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Measuring blood pressure and cardiovascular risk in rural Kenya and The Gambia

Submission date	**Recruitment status**	[_] Prospectively registered
23/02/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/02/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
27/02/2024	Circulatory System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Many people live with high blood pressure in sub-Saharan Africa. In this region, the proportion of people with high blood pressure is one of the highest in the world. However, few people with high blood pressure are treated and this can lead to serious medical issues and even death. This is particularly true in rural areas where treatment and understanding of blood pressure is lower than in cities.

There are many reasons why high blood pressure is a major health problem in rural sub-Saharan Africa, such as a lack of clear symptoms; less access to healthcare; and limited time to travel to clinics for care. One option for improving the management of blood pressure is to use a community-centred approach, where care is brought into the community making it easier to access.

To bring care into the community, we need to find out what is the best way for community health workers to identify who needs to be treated. Standard techniques may not be useful in a rural community and could require too many resources to make them practical. This study aims to determine what is the best way to identify high blood pressure and related health complications in a community setting.

Who can participate?

The study will take place across two sites: one in Kilifi, Kenya and the other in Kiang West, The Gambia. We will enrol 1250 participants, aged 30 years or older, with 625 in each country.

What does the study involve?

Participants who join the study will complete a series of short questionnaires about their general health status. They will then receive 4 different blood pressure measurements over a two-week period. These include a home-based measurement (twice daily for seven days), unattended and attended measurement (once each for 15 minutes) and a 24-hour measurement (the participants will wear a cuff for 24 hours). The blood pressure measurements will be conducted in a different order for each participant. Following the blood pressure measurements, the participants will attend their local clinical facility for tests to determine if they have any organ damage caused by high blood pressure. The tests will look at your heart,

eyes, kidneys, and blood vessels. A single blood draw is required. These tests will require two visits from the participant to the clinic facility. Any relevant findings will be reported back to the participant. After this, participants have completed their involvement in the study.

What are the possible benefits and risks of participating?
Benefits. Participants will have their blood pressure measured and be told whether they have high blood pressure. In addition, participants will be able to find out whether the high blood pressure has affected their organs. After the study, those with high blood pressure will be referred to the appropriate clinics for further care. There is a benefit to society by helping us find the best ways to measure blood pressure and associated organ damage.
Risks: The overall risk profile of this study is very low. Minor risks involved in participating in this study include loss of time completing blood pressure assessments and questionnaires. Additionally, when invited to the hospital for further tests, participants will spend time travelling to the hospital and having the measurements. Participants will be compensated for their travel costs. Finally, there is risk of pain, redness, swelling or infection at the site of the blood draw.

Where is the study run from?
London School of Hygiene & Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
August 2022 to January 2026

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

Who is the main contact?
ihcor_africa@lshtm.ac.uk

Contact information

Type(s)
Public, Scientific

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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
Determining the optimal diagnostic and risk stratification approaches for people with hypertension in two rural populations in Kenya and The Gambia

Acronym
IHCoR-Africa WP2

Study objectives
Sub-Saharan Africa (SSA) has one of the highest prevalences of hypertension worldwide. The impact of hypertension is of particular concern in rural SSA, where access to clinics and hospitals is limited. Improvements in the management of people with hypertension in rural SSA could be achieved by shifting diagnosis and care from the clinic to the community. To develop such a

community-centred programme we need optimal approaches to identify and risk stratify patients with elevated blood pressure. The aim of the study is to improve the evidence base for diagnosis and risk estimation for a community-centred hypertension programme in two rural settings in SSA.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 06/03/2023, London School of Hygiene & Tropical Medicine Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 20 7927 2723; ethics@LSHTM.ac.uk), ref: 28276

2. approved 06/02/2023, KEMRI Scientific & Ethics Review Unit (Center for Geographic Medicine Research, Coast, Kilifi, P.O. Box 230-80108, Kenya; +254 020 2722541; ddrt@kemri.go.ke), ref: KEMRI/SERU/CGMR-C/277/4620

3. approved 06/03/2023, MRC the Gambia Ethics Committee (Atlantic Boulevard, Fajara, PO Box 273, Gambia; +220 44954426 Ext 2308; ethics@mrc.gm), ref: 28276

Study design
Multicentre cross-sectional cohort study

Primary study design
Observational

Study type(s)
Diagnostic, Prevention, Screening

Health condition(s) or problem(s) studied
Hypertension

Interventions
Participants will be identified through demographic surveillance systems and approached to participate. Those who consent will be entered into the study. Participants will have their blood pressure measured in four different ways over two weeks. These assessments include:
1. Attended and unattended Automated Blood Pressure Measurements (aABPM and uABPM), which take 10-15 minutes to conduct, will be performed at the homes of study participants
2. Home-based Blood Pressure Measurement (HBPM) which consist of morning and evening measurements performed by the individual participant for 7 days in a row
3. 24-hour ambulatory BP measurement (24-hr-ABPM) which requires participants to wear a blood pressure monitor for 24-hours.

After the blood pressure measurements, participants will be invited for two clinic visits to assess the impact of the hypertension on their heart, eyes, kidneys and blood vessels. They will receive electrocardiograms, echocardiography, blood tests, and diagnostic imaging of their retina. At these visits information will be collected on demographics, household assets, anthropometrics, diet, physical activity, history of hypertension and medication use. After the clinic visits, participants will be discharged from the study.

Intervention Type

Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Omron 907, Omron m7 Intelli, Omron 24/7, Spacelabs 24 hour ABPM, Abbott iStat, Remidio FOP-NM10, Alivecor KardiaMobile 6L, and Tendiomed Arteriograph 24.

Primary outcome(s)
Measured at baseline:
1. Blood pressure measured by 24-hr ABPM, HBPM, and u/aABPM.
2. Left ventricular hypertrophy measured by transthoracic echocardiogram, 12-lead electrocardiogram and smartphone based 6-lead ECG
3. Left ventricular systolic dysfunction assessed transthoracic echocardiogram, and smartphone based 6-lead ECG
4. Hypertensive retinopathy measured using clinical grade retinal camera and smartphone-based portable retinal cameras
5. Renal dysfunction measured using clinical laboratories and point-of-care clinical chemistry devices
6. Arterial stiffness measured using blood-pressure cuff assessment of pressure wave velocity

Key secondary outcome(s))
1. Cardiovascular risk factors assessed using questionnaire at baseline
2. Participant demographics assessed using questionnaire at baseline

Completion date
31/01/2026

Eligibility

Key inclusion criteria
1. Registered in population registers of the KWHDSS (The Gambia) or KHDSS (Kenya)
2. Aged ≥30 years at the time of enrolment in the study
3. Able to provide written informed consent to participate in the study

Participant type(s)
Healthy volunteer, Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 years

Upper age limit
120 years

Sex
All

Key exclusion criteria
Pregnant women (self-reported)

Date of first enrolment
01/07/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Gambia

Kenya

Study participating centre
KERMI-Wellcome Trust Research Programme
Center for Geographic Medicine Research, Coast
Kilifi
Kenya
P.O. Box 230-80108

Study participating centre
MRC Unit The Gambia @ LSHTM
Atlantic Boulevard
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PO Box 273

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

Results and Publications

Individual participant data (IPD) sharing plan
When the results of this study are prepared and published, anonymised data will be made available in line with the policies of the NIHR, LSHTM, KWTRP and MRCG.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.1	25/01/2023	27/02/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes