


# BMJ Open Detection, linkage to care, treatment and monitoring of hypertension in coastal communities in Accra, Ghana: protocol for a quasi-experimental study (The Ghana Heart Initiative Hypertension Study)

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## ABSTRACT

**Introduction** Over the past few decades, the prevalence of hypertension in Ghana has increased significantly. Insufficient diagnosis and suboptimal management of diagnosed cases result in increased mortality and morbidity due to poor blood pressure control and attendant complications. This highlights the need for new models of hypertension control in highly burdened, urban poor communities. This study aims to identify patients with hypertension in the coastal communities of the Greater Accra region, link patients newly diagnosed with hypertension to appropriate medical care and monitor treatment outcomes using task-shifting strategies.

**Methods and analysis** In this quasi-experimental study, participants with a mean blood pressure of  $\geq 140/90$  mm Hg will be recruited from seven coastal communities of Ghana's Greater Accra region. Based on proportion to the size of these communities, we will screen and recruit 10 000 and 3000 participants, respectively, from all study sites. We will link the recruited individuals to designated health facilities and follow them for a year to assess treatment outcomes, blood pressure control, adherence to treatment, anthropometric measurements, fundoscopic assessment, urinalysis, blood urea nitrogen and creatinine level, ECG and echocardiograms. In addition, we will use mobile health technology to support community screening, blood pressure checks and remote monitoring of patients diagnosed with hypertension, as well as send messages on medication adherence and lifestyle changes. Furthermore, we will conduct focus group discussions among community members and in-depth interviews with persons considered to be newly diagnosed with hypertension, community health workers and religious leaders/representatives to assess the knowledge and perceptions of different study participants regarding hypertension diagnosis, management, control, experiences and treatment.

**Ethics and dissemination** The study was approved by the Ghana Health Service Ethics Review Committee (protocol identification number GHS-ERC 028/08/22). We

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The key strength of this study is its use of task-shifting with community healthcare providers and of electronic blood pressure monitoring that is based on existing national electronic platforms, an approach that aims to make healthcare easily accessible to patients while ensuring good blood pressure control.
- ⇒ The study will gather data to determine the feasibility and cost-effectiveness of this approach in treating high blood pressure in coastal areas where it is prevalent.
- ⇒ The results of this study will guide the development of the first ever electronic platform for community healthcare workers for collecting clinical data which doctors can evaluate in clinics, potentially improving communication between doctors and community healthcare providers in Ghana.
- ⇒ The study may result in a low number of recorded consultations during the evaluation phase due to unreliable internet connectivity and power supply issues, limiting the conclusions that can be drawn.

will obtain written informed consent from each participant. In addition to journal publication, dissemination activities will include a report to the Ghana Health Service on the outcome of the project.

**Trial registration number** ISRCTN76503336.

## INTRODUCTION

Hypertension is a major public health problem given its growing prevalence. It is the leading cause of mortality worldwide, with 10 million people dying from hypertension-related complications.<sup>1</sup> Hypertension-associated mortality is largely due to stroke, heart failure, chronic kidney disease and



peripheral vascular disease.<sup>2-4</sup> The number of people with hypertension in Africa has increased from 54.6 million in 1990 to 130.2 million in 2010, with projections indicating it will reach 216.8 million by 2030.<sup>5</sup> In Sub-Saharan Africa (SSA), the prevalence of hypertension in adults ranges from 30.0% to 31.1%<sup>6-7</sup>; the reported prevalence of hypertension in Ghanaians aged 31–74 years is 30.3%.<sup>8</sup> The burden of hypertension in Africa remains high despite lifestyle changes and medical interventions aimed at preventing and controlling it.<sup>9</sup> Hypertension-related morbidity and mortality tend to affect the economically active age group, and as a result hypertension causes severe economic hardship for many families in Africa.<sup>10</sup> Urban poor or suburban communities, characterised by intake of energy-dense foods and a sedentary lifestyle, bear a disproportionately higher burden of hypertension and its complications.<sup>11</sup>

A study in coastal areas in Indonesia showed a hypertension prevalence of 6.45%–51.1%, with the prevalence of prehypertension ranging from 26.5% to 39.75%.<sup>12</sup> In Indonesia's estuarine areas, the prevalence is 25.3%.<sup>12</sup> High sodium intake is strongly associated with an increased risk of hypertension in these areas. A recent study assessing intake of potassium and salt among Ghanaians using the WHO SAGE wave 3 data showed that more than three-quarters (77.7%) of Ghanaians had salt intake above the WHO maximum recommended level of 5 g/day, with 39% consuming more than twice this level.<sup>13</sup> Furthermore, the study revealed that nearly two-thirds had daily potassium intake below the recommended level of 90 mmol/day.<sup>13</sup> There has been a drastic change in Ghanaians' nutritional behaviour, with most people switching from local healthy diets to energy-dense, nutrient-poor, processed fast foods such as instant noodles and salty snacks, among other things.<sup>14-15</sup> Furthermore, regular consumption of highly salted foods, such as fish and meat, is still part of traditional Ghanaian cuisine, and use of salt in cooking remains high.<sup>16-17</sup> Fishing is the main occupation of people living along Ghana's coast, and salting, drying and smoking fish are the main methods of preserving fish.

Undiagnosed hypertension and suboptimal blood pressure control are of clinical and public health significance as they result in increased morbidity and mortality, including end-organ damage and sudden death.<sup>18</sup> Early diagnosis and optimal blood pressure control are key to preventing hypertension-related morbidity and mortality, often achieved through pharmacological and/or lifestyle modifications. Such an intervention entails identification of reasons for poor hypertension control, including non-compliance with antihypertensives. Existing data show that a myriad of factors account for this non-compliance, including forgetfulness, long travel distances to health facilities, long waiting times in clinics and inadequate funds for transportation to clinics for clinical reviews.<sup>19</sup> Given the increasing cases of hypertension in SSA and poorly resourced health facilities, morbidity and mortality are expected to worsen if implementation gaps in hypertension control are not identified and addressed. Thus,

the primary goal of this study is to identify individuals with hypertension in coastal communities and link them to care. The study also aims to use mobile technology applications via text messages to remind patients with hypertension to visit community health planning and services (CHPs) and community pharmacists for blood pressure monitoring, medication refilling and adhering to treatment plans as outlined by the physician (task-shifting). Task-shifting comprises the rational redeployment of tasks to persons within the healthcare team with fewer qualifications that, conservatively, are not within their scope of work.<sup>20</sup> This organisational technique has been promoted as a significant strategy to improve health system performance, particularly in resource-deprived settings, taking into account any cultural norms that may exist within a country.<sup>20-21</sup> Policymakers will then have an alternative intervention to the current one, enabling them to determine what is cost-effective and feasible with limited resources, thereby guiding the process of scaling up in the real-world context. Furthermore, future programmes and policies will be equipped with the necessary evidence to select this intervention or create programmes with enhanced effectiveness and efficiency.

## METHODS AND ANALYSIS

This will be a multicentre, community-based, quasi-experimental and qualitative study designed to identify persons with hypertension in seven coastal communities in six districts/municipal and metropolitan areas of the Greater Accra region of Ghana, link them to appropriate medical care, explore their perceptions on hypertension and its management and follow them for 1 year. The study will commence on 27 February 2023 and end on 4 October 2024.

### Study setting

In Ghana, the Greater Accra region has the highest proportion of people, accounting for 17.7% of the total population.<sup>22</sup> According to the 2021 Ghana Population and Housing Census, the Greater Accra region has 5 455 692 people. The region is 91.7% urbanised and has an average household size of 3.2. Due to immigration and high population growth rate, this region has the highest population density. From 10 administrative areas in 2010, the region now boasts of approximately 29 administrative areas. The region makes up 1.4% of Ghana's total land area, which is 3245 km<sup>2</sup>. It is bordered by the Central Region to the west, the Volta Region to the east and the Eastern Region to the north and south, with the Gulf of Guinea forming its coastal areas and with Accra being the regional capital<sup>23</sup> (figure 1). The region hosts several manufacturing industries, oil companies, financial institutions, telecommunication, tourism, education and health institutions. Nevertheless, the main economic activity in the coastal zone of Ghana is fishing, and the majority of residents have their lives revolving around this industry. The sector accounts for 4.5% of Ghana's gross



**Figure 1** Study areas in the coastal belt of Accra in the Greater Accra region.

domestic product, employs an estimated two million people and produces a total of 440 000 metric tons of fish annually.<sup>24</sup> In many coastal areas, the fishery sector drives the local economy, and a decline in the ability of the sector to provide employment and income threatens the very survival of the community members. People living in the coastal zone of Ghana, such as in Chorkor, Teshie-Nungua and Jamestown, are particularly subject to poverty due to their vulnerability to shocks from climatic and non-climatic sources. Many of the resources that the urban poor depend on are common pool resources. While this means they are able to use resources such as fish, it also means that a decline in these resources leads to an increase in the incidence of poverty and vulnerability among the coastal people.<sup>25</sup> Nevertheless, the region recorded the highest proportion of persons 12 and older who have functional information and communication technology devices. For instance, 89.2% had smart mobile phones compared with the national average of 73.1%. However, those with non-smart mobile phones (27.9%) were 8 percentage points lower than the national average of 35.9%<sup>26</sup> (figure 2).

