BMJ Open

Understanding the impact, reach and implementation of a health systems intervention to improve diabetes and hypertension care in pluralistic urban public primary care in Bangladesh: a study protocol

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To cite: Barua D, Hicks JP, Elsey H, *et al*. Understanding the impact, reach and implementation of a health systems intervention to improve diabetes and hypertension care in pluralistic urban public primary care in Bangladesh: a study protocol. *BMJ Open* 2026;**16**:e104331. doi:10.1136/bmjopen-2025-104331

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2025-104331).

Received 28 April 2025
Accepted 13 March 2026

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ABSTRACT

Introduction In Bangladesh, government provision of primary care in rural areas has seen the development of services for non-communicable diseases, particularly hypertension and diabetes (given their substantial rise in recent decades). However, in the context of cities, which are characterised by a plurality of providers that have sprung up to meet the demands of a rapidly growing urban population, such provision is very limited.

Methods and analysis We will conduct a mixed-methods study, based on the RE-AIM framework, to understand the (1) reach, (2) effectiveness, (3) adoption, (4) implementation and (5) maintenance (the five RE-AIM domains) of a health systems intervention to strengthen management processes for hypertension and diabetes within government and non-governmental organisation (NGO-run) primary care facilities. To evaluate the effectiveness of the intervention, we will use a quasi-experimental, difference-in-differences design. We will recruit 20 purposively selected urban government-run and NGO-run primary care facilities across Dhaka North and South City Corporation areas. Ten facilities will be purposively allocated to an intervention group and receive training and guidance materials on diabetes and hypertension care, based on the WHO Package of Essential Non-communicable (PEN) Disease Intervention for Primary Care, and the use of an e-health application for patient records. The remaining facilities will be allocated to the existing care group and receive no intervention inputs, with identical data collection processes carried out in both groups. We aim to collect data on 50 patients visiting each facility during a baseline period and at 6 and 12 months after implementing the intervention. We will estimate the average treatment effect on the treated (ATT) for the intervention at 6 and 12 months after implementing the intervention on a primary outcome that measures how many of eight key management processes are appropriately carried out for each patient visit at a study facility (with the appropriateness of each management process determined by assessing criteria based on how patients should be managed according to the intervention guidelines). We will also estimate the ATT for the intervention at 6 and 12 months after implementing the intervention on each of the appropriate management processes making up the primary outcome as separate secondary outcomes. Alongside this design, we will collect a range of additional quantitative and qualitative data to evaluate the other RE-AIM domains, using sequential mixed methods approaches, focusing on understanding potential facilitators and barriers in relation to these domains.

Ethics and dissemination Ethics approval has been received from the Research Governance Committee at the University of Leeds, UK (MREC 21-008) and from the Bangladesh Medical Research Council (BMRCAIREC/20 I 9-2022/485). We will use a variety of channels to share our findings with policy makers, service providers, academicians and relevant stakeholders.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Although we cannot use an experimental study design we will use a robust, widely used observational study design to evaluate the effectiveness of the intervention under real-world conditions.
⇒ We will use the reach, effectiveness, adoption, implementation and maintenance framework to structure and plan our evaluation, allowing us to assess multiple dimensions of implementation under real-world conditions and therefore provide detailed insights for decision-making on the potential future scale-up of the intervention in urban Bangladesh.
⇒ We are not able to conduct a randomised trial to evaluate intervention effectiveness due to feasibility issues and lack of resources.
⇒ We cannot evaluate for a longer time scale than 12 months due to project funding and timeline constraints.

INTRODUCTION

WHO recommends strengthening primary healthcare (PHC) systems in all countries to provide fair and efficient care, to contribute to better health outcomes, lower healthcare costs and to reduce health disparities.[1 2] In response to the rising burden of non-communicable diseases (NCDs), WHO's *Global Action Plan for the Control of Noncommunicable Diseases 2013–2020* recommended that countries strengthen their health systems and address NCDs through people-centred PHC and universal health coverage (UHC).[3] More specifically, WHO's Package of Essential Non-communicable Disease Interventions for Primary Healthcare[4] (from here on referred to as PEN) has been recommended as a 'best buy' for low- and middle-income countries (LMICs) seeking to improve the coverage of appropriate services for people with NCDs in primary care settings. PEN includes cost-effective interventions for the early detection and management of NCDs, and has been successfully implemented in rural settings in many LMICs.[5]

However, in many LMICs there are significant differences in the healthcare system between rural and urban areas, often due to national context, government and donor priorities. This is the case in Bangladesh, where this study is located, with the urban PHC system having a different structure and service delivery modality than in rural areas. Specifically, in rural areas PHC service provision is managed solely by the Ministry of Health and Family Welfare (MoHFW). However, while the MoHFW also manages some government-run PHC facilities in urban areas, the Ministry of Local Government, Rural Development and Cooperatives (MoLGRD&C) is responsible by law for the provision of PHC to the urban population, and this is done primarily through contracted non-governmental organisations (NGOs).[6]

In rural Bangladesh, within each subdistrict a public PHC facility, known as an Upazila Health Complex, provides specialist NCD services, including for hypertension, diabetes and chronic obstructive pulmonary disease, in areas of the facility known as an NCD corner.[7] NCD corners operate according to Bangladesh's *National Protocol for Management of Diabetes and Hypertension*[8] (referred to hereafter as the National Protocol), which has been adapted from WHO's PEN[4] by the MoHFW and guides health workforce on the management of hypertension and diabetes mellitus (hereafter referred to as diabetes) at PHC settings.[9] However, a recent needs assessment found that urban PHC facilities in Bangladesh lack any equivalent NCD service provision.[10–12]

Similarly, given that both hypertension and diabetes are long-term conditions requiring considerable patient follow-up and complex management, a robust individual, patient-level recording system is required and recommended by PEN. Rural PHCs have an NCD patient record-keeping system, either paper-based or digital, although it is not always very effective,[9 13] and a digital health information system, named the *Simple App*, is currently being used at some rural PHC facilities with plans for wider roll-out under the supervision of MoHFW. The app is linked to the National Health Dashboard and can thus be used by public health decision-makers to understand the distribution of these conditions and plan programmes and policy in response.[13] However, while in urban areas government and NGO PHC facilities have paper-based patient recording systems, they are not adapted for NCD patient management.[10–12]

As with other LMICs, the implementation of PEN within PHC facilities in urban areas in Bangladesh has not yet occurred, due in part to the complexity of primary care provision in urban areas. However, it is well known that the prevalence of NCDs, particularly hypertension and diabetes, along with their known and potential causes, have risen greatly in LMICs, including Bangladesh, in recent decades, particularly in urban areas.[14 15] Therefore, this study aims to address the gap in the evidence base of how to implement PEN within the pluralistic PHC context found in urban Bangladesh, and to inform such work in LMIC urban areas more widely. More specifically, this study aims to evaluate the implementation and effectiveness of an intervention package for urban PHC facilities, both government and NGO run, in the capital city Dhaka, comprising the National Protocol (based on PEN) and the Simple App (online supplemental table 1), which seeks to improve the management of hypertension and diabetes.

Understanding how to implement such an intervention within the complexities of the urban health system in this rapidly expanding and dynamic urban environment requires a multidimensional exploration of the implementation process as well as the intervention's potential effectiveness. Therefore, we will use the RE-AIM framework[16] to structure our evaluation. The RE-AIM framework addresses five broad outcomes relating to the reach, effectiveness, adoption, implementation and maintenance of an intervention. Based on this framework, the primary objectives of this study are to:

1. assess the reach of the intervention to all patients aged ≥40 years;
2. assess the effectiveness of the intervention at improving the appropriate management of patients aged ≥40 years (according to the National Protocol guidelines);
3. assess the extent to which the intervention is adopted, and any facilitators or barriers to the uptake of all components of the intervention, by facilities and healthcare providers (HCPs);
4. identify the facilitators and barriers to the implementation of the intervention within routine practice, including fidelity to all components of the intervention and any unintended consequences;
5. assess the extent to which the intervention is maintained, and how successfully, 6 months after the implementation period, and explore stakeholder perspectives on scale-up of the intervention across urban Bangladesh.

METHODS AND ANALYSIS

Below we describe the methodology we will use to evaluate the effectiveness of the intervention, which is our primary objective and involves the more complicated quantitative methods, and then after we describe how we will evaluate the remaining RE-AIM domains, which are our secondary objectives. For an overview of the link between the RE-AIM objectives and their data sources, see online supplemental table 2.

Study design

We will estimate the causal effect of the intervention on the level of appropriate management of patients in relation to hypertension and diabetes (as per the National Protocol guidelines) in comparison with existing practice using a quasi-experimental difference-in-differences (DiD) design.[17] This DiD design will collect cross-sectional, patient-level data during three periods: at baseline (1 month prior to implementing the intervention) and then at 6 and 12 months after intervention implementation. The aim is to estimate the intervention's short-term and long-term causal effect on our outcomes, with the 12-month data collection period allowing us to explore the sustainability and maintenance of any intervention effects.

Alongside the DiD study, we will evaluate the other domains of the RE-AIM framework, namely the reach, adoption, implementation and maintenance, via a range of quantitative and qualitative data that we will either collect during one or more of the above data collection periods or separately.

