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Screening to detect high blood pressure among coastal community dwellers and link them to appropriate care

Submission date
01/10/2023

Recruitment status
No longer recruiting

Registration date
04/10/2023

Overall study status
Completed

Last Edited
07/11/2024

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
In Ghana, there has been a significant rise in the number of people dealing with high blood pressure (known as hypertension) in recent years. Unfortunately, not enough people are getting diagnosed, and even when they are, their treatment isn't always as effective as it should be. This leads to more health problems and even deaths because blood pressure isn't well-managed.

This situation shows that we need to find new ways to treat hypertension, especially in areas where a lot of people are struggling with it, like in poor neighborhoods in cities. This study's goal is to find people who have hypertension in coastal communities around the Greater Accra region, make sure they get the right medical care if they're newly diagnosed, and keep an eye on how well their treatment is working. We'll be using strategies where certain healthcare tasks can be handled by different trained individuals to make this process smoother and more efficient.

Who can participate?
The study will recruit participants with a mean blood pressure of ≥ 140/90mmHg in seven coastal communities in Ghana’s Greater Accra region.

What does the study involve?
Those who are selected for this study will be connected to specific healthcare facilities and monitored for a year to see how their treatment is going. During this time, we'll check things like how well their blood pressure is controlled, if they're following their treatment plan, their physical measurements, eye health, protein in their urine, kidney function, heart's electrical activity (electrocardiogram), and heart imaging (echocardiograms).

We're also going to use mobile health technology (mHealth) to help with things like screening people in the community, checking their blood pressure, keeping an eye on diagnosed hypertensive patients from a distance, and sending messages about taking medicine and making lifestyle changes.

To understand what people know and think about diagnosing, treating, and managing hypertension, we'll have group discussions with community members and more in-depth conversations with newly diagnosed hypertensive individuals, community health workers, and religious leaders or representatives.

What are the possible benefits and risks of participating?
The study outcomes will help improve treatment and control rates and reduce the incidence of target organ damage. potential risk will stress of knowing hypertension status, and also pain from the needle prick during sampling

Where is the study run from?
Deutsche Gesellschaft für Internationale Zusammenarbeit (Germany)

When is the study starting and how long is it expected to run for?
February 2023 to October 2024

Who is funding the study?
1. Deutsche Gesellschaft für Internationale Zusammenarbeit (Germany)
2. Bayer (Germany)

Who is the main contact?
Prof Vincent Boima, vboima@ug.edu.gh
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Study website
https://reporting.giz.de/2021/our-work-around-the-world/global-health/ghana-heart-initiative/

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
68.3025.1-001

Study information

Scientific Title
Detection, linkage to care, treatment, and monitoring of hypertension: a quasi-experimental study in coastal communities in Accra - The Ghana Heart Initiative Hypertension study protocol

Study objectives
Screening to detect and link hypertensive patients to care will improve the treatment rate, control rate, and reduce the incidence of hypertension-associated target organ damage

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/02/2023, Ghana Health Service Ethics Review Committee (Research and Development Division, Ghana Health Service, Accra, P.O. Box MB 190, Ghana; +233 302681109; ethics.research@ghs.gov.gh), ref: GHS-ERC: 028/08/22

Study design
Multicenter community-based quasi-experimental and qualitative study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Diagnostic, Prevention, Screening, Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Detection, and treatment of hypertension and prevention of hypertension-associated target organ damage

Interventions
Quantitative data will be collected by trained research assistants. We will screen 10,000 people in the 7 coastal communities in the Greater Accra Region to identify 3,000 people with hypertension. These patients will be linked to clinics, hospitals, and healthcare centers in their communities or nearby communities (evaluation centers for the study). baseline data including clinical and laboratory parameters, medication adherence, ECG, and ECHO. Patients will be assessed again in 6 and 12 months respectively.