### Study participants

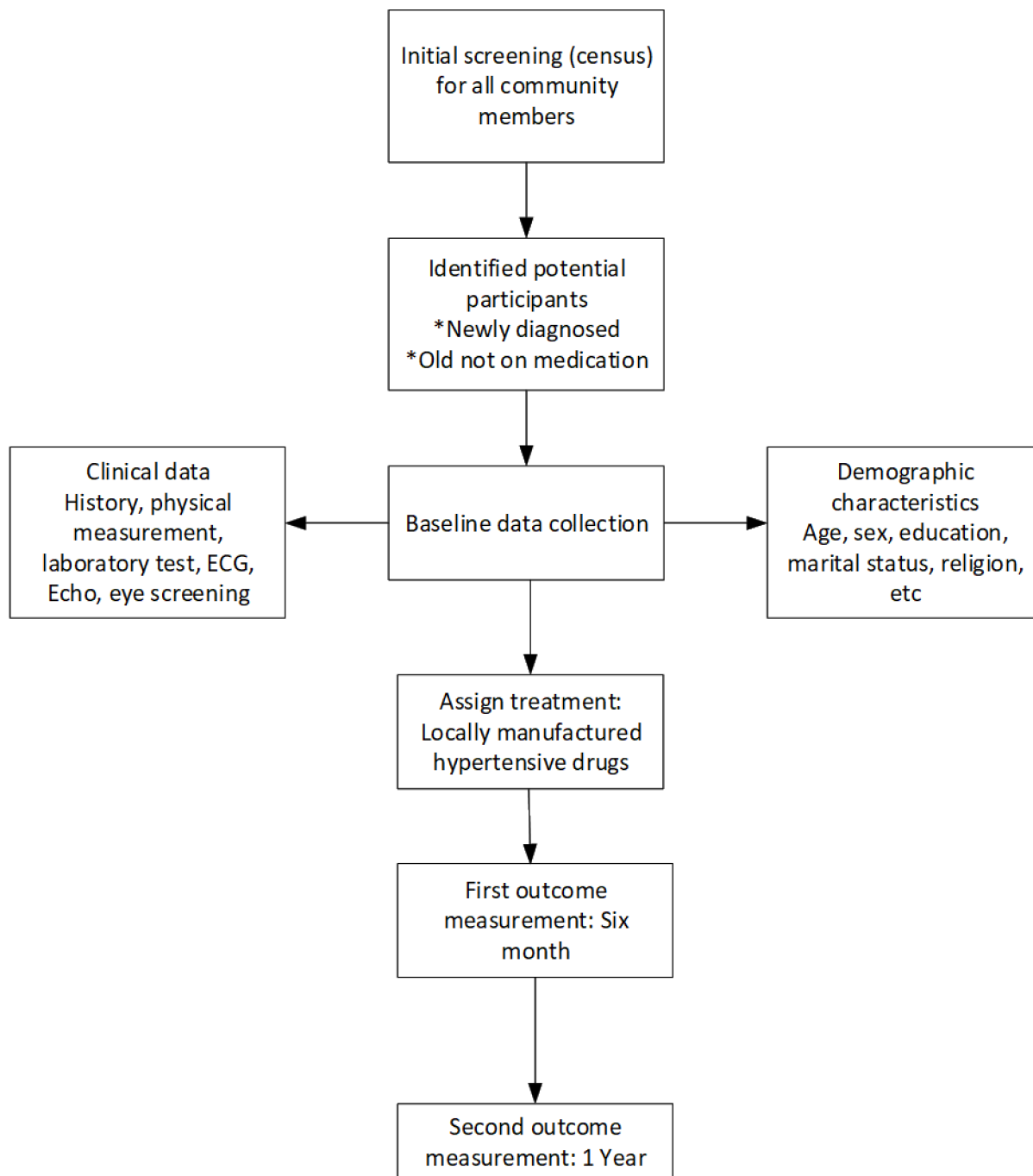
The study population will be permanent residents 18 years and older who record a three-time mean blood pressure of 140/90 mm Hg and above at the time of recruitment in the eight study sites in seven coastal communities of the Greater Accra region in Ghana. The following are the inclusion criteria: (1) resident of the Greater Accra region of Ghana, (2) resident of the selected urban coastal communities, (3) aged 18 years or older as of

last birthday, (4) have no intention of relocating outside of the study communities prior to enrolment or during the study period, (5) have a three-time blood pressure recording with a mean of  $\geq 140/90$  mm Hg at the time of recruitment, (6) with newly diagnosed hypertension and (7) willing to participate and has the ability to give consent. The following are the exclusion criteria: (1) not a resident of the Greater Accra region and the selected coastal communities, (2) residents who intend to travel or relocate before or during the study period, (3) known participants with hypertension who are already on medication, (4) known end-organ dysfunction on treatment and (5) not willing to participate in the study or do not give consent.