Study setting and study facilities

The study will be conducted in Dhaka, Bangladesh. Bangladesh is a South Asian country, sharing its borders with India and Myanmar, and is divided into eight administrative divisions, including the Dhaka division, which is further divided into 17 districts. One of these districts is Dhaka District, and within Dhaka District the most urbanised area is split into five municipalities and two city corporations, namely Dhaka North City Corporation (DNCC) and Dhaka South City Corporation (DSCC). This study will be conducted within these two city corporations, which have been chosen due to their high population and densely crowded neighbourhoods, similar to the other 10 city corporations in the country.[18]

Within these two city corporations' residents seeking low-cost or free PHC have two main options, as of 2025. First, they can use one of 19 government-run urban dispensaries (UDs), which provide basic PHC services that are free to the user (see table 1 for their key characteristics). These facilities are managed by the MoHFW. Second, they can use one of 65 NGO clinics, of which 55 provide general PHC services and 10 provide maternal and neonatal focused primary care services, where the user must pay services are subsidised and provided at low cost (see table 1 for their key characteristics). These facilities operate under the MoLGRD&C through the Urban Primary Healthcare Services Delivery Project (UPHCSDP). Additionally, residents may also access PHC services from the outpatient departments of tertiary hospitals, but this is only common among residents living near to such facilities. Therefore, in this study, we will just be working within UDs and NGO clinics.

The UPHCSDP programme has been delivered through four phases, with the aim of supporting Bangladesh's urban primary health system by increasing the accessibility of PHC to the urban poor. The programme has been found to be effective in improving child and maternal health indicators through increased antenatal care coverage, skilled birth attendance and breastfeeding practices and to reduce diarrhoea and acute respiratory infection prevalence in children. Additionally, the programme has also been shown to be effective at decreasing sexually transmitted infections through improved HIV/AIDS awareness and increased prevalence of contraceptive use.[19]

However, a recent needs assessment conducted by our team assessed the preparedness of UDs and NGO clinics to deliver hypertension and diabetes management services.[10–12] In general, the level of preparedness and ability to deliver hypertension and diabetes management services was found to be low. A more detailed summary of these facilities' characteristics, with a focus on the hypertension and diabetes services, is given in table 1, with further discussion of the needs assessment in the *Intervention description* section.

Target population

Our target population are individuals aged 40 years and above who use UDs and/or NGO clinics present in urban areas of Bangladesh, and the UDs, NGO clinics and the medical staff of those facilities who are involved in managing patients in relation to hypertension and diabetes.

Study facility eligibility criteria

We have minimal eligibility criteria for study facilities to maximise the generalisability of our findings:

- Facilities must have been operating consistently for at least a year.
- Facilities must have been providing healthcare services to all types of patients and not restricted to subgroups such as children, pregnant women and newborn babies.
- Facilities present in general population areas and not inside government-restricted working areas.
- Facilities must have a typical patient load of at least 50 eligible patients per day.
- Facilities must have at least one person in each of the following health workforce roles:
  - Doctor.
  - Medical assistant (for UDs this would be a Sub-Assistant Community Medical Officer (commonly known as a SACMO), and for NGO clinics this would be a paramedic).

Table 1 Characteristics of urban dispensaries and NGO clinics

Characteristics	Urban dispensaries	NGO clinics
Leadership and governance	► Public/Government owned. ► Managed and supervised by Dhaka Civil Surgeon Office and Upazila Healthcare (within the Dhaka Civil Surgeon Office), under the MoHFW. ► The clinic in-charge is a medical doctor and is responsible for managing the clinic in addition to providing clinical care.	► Owned by national NGOs and part of a public-private partnership. ► Managed and supervised by the Project Director Office of Urban Primary Healthcare Service Delivery Project, under the DNCC, and by the DSCC, under the MoLGRD&C, and by the NGOs. ► The clinic in-charge is a medical doctor and is responsible for managing the clinic in addition to providing clinical care.
Service delivery	► Services focus on all health issues, especially communicable diseases. ► Diagnostic or lab equipment are not available other than a blood pressure machine and a weight machine.	► Services focus on maternity services and vaccination. ► Wide range of diagnostic services are typically available including for NCDs, such as hypertension and diabetes, plus blood testing, ultrasound services, etc.
Health system financing	► All services are free of cost. ► Funded by MoHFW. ► No bidding process.	► Ultra poor patients attending these facilities are identified through a survey conducted under the MoLGRD. These patients are then provided with an essential health card, commonly known as a red card, through which they can receive all services and medicines for free. Other patients who do not have the card can obtain subsidised services. Furthermore, the doctors at these clinics can provide a discount up to 15% on services and medicines as per their judgement. ► Funded through a soft loan granted by the Asian Development Bank, which is managed by the MoLGRD&C. ► NGOs are selected through a bidding process.
Health workforce	► Four to six staff in each clinic, typically: two doctors, two Sub-Assistant Community Medical Officers (medical assistants), one pharmacist and one maintenance staff.	► 12–14 staff in each clinic, typically: one doctor, three paramedics, one counsellor, one administrator, one management information specialist, one receptionist, one lab technician, four service promoters and one field supervisor.
Medications	► Hypertension and/or diabetes medication may or may not be available, but if available it is unlikely to be as per the National Protocol guidelines.	► Some pregnancy-specific hypertension medication is available, but hypertension medication recommended by the National Protocol is not, and no diabetes medication is available.
Health information systems	► Paper-based patient record systems exist but are not adapted for managing NCDs such as hypertension and diabetes. ► Provide monthly service provision reports to the Dhaka Civil Surgeon Office. ► Patient feedback systems are not available.	► Paper-based patient record systems exist but are not adapted for managing NCDs such as hypertension and diabetes. ► Provide quarterly service provision reports to the Project Director Office. ► Patient feedback system is available.

DNCC, Dhaka North City Corporation; DSCC, Dhaka South City Corporation; MoHFW, Ministry of Health and Family Welfare; MoLGRD&C, Ministry of Local Government, Rural Development and Cooperatives; NCD, non-communicable disease; NGO, non-governmental organisation.

- Pharmacist.
- Facilities with at least three rooms.
- Facilities not existing within 3 km of each other.

Patient eligibility criteria

We also only have one eligibility criteria to maximise the generalisability of our findings: patients must be aged 40 years or above. This age limit comes from the National Protocol guidance that all patients aged 40 years or above should be screened for hypertension and diabetes.

Intervention description

Context of the intervention package

Prior to the development of the intervention package, as previously discussed, we carried out a needs assessment to identify the existing gaps within hypertension and

diabetes management in the urban PHC system using the WHO Health Systems Building Blocks framework.[11 12] In this assessment, we identified gaps across all building blocks. Specifically, within urban UD and NGO facilities, there was often a lack of clinical training and guidelines on hypertension and diabetes management, a lack of screening for hypertension and diabetes, a lack of equipment to diagnose diabetes, a lack of counselling on how to prevent and/or manage hypertension and diabetes and a lack of follow-up and referral processes for patient management.

The findings of the assessment were then presented to relevant stakeholders, specifically representatives from the NCDC Programme, the MOHFW, the Urban PHC Management Unit under the MoLGRD&C, urban health experts and academics. During this meeting, it was agreed with the Government stakeholders that we would prioritise addressing gaps in service delivery, the health workforce and health information systems. The intervention package was then decided on collaboratively with the government stakeholders as a potential solution to the identified key gaps. It was decided that the intervention would include three main components:

1. Training clinical staff at urban PHC facilities on how to manage hypertension and diabetes using the National Protocol guidelines and on how to use the patient health information system.
2. Providing urban PHC facilities with the National Protocol guidelines on managing hypertension and diabetes and copies of a one-page desk-aid summary of those guidelines.
3. Providing urban PHC facilities with a smartphone-based/tablet-based digital health information system to manage patients with hypertension and diabetes (ie, diagnosis, prescription, follow-up and referral recording).

Intervention component details

National protocol for management of high blood pressure and diabetes

As previously mentioned, the National Protocol has been adapted from the WHO's PEN, which has been designed for settings with low resources.[4 8 20] WHO's PEN package has been nationally adapted in several other countries such as Bhutan, Iran and several African countries.[21–23] The National Protocol has been introduced by the MoHFW in Bangladesh, and is currently being implemented across rural PHC facilities.[9] The National Protocol provides clinical guidelines for the screening and assessment of all those aged 40 years and above to identify those at risk of developing NCDs, specifically cardiovascular diseases, hypertension and diabetes. It also provides clinical guidelines regarding the management of these within PHC settings. Through set diagnostic criteria for hypertension and diabetes, it states the first, second and third line of treatment medications, which are low cost and usually easily accessible. It also provides guidance on when patients should be followed up, depending on the hypertensive and diabetic status of the patient, or referred, in the case of serious/complicated cases. The National Protocol also provides clinical guidance on brief counselling that should be provided to patients regarding improved lifestyle behaviours, particularly in relation to diet, exercise and the use of tobacco and alcohol, to prevent and/or manage cardiovascular disease, hypertension and diabetes. This counselling is designed to be delivered within short consultations that are deemed feasible within the often-heavy patient loads in urban PHC facilities. Being adapted from WHO's PEN, the National Protocol encourages managing patients through a team-based approach through distribution of tasks among other relevant healthcare workers such as medical assistants, thereby aiming to reduce individual workload and has been reported to be feasible in PHC settings.[4 8 24] Considering the importance of team-based approach, an implementation pathway has been developed (figure 1), which distributes tasks within patient management across different PHC workers.

Information poster

A one-page A3-sized information sheet has been developed that aims to provide clinical staff with a highly concise overview of the key points in managing patients in relation to hypertension and diabetes according to the National Protocol. This covers whom to screen, the diagnosis criteria, the medication prescribing pathway and the lifestyle modifications about which the patients should be counselled on.

Patient health information system: Simple App

The international NGO *Resolve to Save Lives* developed and introduced a digital health information system, named Simple App, to several LMICs, including Bangladesh, in association with the *National Heart Foundation*.[13] The app has been developed for hypertension and diabetes programmes with the goal of supporting patients to keep their blood pressure and blood glucose levels under control by recording individual patient data (see table 2 for an overview of the data collected).

