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Effect of health extension workers led home-based intervention on hypertension management in Northwest Ethiopia, 2021: study protocol for a cluster randomised controlled trial

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ABSTRACT

Introduction Although hypertension is highly prevalent in Ethiopia, it is poorly diagnosed, treated and controlled. Poor access to care and a shortage of healthcare providers are major barriers. This study aims to evaluate the effects of health extension workers' led home-based intervention on hypertension management in patients with hypertension in rural districts of northwest Ethiopia.

Methods and analysis A two-arm cluster randomised controlled trial will be conducted among 456 hypertensive patients. Adults aged ≥25 years who have a diagnosis of hypertension both in the home-based hypertension screening study and at another measurement prior to recruitment will be eligible for the study. Randomisation will be done at the kebele level. In the intervention clusters, trained health extension workers will provide home-based intervention for hypertensive patients every 2 months for 9 months. The primary outcomes of the trial will be clinical linkage and blood pressure changes, whereas the secondary outcomes will be lifestyle modification, medication adherence and blood pressure control. Intention-to-treat analysis will be used for all primary analyses. A linear mixed-effect regression model will be used to model the change in blood pressure, while a mixed effect logistic regression model will be used to evaluate the intervention's effect on the binary outcomes. Effect sizes such as mean difference for the continuous outcomes and relative risk, attributable risk and population attributable risk for binary outcomes will be used. All statistical analyses are two sided and a $p<0.05$ will be used.

Ethics and dissemination This study has been approved by institutional review board of the University of Gondar (Ref. No: V/P/RCS/05/2293/2020). The district's health office will grant permission for cluster randomisation, and each participant will provide written informed consent for participation. The findings will be presented at scientific conferences and published in peer-reviewed scientific journals.

Trial registration number PACTR202102729454417.

Strengths and limitations of this study

- This ongoing trial will be the first in the Ethiopia to evaluate the effect of community health workers on hypertension management.
- The trial will target hypertensive patients in the rural communities with limited access to healthcare and a shortage of healthcare providers.
- This study will serve as a springboard for integrating hypertension management at the primary healthcare level through a health-system strengthening approach.
- The use of qualitative research in the randomised controlled trial design will allow us to explore the barriers and enablers of clinical linkage to hypertension care and treatment.
- Because of the nature of the intervention, randomisation will take place at the cluster level, and the person who will carry out the intervention will not be masked.

INTRODUCTION

Ethiopia has a triple disease burden due to communicable, non-communicable diseases, and injuries.[1 2] According to the 2018 Ethiopian Noncommunicable Disease and Injury Commission Summery Report, noncommunicable diseases, including cardiovascular disease, accounted for 37.5% of the disease burden and 43.5% of deaths in the country.[3] Hypertension, which affects nearly one out of every four Ethiopian adults, is now recognised as a public health issue,[4–6] accounting for 62.3% of cardiovascular diseases,[7] 36.3% to 69.3% of stroke cases[8–12] and 3.5% of all deaths.[13] The pooled prevalence of hypertension in Ethiopia was 21.8% in 2020, according to a national systematic review and meta-analysis, with a slight difference between rural (18.45%) and urban (22.85%) populations.[14] However, a significant proportion of hypertensive patients in the country remain undiagnosed, untreated

and uncontrolled.[15] Epidemiological studies revealed that less than 40% of hypertensive patients in Ethiopia were identified as such. Only 28% of those identified received antihypertensive treatment, and only 26% of those on treatment have adequate blood pressure control.[3 5 6 16 17] This indicates that there is an unmet need in the country for early detection, treatment and care of hypertension.