### Sample size and sampling procedure

A recent systematic review and meta-analysis reported a pooled hypertension prevalence of 30.0% in SSA.<sup>6</sup> A more recent systematic review and meta-analysis on the prevalence of hypertension in Ghana also reported a pooled prevalence of 30.3%.<sup>8</sup> Based on the fact that 30% of people in the population have high blood pressure,<sup>6,8</sup> we plan to screen a total of 10 000 people in the community to identify 3000 participants whose three-time mean blood pressure reading is 140/90 mm Hg or higher at the time of recruitment. Furthermore, we will sample and recruit the expected 3000 participants from the eight study sites, taking into account the proportion of their respective populations from the 2021 Population and Housing Census,<sup>27</sup> respectively.

The district, municipality or metropolitan areas from the specific study site determine the number of people



**Figure 2** Organogram defining the study procedure and outcome measurements. \*To be identified and linked to local health care facilities for care and follow-up.

to sample and recruit, as shown in [table 1](#). We will use a stratified two-stage cluster sampling method to ensure the results accurately reflect the eight coastal districts of Accra. The sampling frame for the study will leverage the updated frame prepared by the Ghana Statistical Service based on the 2021 Population and Housing Census. Using a probability proportional to the size of each community, we will select clusters within the eight districts from the sampling frame in the first stage. Following this, a systematic random sampling will be used to select 82 clusters with equal probability from the clusters selected in the first phase. We will then proceed with household listing

and map updating operations in all the selected clusters to create a comprehensive list of all the households within each cluster. We will use this list as a guide to select the households that will comprise the final sample. To create the study's sample, we will start by enumerating areas within the selected clusters, then select one in three households using systematic random sampling method. Once the household is selected, all adults 18 years and older within the household who satisfy the inclusion criteria will be recruited.

During the qualitative phase of the study, we will select community health workers (CHWs), patients with

**Table 1** Expected number of participants to be screened and followed for evaluation

	Expected participants to be screened (n)	Expected participants to be diagnosed (n)	CHNs (n)	Number of devices being used to collect the data	Participants to be screened weekly (n)	Participants to be followed weekly (n)
AMA: Ashiedu Keteke	722	217	12	8	30	7
AMA: Ablekuma South	897	269	15	10	30	7
Ga South: Old Bortianor and Kokrobite	2853	856	45	29	33	7
Krowor: Nungua	1165	350	20	12	32	7
La Dade-Kotopon: La Kakramadu	1143	343	20	12	32	7
Ledzokuku: Teshie	1770	531	30	18	33	7
Tema: Mahean	1450	435	25	15	32	7
Total	10000	3000	167	104	32	7

AMA, Accra Metropolitan Assembly; CHN, community health nurses.

hypertension, religious leaders or representatives, and community members (men and women) for indepth interviews (IDIs) and focus group discussions (FGDs) using a purposive sampling method. Each of the eight study sites will host a total of 14 FGDs, with six to eight participants per group and two FGDs each. Each of the study sites will also conduct eight IDIs. The eight IDIs will consist of two health workers involved in Non-communicable Diseases (NCD) service provision, two individuals newly diagnosed with hypertension and two community representatives (table 2).

### Community engagement

Permission to conduct the study in the various districts will be sought from the Regional Director of Health Services and the directors of the various intervention districts. A meeting will be held with district directors and the district directors of nursing from the implementation districts to inform and educate them about the screening evaluation and follow-up strategies for the intervention. The district directors will also inform and educate the subdistrict public health nurses and community health nurses (CHNs) on the intervention strategies. In addition, they

will engage with opinion leaders and members of the community health management committee, as well as leaders of mosques and churches, to provide them with a detailed explanation of the intervention, emphasise its significance and request their support. Subsequently, each district will launch the project in a community that is near the facility chosen for the evaluation. At this event, the intervention will be presented to the community. Education about hypertension and its implications will be provided. There will be a video presentation on hypertension and its associated problems. The invited attendees will include the community health committee member, influential figures, the assembly representative and the chief or queen mother. Stakeholders will be enlisted in the subdistrict where the intervention will occur. On the designated meeting day, the CHN will meet with different stakeholders in their respective zones. Each district will select a radio station that has a significant listenership among the residents of the neighbourhoods to provide educational information about the intervention. Additional information about the training programme can be found in online supplemental file 1.

**Table 2** Number of study participants by study site and by type of study population

District, municipality/metropolitan	FGDs		IDIs
	Female	Male	
AMA: Ashiedu Keteke	1	1	8
AMA: Ablekuma South	1	1	8
Ga South: Old Bortianor and Kokrobite	1	1	8
Krowor: Nungua	1	1	8
La Dade-Kotopon: La Kakramadu	1	1	8
Ledzokuku: Teshie	1	1	8
Tema: Mahean	1	1	8
Total	7	7	56

AMA, Accra Metropolitan Assembly; FGD, focus group discussion; IDIs, indepth interview.