The app requires a median time of 76 s to register patients, which has been shown to be quicker than the time needed to register patients using paper forms.[13] In addition, the app can be used in an offline mode, following which data can be synchronised when internet is accessed.[13] It is currently used at rural PHC facilities in 25 districts, by health workers, community healthcare workers and health assistants under the supervision of MoHFW and is linked to the National Health Dashboard.[13 25] In addition, the Directorate General of Health Services (DGHS) of Bangladesh is scaling up the use of the app across other rural PHC facilities; however, it is yet to be implemented across urban PHC centres.[25] The app runs on the Android operating system and so can be used on many smartphones and tablet computers. Due to the user-friendliness of the app, its use to register patients with hypertension and diabetes has been allocated to the

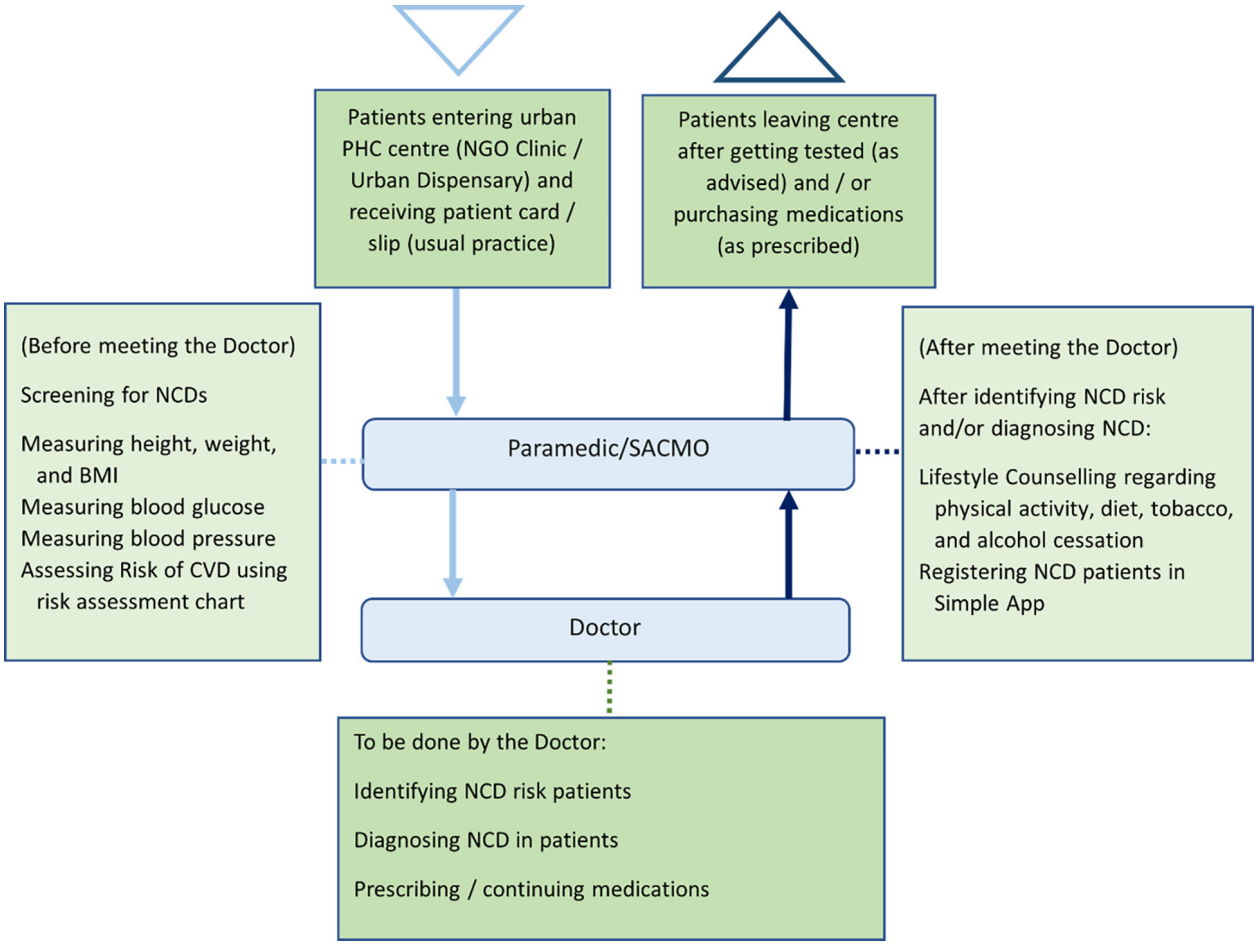

Figure 1 Patient pathway through the intervention. BMI, body mass index; CVD, cardiovascular disease; NCD, non-communicable disease; NGO, non-governmental organisation; PHC, primary healthcare; SACMO, Sub-Assistant Community Medical Officer

Table 2 Data recorded by Simple App

Sociodemographic factors	Age
	Sex
	Address
Clinical data	Medical history of whether the patient has suffered from:
	Heart attack
	Stroke
	Kidney disease
	Blood pressure measurement
	Blood glucose measurement
	Hypertension/Diabetes mellitus diagnosis
Treatment	Drugs prescribed for hypertension/ diabetes mellitus
Advice	Next follow-up date
	Referral status

medical assistant in the developed intervention pathway (figure 1).

Training on the National Protocol and Simple App

A main, 4-day, training programme will be provided to a doctor and a medical assistant from each urban PHC facility in the intervention group, with the individuals selected by their respective management authorities. Trainers will be recommended by the Non-Communicable Disease Control (NCDC) Programme under the DGHS, and will comprise diabetes and hypertension specialists, urban health experts and experts on the use of the Simple App. During the first 3 days, trainees will be trained on the National Protocol, specifically around NCD risk factors, screening, management, lifestyle counselling, follow-up and referral. The training duration has been considered sufficient in consultation with NCDC and DGHS, given their experience of conducting similar training sessions for rural PHC healthcare workers.[26] The training will be interactive and include role play scenarios to enable health professionals to practice the management of patients, as per the National Protocol. On the fourth day,

trainees will be trained on the use of the Simple App for registration and recording of patient with hypertension and diabetes. Although training a healthcare worker at a hospital would require less than an hour,[13] we will conduct the training for a day considering the difference in backgrounds of the trainees. Similar to the training on the National Protocol, this session will also be interactive with role play scenarios. We will also advise those trained to speak to any other relevant staff at their facility who may support the implementation of these processes about the training and how they can assist in implementing (eg, other medical assistants/paramedics/pharmacists).

Refresher training will also be carried out by research staff for the staff trained during the main training programme approximately 2 weeks after the main training is delivered. This will be delivered within intervention facilities and will just focus on the key issues covered in the main training and will take 2–3 hours. This will then be repeated after a further (approximately) 1 month.

See table 3 for a comparison between the intervention components and the corresponding components (or lack of) in the existing care group.

Intervention treatment pathway

Medical assistants (SACMO/paramedics) will screen all patients aged 40 years and above, who attend the urban PHC facilities, as per the National Protocol. Based on the results of the screening, a doctor will then identify those at risk of developing cardiovascular disease, hypertension and/or diabetes or diagnose those who have hypertension and/or diabetes. Patients identified as being at risk of developing one or more of these conditions, or as having one or more of these conditions, will be managed as guided by the National Protocol. All patients will be advised to have a follow-up appointment, with those at risk/diagnosed with one or more of these conditions advised to have this sooner. And those patients diagnosed with one or more of these conditions will be prescribed appropriate medicines (as per the National Protocol) and/or referred elsewhere if needed (in the case of severe cases). All patients will then be sent back to the medical assistant to receive face-to-face lifestyle counselling, based on their NCD status, in line with the National Protocol. Additionally, the medical assistant will register those identified with one or more of these conditions in the Simple App.

See figures 1–3 for an overview of the patient treatment pathways under the intervention.

Outcomes

Primary outcome

Our primary outcome will measure the extent to which eligible patients (anyone aged ≥40 years attending study facilities) are appropriately managed in relation to hypertension and diabetes as per the National Protocol guidelines (which are based on PEN) for the management of these conditions (including their screening and diagnosis) in primary care facilities. We will measure this outcome at baseline and at 6 and 12 months after implementation of the intervention based on direct observation of patient-doctor consultations (see the *Data collection* section for more details). The outcome will allow us to understand whether, and to what extent, the intervention has improved the overall level of appropriate management in relation to hypertension and diabetes for patients aged ≥40 years as per the National Protocol guidelines, which providers are trained on and expected to adhere to as part of the intervention (supported by a desk aid summary of the guidelines). Although this outcome may be affected by the digital patient health information system that is part of the overall intervention package, we do not expect any causal effect of this component of the intervention on this outcome. Therefore, we will try to assess the direct effects of this component of the intervention separately via a separate outcome, for reasons further explained below.

This primary outcome of appropriate management will look at eight key management processes relating to hypertension and diabetes that cover the full management lifecycle including screening, diagnosis, treatment and follow-up. It will objectively assess whether each one was appropriately carried out or not according to the National Protocol guidelines but with some pragmatic adaptations to allow for the fact that clinical staff and data collectors/researchers will not always have all the required information assumed by the National Protocol (eg, patients may not know whether they have been previously diagnosed with hypertension/diabetes, and so clinical staff will not always be able to ascertain this), so they are not penalised by our assessments in situations where they cannot reasonably be expected to follow all the guidelines strictly. Specifically, for each patient the outcome will measure how many of these eight management processes were appropriately carried out in terms of an overall 0–8 score, with each process contributing 1/0 to the score depending on whether it was appropriately (1) or not appropriately (0) carried out. We describe each of these management processes and define how we objectively classify whether the process has been appropriately or not appropriately carried out.

