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Studying the practicality and acceptability of a community intervention to manage high blood pressure in rural Kenya and The Gambia

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Registration date 10/02/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 09/04/2025	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

High blood pressure (known medically as hypertension) is a major cause of death worldwide, causing over 10.8 million deaths each year. In sub-Saharan Africa (SSA), high blood pressure is very common and often leads to serious health problems like heart failure, stroke, and kidney disease. In rural areas of SSA, many people do not know they have high blood pressure, or they do not receive the treatment they need. This study aims to find better ways for the diagnosis and management of high blood pressure in these regions.

This study wants to find out whether trained community health workers can help identify people with high blood pressure in rural areas of Kenya and The Gambia by checking their blood pressure and sending those with high blood pressure to a health facility. At the health facility, healthcare providers will do more checks, and if needed, give them a simple treatment of one pill that contains two medicines for treating high blood pressure (Fixed Dose Combination). These medicines are called ‘Amlodipine’ and ‘Perindopril’. Research has shown they are safe and effective, and they are approved and licensed for sale and use in Kenya and The Gambia. They have been chosen because research evidence shows that most patients need two medicines to control their blood pressure and that Amlodipine works well in treating blood pressure for patients of black African origin. The study will examine if this way of identifying and managing high blood pressure is practical and acceptable to both healthcare providers and patients. The study will also assess any challenges faced in using this way of delivering high blood pressure services and how it can be made to work in the long term.

Who can participate?

The study will take place in two rural sites: Kilifi South and Kilifi North in Kenya and Kiang West in The Gambia, and plans to include 500 participants, with 250 from each country. Participants will be chosen randomly from the local population in Kilifi North and South, areas that are covered by the Kilifi Demographic Health Surveillance System and Kiang West in the Gambia, and they will be between 30 to 80 years old.

What does the study involve?
This study will involve three main parts. First, Community Health Promoters (CHPs) in Kilifi, Kenya or Village Health Workers (VHWs) in Kiang West, in The Gambia will visit people's homes to check their blood pressure using a simple machine. If someone has high blood pressure, they will be sent to a health facility for more tests to see if they are at risk for heart disease or if their organs (such as the heart, kidneys, or eyes) have been affected. People who have high blood pressure will be advised on lifestyle changes by the healthcare provider (nurse/clinical officer), and if they are at high risk for heart disease or their organs are affected, the healthcare provider at the health facility will provide a fixed-dose combination (FDC)- (a single pill that combines two medicines) to lower their blood pressure. After that, community healthcare providers will continue to visit participants at their homes to check their blood pressure and make sure they are taking their medication regularly. If someone's blood pressure is still high, they will be asked to go back to the health facility for further help. The frequency of home visits for those patients put on the FDC pill (one pill with two high blood pressure drugs) will vary depending on whether participants' blood pressures are well-controlled or not.

In addition to this process to identify and treat people with high blood pressure, members of the study team will also talk to participants and healthcare providers to understand their experiences with it. They want to know if this way of managing high blood pressure is easy to use and acceptable for everyone involved, and what challenges they may face. This will help us learn how to improve this approach in the future. They will also observe some community healthcare workers and healthcare providers at the health facilities to see if they are doing everything they are supposed to do correctly. This will help us understand whether their training was effective, and whether the tasks are practical or if they are too difficult or complex to do.

What are the possible benefits and risks of participating?
For healthcare providers, being part of the study might mean seeing more patients than usual, especially during the first month when blood pressure screenings are happening. The study will schedule activities on the same day as the regular blood pressure (hypertension) clinic. While there are no direct personal benefits for healthcare providers, their participation will help improve our understanding of how to manage high blood pressure in the community and shape future health policies.

For community participants, the main risk during the study is a brief discomfort when their blood pressure is checked using a cuff that squeezes their upper arm, but this will only last a few seconds. The study visits and activities in the community will take about 15 minutes and will be done at their homes, so they do not need to travel and it shouldn't disrupt their daily routine. If someone is found to have high blood pressure, they will need to go to a healthcare facility for further tests, which might take more time and they will need to cover their own travel costs.

