation of health determinants).

Training of informal health workers in the prevention and control of type 2 diabetes was done by the Diabetic Association of Bangladesh across all intervention and control villages during the intervention period. Project mapping of services in the study areas identified all informal care providers (eg, village doctors, pharmacy owners), who were then invited to participate in service-strengthening activities on a voluntary basis. This service strengthening included day-long workshops and provision of guidelines to cadres of largely unregulated care providers who had not received formal accredited training but might have had some degree of informal training through apprentices, workshops, or seminars. These informal care providers are typically the first point of care in health seeking by individuals in rural Bangladesh.[20]

A sampling frame of all permanent residents aged 30 years and older was developed from a household census done between Aug 21, and Oct 28, 2015. 143 households with at least one eligible resident were then selected from each village by use of probability proportional to size sampling. A single eligible adult was selected from each of the 143 households for inclusion in the survey via simple random sampling. A baseline cross-sectional survey among the sampled individuals to obtain sociodemographic characteristics, behaviours, and knowledge of type 2 diabetes was done between Jan 23, and May 30, 2016. The survey included an overnight fasting blood glucose measurement in whole capillary blood obtained by finger prick in the middle or ring finger. All individuals without diagnosed type 2 diabetes then received a 75 g glucose load dissolved in 250 mL water. A 2-h post-prandial repeat capillary blood test was done to determine glucose tolerance status and di erentiate between individuals with intermediate hyperglycaemia (defined as impaired fasting glucose or impaired glucose tolerance) and those with type 2 diabetes, based on WHO criteria (appendix).[21] These baseline data were used to identify an intermediate hyperglycaemia cohort and to compare sociodemographic characteristics between the three trial groups.

Following intervention, the sampling frame was updated and a new random sample of adults aged 30 years and older was selected via the same sampling method as used at baseline. By chance, approximately 25% of individuals sampled for the end-of-study survey had also been included in the baseline survey. In addition, all individuals identified with intermediate hyperglycaemia at baseline were followed-up in the end-of-study survey to measure type 2 diabetes incidence in this cohort. An end-of-study survey of sociodemographic data, knowledge and behaviours, and anthropometric measures of weight, height, blood pressure, and fasting and 2 h post-prandial blood glucose measures was completed in the random cross-sectional sample and the baseline intermediate hyperglycaemia cohort between Jan 16, and April 30, 2018, using the same methods as at baseline.

Data were collected by 16 pairs of fieldworkers (one man and one woman in each pair) with at least secondary education, who underwent extensive training in survey methods, including supervised field practice. Most data collection took place in testing centres established by the field team for the purposes of the study, with additional data collection with pretested questionnaires taking place at respondents' homes.[17,22] Data collectors were supervised by four field supervisors responsible for observing and verifying data. Data quality-control measures were implemented within the direct digital data capture system used (eg, range and consistency checks), through repeat measures by supervisors on a random basis, and where outlier data were detected on data inspection. Data collectors, supervisors, and managers were unaware of randomisation assignments at baseline, but might have been able to deduce assignment during data collection at the end of the study. Access to end-of-study data was restricted to the monitoring and evaluation managers until collection was complete, at which point the data were available for masked analysis by the lead author (EF).

Process evaluation data will be reported in detail elsewhere. We collected data in all four intervention upazillas of Faridpur district, including small group discussions with men and women attendees, with small groups of men and women with type 2 diabetes, and with group non-attenders. Later we met groups of men and women to explore triangulation and seek consensus on community changes. We also met with men's and women's group facilitators. In some of the groups we used participatory photography where they had identified and represented issues of importance to them using mobile phone cameras. Focus group discussions were digitally recorded and one author (KAk) made notes about the findings in English and translated field observation notes to English for analysis. Key themes around individual, household, and community change were compared with the theory of change drafted after the formative phase of research.

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Outcomes

We prespecified two primary outcomes: the prevalence of intermediate hyperglycaemia and type 2 diabetes at the end of the study and the 2-year cumulative incidence of type 2 diabetes among the cohort with baseline intermediate hyperglycaemia.