1. Whether the patient has been appropriately screened for hypertension. The patient is considered to have been appropriately screened for hypertension if the HCP measured the patient's systolic blood pressure (SBP) and diastolic blood pressure (DBP) and inappropriately screened if the HCP does not measure the patient's SBP and/or DBP.
2. Whether the patient has been appropriately screened for diabetes. The patient is considered to have been appropriately screened for diabetes if the HCP measured the patient's fasting plasma glucose (FPG) or random plasma glucose (RPG) and inappropriately screened if the HCP did not measure either their FPG or RPG.
3. Whether the patient has been appropriately diagnosed in relation to their hypertension status. Diagnosis in relation to a patient's hypertension status will be consid-

Table 3 Intervention components and corresponding existing care comparison within study facilities

Intervention component	Intervention group	Existing care group
Hypertension and diabetes management tools and processes	National Protocol guidelines for managing hypertension and diabetes will be made available at urban PHC facilities.	No guidelines currently available.
	A one-page, A3-sized, information poster summarising the key management processes from the National Protocol guidelines for managing patients in relation to hypertension and diabetes will be made available at urban PHC facilities.	Not currently available.
	All patients aged ≥40 years attending the facility will be screened by a doctor/medical assistant for hypertension and diabetes, as per the National Protocol. This will help identify patients who are either at risk of developing, or who have developed, hypertension and/or diabetes.	Screening of patients aged ≥40 years for hypertension and diabetes is rarely done/there is no systematic screening process. Consequently, patients at risk of developing, or who have developed, hypertension and/or diabetes are rarely identified.
	All patients aged ≥40 years will be counselled on lifestyle behaviour modification, as per the National Protocol.	Usually, only patients aged ≥40 years who are already diagnosed with hypertension and/or diabetes are counselled on lifestyle behaviour modification by the medical officer/medical assistant, which will be as per their initial training, often leading to non-uniformity across facilities.
	All patients aged ≥40 years will be advised about follow-up by the doctor/medical assistant, as per the National Protocol.	Usually, only patients aged ≥40 years who are already diagnosed with hypertension and/or diabetes are advised about follow-up by the doctor/medical assistant, and this will be as per their initial training, often leading to non-uniformity across facilities.
	All patients aged ≥40 years who are newly diagnosed as having hypertension and/or diabetes will be prescribed medications by the doctor/medical assistant, as per the National Protocol.	All patients aged ≥40 years who are newly diagnosed with hypertension and/or diabetes will be prescribed medications by the doctor/medical assistant, but this will be as per their initial training, often leading to non-uniformity across facilities.
	All patients aged ≥40 years who are known to have existing hypertension and/or diabetes and are already on medications and have controlled blood pressure and/or blood glucose levels will be asked to continue their already prescribed medicines by the doctor/medical assistant.	All patients aged ≥40 years who are known to have existing hypertension and/or diabetes will usually be asked to continue taking their previously prescribed medications by the doctor/medical assistant.
Patient health information system for hypertension and diabetes management	All patients aged ≥40 years who are newly or previously diagnosed with hypertension and/or diabetes will be recorded in the Simple App by the doctor/medical assistant.	All patients aged ≥40 years who are newly or previously diagnosed with hypertension and/or diabetes will be recorded in the existing paper-based patient records system by the doctor/medical assistant.
Training of the urban PHC workforce to manage hypertension and diabetes	Doctors and medical assistants will receive a 3-day training programme on how to implement and use the National Protocol for managing hypertension and diabetes, as well as brief refresher training on the key issues covered 2 weeks and 6 weeks later.	No such training is currently given or will be given as part of this study.
	Doctors and medical assistants will receive a 1-day training session (following the above 3-day training programme) on the use of Simple App, as well as brief refresher training on how to use the app 2 weeks and 6 weeks later.	

PHC, primary healthcare.

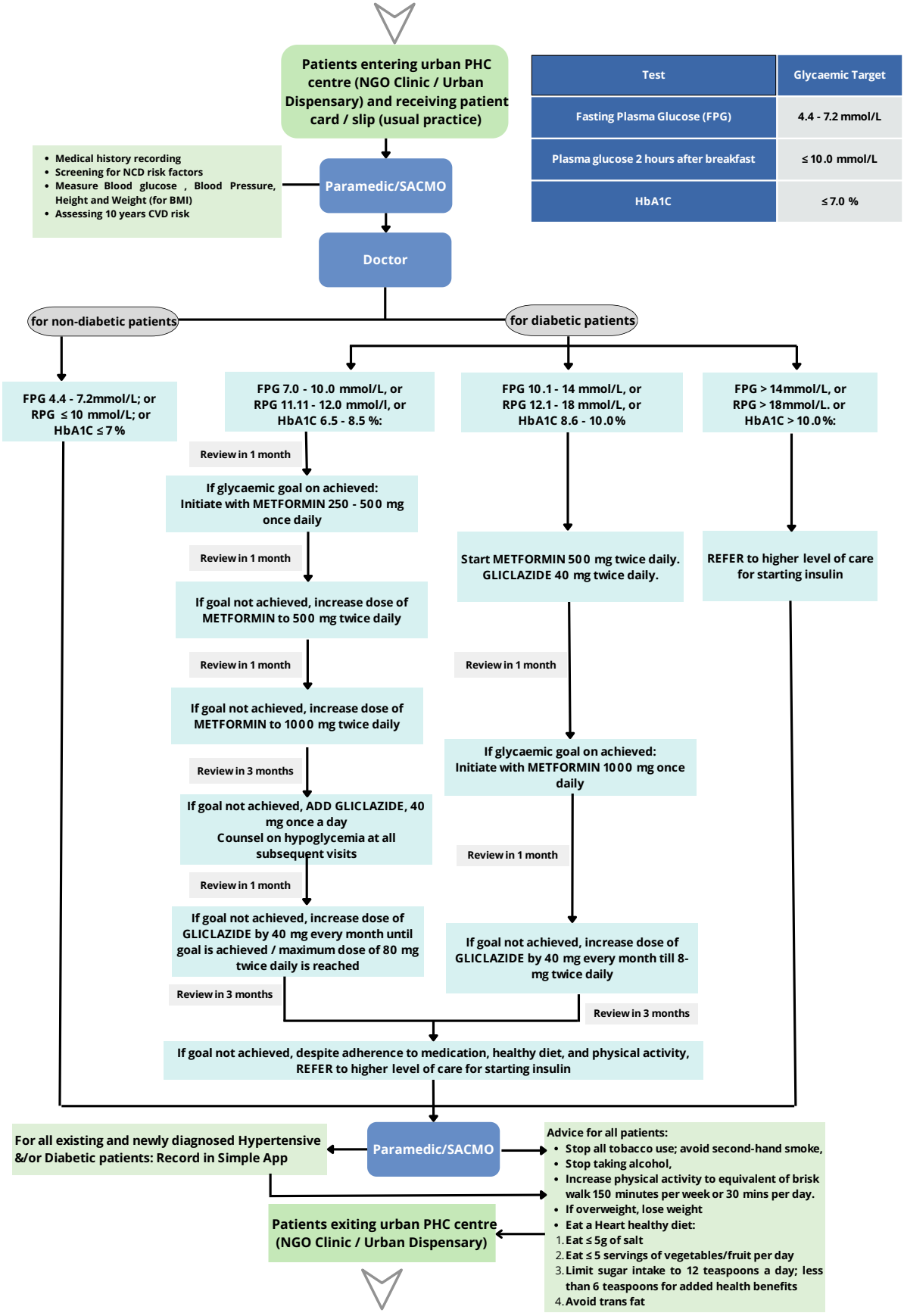

Figure 2 Diabetes management pathway. BMI, body mass index; CVD, cardiovascular disease; FPG, fasting plasma glucose; HbA1c, glycated haemoglobin; NCD, non-communicable disease; NGO, non-governmental organisation; PHC, primary healthcare; RPG, random plasma glucose; SACMO, Sub-Assistant Community Medical Officer.