### Training of fieldworkers

To ensure standardisation and accuracy of data to be collected, all fieldworkers will be trained in all aspects of the study, including blood pressure measurement, participant recruitment and participant consenting process. The training will be conducted in four clusters, involving all implementing districts. The training will involve the evaluation centre staff and the subdistrict team. Fieldworkers will include CHWs, pharmacy staff in community pharmacies, medical doctors, nurses and laboratory scientists. They will assist in the administration of the questionnaires and in the measurement of physiological variables and blood samples. Specialist cardiologists will conduct the ECG and echocardiogram, while specialist ophthalmologists and trained technicians will perform the fundoscopic assessment. The details are available in online supplemental files 1 and 2.

### Data collection methods and procedures

Before the start of the project, community sensitisation will be carried out to get the support of the public, community members and their leaders/gatekeepers. Information about the study and their role as potential participants will also be made clear to ensure full participation and cooperation. There will be social mobilisation by stakeholders in each community to create awareness about the research.

Data collection will be carried out by trained health personnel and the project team using a hybrid method, that is, in person and on the phone, where possible, after obtaining informed consent. While both baseline and endline data collection will be conducted in person, the cohort study component of this project may use other methods, such as phone calls for follow-up with study participants, to ensure proper monitoring and adherence to study protocol. Throughout this process, participants' privacy and confidentiality will be guaranteed. Data collection will take an average of 50 min. Although all study participants will be recruited from their homes, interviews will be conducted at places convenient for them. Expert opinion and pretesting will be used to validate data collection tools.

Quantitative data in the form of records and logs will be generated from baseline interviews, screening and monitoring of blood pressure, including clinical and laboratory information, as shown in [table 3](#) and [figure 1](#). We will deploy CHWs into various communities to conduct initial screenings during late afternoons and weekends, a time when a significant portion of the coastal community's target population is available. We will recruit community members who meet the criteria and provide informed consent for the study. We will also train community pharmacies, workers in CHP compounds and chemical sellers within the study areas to recruit individuals who meet the inclusion criteria. These agents will be responsible for identifying persons with hypertension in the communities, collecting the demographic data and linking them to a designated health facility for appropriate medical care.

Cases identified and linked to the health facility will have baseline demographic, clinical and laboratory information collected ([table 3](#)). We will record the baseline information in a database for further comparative analysis. The health facilities will start the patients on antihypertensive medications and modify their lifestyles according to cardiovascular disease guidelines. They will follow up at 6 months and 12 months, respectively, to monitor compliance with medication and lifestyle changes, treatment rate, control of hypertension and detection of target organ damage ([table 3](#)).

Trained research assistants will collect quality data. They will use semistructured interview guides to conduct individual face-to-face IDIs with all study participants, as well as FGDs with community members. All IDIs will be conducted one-on-one with the participants in an enclosed area, away from others, to ensure privacy and confidentiality. Participants of the FGDs will also be urged to respect each other's confidentiality. Discussions and interviews will take approximately 90 min and 50 min, respectively. Permission will also be sought from both FGD and IDI participants to record the discussions and interviews on a digital recorder. After transcribing the data, these will be permanently deleted from the digital recorder. All discussions and interviews will be conducted at convenient locations for the participants. Expert opinion and pretesting will validate both data collection tools. Information such as demographic and socioeconomic characteristics; knowledge, attitudes, practices and experiences regarding hypertension; knowledge about hypertension, diagnosis and treatment; support systems; and the impact of hypertension on life and family will be collected.

### Screening visit

This initial meeting with the community participants will include an assessment of hypertension status. We will recruit those who meet the inclusion criteria after obtaining their informed consent. They will then be directed to the evaluation centre (health facility) with a medical doctor for baseline data collection using a structured electronic data collection instrument that collects demographic, clinical and laboratory data, including blood and urine samples ([table 3](#)).

### Monitoring and follow-up at the community level

CHWs, including pharmacists, chemical sellers, medical doctors and nurses, will conduct monthly monitoring at the community level. [Figure 2](#) summarises the main activities. The monitoring and evaluation plan for data collectors is available in online supplemental file 3.

