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Phone-based support for high blood pressure control feasibility study

Submission date 06/12/2020	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 06/05/2021	**Overall study status** Stopped	
Last Edited 22/06/2022	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
High blood pressure (also called hypertension) is a leading cause of stroke and heart attacks around the world. Controlling high blood pressure with medicines and living a healthy lifestyle reduces the risk of developing stroke and heart attacks. In Botswana and other countries, many people with high blood pressure do not have their condition under control. This includes people who are on blood pressure medicines and are receiving care from their local clinic.
This study seeks to address some of the challenges faced by patients and improve control of blood pressure by:
1. Developing supports, delivered over the mobile phone, to assist patients with taking medications as advised. These supports will be in the form of phone calls or SMS text messages that provide helpful information about high blood pressure and clinic appointment reminders.
2. Assessing whether these phone-based supports can be provided to participants as intended and using a type of study design called a cluster-randomised trial. This study design means that participants will be allocated randomly to either receive phone-based supports with usual clinic care or to receive usual clinic care alone, depending on the community (village) in which they live.

Who can participate?
Individuals aged 30-69 years old who have hypertension, are residents of the six study communities and are receiving care at public primary care clinics in these communities will be enrolled. In order to participate, individuals must also be citizens of Botswana, either own a cell phone or have daily access to a shared cell phone and know how to read in order to understand study SMS text messages sent. Written informed consent will be required for participation

What does the study involve?
Participants will be followed for a total of six months, and undergo a total of two 1.5 hour in-person assessments - one at baseline and the other at six months. Assessments will be in the form of an interview, physical measurements (blood pressure, weight, height, waist circumference) and review of medical records. Assessments will be conducted by trained research personnel, in a private room at the participant's local clinic.

What are the possible benefits?
While this study may not directly benefit participants, we anticipate that the knowledge gained

from this study will help to develop a package of support services for people with high blood pressure. It may also guide policymakers to improve healthcare services for managing high blood pressure in Botswana or other countries and, in the long term, reduce deaths due to stroke and heart attacks.

When does the study start and how long is it expected to run for?
From December 2020 to December 2022. Participation in the study itself by individuals will be for six months, starting from the day of written informed consent until the final face-to-face assessment six months later.

Who is funding the study?
DFID MRC NIHR Wellcome: Joint Global Health Trials (UK)

Who is the sponsor for the study?
University of Oxford (UK)

Who is the main contact?
Dr Neo Tapela (PI)
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
MR/V004492/1

Study information

Scientific Title
Improving control of hypertension in a high HIV prevalence setting: a feasibility cluster-randomized trial

Acronym
coHHP

Study objectives
It is feasible to conduct a community-randomized trial for hypertension control in a rural African setting and achieve target sample size and >95% complete follow up in both intervention and control arms?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending, Botswana (HRDC, Ministry of Health) and UK (Oxtrec, University of Oxford)

Study design
Two-arm parallel-group pair-matched cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Hypertension managed at government primary care clinics in rural Botswana

Interventions
Matched pairs cluster randomization (ratio 1:1) will allocate the six study communities to the intervention versus control (enhanced usual care) groups. The community, corresponding to a village (average total population ~8,000), will serve as the unit of randomization. Pair matching will be based upon geographic location, level of urbanization and allocation arm in the BCPP study. Randomization will employ computer-generated (STATA) sequence performed at a central location (Oxford, UK) by an independent statistician who will not be involved in any other study activities. To minimize recruitment bias, cluster randomization will be performed following the enrolment of all participants.

The intervention component being assessed in this feasibility trial is mobile phone-based adherence support. Participants residing in intervention communities will receive mobile phone-based adherence support, which will be delivered as:
1. Personalized automated SMS reminders of scheduled clinic appointments, sent 48h before the appointment
2. Personalized automated information-only SMS messages providing hypertension-related educational and motivational messages, sent weekly
3. Participant-initiated SMS or phone calls to a toll-free line, as needed by participants

For participants assessed at baseline to be at high risk for non-adherence to medicines or to clinic visits, the intervention additionally involves study-initiated check in phone calls following each routinely scheduled clinic appointment.

Intervention Type
Behavioural

Primary outcome(s)
1. Follow-up rate, defined as the proportion of participants who complete the follow-up assessment out of those who are enrolled and not known to have died, measured using patient notes at 6 months
2. Good medication adherence, defined as achieving ≥80% proportion of medication days covered (PDC) measured using an investigator-designed patient questionnaire at 6 months

Key secondary outcome(s))
1. Blood pressure measured using sphygmomanometer at baseline and 6 months
2. Clinic appointment attendance rate measured using patient notes at 6 months
3. Hypertension knowledge measured using an investigator-designed patient questionnaire at 6 months
4. Intervention acceptability measured using an investigator-designed patient questionnaire at 6 months
5. Medication adherence measured using the 8-item Morisky Medication Adherence Scale at baseline and 6 months

Completion date
31/12/2022

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Aged 30 - 69 years old
2. Diagnosed with hypertension (“Evidence of hypertension diagnosis” is defined below)
3. Prescribed antihypertensives, documented in medical records
4. Self-report of current (in the last 2 weeks) antihypertensive use
5. Presenting to clinic during enrolment period
6. Systolic BP ≥120 mmHg or diastolic BP ≥80 mmHg (means of three measurements)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Hospitalization for acute myocardial infarction or stroke, or a revascularization procedure, within last 3 months
2. Indication for care by a specialist doctor for hypertension/CVD management, according to national guidelines
3. A medical condition that, in the clinical judgement of providers and clinician-researchers, is likely to limit survival such that goals of care focus less on stringent hypertension control, e.g. end stage cancer (stage IV), heart failure (NYHA class IV), renal disease (stage 5)
4. Pregnant, by self-report
5. Not a citizen of Botswana, per self-report or not producing Omang ID card/number
6. Factors likely to limit adherence to the intervention protocol, such as:
6.1. Not a stable resident (defined below) of one of the coHHP study communities, or planning to move outside the study community in the next 6 months
6.2. Significant cognitive or physical impairment, such that cannot independently achieve activities of daily living (ADLs)
6.3. Without regular access to a mobile phone (owned or shared)
6.4. Not literate
6.5. Incarcerated
6.6. Unable or unwilling to provide consent

Date of first enrolment
01/10/2021

Date of final enrolment
31/01/2022

Locations

Countries of recruitment
Botswana

Study participating centre
Botswana Harvard AIDS Institute Partnership
Private Bag BO 320
Gaborone
Botswana
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Other

Funder Name
DFID MRC NIHR Wellcome: Joint Global Health Trials scheme

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request, following an initial period of data consolidation, validation and analysis (estimated as up to one year following completion of study follow-up). Request for de-identified participant-level data for research and local research capacity building purposes are particularly encouraged. A Data Access Committee (DAC), will set-up systems for processing and tracking all requests for data and samples. A project webpage, including information on type of data available and request procedures, will be developed and added to BHP's website.

IPD sharing plan summary
Available on request