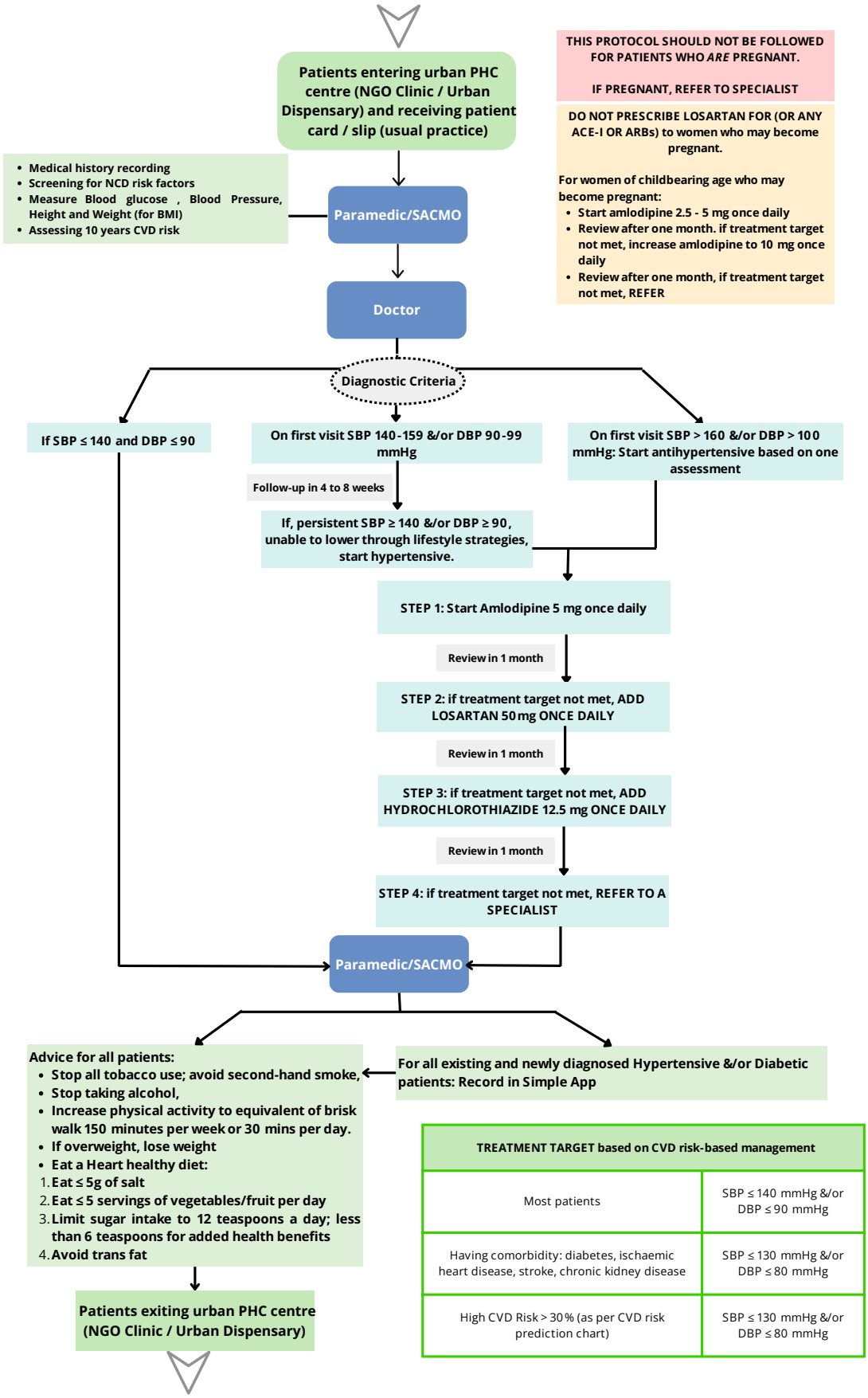

Figure 3 Hypertension management pathway. ARB, angiotensin receptor blocker; BMI, body mass index; BP, blood pressure; CVD, cardiovascular disease; DBP, diastolic blood pressure; NGO, non-governmental organisation; PHC, primary healthcare; SACMO, Sub-Assistant Community Medical Officer; SBP, systolic blood pressure.

ered appropriately carried out if one of the below sets of criteria are met for the patient and inappropriately carried out if none of the below sets of criteria are met for the patient.

The patient (i) was not previously diagnosed by an HCP with hypertension, (ii) had an SBP <140 mm Hg and a DBP <90 mm Hg and (iii) was not diagnosed with hypertension.

The patient (i) was not previously diagnosed by an HCP with diabetes, (ii) had an SBP ≥160 mm Hg and/or a DBP ≥100 mm Hg and (iii) was diagnosed with hypertension.

The patient (i) was previously diagnosed by an HCP with hypertension, (ii) was already on antihypertensive medications and (iii) was diagnosed with hypertension.

The patient (i) was previously diagnosed by an HCP with hypertension, (ii) was not already on any antihypertensive medications, (iii) had an SBP of 140–159 mm Hg and/or a DBP of 90–100 mm Hg and (iv) was diagnosed with hypertension.

4. Whether the patient has been appropriately diagnosed in relation to their diabetes status. Diagnosis in relation to a patient's diabetes status will be considered appropriately carried out if one of the below sets of criteria are met for the patient and inappropriately carried out if none of the below sets of criteria are met for the patient.

   The patient (i) was not previously diagnosed by an HCP with diabetes, (ii) had an FPG <7 mmol/L or an RPG of <11.1 mmol/L and (iii) was not diagnosed with diabetes.

   The patient (i) was previously diagnosed by an HCP with diabetes, (ii) was already on antidiabetic medications and (iii) was diagnosed with diabetes.

   The patient (i) was previously diagnosed by an HCP with diabetes, (ii) was not currently on any antidiabetic medications, (iii) had an FPG of 7–10 mmol/L or an RPG of 11.1–12 mmol/L and (iv) was diagnosed with diabetes.

   The patient (i) was not previously diagnosed by an HCP with diabetes, (ii) had an FPG ≥10.1 mmol/L or an RPG ≥12.1 mmol/L and (iii) was diagnosed with diabetes.

5. Whether the patient has been appropriately prescribed the correct medications, or appropriately not prescribed any medications, in relation to their hypertension status. Prescription in relation to a patient's hypertension status will be considered appropriately carried out if one of the below sets of criteria are met for the patient and inappropriately carried out if none of the below sets of criteria are met for the patient.

   The patient (i) was not previously on any antihypertensive medications, (ii) had an SBP <140 mm Hg and a DBP <90 mm Hg and (iii) was not prescribed any antihypertensive medications.

   The patient (i) was not previously diagnosed by an HCP with hypertension, (ii) had an SBP of 140–159 mm Hg and/or a DBP of 90–99 mm Hg and (iii) was not prescribed any antihypertensive medications.

   The patient (i) was previously on antihypertensive medications, (ii) had an SBP <140 mm Hg and/or a DBP <90 mm Hg and (iii) was prescribed the antihypertensive medications that they were already on.

   The patient (i) was previously diagnosed by an HCP with hypertension, (ii) was not already on any antihypertensive medications, (iii) had an SBP of 140–159 mm Hg and/or a DBP of 90–99 mm Hg and (iv) was prescribed amlodipine.

   The patient (i) was not previously diagnosed by an HCP with hypertension, (ii) had an SBP ≥160 mm Hg and/or a DBP ≥100 mm Hg and (iii) was prescribed amlodipine.

   The patient (i) was already on amlodipine, (ii) had an SBP >140 mm Hg and/or a DBP >90 mm Hg and (iii) was prescribed losartan.

   The patient (i) was already on amlodipine and losartan, (ii) had an SBP >140 mm Hg and a DBP >90 mm Hg and (iii) was prescribed hydrochlorothiazide.

6. Whether the patient has been appropriately prescribed the correct medications, or appropriately not prescribed any medications, in relation to their diabetes status. Prescription in relation to a patient's diabetes status will be considered appropriately carried out if one of the below sets of criteria are met for the patient and inappropriately carried out if none of the below sets of criteria are met for the patient.

   The patient (i) was not previously diagnosed by an HCP with diabetes, (ii) had an FPG ≤10 mmol/L or an RPG ≤12 mmol/L and (iii) was not prescribed any diabetes medications.

   The patient (i) was previously on antidiabetic medications, (ii) had an FPG <7 mmol/L or an RPG <11.1 mmol/L and (iii) was prescribed the antidiabetic medications that they were already on.

   The patient (i) was previously diagnosed by an HCP with diabetes, (ii) was not currently on any antidiabetic medications, (iii) had an FPG of 7–10.0 mmol/L or an RPG of 11.1–12.0 mmol/L and (iv) was prescribed metformin.

   The patient (i) was not previously diagnosed by an HCP with diabetes, (ii) had an FPG of 10.1–14 mmol/L or an RPG of 12.1–18 mmol/L and (iii) was prescribed metformin and gliclazide.

   The patient (i) was already on metformin, (ii) had an FPG >7 mmol/L or an RPG >10 mmol/L and (iii) was prescribed metformin or metformin and gliclazide.

   The patient (i) was already on metformin and gliclazide, (ii) had an FPG >7 mmol/L or an RPG >10 mmol/L and (iii) was prescribed metformin and gliclazide or also with insulin.

   The patient (i) had an FPG >14 mmol/L or an RPG >18 mmol/L and (ii) was prescribed insulin.

7. Whether the patient has been appropriately counselled about healthy lifestyle behaviours at least in terms of diet and exercise. Counselling in relation to

healthy lifestyle behaviours at least in terms of diet and exercise will be considered appropriately carried out if the patient has been counselled about healthy lifestyle behaviours in terms of diet and exercise and inappropriately carried out if they have not been counselled about healthy lifestyle behaviours in terms of diet and/or exercise.

8. Whether the patient has been appropriately advised about follow-up, given their current hypertension and/or diabetes status and risk. Follow-up will be considered appropriately carried out if one of the below sets of criteria are met for the patient and inappropriately carried out if none of the below sets of criteria are met for the patient.
   The patient (i) was not previously diagnosed by an HCP with hypertension and/or diabetes, (ii) was not diagnosed with hypertension and/or diabetes and (iii) was advised to return for a follow-up in 6–12 months.
   The patient (i) was not previously diagnosed by an HCP with hypertension, (ii) had an SBP of 140–159 mm Hg and/or a DBP of 90–99 and (iii) was advised to return for a follow-up in 1–2 months.
   The patient (i) was not previously diagnosed by an HCP with diabetes, (ii) had an FPG of 7.0–10.0 mmol/L or an RPG of 11.1–12.0 mmol/L and (iii) was advised to return for a follow-up in 1 month.
   The patient (i) was prescribed antihypertensive medications and (ii) was advised to return for a follow-up in 1 month.
   The patient (i) was prescribed metformin with a dose up to 500 mg twice daily and (ii) was advised to return for a follow-up in 1 month.
   The patient (i) was prescribed metformin with a dose of 1000 mg twice daily and (ii) was advised to return for a follow-up in 3 months.
   The patient (i) was prescribed metformin with a dose of 1000 mg twice daily and gliclazide with a dose up to 120 mg and (ii) was advised to return for a follow-up in 1 month.
   The patient (i) was prescribed metformin with a dose of 1000 mg twice daily and gliclazide with a dose >120 and ≤160 mg and (ii) was advised to return for a follow-up in 3 months.

Secondary outcomes

Appropriate management practices

We will also treat each of the eight binary components of the primary outcome score, as described above, as eight separate secondary outcomes to allow us to explore how each of the different patient management processes targeted by the intervention have or have not changed under the intervention.

In addition, we will also collect a binary secondary outcome indicator from each patient consultation measuring whether the patient has been appropriately referred (in relation to their hypertension and/or diabetes status), but restricted to only those patients who are newly diagnosed with hypertension and/or diabetes or are known to already have either condition (as patients without either or both conditions would not be expected to be referred). We will also measure this outcome at baseline and at 6 and 12 months after implementation of the intervention. Referral will be considered appropriately carried out if one of the below sets of criteria is met for the patient and inappropriately carried out if none of the below sets of criteria are met for the patient.

- The patient (i) had an SBP >200 mm Hg and/or a DBP >120 mm Hg and (ii) was referred.
- The patient (i) had an SBP >180 mm Hg and/or a DBP >110 mm Hg, (ii) a severe headache, chest pain, shortness of breath, blurred vision, nausea, vomiting or signs of heart failure and (iii) was referred.
- The patient had an SBP >140 mm Hg and/or a DBP >90 mm Hg, (ii) was already on three antihypertensives and (iii) was referred.
- The patient (i) had an RPG ≥18 mmol/L and (ii) was referred.
- The patient (i) had an FPG >7.2 mmol/L or an RPG >10 mmol/L, (ii) was already on the maximum dose of metformin and gliclazide and (iii) was referred.

Simple App utilisation

We will also collect a binary secondary outcome from patient consultations measuring whether the patient is registered into the Simple App or not by the HCP, but restricted to only those patients who are newly diagnosed with hypertension and/or diabetes, or who are existing cases, and only in intervention group facilities (because the Simple App is not being implemented in the existing care group). We will also measure this outcome at baseline and at 6 and 12 months after implementation of the intervention.

Healthcare provider knowledge

Additionally, we will measure the level of knowledge about the appropriate management of hypertension and diabetes, according to the National Protocol guidelines, among all HCPs from intervention group facilities who receive the intervention training. Their level of knowledge will be measured as the percentage of correctly answered questions assessed via a multiple-choice questionnaire, based on WHO's knowledge assessment tool for PEN. The knowledge test will have around 25 questions around case-based scenarios. The questions will be about hypertension and diabetes risk factors, lifestyle modification counselling, medications, follow-up and referral. The knowledge test will be given before and at the end of the intervention training programme.

Sample size

We based our sample size on being able to detect a given difference in our primary outcome between the intervention and comparison groups at 6 months after implementation of the intervention. We assumed we would have four UDs and six NGO clinics per treatment group, which was chosen based on the constraints of our resources and

timeframes. We assumed we would be able to recruit 50 patients per facility at baseline and at 6 months after implementation of the intervention, based on patient flow data and our resources and timeframes. We assumed the primary outcome of appropriate management would be 12.5% (1/8 management processes appropriately carried out) at baseline across both treatment groups (based on contextual knowledge and our facility needs assessment work) and would remain at 12.5% in the existing care group. We assumed an intracluster correlation coefficient of 0.1, based on a conservative rounding up of intracluster correlation coefficient estimates (computed via the analysis of variance method) taken from our previous research into Bangladesh's rural, public, primary care facilities known as community clinics, where we also looked at a similar appropriate management outcome.[27]

We then used a simulation-based approach to estimate the power we would expect given these assumptions and different assumptions about the increase in the primary outcome level in the intervention group. For each scenario, this involved simulating primary outcome data for 50 patients in each of the 10 facilities in each treatment group for each study period, with a 12.5% outcome level in the existing care group at baseline and 6 months and a 12.5% outcome level in the intervention group at baseline but varying the assumed outcome level in the intervention group at 6 months in each different scenario (ie, the assumed increase in the outcome due to the intervention). For each scenario, we ran 5000 simulations generating 5000 datasets.

We then analysed each dataset using the standard DiD linear regression model,[28] with covariates for period, treatment group and their interaction, and computing clustered SEs for the model coefficients, with the HC3 correction for a small cluster sample size.[29] For each scenario, we then extracted the two-tailed p value (based on the t-distribution) for the null hypothesis that the interaction term was 0 from all the models fitted to the 5000 datasets. Assuming an alpha of 0.05, we then computed the proportion of those p values that were <0.05, as our empirical measure of power. From this, we found that if the above assumptions hold, we should be able to detect an increase in the appropriate management outcome to 37.5% (3/8), that is, a 25 percentage point increase, with 80% or greater power (based on obtaining a two-tailed p value of 0.05 or lower for the null hypothesis test of the interaction term).

Facility sampling and recruitment

Within the DNCC and DSCC, there are 19 UDs. Of these, 12 are within areas accessible to the general population and will be assessed on the other eligibility criteria. Of the remaining seven facilities, three are within government working areas, thereby making them less accessible to the public, three are school health clinics and one is a maternity clinic, and these will all be excluded from the study. Across the two city corporations, there are 65 NGO clinics. Of these, 55 are primary healthcare facilities and will be considered for inclusion in the study. The remaining 10 facilities are comprehensive reproductive healthcare centres, which specifically cater to pregnant women and newborn babies and will therefore be excluded from the study.

To determine which facilities will be included in the study, we will carry out a needs assessment of the available facilities and, taking the results into consideration in terms of which facilities could potentially implement the intervention based on available staffing and ongoing service delivery, consult with the Dhaka Civil Surgeon Office and both Dhaka City Corporations. As per the sample size calculation, eight UDs and 12 NGO clinics will be selected for inclusion in the study based on the needs assessment, the facilities with which the researchers have a good working relationship and—following consultation—the willingness and interest of facility managers to participate.

Facility and staff consent

We will verbally brief all health facility managers from the selected PHC facilities on the project and give them an information sheet about what it would involve for them and their facility, staff and patients. For all managers, this information will cover data collection methods, while for those managers in the intervention group, the information will also cover the intervention package. If the facility managers consent to be a part of the study, they will be asked to sign a consent form. We will also verbally brief HCPs, iethat is, the doctor and medical assistant from each facility responsible for patient management, about the project and provide them with an information sheet. For all staff, this information will cover data collection methods, while for those staff in the intervention group, the information will also cover the intervention package. Those who agree to participate will be asked to sign a consent form.

Facility allocation

We will ensure that there are an equal number of UDs and NGO clinics per treatment group (figure 4). As described above, the Dhaka Civil Surgeon Office and both Dhaka City Corporations will decide which facilities to include in the study. They will then decide which facilities to allocate to the intervention or control group, based on the facilities with which they have a good working relationship.

Patient sampling and recruitment

We will collect all study data from patients via visits to the study facilities when those patients are attending for treatment. Specifically, during the data collection period, research assistants will be present at the study facilities 6 days a week, from Saturday to Thursday, as per their operating days. One research assistant will be placed at each study facility. Research assistants stationed at the UDs will be there from 08:30 to 14:20 hours, and those stationed at the NGO clinics will be present from 09:00 to 16:00 hours, in line with the operating hours of the

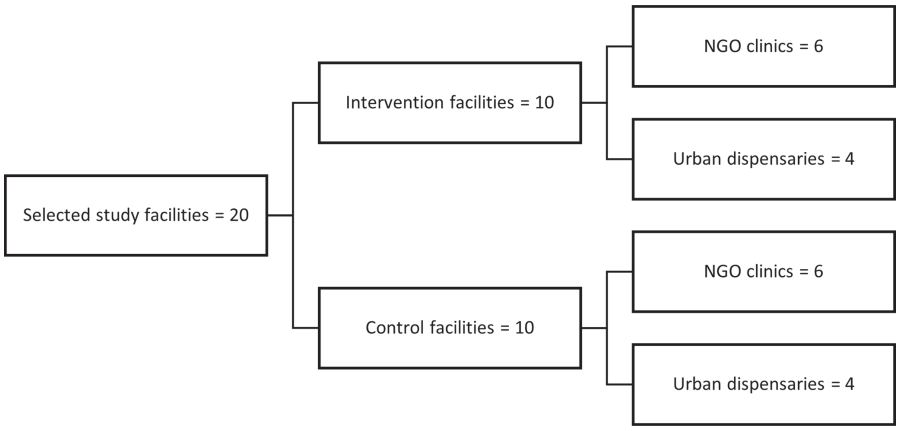

Figure 4 Study facility allocation details. NGO, non-governmental organisation.

respective facilities. During each data collection period, patients who meet the eligibility criteria and consent to be a part of the study will be consecutively recruited until the desired sample size for that facility is reached.

Data collection

To collect our study outcomes and related data (ie patient characteristics), the research assistants present at both intervention and existing care facilities will observe each recruited patient's consultation with the relevant HCPs. They will collect all data via a questionnaire, running on tablet computers, which was developed using Research Electronic Data Capture (REDCap) digital survey software and pretested internally. Additionally, they will also collect prescription data for patients who are prescribed any medicines, which will be collected from the patient's paper prescription.

Data management and quality

Overall data quality will be ensured through in-depth training and supervision of data collectors from the research team. All quantitative data will be recorded via mobile digital tablets by the field data collectors, using the REDCap digital survey application. The quality of the quantitative data will be maximised by careful design of the data collection tool, including automated checks, and extensive pretesting. Specifically, the questionnaire has been designed to restrict possible entries to avoid data entry errors, and with an automated question order that forces data collectors to record a response for each question and with appropriate skips to ensure only those questions that should be asked are. We will use an online data tracker to monitor timely data collection at all the sites. This will involve staff at the central office monitoring the data being collected in real time and providing feedback as required and/or making requests if data need to be checked/confirmed. There will also be a weekly data quality checking process run at the central office to provide a second layer of data quality assurance. Once completed, the data will then be exported to a Stata format database for a final data quality and preparation process prior to analysis.

Statistical analyses

We will use Stata[30] and R[31] statistical software for all data processing and analysis.

Primary and secondary outcomes: causal estimands

For both our primary outcome and secondary outcomes of appropriate management practices, we will estimate the effect of the intervention compared with existing care (see *Intervention description* section for full details) at 6 months after intervention implementation compared with baseline and (separately) at 12 months after intervention implementation compared with baseline. For each of these outcomes, we will estimate the causal effect in terms of the average treatment effect on the treated (ATT, box 1), presented as a prevalence difference.

Primary and secondary outcomes: main analyses

In our main analyses, we will estimate the ATT for the primary outcome and secondary outcomes of appropriate management practices using generalised linear models with logit-links and binomial (for the primary outcome) or Bernoulli (for the secondary outcomes of appropriate practices) errors (ie, logistic regressions), given the binomial and binary outcomes.[28] As our DiD design follows the basic two-period, binary treatment setup, all models will include binary covariates for study period (either baseline/6 months or baseline/12 months), treatment group (intervention/comparison) and the interaction between

Box 1 Common targeted causal estimand for the primary outcome and secondary outcomes related to appropriate management practices

Average treatment effect on the treated: $E\left[Y^1(2) - Y^0(2) \mid A = 1\right]$

Where $Y^a(t)$ is the potential outcome given treatment a at time t. Here, $a=1$ represents the counterfactual scenario with the intervention applied and $a=0$ represents the counterfactual scenario with the intervention not applied, $t=2$ represents the data collection period at 6 or 12 months after implementation of the intervention and $A=1$ represents patient consultations in facilities that received the intervention.

study period and treatment group, as well as additional covariates to try and adjust for potential confounders (see fourth paragraph below). However, as we are using generalised linear models with logit-links, we will use standardisation (also called marginalisation in econometrics) to obtain our estimates of the ATTs, as we cannot obtain the estimates directly from the model coefficients.[28]

Given the clustered (facility-based) assignment of the intervention and likely clustering of outcomes within facilities, we will compute cluster robust SEs (with clustering at the facility level) for the relevant estimates, based on the bias-reduced linearisation (CR2) method with a Satterthwaite-type correction to the df given the small numbers of clusters[32 33] (via the R clubSandwich package).[34] Based on these SEs, we will compute 95% CIs and we will base our statistical inferences about the likely values of our target causal estimands on these 95% CIs.

There are several assumptions that are discussed in the relevant literature as being required to validly estimate ATTs from DiD analyses.[28 35]

First, parallel trends (often referred to as the key assumption). This states that the mean change in an outcome between baseline and any relevant time period in the comparison group follows a 'parallel trend' (ie, with an identical slope) to the corresponding change that would have occurred in the intervention group if the intervention had not been implemented (ie, the counterfactual scenario). This is a weaker version of the more general causal inference identification assumption of conditional exchangeability. Unfortunately, there are no relevant longitudinal data available from the study facilities to assess this, as is often available for DiD studies using routine data, so this will be a key limitation that we cannot assess.

However, given the risk of confounding bias (ie, failure of the parallel trends assumption) arising from the observational design and the use of repeated cross-sectional data—which may lead to changing composition of treatment groups between baseline and 6 and 12 months—we will adjust our DiD estimation models for the following consultation-level confounders:[35] patient age (and a quadratic term for age)[2] and patient sex (female/male). Unfortunately, we will not have access to any additional data on any other sociodemographic or health-related characteristics for patients or any clinical staff characteristics that may be further confounding variables, which will be a further key limitation of our analyses.

Second, positivity. This states that all facilities had a non-zero probability of being assigned to the intervention group. All facilities included in the study can, in theory, implement the intervention based on having sufficient staff and ongoing service delivery. However, as we cannot control the allocation and as it will ultimately be based on largely subjective considerations relating to the strength of existing relationships between facilities and authorities, there will be some ambiguity with whether this assumption is truly met that we cannot resolve, which will be another limitation.

Third, no anticipation. This states that the intervention does not have any causal effect on an outcome before it is implemented. We believe it is unlikely that any such effects will occur. While it is conceivable that HCPs might become aware of the intervention plans prior to implementation, it is unlikely, based on contextual knowledge, that they would have the time or capacity to seek out relevant information and modify their practices accordingly.

Fourth, no spillover (also called no interference). This states that any causal effects of the intervention did not affect the comparison group. There is no plausible way that staff in control facilities could receive the training. In theory, they could obtain the National Protocol guidelines and desk aid from staff in intervention facilities, but we believe this is unlikely. We are aware that medical staff in UDs are sometimes transferred between facilities. We will therefore request that no staff are transferred between intervention and control facilities. We are not aware of similar processes in NGO clinics. In UDs, we are also not aware of any centralised management or training processes (given the limited funding and lack of management systems in place) that could bring staff from separate facilities together and which could lead to spillover effects. However, we are aware of centralised meetings that bring staff from separate NGO clinics into contact with one another. Therefore, we cannot rule out that staff from intervention UDs or NGO clinics might speak to staff from control facilities, either informally or (for staff in NGO facilities) via such meetings, and share information about the intervention with staff from control facilities. However, we believe any informal sharing of information about the intervention with staff in control facilities is unlikely to cause any important spillover effects in the absence of them receiving the formal intervention training.

Fifth, consistency. This states that the observed treatment is equal to the counterfactual treatment (this relies on the no anticipation and no spillover assumptions holding). We are interested in the effect of the treatment under real-world routine conditions. Therefore, we are interested in the effect of delivering the intervention and allowing it to work under real-world conditions thereafter. Based on past relevant experience with similar research in this setting, we are confident that we will be able to effectively deliver the intervention to all relevant clinical staff in all intervention facilities during the planned intervention implementation phase and so our data from intervention facilities should reflect this intervention assumed in the targeted causal estimand.

Primary and secondary outcomes: sensitivity analyses

We will also carry out a range of sensitivity analyses to explore the robustness of our results. Primarily, we will repeat the main analyses described above, but excluding any covariates from the models that were included as potential confounding variables, to assess how sensitive the results are to adjustment for these covariates. We will also repeat our main analyses but using linear regression

models (for the primary outcome this will require first converting it to proportion values) and estimating the ATTs directly from the model coefficient for the interaction between treatment group and study period (again using the same clustered SEs when computing the 95% CIs), and we will repeat these analyses while excluding the potentially confounding covariates.

Primary and secondary outcomes: effect modification

We will also explore possible effect modification of the intervention effect by facility type (UD vs NGO clinic) and patient sex (female vs male). In both cases, we will first compute the intervention effect via the approach described above for the main analyses for each subgroup separately, and then the difference between those two subgroup-specific intervention effects via DiD or triple difference estimator[36]—but using a standardisation-based approach given the use of generalised linear models with logit-links. Again, we will compute the relevant 95% CIs as described above for the main analyses. As these analyses will be underpowered, they will be treated strictly as exploratory.

Primary and secondary outcomes: missing data

Aside from patients who do not consent to participate, we do not expect any missing data to occur other than through accidental omission (based on our data collection design and experience with conducting similar studies in this setting). Therefore, if any missing data are present, we will in the first instance carry out complete case analyses as the amount of any missing data should be very minimal.

Simple App usage

We will estimate the usage of the Simple App by computing the percentage of patients in the intervention group at 6 and at 12 months who are recorded in the Simple App, along with 95% CIs for these point estimates. We will compute each 95% CI by fitting an intercept-only logistic regression model to the outcome and deriving a Wald-based CI on the log-odds scale, which will then be transformed to the probability scale and expressed as a percentage. We will adjust the standard errors for the clustered data using a standard complex sampling design adjustment based on Taylor series linearisation methods.[37]

Healthcare provider knowledge

We will estimate the change in HCP knowledge before and after the intervention training programme by computing the mean of the changes in HCP knowledge scores and the 95% CI for this point estimate based on the t-distribution (ie. a paired t-test).

Evaluation of other RE-AIM domains

To evaluate the other RE-AIM domains (other than effectiveness), we will use a mix of qualitative and quantitative data. The quantitative data will either be from the effectiveness study data described above (see *Statistical Analyses*) or described separately below within each of the other RE-AIM components (see *Reach*, *Adoption*, *Implementation* and *Maintainence*). The qualitative data will come from in-depth interviews with patients and stakeholders. These are explained in more detail in each section below.

Reach

Quantitative data

We will assess the reach of the intervention in several ways. First, we will use study facility records to look at the total number of individuals aged ≥40 years (also disaggregated by sex, age and red card holder status) who would likely benefit each year from the intervention across the study facilities and (by extrapolating) then also including those facilities where the intervention may be scaled up in the future, conditional on our evaluation and future evidence and decisions. Second, more speculatively, we will also look at how many individuals aged ≥40 years (also disaggregated by sex, age and red card holder status) are living within the catchment areas of both the study facilities and those facilities where the intervention might be scaled up. These individuals would therefore have the potential to benefit from the intervention at some point, should they visit a UD or NGO-type PHC facility, conditional on scale-up. We will obtain these data from the census records for catchment area populations available from the DNCC, DSCC and the Civil Surgeon Office. The latest patient census was conducted in 2022 and contains ward-wise population sizes disaggregated by sex in both the city corporations. Third, we will also describe the distribution of key characteristics among patients attending the study facilities, such as sex, age and red card status.