Fixed dose combinations are included in the guidelines for the management of high blood pressure. There is already a strong evidence base for their effectiveness and potential to reduce treatment burden. The specific product proposed is already authorised for marketing in Kenya and it will be used exactly as licensed in the proposed feasibility study. The study will meet the costs of the tests offered at the primary healthcare facility and drugs for the patients who are put on FDC (one pill with two medications for hypertension treatment). The drugs used in this study are already available in the Kenyan market. One year's worth of the medication will be to study participants and are working with Kilifi County Health Department and KEMSA to facilitate procurement for the longer term.

For the part of the study that talks to participants about their experiences, they will be asked to come to a convenient location and their travel costs will be covered. Patient/caregiver

participants will be reimbursed for travel costs incurred and Kshs 500 r for out-of-pocket expenses for any interviews or focus group discussions conducted at the health facility. These talks will also be scheduled at times that suit them. During these conversations, participants can choose not to answer any questions they find uncomfortable. If participants need medication to manage their high blood pressure, there may be some side effects, which a healthcare provider will explain to them in detail. The main benefit for patients is finding out if they have high blood pressure and getting help to manage it early.

When does the study start and how long is it expected to run for?
August 2024 to December 2025. The study will start once ethical approval is obtained and run until December 2025. The overall study duration for the participants receiving the intervention will be 6 months.

Who is funding the study?
National Institute for Health and Care Research (NIHR), UK

Who is the main contact?
Prof Pablo Perel, pablo.perel@lshtm.ac.uk
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Feasibility of a community-based intervention for the diagnosis and management of hypertension in two rural populations in Kenya and The Gambia

Study objectives
The hypothesis of this study is that a community-based intervention for hypertension management is feasible and acceptable in rural Kenya and The Gambia. Specifically, the intervention will demonstrate successful adoption and high fidelity among community health workers and facility-based healthcare providers, and broad reach among community members. Additionally, the intervention will be positively received by communities, healthcare providers, and policymakers, and the associated costs will be manageable. These outcomes will support the implementation of a future full-scale trial aimed at effectively managing hypertension in these rural settings.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 21/03/2025, London School of Hygiene and Tropical Medicine Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 20 7636 8636; ethics@lshtm.ac.uk), ref: 31372

2. approved 13/01/2025, Gambia Government/Medical Research Council Joint Ethics Committee (Medical Research Council, Banjul, PO Box 273, Gambia; +220 4495442-6 EXT.2308; ethics@mrc.gm), ref: 31372

3. approved 05/03/2025, National Committee for Science, Technology and Innovation (NACOSTI) (off Waiyaki Way, Upper Kabete, Nairobi, P. O. Box 30623, Kenya; +254 20 8001077; customercare@nacosti.go.ke), ref: 466782

Study design
Mixed-methods non-randomized single-arm feasibility study

Primary study design
Interventional

Study type(s)
Diagnostic, Screening, Treatment

Health condition(s) or problem(s) studied
Hypertension in adults aged 30-80

Interventions
The intervention comprises four core components aimed at enhancing hypertension management in rural Kenya and The Gambia.

First, the intervention involves task-sharing between clinicians and community health promoters (CHPs) in Kenya/village health workers (VHWs) in The Gambia for blood pressure screening. CHPs /VHWs conduct automated blood pressure measurements (aABPM) at participants' homes, performing three consecutive readings to ensure accuracy (baseline assessment). Participants with blood pressure readings ≥130/80 mmHg are referred to primary healthcare facilities for further risk stratification and potential treatment initiation. Those with readings ≥180/110 mmHg undergo expedited evaluations for hypertensive crises and, if symptomatic, are referred to higher-level healthcare facilities for advanced care (Referral assessment).

Second, at the primary healthcare facilities, participants undergo comprehensive diagnosis and risk stratification, including assessments for hypertension-mediated organ damage (HMOD) and cardiovascular disease (CVD) risk factors using point-of-care tests such as electrocardiograms (ECG) and urine dipsticks.

Third, based on these clinic assessments, participants are either provided with non-pharmacological lifestyle interventions or initiated on fixed-dose combination (FDC) therapy consisting of Amlodipine and Perindopril, tailored to their clinical profiles.

The fourth component involves the dispensing and ongoing management of FDC medications, with CHPs/VHWs conducting regular community follow-ups to monitor adherence and blood pressure control (follow-up assessments). This structured follow-up includes multiple visits over six months, allowing for dose adjustments and referrals as necessary. Additionally, comprehensive training is provided to all healthcare providers involved in the study, encompassing both theoretical and practical sessions to ensure proficient implementation of the intervention components.

This multi-faceted approach aims to evaluate the practicality and acceptability of the hypertension management strategy, addressing potential challenges and ensuring sustainable health outcomes.

Intervention Type
Mixed

Primary outcome(s)
The primary outcomes involve the feasibility and acceptability of a community-based hypertension management intervention in rural Kenya and The Gambia, to inform the design of a future full-scale trial.

Feasibility will be assessed through the following key variables:
1. Reach and dose measured using data collected on sampling rate, eligibility rate, consenting rate, screening rate, data completeness, data accuracy, loss to follow-up rate, delayed follow-up rate, withdrawal rate, and retention ratio
2. Fidelity measured using data collected during direct observations of healthcare workers to determine their adherence to the intervention protocols and training received
3. Adoption and acceptability measured using data collected during qualitative interviews and focus group discussions with healthcare providers and participants to evaluate the extent to which the intervention is accepted and integrated into existing healthcare practices.

These variables will be systematically measured using standardised data collection instruments and protocols throughout the study period to ensure consistency and reliability at multiple points throughout the study: at baseline screening by community healthcare workers, at referral clinics by healthcare providers, and follow-up visits by community health care workers, mid-term evaluations, and post-intervention, to ensure continuous monitoring and accurate assessment of the intervention’s practicality and acceptance.

Key secondary outcome(s))
Direct and indirect costs to patients and their households and the healthcare system associated with the implementation of the intervention and standard care. The two primary sources for resource use estimation will be: reviews of financial and project records during the intervention duration and interviews with project staff and front-line healthcare providers for time and

resource use over the past month. Prospective time and motion studies will also be conducted including direct observation of staff carrying out their normal duties and asking staff to fill time sheets over a typical week of work.

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Aged 30 to 80 years old at the time of consent
2. Able to complete all study procedures

Participant type(s)
Health professional, Population

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
30 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. Existing hypertension treatment (self-reported)
2. Pregnant women (self-reported)
3. Women who are breastfeeding (self-reported)

Date of first enrolment
01/05/2025

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
Gambia

Kenya

Study participating centre
MRC Unit The Gambia at LSHTM
Atlantic Boulevard
Fajara
Banjul
Gambia
PO Box 273

Study participating centre
Karantaba Minor Health Centre
Kiang West, Lower River Region
Karantaba
Gambia
9R2X+RWC

Study participating centre
Jifarong Community Health Clinic
Jifarong, Kiang West,
Lower River Region
Jifarong
Gambia
74XM+43

Study participating centre
KEMRI-Wellcome Trust Research Programme
Kilifi
Kenya
PO Box 230-80108

Study participating centre
Chasimba Health Centre
Kilifi -Kaloleni road near Chasimba Trading Centre
Dzitsoni
Kilifi
Kenya
P.O Box 1129

Study participating centre
Matsangoni Model Health Centre
Along Mombasa- Malindi highway. Near Matsangoni Primary school

Matsangoni
Kilifi
Kenya
P.O Box 9 Kilifi 80108

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available to the wider research community upon request in accordance with the Wellcome-Trust overseas programme and LSHTM policy on data sharing and subject to agreements with the Kenya Medical Research Institute and MRCG.

IPD sharing plan summary
Available on request