### Linkage to care

The community will link participants to nearby community pharmacies and chemical sellers for medication refills and blood pressure monitoring. This will help reduce travel distance to health facilities for follow-up

**Table 3** Assessments during screening and scheduled visits

Variable	Schedule of visits				
	Screening	Monthly community visits (CHW)	Visit 1 (baseline)	Visit 2 (6 months)	Visit 3 (12 months)
Eligibility confirmation	X				
Informed consent	X				
Hypertension: old or newly diagnosed	X				
Demographic information: age, gender, house number/address, digital address, occupation, educational level, income level, telephone number, NHIA card, spouses'/relatives' name and contact, and assigned CHN			X		
Site: community/household, CHPs, health centres and community wellness clinics			X		
Lifestyle: smoking, alcohol intake, physical activity, salt intake, psychosocial stress, insurance status and medical history using the short version of WHO STEPS questionnaire			X	X	X
Drug: hypertension and concomitant drugs			X	X	X
Medical history: comorbidities, reproductive history and infectious history			X		
Physical examination: BP measurement, anthropometric measurements (weight, height, WC, WH ratio) and funduscopy			X	X	X
Evaluation and monitoring of hypertension at baseline, 6 months and 12 months			X	X	X
Laboratory tests/imaging: FBS, LP, BUE Cr, LFT, urinalysis, UACR, 24-hour urine sodium, chest X-ray, ECG and/or echocardiogram			X	X	X
WHO region D (African) CVD risk calculator score			X	X	X
Treatment of hypertension and comorbid conditions			X		
mHealth technology		X	X	X	X
Medication adherence using the Hill-Bone Compliance to High Blood Pressure Therapy Scale			X	X	X
Community monitoring/refill of medication: BP measurement at home and input by the client into the app (monitored by CHN/NO/MO); follow-up at the community pharmacy and by the CHN (home visits/CHPs): complaints/concerns, adverse drug reactions, pill burden, compliance/adherence to treatment and lifestyle modification, BP reading (1, 2, 3 and average), FBS (only for patients with diabetes), feedback from the hospital (designated nurse/MO) through the app, electronic tracking of prescription and medication refill at the community pharmacy		X			

BP, blood pressure; BUE Cr, blood Urea and Creatinine; CHN, community health nurse; CHPs, community health planning and services; CHW, community health worker; CVD, Cardiovascular Disease; FBS, Fasting Blood Sugar; LP, Lipid Profile; mHealth, mobile health; MO, Medical Officers; NHIA, National Health Insurance Authority; NO, Nursing Officers; UACR, Urine Albumin Creatinine Ratio; WC, waist circumference; WHO STEPS, World Health Organization STEPwise approach to NCD risk factor surveillance.

visits, as well as allow for monthly blood pressure checks at these sites.

### Study visits

The CHWs in various communities will conduct monthly follow-up visits to ensure and reinforce antihypertensive drug compliance, as well as perform weekly blood pressure checks. The CHWs will also use the opportunity to carry out health education and encourage communities to register for the National Health Insurance Scheme, which gives participants access to health services at a subsidised fee. Reduction in participants' financial burden will aid in maintaining continuity of health facility visits.

This will improve medication monitoring and refilling at the community pharmacy. The CHWs will record blood pressure in the electronic data system, allowing doctors at the evaluation centre to assess them electronically during scheduled physician follow-up visits for evaluation (online supplemental file 4).

### Evaluation visits

This is the follow-up encounter with participants after the initial screening and baseline data collection. The following data will be collected during these visits at 6 and 12 months to evaluate hypertension-mediated target organ damage (HMTOD): self-reported stroke,

electrocardiography/echocardiography, kidney function tests including urinary albumin to creatinine ratio, and funduscopy (table 3). Patients will continue their usual standard care and follow-up visits with their doctors. The following samples will be collected during each visit: 5 mL of blood (collected into EDTA tubes and stored in a  $-80^{\circ}\text{C}$  freezer for analysis of APOL1 genetic polymorphisms to determine its association with high blood pressure) and 5 mL of early morning midstream urine (to be stored in a  $-80^{\circ}\text{C}$  freezer for assessment of measures including urine sodium: creatinine, albumin to creatinine ratio, and potassium to creatinine ratio).

### Electronic monitoring of blood pressure

The screening will direct all eligible participants diagnosed with hypertension to a community-based clinic for evaluation and follow-up. The long-term goal is to enrol these individuals in regular care at wellness clinics situated within or close to the community. The health-care delivery model that integrates digital technology will register these individuals. The District Health Information Management System (DHIMS) with electronic tracker (e-tracker) services will be useful in community screening, blood pressure checks and remote monitoring of patients diagnosed with hypertension, with personalised follow-up automatically generated. This is an electronic application that records client transactions and tracks the care continuum using an electronic healthcare register. The US Agency for International Development<sup>28</sup> has launched and made this application accessible at the subdistrict level in Ghana's community health facilities. The Policy, Planning, Monitoring and Evaluation Division of the Ghana Health Service designed the e-tracker for this project and integrated it into the DHIMS electronic platform, which is accessible at all Ghana Health Service facilities. This will ensure longitudinal data-driven care, timely feedback and easier access to healthcare.

### Assessment of adherence

We will adopt the Hill-Bone Compliance to High Blood Pressure Therapy Scale<sup>29</sup> to measure participant adherence, aiding in process monitoring and evaluation. Given its validation in controlling hypertension in human populations, the study will employ this tool.<sup>29</sup> We will divide patients in each health facility into two groups: the intervention arm and the control arm. The control arm will receive standard care, including education on lifestyle changes and usual antihypertensive medication. Using the DHIMS e-tracker, the intervention arm will receive the usual standard care plus mobile health (mHealth) messages. The messages to participants in the intervention group will include healthy lifestyle choices, including fruit and vegetable consumption, low-salt diet, smoking cessation, alcohol reduction and moderate exercise for a minimum of 30 min daily for 5 days a week. The device will also send messages reminding participants of the need to take their antihypertensive medications. Throughout the 12-month study period, the device will send these messages

twice a week. The mHealth technology will indicate that the participant has received and read the messages. The 6th and 12th months of the study will see follow-ups for both the control and intervention arms. We will divide the seven study sites into two clusters and randomly assign them to either the intervention arm or the usual standard care arm using simple random sampling. We will carry out the randomisation through balloting.

### Clinical measurements and definitions

Blood pressure will be measured three times using an Omron blood pressure monitor (from Detronix Biomedical Technologies) in a sitting position after at least 5 min of rest using appropriate cuffs around the left upper arm. The mean of the last two measurements will be recorded. Hypertension will be defined based on the 2018 European Society of Cardiology guidelines: 'SBP values  $\geq 140$  mmHg and/or diastolic BP (DBP) values  $\geq 90$  mmHg and known hypertensives already on medication'.<sup>30</sup> We will use a stadiometer (Lifecare USA) to measure the participant's body weight and height while barefoot and wearing light clothing, to the nearest 0.1 kg for weight and 0.1 cm for height. We will measure the waist circumference (WC) and hip circumference (HC) using tape measure in a standing position, to the nearest 0.1 cm. We will measure WC and HC in the middle of the lowest gear, the highest point of the iliac crest and the largest external gluteal muscle, respectively. Body mass index of  $>30$  kg/m<sup>2</sup> and WC  $>102$  cm in men and  $>88$  cm in women will be considered obesity. We will assess psychological distress using the Kessler Psychological Distress Scale (K10), which consists of 10 questions about emotional states, each with a five-level response scale.<sup>31</sup> Albuminuria of  $\geq 300$  mg per 24 hours or random protein to creatinine ratio of  $\geq 0.5$  g/g or random urine albumin to creatinine ratio of  $>30$  mg/mmol will be considered clinically significant. We will evaluate salt restriction of less than 5 g/day; alcohol consumption of less than 14 units per week for men and less than 8 units per week for women; increased consumption of vegetables, fruits and nuts; low consumption of red meat; and consumption of low-fat dairy products. Left ventricular hypertrophy will be defined using the Sokolow-Lyon criteria.

### Outcome variables

The main outcome measure is the control of hypertension and the incidence of HMTOD in urban coastal communities in Accra. Secondary outcome measures include the prevalence of hypertension at baseline, the proportion of patients with hypertension linked to care in an urban coastal community in Accra, the medication adherence rate among patients with hypertension linked to care and the perception and lived experiences of community members regarding hypertension and its management.

### Future plans

The current project, which is limited to the coastal areas of the Greater Accra region, will be expanded to other

regions in the country. Furthermore, we plan to follow up on patients with hypertension in these communities to determine their long-term adherence to lifestyle changes and medications and to assess control and treatment rates over time. Again, it is part of Ghana Heart Initiative's long-term goal to ensure continuity of care in these communities and prevent or delay the development of HMTOD. As part of this project, we will store samples for future analysis to determine the association between APOL1 polymorphisms and hypertension with or without proteinuria.

## Data management and analysis

### Quantitative data analysis

Both paper-based and electronic-based data sets will be pulled together into Microsoft Excel format for management. This is to check for completion, blanks and inconsistencies. Data will be further exported into the latest versions of SPSS (version 18) and STATA (version 26) for analyses. Data analyses will be achieved via descriptive and inferential statistical analyses. The characteristics of the intervention and control arms will be compared using  $\chi^2$  or Fisher's exact test of independence, Mann-Whitney U test for rank-ordered variables and independent t-test for overall outcome and according to cluster. To compare baseline and endline variables within each arm, McNemar's  $\chi^2$ /binomial test, sign test/Wilcoxon signed-rank test and paired t-test will be used for proportions, ranked-ordered variables and measured variables, respectively. The difference-in-difference method will be employed to understand the effect of the intervention on hypertension control. A multivariate technique, that is, a data reduction method factor analysis, will be used to identify the number of distinct dimensions for medication adherence.

### Qualitative data analysis

After data collection is completed, the recorded IDIs and FGDs will be transcribed by trained personnel. IDIs and FGDs conducted in the local language will be translated first to English and then transcribed following best practices in qualitative research,<sup>32</sup> while those conducted in English will be transcribed directly. Manually transcribing qualitative data often results in a higher level of accuracy and deeper immersion in the data compared with the use of a transcription software, where poor audio quality, heavy accents or technical jargons can affect the quality of the transcript. Clean verbatim transcription approach will be used in this study.<sup>33</sup> This approach focuses on the content of the interaction with the participants rather than the style or way they speak. Transcriptions done using this approach capture every word spoken, but omit stutters, repetitions, false starts and filler words, ensuring a cleaner, more readable transcript.

After the transcripts are completed, each will be quality-checked by the study team members for accuracy and readability. This will be done by cross-checking the recording with the transcribed data to ensure the transcript best

reflects the interaction with the study participants. This process may include corrections and refining the transcript until it accurately represents the interview or group discussion. All transcripts will be anonymised, appropriately labelled and stored on a password-protected device which can be accessed only by the study team members.

The transcribed data will be analysed using the thematic analysis approach, which involves generating codes and organising them into themes.<sup>34</sup> The initial coding of the data will be done using both the deductive and inductive approaches. Deductive codes will be derived from existing studies conducted in Ghana and other African countries with a similar context. On the other hand, inductive codes will be derived from unexpected insights from the data, which can be linked to the study's objectives. The next stage of the analysis will involve a nuanced linkage of the generated codes into organising themes, which will be informed by the study's objectives.<sup>35</sup> The generation of codes and themes will be discussed among the study team to validate the coding and overall analysis. Representative quotes that best capture the codes will be presented for illustration. The analysis will be facilitated by the qualitative software package Atlas.ti.

## Patient and public involvement

None.

## ETHICS AND DISSEMINATION

The Ghana Health Service Ethics Review Committee approved the study and assigned the protocol identification number GHS-ERC 028/08/22. The study has been registered with ISRCTN registry under number ISRCTN76503336. We will conduct the study in accordance with the 1964 Helsinki Declaration on Human Experimentation, with subsequent revisions. We will only recruit individuals who meet the eligibility criteria for the study. We will adequately inform the study participants about the purpose, nature, procedures and potential risks of the study. We will emphasise the importance of anonymity, confidentiality and the freedom to decline participation or withdraw from the study without any penalty. The electronic data collection system (DHIMS) secures the collected data, and only the study biostatistician and investigators have access. We will obtain written informed consent from each participant of the study (online supplemental file 5). Dissemination activities, in addition to journal publication, will include a report to the Ghana Health Service on the project's outcome, outlining how the project can enhance efforts in preventing and reducing morbidity and mortality associated with hypertension in these communities.

## DISCUSSION

The study incorporates a cross-sectional assessment at baseline, a quasi-experiment and a qualitative analysis, making it impossible to establish the causal relationship



between the intervention and the desired study outcome. Nevertheless, this design, in the absence of an experiment, provides a high level of evidence without randomisation. Additionally, the findings from both FGDs and IDIs may not necessarily reflect the views of entirely different urban coastal communities, but provide relevant information on hypertension control from the perspectives of health workers, patients with hypertension and members of the communities. Again, we foresee some other challenges carrying out this project. First, there is a possibility that the data collection period will be prolonged due to variations in community dynamics that may exist in these urban coastal communities. The study team looks forward to strongly collaborating with the key gatekeepers in the different study sites to ensure a smooth and successful take-off and recruitment of study participants. The team also acknowledges the sensitivity surrounding illness in Ghanaian culture, as it does in other cultures. Nevertheless, many Ghanaians may freely discuss issues related to their health conditions with their primary caretakers and health providers. We anticipate that the study participants will use these opportunities, when suitable, to impart the knowledge they gained from the community health education. The study team will ensure that all core research activities surrounding formal recruitments, such as ensuring voluntary informed consent and other mandatory ethical requirements, strictly involve trained, experienced and qualified members of the research team. Qualified clinicians on the research team will exclusively handle all clinical aspects of the study. Additionally, the study team will encourage the study participants by continuing to highlight the expected positive outcomes of the study in order to reduce the high likelihood of lost to follow-up or withdrawals. Furthermore, this study will provide community-level information on hypertension and its management from the diverse perspectives of healthcare workers, opinion leaders and patients with hypertension. This will guide the introduction of community-specific interventions that will help detect hypertension early and introduce cost-effective treatments that can reduce the burden of hypertension-associated target organ damage. The results of this study will assist policymakers in improving the use of task-shifting methods in treating patients in these coastal communities.

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