Qualitative data

To understand why the intervention may reach some patients and not others, we will identify a UD and an NGO clinic with better reach and one of each facility type with lesser reach, based on the observation data collected in 6 months after implementation of the intervention. We will then interview a sample of eight HCPs purposively selected from these facilities. The interviews will explore any differences that they perceive in the types of patients accessing and benefiting from the intervention and whether there are some in the facility catchment area that they believe may not be benefitting from the intervention and their perceptions of why this may be. Interview guides will also explore whether the HCPs report any challenges in delivering the lifestyle counselling to specific groups of patients (eg, by gender, age, literacy level or socio-economic status).

Additionally, a sample of 14 patients aged ≥40 years attending the four purposively selected intervention facilities will be interviewed after they exit the facilities to identify any differences in their experience while receiving the intervention. Participants will be purposefully sampled based on their age, gender and whether they are a red-card holder or not, and their NCD status, to understand their experience of screening.

Adoption

Quantitative data

The adoption of the intervention by facilities and by staff within the facilities will be assessed by measuring the number and proportion of facilities invited to participate in the intervention group that accepted or declined, and the number and proportion of HCPs invited for training that accepted and declined. Following training, we will also measure the number and proportion of facilities and HCPs that begin and do not begin implementation, and the number and proportion that completely stop delivering the intervention.

Qualitative data

We will purposively select and interview facility managers (in-charges) and HCPs that have not adopted the intervention, or one or more specific components of the intervention, to explore the reasons for the lack of adoption. We will also purposively select and interview facility managers and HCPs that have fully adopted the intervention to understand their motivations for taking up the intervention.

Implementation

Quantitative data

In the RE-AIM framework, the implementation domain focuses on the fidelity and consistency with which the intervention is delivered as intended. Therefore, as our effectiveness outcomes look at whether the different patient management processes that are intended to occur under the intervention are being appropriately carried out or not, our primary and particularly secondary outcomes will also therefore be used to assess this domain. However, whereas the assessment of the effectiveness domain will involve comparing these outcomes between the intervention and existing care groups, for the assessment of the implementation domain, we will use these outcomes to describe the level of fidelity to the intervention components occurring within the intervention group at the patient level and facility level, and how this fidelity varies across all facilities and between facility types at 6 months after implementation of the intervention.

Qualitative data

Healthcare providers

During the HCP training programme, a researcher will be present to observe the process of training and qualitatively document any observed facilitators and barriers during the sessions. We will also aim to interview eight HCPs who receive the intervention training to understand their perceptions regarding the training programme.

We will also identify a UD and an NGO clinic showing better adoption of the intervention, and another UD and an NGO clinic showing poorer adoption, based on the outcome data collected at 6 months after implementation of the intervention. Within these facilities, qualitative observations will be conducted by a senior qualitative researcher to observe the implementation of the intervention. This will be done to identify factors which may be affecting the implementation of the intervention within the facility, such as lack of privacy, noise, lack of electricity, lack of washrooms and shortages of medications or diagnostic equipment.

Within these same facilities, we will identify one HCP and one facility manager from each facility and interview them about their experiences of implementing the intervention, focusing on the facilitators and barriers to implementation of all components of the intervention that they report. Both managers and HCPs will also be asked to share their perceptions of any unintended consequences (positive or negative) of including the intervention within their routine practice in the facility (eg, lack of time for other activities, better relations with patients or referral institutions).

Patients

As described in the *Reach* section, in the patient exit interviews, we will also ask those 14 patients about their experiences of the intervention to understand which elements of the intervention they remember receiving and any reflections of their interaction with the HCP and the facility. We will also ask those patients how confident they feel to adhere to the advice given to help them manage their diabetes and/or hypertension and any challenges they think they will experience. We will also ask them about any costs they have incurred during their visit or in buying medications.

Policy makers

We will interview policy makers, including government officials and development partners, about their opinions regarding the intervention. Specifically, we will seek to understand how they found the intervention co-creation process, why they wanted to base it on the National Protocol and Simple App, how it has been working in rural facilities, the challenges we have found it may be facing in urban facilities and their views on how we might overcome or mitigate those challenges to allow scale-up and ensure sustainability.

Maintenance

Quantitative data

To assess maintenance of the intervention, we will also make use of the appropriate management outcomes. However, similar to our use of them to assess the implementation domain, we will use these outcomes to describe the level of fidelity to the intervention components occurring within the intervention group at the consultation level and facility level, and how this fidelity varies across all facilities and between facility types, but now at 12 months after implementation of the intervention. To further assess maintenance, we will also evaluate the long-term effectiveness of the intervention via our 12 months postintervention effectiveness analyses.

Qualitative data

We will again interview the HCPs sampled for the implementation domain qualitative interviews, but now after

the implementation period, to understand the reasons for continuation or discontinuation of the intervention and its separate components. Simultaneously, we will also interview HCPs in existing care facilities to understand the reasons for any changes, or lack thereof, in their NCD management practices and data recording. This will help us to assess whether there has been any contamination between the intervention and existing care groups.

Data analyses for other RE-AIM domains

Quantitative data

For the reach and adoption domain, we will estimate simple summary statistics (counts and percentages) appropriate for the planned measures, plus 95% CIs for the percentages as appropriate. For the implementation and maintenance domain descriptive analyses, we will summarise all outcomes in terms of percentages and their 95% CIs, and for just the maintenance domain, we will estimate intervention effects at 12 months as described in the *Statistical analyses* section for the effectiveness domain.

Qualitative data

We will transcribe all interviews verbatim in Bengali and then translate those transcriptions into English for members of the research team who do not speak Bengali. This will be done for quality assurance and transparency of data among Bengali-speaking and non-Bengali-speaking members of the research team. We will use the Framework Approach[38] with an a priori framework structured according to the RE-AIM domains. We will generate codes inductively from our data and group them within each of these broad domains. The coding will be done by three trained qualitative researchers who will start by familiarising themselves with each transcript. Two of the researchers will initially code the transcripts independently. The third coder will then assist in resolving any differences in coding. They will then all discuss the codes and agree how they can best be grouped within the framework of RE-AIM domains. Once the codes are finalised, they will then apply the framework to all the qualitative data collected from both HCPs, managers and patients. We will use NVivo[39] software to conduct qualitative data analysis.

They will then develop narrative summaries under each of the domains of the RE-AIM framework, which will highlight differences in findings between facility types and between patients of different genders, socioeconomic backgrounds and NCD statuses (those with hypertension and/or diabetes). This will inform the respective RE-AIM domains from an equity perspective. To integrate our quantitative and qualitative findings, we will develop a meta-inference table using the RE-AIM domains, which will highlight similarities and differences in findings between the different types of data and/or different participant groups (HCPs, managers and patients).[40]

Qualitative data management and quality

For details on quantitative data management and quality, see *Data management and quality* section. We will collect all qualitative interview data using digital audio recorders, with the data transferred to the password-protected computer of the qualitative researchers. The recording will be deleted from the recorder once the verbatim transcript is produced. Overall data quality will again be ensured through in-depth training and supervision of data collectors from the research team, focusing on good questioning and probing techniques for the qualitative data collectors. Detailed feedback will also be provided on the qualitative transcripts and analyses by senior researchers.

DISCUSSION

In Bangladesh, the prevalence of NCD risk factors, hypertension and diabetes is higher among those living in urban areas compared with those living in rural areas.[14 15] The burden of this eventually falls on Bangladesh's pluralistic urban PHC system.[6] Although there are many different types of PHC facilities in urban areas, this study focuses on those UDs and NGO clinics that provide services and medications at no or minimal cost to patients. The aim of the planned intervention is to strengthen the ability of these UDs and NGO clinics to manage the rising tide of hypertension and diabetes, and reduce patients' risk of other cardiovascular diseases, through timely management of patients either at risk of developing these conditions or those found or known to have these conditions, by systematic and effective screening, diagnosis, lifestyle counselling, use of appropriate medication and effective follow-up and referral processes. The long-term goal is for this evidence, if positive, to justify the government to support scale-up of the intervention across all such facilities in urban Bangladesh.

Ethics and dissemination

Ethics approval has been received from the Research Governance Committee at the University of Leeds, UK (MREC 21-008) and from the Bangladesh Medical Research Council (BMRCAIREC/20 I 9-2022/485). We will use a variety of channels to share our findings with policymakers, service providers, academicians and relevant stakeholders.

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Contributors DB, RH, JPH and HE conceived the study and wrote the first and all subsequent drafts. TE, BE, MD, KI, RC, MA, USA and NBJ made comments and suggestions on the draft paper. All authors participated in manuscript revisions and edits and read and approved the final manuscript. DB is the guarantor.

Funding This study is funded by a grant from UK aid from the UK government (Grant 301132).

Disclaimer The views expressed do not necessarily reflect the UK government's official policies.

Competing interests None declared.

Patient and public involvement Patients and/or the public will be involved in the design and intervention co-creation, reporting, and dissemination plans of this research

Patient consent for publication During each data collection period, we will invite eligible patients who enter health facilities to participate in the study. Those who are interested will be verbally briefed on the project and provided with an information sheet. If the patient is unable to read the information sheet, it will be read to them. For all patients, this information will cover the data collection methods, while for those patients in the intervention group, the information will also cover the intervention package that has been implemented in the facility. If the patient agrees to participate, we will take either written or (if they are illiterate) verbal informed consent to collect data during their consultation and, to access their NCD-related records from the patient register, and to access their prescription information (when necessary). Patients will be informed that they can withdraw from the study at any time until their data isare analysed. If they withdraw prior to this, all their data in the dataset will be set torecorded as missing.

Provenance and peer review Not commissioned; externally peer reviewed.

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