On a monthly basis before each assessment at the evaluation centers, patients will be seen by the community healthcare nurses and community pharmacists for blood pressure measurement and a refill of their medications. The data will be collected electronically using the already existing electronic data collection systems with the aid of electronic devices (tablets). The electronic database system has an e-tracker component which has been programmed to be used for sending messages to patients regarding adherence to medication and lifestyle changes. The messages will be sent twice a week throughout the study period (12 months). Patients in each health facility will be divided into the intervention arm and the control arm to receive or not receive the messages.

Both control and the intervention arm will be followed up in the 6th and 12th months of the study. Qualitative data collection will be done by trained research assistants. They will use semi-structured interview guides to conduct individual face-to-face in-depth interviews with all study participants, as well as focus group discussions with community members. To ensure privacy and confidentiality, all IDIs will be conducted one-on-one with participants in an enclosed area detached from others. In addition, participants in FGDs would be urged to respect each other’s confidentiality.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 20/05/2024:

Measured at baseline, 6, and 12 months:
1. Blood pressure measured using a sphygmomanometer

2. Hypertension mediated target organ damage (HMTOD):
2.1. ECG and ECHO for heart damage
2.2 Creatinine, proteinuria

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Previous primary outcome measure:

Measured at baseline, 6, and 12 months:
1. Blood pressure measured using a sphygmomanometer
2. Hypertension mediated target organ damage (HMTOD):
2.1. ECG and ECHO for heart damage
2.2. Proteinuria and Creatinine for kidney damage

Secondary outcome measures
Current secondary outcome measures as of 20/05/2024:

1. Baseline prevalence of hypertension
2. The proportion of hypertensive patients linked to care in an urban coastal community in Accra measured using patient records at the end of the study
3. Medication adherence rate among hypertensive patients linked to care measured using Hill-Bone HBP Compliance to High Blood Pressure Therapy Scale (HB-HBP) at baseline, 6, and 12 months
4. The perception and lived experiences of community members on hypertension and its management measured using in-depth interviews and focus group discussions at baseline

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Previous secondary outcome measures:

1. Proportion of hypertensive patients linked to care in an urban coastal community in Accra measured using patient records at the end of the study
2. Medication adherence rate among hypertensive patients linked to care measured using Hill-Bone HBP Compliance to High Blood Pressure Therapy Scale (HB-HBP) at baseline, 6, and 12 months
3. The perception and lived experiences of community members on hypertension and its management measured using in-depth interviews and focus group discussions at baseline

Overall study start date
27/02/2023

Completion date
04/10/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/05/2024:

1. Resident in the Greater Accra Region of Ghana
2. Resident in 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 and during the study period
5. Have a three-time blood pressure recording with a mean of ≥140/90mmhg at the time of recruitment
6. Newly diagnosed hypertensive; and
7. Willing to participate and has the ability to give consent.

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Previous inclusion criteria:

Adults 18 years and above in coastal communities in the Greater Accra Region of Ghana

Participant type(s)
Population

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
10,000

Key exclusion criteria
1. Not a resident of the Greater Accra region and the selected coastal communities
2. Residents who intend to travel or re-locate before or during the study period
3. Known hypertensive participants who are already on medication
4. Known end-organ dysfunction on treatment
5. Not willing to participate in the study or do not give consent

Date of first enrolment
04/10/2023

Date of final enrolment
04/02/2024

Locations

Countries of recruitment
Ghana

Study participating centre
Greater Accra Region of Ghana
GA-076-0913
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Sponsor information

Organisation
Deutsche Gesellschaft für Internationale Zusammenarbeit

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Sponsor type
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ROR
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Funder(s)

Funder type
Government

Funder Name
Deutsche Gesellschaft für Internationale Zusammenarbeit

Funder Name
Bayer

Results and Publications

Publication and dissemination plan
In addition to journal publication, dissemination activities will include a report to the Ghana Health Service on the outcome of the project.

Intention to publish date
06/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (District Health Information Management System (DHIMS)/Ministry of Local Government, Decentralisation & Rural Development (dddp.gov.gh)

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		04/11/2024	07/11/2024	Yes	No