Secondary outcomes were mean diastolic and systolic blood pressure, prevalence of hypertension, hypertension control (among those with known hypertension), BMI, prevalence of overweight and obesity and abdominal obesity (waist to hip ratio >0·9 for men and >0·85 for women), health related quality of life (using EQ-5D score), physical activity, fruit and vegetable consumption, and knowledge of the causes, symptoms, complications, prevention and control of type 2 diabetes. Additional secondary outcomes among people with type 2 diabetes were self-awareness of diabetes status and, among those with known diabetes, prevalence of diabetes control, psychological distress (with SRQ-20 screening tool), and receipt of professional medical treatment or advice for diabetes. Full specification of secondary outcomes and methods of assessment have been described previously.[17]

Additional pre-specified outcomes were intervention costs, incremental cost-e ectiveness ratios and costs per disability adjusted life years (DALYs) averted for any e ective intervention, and process indicators of intervention coverage and qualitative assessments of behaviour change caused by the interventions. An additional outcome of diabetes-only prevalence (excluding intermediate hyperglycaemia) was included post-hoc. Key findings from the qualitative, process assessments of behaviour change are sumarised below, but full analyses are to be reported in a forthcoming publication.

Statistical analysis

We estimated that a target sample of 143 adults per village (total 13728, including 10% oversample for non-response) would provide 80% power at 95% confidence to detect a minimum 21·5% reduction in combined prevalence of type 2 diabetes and intermediate hyperglycaemia and 78% power to detect a 33% reduction in cumulative incidence of type 2 diabetes among the baseline intermediate hyperglycaemia cohort in intervention clusters relative to control clusters.[17]

Analysis of intervention e ect on the combined prevalence of type 2 diabetes and intermediate hyperglycaemia included all individuals who provided blood

intermediate hyperglycaemia. Baseline characteristics were similar among all study groups (table 1, appendix),

Increases in ability to report one or more valid causes, symptoms, complications, and strategies for prevention and control of diabetes were observed in both intervention groups compared with control, with the e ect consistently greatest in the PLA group (table 4). Self-awareness of diabetes status among individuals identified as having type 2 diabetes by blood glucose testing was five-times higher in the PLA group than in the control group (aOR 5·09,

(table 3, figure 2). There was also no evidence of an e ect of the mHealth intervention on the prevalence of type 2 diabetes alone in our post-hoc analysis (563 [15%] of 3797 *vs* 493 [13%] of 3821; adjusted [stratified, clustered design, and wealth] aOR 1·18, 0·95–1·48; p=0·139).

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was easier to initiate and sustain. PLA groups and their activities made community members feel in control of their health and able to prevent diabetes. The PLA intervention also destigmatised blood glucose testing and healthy behaviours such as physical activity, reduced or no sugar in tea, and healthy eating while socialising.

Total and average annual costs of the PLA intervention were INT$601 484 and $240 594, respectively. Total and average annual costs of the mHealth intervention were $312 630 and $125 052, respectively. The average annual costs of the PLA and mHealth per beneficiary (adults ≥30 years) covered were $14 and $7, respectively, with

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costs per total population (all ages) being $6 and $3, respectively. The incremental cost-e ectiveness ratios for PLA were $316 per case of intermediate hyperglycaemia or type 2 diabetes prevented (or $124 per DALY averted) and $6518 per case of type 2 diabetes prevented (or $2551 per DALY averted) among individuals with intermediate hyperglycaemia at baseline.

Discussion

We assessed two community interventions to prevent and control type 2 diabetes and intermediate hyperglycaemia in rural Bangladesh. Facilitated PLA community mobilisation led to large, significant reductions in the combined prevalence of type 2 diabetes and intermediate hyperglycaemia and 2-year incidence of type 2 diabetes among an intermediate hyperglycaemia cohort. The mHealth intervention had no e ect on diabetes status. Both inter

activities and facilitated community engagement and intervention development activities. KAz coordinated project activities in Bangladesh, co-led the project, and contributed to intervention development and study design. All authors contributed to the interpretation of study findings and had the opportunity to review and revise the final manuscript.

Declaration of interests
We declare no competing interests.

Data sharing
De-identified data collected for this study and a data dictionary are available from the corresponding author on reasonable request.

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