Poor access to healthcare and a shortage of healthcare providers are major determinants that limit hypertension care at the primary healthcare level, where most people receive their care.[18] In Ethiopia, for example, there was only 0.96 health workforce per 1000 population, which is five times less than the WHO's minimum threshold of 4.45 per 1000 population set to meet the Sustainable Development Goal health targets.[19] The greatest shortage is for physicians, whose numbers are declining and are now 1:42 706 population. This is one of the lowest ratios in sub-Saharan Africa (2 physicians per 10 000 population).[6 20]

One strategy to improve the hypertension care cascade and bridge the gap between the community and the health system in other contexts is task-sharing, in which specific tasks are shared from a more qualified healthcare cadre to a less trained cadre such as community health workers.[21 22] Community-based health education and healthy lifestyle counselling interventions implemented by community health workers, for example, have shown promising results in early detection of hypertension, linkage to the health facilities,[23–25] medication adherence,[26–29] mean blood pressure reduction[30–32] and blood pressure control.[30 33 34]

While Ethiopia has a health extension programme for certain communicable diseases, maternal and child health, hygiene and sanitation, health extension workers (HEWs) currently do not provide hypertension care and thus there is no evidence on how effective it will be in this context.[35 36] Hence, we planned to conduct a cluster randomised controlled trial to evaluate the effect of HEWs led home-based intervention on linkage to hypertension care, lifestyle modification, medication adherence, blood pressure change and optimal blood pressure control in rural areas of northwest Ethiopia.

METHODS AND ANALYSIS

Trial design

A two-arm parallel cluster randomised controlled trial design will be used to evaluate the effects of home-based intervention led by HEWs on clinical linkage and treatment, lifestyle modification, medication adherence, mean change in blood pressure and optimal blood pressure control in hypertensive patients. The trial will enrol 456 hypertensive patients in rural areas of northwest Ethiopia for 9 months from 12 March 2021 to 12 December 2021.

Study setting

The trial will be conducted in rural areas of northwest Ethiopia (Dabat and Gondar Zuria districts). Dabat is one of the districts in the North Gondar Administrative Zone of the Amhara Region in Ethiopia. Dabat town, the capital of Dabat district, is located about 821 km northwest of Addis Ababa and 75 km from Gondar city. Gondar Zuria district is one of the districts in the Central Gondar Zone, which is located 700 km northwest of Addis Ababa, the capital of Ethiopia. According to the Ethiopian Central Statistical Agency population projections for 2014–2017, the total population of Dabat and Gondar Zuria districts were 177 294 and 231 830, respectively. The districts have both urban and rural kebeles (Ethiopia's lowest administrative levels). There are 31 and 41 rural kebeles in Dabat and Gondar Zuria district, respectively, with limited health services. Each rural health centre has five health posts that work in collaboration with a primary hospital to form the primary healthcare unit. Each health centre with health posts serves 15 000–25 000 people.[37]

HEWs are the backbone of the health extension programme in Ethiopia. Two HEWs are assigned to each health post to serve 3000–5000 people in a village 'kebele'.[38] HEWs are females and are recruited based on nationally agreed-upon criteria such as residence in the village, age of at least 18 years old, ability to speak the local language, completion of 10–12th grade, and willingness to remain in the village and serve communities.[39] All HEWs received a year of theoretical training in training institutions and practical training in health centres.[40]

HEWs divide their time to provide health services at health posts and community promotion and education programmes at the household level. HEWs spend 50% of their time at health posts providing services such as immunisations, injectable contraception and limited basic curative services such as antimalaria treatment, first aid and diarrheal diseases and intestinal parasite management.[38] During the home visit, HEWs support households in making behavioural changes and encourage them to use primary healthcare services. According to the district Public Health Office, there were 77 and 102 rural HEWs in Dabat and Gondar Zuria districts, respectively, in 2018.

Patient and public involvement

Participants in this study were not involved in the formulation of research questions, trial design, outcome measures, recruitment or study execution. The investigators of this study developed the research questions and study design, which were then reviewed by institutional review board of the University of Gondar. They will, however, be involved in disseminating the main findings to the community in collaboration with the HEWs after the findings have been translated into the local language (Amharic).

Participants

A home-based hypertension screening survey was carried out by trained health professionals (MSc nurses and health officers) and HEWs among adults aged ≥25 years

who live in the 20 clusters to estimate the proportion of undiagnosed hypertension in northwest Ethiopian rural areas and to prepare a list of eligible participants for our cluster randomised controlled trial. All adults with hypertension who participated in the home-based hypertension screening study will be the source population. Adults aged 25 years and more who live in the 20 kebeles, have a diagnosis of hypertension (≥130/80 mm Hg) both in the home-based hypertension screening study and at another measurement prior to recruitment, and are willing to participate in the study will be eligible to evaluate the intervention's effect on clinical linkage, lifestyle modification, medication adherence, blood pressure change and optimal blood pressure control. However, pregnant women, patients who participated in a previous cardiovascular diseases study, patients with hypertension requiring immediate hypertension care (BP ≥180/110 mm Hg and one or more of the following symptoms: visual disturbance, dizziness, numbness, confusion, headache, chest pain, shortness of breath or leg swelling),[41] patients on renal dialysis or transplant, and patients with a history of heart attack, stroke or congestive heart failure will be excluded.

Eligibility criteria for clusters

In this study, a cluster is defined as a kebele with one health post that serves up to 1000 households with a population of 3000–5000 people. Kebeles that have at least two working HEWs at the health post are eligible for the study. As a result, we have 70 rural kebeles that are eligible for enrolment. During the home-based hypertension screening/prevalence study, 30% of the total rural kebeles in each district were selected using a simple random sampling technique. As a result, we will have a total of 20 kebeles with preidentified hypertension cases that will be randomly assigned to either of the intervention or control groups. In between, there are buffering kebeles to minimise the risk of information contamination from the intervention to be provided by trained HEWs.

Intervention package

The intervention for this study is named 'HEWs-led home-based intervention'. This intervention package includes home health education about hypertensive disease, behavioural counselling intervention, medication adherence counselling and referral to a nearby health facility. The intervention aims to improve clinical linkage to hypertension care and treatment, lifestyle modification, medication adherence, optimal blood pressure control and blood pressure reduction in hypertensive patients.

Intervention group

Following randomisation, the 20 HEWs in the intervention group will be trained for 3 days about patient home health education, behavioural counselling intervention, medication adherence counselling, and referral to the nearby health facility to teach patients and family members. The HEWs will visit participants' homes every 2 months for 9 months. During the first visit, the HEWs will provide a 60 min family-based health education to discuss general hypertensive disease and treatment knowledge. Every 2 months, three 40 min follow-up visits will be performed to provide home health education, behavioural counselling intervention, and clinical linkage. The detailed descriptions of the intervention are provided below.

Home health education

The HEWs will provide individualised and family-based brief health education with the goal of increasing patients' knowledge and understanding of the disease and the importance of attending chronic care appointments. They will give the participants a brief explanation of hypertension and its major modifiable risk factors. This session will also cover education about the chronic nature of the disease, the potential complications of untreated and uncontrolled hypertension, and the possibility of needing lifelong medications.

Behavioural counselling intervention

HEWs will use the Health Belief Model approach to counsel patients on healthy dietary habits (such as consuming a diet rich in fruits, vegetables, and low-fat dairy products, a low salt diet, the use of vegetable cooking oil and the use of whole grains), alcohol moderation and regular blood pressure check-ups. To encourage participants to change unhealthy lifestyle behaviours, HEWs will use motivational and effective communication, goal setting, and family support for behaviour change. They will provide intensive counselling for patients on healthy lifestyle modification using the five A's approach: Ask, Advise, Agree, Assist and Arrange.[42]

Referral for clinical linkage to health facility

The HEWs will provide patients with hypertension a referral slip that explains the nature of the disease, the reason for the referral and the importance of starting treatment as soon as possible if they are eligible. Furthermore, through a home visit, the HEWs will remind participants to seek treatment and care at a nearby health facility.

Medication adherence counselling

HEWs will teach participants about the purpose of using medications, the negative effects of non-adherence, the positive effects of treatment, etc.

Control group

This group of HEWs will not be involved in the intervention and will not be informed about the study's goal. Hence, they will not provide any of the above-mentioned intervention components to study participants. They will deliver routine care (the usual home visits for maternal and child health service, malaria prevention and control, family planning services and latrine construction) based on existing community services without any additional training. However, both

participants in the intervention and control group can take antihypertensive medications prescribed by the healthcare providers.

Intervention fidelity

Intervention fidelity refers to the extent to which core components of interventions are delivered as intended in the protocols.[43 44] To improve the intervention fidelity, the following measures will be implemented: a manual of operating procedures (MOPs) has already been developed, intensive training for the interventionists (HEWs) will be provided, routine communication with the interventionists will be established, and the supervisory team will conduct a spot check when the HEWs deliver the intervention to the study participants. The intervention's fidelity will be evaluated at the end of the intervention using a fidelity checklist that includes the frequency, duration and intensity of the intervention.

Outcome measures

The primary outcomes of this trial includes (1) the proportion of clinical linkage to hypertension care and/or treatment at 3, 6 and 9 months of follow-up following the intervention. At each follow-up visit, participants will be asked whether they sought hypertension care and/or treatment. A successful linkage to care is defined as visiting a healthcare facility for hypertension care and treatment within 9 months of followed up period. The proportion of patients with hypertension who are linked to hypertension care and/or on antihypertensive treatment will be calculated as the number of hypertensive patients who are linked to hypertension care and/or on antihypertensive treatment divided by the total number of hypertensive patients. (2) The changes in mean systolic and diastolic blood pressures (DBP) at 3, 6 and 9 months from baseline and will be compared among patients with hypertension in the intervention arm to those with hypertension in the control arm.

The secondary outcomes include (1) the proportion of hypertensive patients with optimal blood pressure control at 3, 6 and 9 months following the intervention; (2) change from baseline in the proportion of lifestyle modification (alcohol intake, high salt intake, low fruit and vegetable consumption, and low level of physical activity) at the end of the intervention and (3) proportion of medication adherence at the end of the intervention. The proportion of patients with controlled hypertension during the follow-up period in the intervention arm will be compared with patients with controlled hypertension in the control arm at 3, 6 and 9 months following the intervention. The change from baseline in the proportion of hypertensive patients with lifestyle modification will be compared between the intervention and control groups at the end of the follow-up period. At the end of the follow-up period, the proportion of medication adherence will also be computed and compared between the intervention and control groups.

Process measures

This trial will also plan to evaluate the intervention process measures such as (1) change from baseline in the mean score of hypertensive disease knowledge among individuals with hypertension and (2) change from baseline in the mean score of health beliefs about hypertension among hypertensive patients.

Participant time line

The participants' time line or the recommended content for the schedule of enrolment, interventions and assessments of the study protocol is available in online additional file 1.

Sample size determination

The sample size is calculated according to the double population proportion formula for individual randomisation. The design effect is considered to account for the lack of independence between patients within clusters and increase the power of the study. The design effect is defined as $1+ (m - 1) \rho$, where m is the average cluster size and ρ is the intra-cluster correlation coefficient for the specific outcome. Accordingly, the minimum sample size to determine the effect of HEWs led home-based intervention on clinical linkage and treatment is calculated using a 65.1% proportion of clinical linkage in patients with hypertension in the intervention group and a 46.7% proportion of clinical linkage in patients with hypertension in the absence of intervention.[45] The 95% CI (α=0.05), 80% power (β=0.20), an intraclass correlation of 0.03, and the number of clusters per arm to be 10 are also considered to obtain a total of 190 patients with hypertension per arm. Taking a 20% lost to follow-up into account, the total number of 456 participants (228 in each arm) will be included.

The sample size needed to evaluate the effect of HEWs' led home-based intervention on systolic blood pressure (SBP) change is calculated using the assumptions of mean SBP reduction from 151.7 mm Hg baseline to 132.4 mm Hg endline in the intervention group and mean SBP reduction from 149.8 mm Hg baseline to 137.7 mm Hg endline in the usual care group, yielding a mean difference of 5.3 mm Hg. An SD of 10 mm Hg in both the intervention and control groups, an intracluster correlation of 0.077[30] and a 20% lost to follow-up are also used to calculate a final sample size of 132 hypertensive patients in each arm. We will use the larger sample size (456 participants) because the sample size required to evaluate clinical linkage is greater than the change in SBP.

Cluster and participant recruitment

Of the 72 rural kebeles in the two districts, 70 eligible kebeles were identified with the help of each district health officer prior to the hypertension screening study conducted earlier. A total of 20 kebeles were selected among the eligible kebeles using a simple random sampling method. Data were collected from 2423 study participants out of a total of 2436 adults aged ≥25 years

approached for the home-based hypertension screening study. Seven hundred and fifty eight of the 2423 adults who had their blood pressure measured as part of the hypertension screening study were found to have hypertension. In order to recruit participants, the research team will remeasure the blood pressure of adults who were identified as potentially hypertensive in a previous home-based hypertension screening study 5 min apart for the second time. Adults who have been diagnosed with hypertension for the second time will be evaluated for eligibility. A simple random sampling method will be used to enrol an average of 23 hypertensive cases per cluster. An epidemiologist from the research team will complete the participants' eligibility forms and enrol participants in the follow-up study.

Randomisation

A baseline survey will be conducted prior to randomisation to reduce selection bias during the allocation of kebeles to either of the intervention or control groups. To achieve balance across geographic healthcare access, randomisation will take place at the kebele level and be stratified by physical distance to the nearest healthcare facility. We have two distance strata: close distance (within 5 km) and far distance (greater than 5 km). We will randomly assign 10 kebeles (four from Dabat and six from Gondar Zuria district) within five km and another 10 kebeles (four from Gondar Zuria and six from Dabat district) at a distance greater than 5 km to either the intervention or control groups with preidentified hypertension cases. Randomisation codes will be generated using computer-generated random numbers. Randomisation at the kebele level will ensure that only patients in the intervention group receive home-based intervention from HEWs.

Implementation

A biostatistician, a member of the research team who does not interact with the study participants, will use a 1:1 allocation ratio to randomly assign 20 kebeles with preidentified hypertensive cases to either the intervention (10 kebeles with 228 hypertensive patients) or control group (10 kebeles with 228 hypertensive patients) (figure 1).

Awareness of assignment

Neither the participants nor the HEWs will be masked with respect to the participants' group assignment. The risk of contamination will be minimised by using buffering kebele/s, whereby the intervention and control kebeles will be geographically separated and the chance of intervention cluster participants meeting control cluster participants will be insignificant. HEWs in the intervention clusters will be taught not to share information about the study with those HEWs in the control group. The outcome assessors will be masked to the intervention allocation of participants.

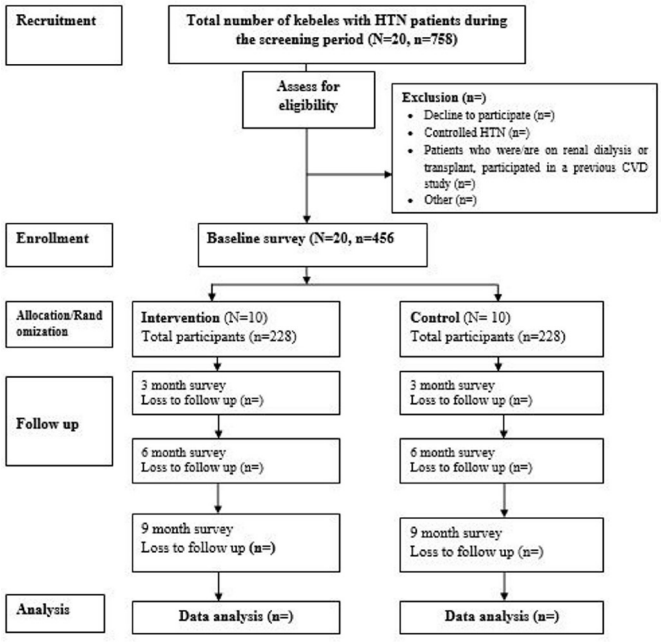

Figure 1 The CONSORT planned flow of participants diagram. CONSORT; Consolidated Standards of Reporting Trials

Study visits and data collection procedures

Baseline survey

Baseline survey will be conducted before randomisation. The WHO STEP wise Approach to Surveillance Non-communicable Diseases[46] questionnaire will be adapted and used to collect data regarding sociodemographics and economic factors (sex, age, marital status, educational level, occupation, income), behavioural risk factors (tobacco and khat use, alcohol consumption, dietary behaviours such as fruit and vegetable intake, salt intake, and physical activity), psychosocial stress levels, and history of non-communicable diseases. Participants' knowledge and beliefs towards hypertension, distance to the nearby health facility, health insurance coverage and access to healthcare will also be collected. Physical measurements such as height, weight and blood pressure will be measured.

The data collection tool is prepared in English and translated into the local language (Amharic) by two bilingual experts. An expert panel consisted of two translators, a methodologist, and a subject expert held a discussion on the translated tools and reached consensus. The translated Amharic version was translated back to the original language by two other bilingual experts, one of whom had knowledge about the subject matter to see the tools for equivalence. Five health professionals and five supervisors will take 3 days of training on how to conduct interviews with patients, measure blood pressure, weight and height. Data will be collected through face-to-face interviews using an interviewer administered Amharic version of the questionnaire. An independent trained data collectors masked to randomisation status of the clusters will visit participants' homes and collect the data.

Follow-up and end line survey

A follow-up survey will be conducted at 3 and 6 months and an endline survey will be conducted at the end of 9 months in both the intervention and control groups. Data on clinical linkage and initiation of care and/or treatment will be collected in both the intervention and control groups at 3, 6 and of 9 months. Moreover, at the end of the intervention outcome data on lifestyle modification, medication adherence, knowledge about hypertension, and health beliefs towards hypertension will be collected in both the intervention and control groups, while compliance with the intervention during the follow-up period will be collected in the intervention arm only. Blood pressure will also be measured at each visit twice at a 5 min interval.

Variable measurement and definition

The rural community's household assets, such as the type of flooring, roof and walls; the number of rooms in the house; agricultural land ownership and total amount of agricultural products; livestock ownership, bank account, and solar light source, will used to calculate the wealth of the families.[47] These will be combined into a single wealth index and then divided into three equal-sized groups (poor, medium, and reach) based on their relative position on the household wealth index. The question 'Does your household have community-based health insurance membership?' will determine health insurance status. Those who respond 'no' will be categorised as uninsured. Those who respond 'yes' will then be asked the question, 'Does the insurance cover all healthcare costs?' Participants who respond 'no' to this question will be categorised as underinsured. Participants who respond 'yes' to this question will be categorised as adequately insured.

The lifestyle modifications of the study participants will be measured by using the following behavioural risk factors: alcohol consumption, fruit and vegetable consumption, salt reduction and level of physical activity. Weekly alcohol consumption is defined as consuming at least one alcoholic drink per week. The international physical activity questionnaire short form will be used to assess the participants' physical activity. A low level of physical activity is defined as any combination of walking, moderate or vigorous intensity activity <600 metabolic equivalent tasks-minutes per week.[48] The salt used in cooking will be used to determine the amount of salt intake, with a response ranging from never to always (always, almost always, sometimes, and rarely or never). Excessive salt intake will be defined as always or almost always adding salt to a plate or cooking.

The Hill-Bone Medication Adherence Scale (HBMAS) will be used to measure medication adherence. Permission to adapt and use the scale was obtained from the Hill-Bone Scales team (online additional file 2). The scale consists of nine items with a 4-point Likert response format ranging from 1 (none of the time) to 4 (all of the time), where 1 represents good adherence and 4 represents poor adherence. The items will be summed to provide total score ranging from 9 to 36, with higher the score the poorer adherence to medication.[49] The percentage adherence level will be calculated using the formula %adherence= (36-HBMAS score/27)*100. The denominator (27) is the range of HBMAS scores (36-9). Good medication adherence is defined when the proportion of patients with adherence levels to antihypertensive therapy ≥80%.[50]

Participants' knowledge of hypertension and its treatment will be assessed using the validated tool. The questions enquire about information related to hypertension symptoms, consequences, treatment and prevention. A correct response will be coded as 1, and a wrong or don't know response will be coded as 0. The sum/mean score will be computed, and the higher the sum/mean score, the higher the knowledge will be. Beliefs about hypertension will also be assessed using the health belief model, which consists of six domains: perceived susceptibility, perceived severity, perceived benefits, perceived barriers to take action, perceived self-efficacy and cues to action. Participants will be asked to rate each item on a 5-point Likert scale, ranging from strongly disagree (1) to strongly agree (5). The mean score for each subscale will be calculated by dividing the total scores of the subscale items by the total number of subscale items.

Blood pressure will be taken in the sitting position on the left arm to the nearest 2 mm Hg using an aneroid sphygmomanometer and stethoscope. Participants who smoked, drank caffeinated beverages such as tea or coffee, or have been working within 30 min will be made stay for 30 min before blood pressure measurements. Participants will be told to empty their bladder and rest for at least 5 min before the measurements. The data collectors will make sure that participants sit with their back straight and supported on a chair or wall, their feet flat on the floor, and their legs uncrossed with their upper arm at heart level. They will also make sure the bottom of the cuff is placed directly above the bend of the elbow. The first reading will be taken after resting for at least 5 min, and the second will be measured 5 min after the first measurements. If the difference in blood pressure measurement between the first and second is higher than 10 mm Hg, a third measure will be taken 5 min after the second measurement. The average of the last two will be taken. According to the new guideline,[51] hypertension (or high blood pressure) is defined as a mean SBP of ≥130 mm Hg or a DBP of ≥80 mm Hg. Optimally controlled blood pressure will be defined as an average blood pressure <130/80 mm Hg for all adults.[51] Every morning, the aneroid sphygmomanometer will be tested and compared against the mercury sphygmomanometer (reference) to check and adjust the accuracy of the instrument before measuring the blood pressure of the participants. If measurements will be different, calibration will be done by the trained data collectors to adjust the readings of the test device to match the readings of the reference device.

Anthropometric measurements such as weight and height will be taken using standard procedures. Participants will be asked to wear light clothing, and their weight will be recorded using a digital scale to the nearest 0.1 kg. The participants' heights will be measured with a tape to the nearest 0.1 cm. Participants will be asked to stand upright without shoes, with their heels together and their eyes directed forward. The body mass index will be computed using the formula weight in kg/height in m^2 and categorised as underweight (<18.5), normal weight (18.5–24.9), overweight (25–29.9) or obese (≥30).[52]

Qualitative data

At the end of the intervention period, a phenomenological study design will be used to investigate the barriers and facilitators of clinical linkage for hypertensive care and treatment from the perspectives of patients, the community and healthcare providers. To explore the common barriers and facilitators of clinical linkage and retention in care, focus group discussions and in-depth interviews will be used. Focus group discussions will be held for intervention participants, with each group consisting of 6–8 people. The discussions will be held separately for each participant group of hypertensive patients. Trained data collectors, with the help of the local HEWs will identify the target groups. An interview guide with questions about the barriers and facilitators of clinical linkage to hypertension care and treatment will be developed. Participants will be asked probing questions to provide detail responses to the prepared interview questions. A facilitator will moderate the discussions, and will be open until a saturation point is reached for each topic. The audio of all focus group discussions and in-depth interviews will be recorded using a voice recorder. In addition, a research assistant will take notes on the session proceedings. The focus group discussions and in-depth interviews audio recordings will be transcribed. Informed consent will be obtained prior to data collection and the commencement of audio recording.

Trial management

For both the intervention and data collection, MOP is developed. The MOP describes the procedures for staff training, participant recruitment, instructions for all forms and procedures, patient education, behavioural counselling intervention, blood pressure measurement and other operational aspects of the study. The research team will monitor the data collection process on a daily basis using telephone and onsite supervision. Efforts will be made to retain study participants throughout the trial period in order to ensure the success of the study. The names and contact information of individuals closely related to the participant will be obtained during enrolment.

Data management

The data clerk will inspect the data before entering it into an Epidata software file. Then the data will be entered into Epidata and analysed using R. Coding and data cleaning will be done (checking frequencies and crosstab for each item). The Consolidated Standards of Reporting Trials (CONSORT) flow chart will be used to summarise the number of participants who will be assessed for eligibility; the reasons for screening failure; the number of participants who will be enrolled, lost from follow-ups, have completed the baseline and follow-up visits; and the number of participants who will be analysed in the trial.

Statistical analysis

All the primary analyses will follow the intent-to-treat principle. Hence, outcome assessments for participants who will be lost from the follow-ups will be included in the primary analyses as they were followed until the end of the follow-up. Participants' baseline characteristics will be described using frequency and proportions for categorical variables and mean with SD for continuous variables. Spaghetti plots by time will be used to investigate the overall and intervention-specific change in SBP and DBP over time. The mean profile will also be used to investigate the participants' mean SBP and DBP over time by the intervention groups.

The baseline characteristics of the study participants between the intervention and control group will be compared for uniformity using a χ^2 test for categorical variables, a two-tailed independent t-test for the continuous variables, and a Mann-Whitney U test for the continuous variables with skewed distributions. To test within-group differences between baseline and follow-up, NcNemar tests and two-tailed paired t-tests will be used for each categorical and continuous outcome variable, respectively.

A linear mixed-effect regression model will be used to estimate the mean SBP and DBP changes from baseline to 3, 6 and 9 months, accounting for the effects of intrasubject correlations. An unstructured covariance matrix will be selected to model the repeated measures or the within-subject variance-covariance structure. If this model fails to converge, other variance covariance structures will be considered. We will use Y_{ij} to denote the SBP and/or DBP measurements for subject i at j visit, assuming a normal distribution with an identity link function. Thus: $Y_{ij}=\beta_0 + b_{oi} + \beta_1 Int_i + (\beta_2 + b_{1i})\ time_{ij} + \beta_3 Int_i \times time_{ij} + \varepsilon_{ij}$. Where β_0 is the fixed intercept, Int_i is the intervention variable for subject i, β_1 is the intervention variable's regression coefficient, β_2 is the regression coefficient for time variable, β_3 is the regression coefficient for the interaction of the intervention and time variables, b_{oi} is the random intercept, b_{1i} is the random slope for time variable, and ε_{ij} is the measurement error for subject i at time j and is normally distributed. Thus, in this model, the intervention arm and the interaction of the intervention arm with time are fixed effects, whereas time is the random effects.

A mixed-effect logistic regression model will be fitted to compare the proportions of clinical linkage to hypertension care and optimal blood pressure control at 3, 6 and 9 months, taking repeated measures into account.

We'll use Y_{ij}, a binary response to denote the outcomes measured for subject i at time j. We define the probability of the response equal to one as $\pi_{ij} = p(Y_{ij}=1)$ and be modelled using a logit/log link function assuming that follows a binomial distribution. Thus, Logit $(\pi_{ij}) = \beta_0 + b_{oi} + \beta_1 Int_i + (\beta_2 + b_{1i})\, time_{ij} + \beta_3 Int_i \times time_{ij.}$ Where β_0 is the intercept, Int_i is the intervention variable for subject i, β_1 is the intervention variable's regression coefficient, β_2 is the regression coefficient for time variable, β_3 is the regression coefficient for the interaction of the intervention and time variables, b_{oi} is the random intercept, and b_{1i} is the random slope for variable time. The same mixed-effect logistic regression model will be used to compare the proportions of lifestyle modifications and medication adherence between the intervention and control groups.

Individual-level data will be used to analyse the change in the mean scores of hypertension knowledge and health belief towards hypertension between the baseline and end line survey. Participant-level analysis using difference-in-difference will be used to calculate between and within-group differences in the mean scores of hypertension knowledge and hypertension health belief. As a result, effect=$[Y_{i(t=9)}-Y_{i(t=0)}]-[Y_{c(t=9)}-Y_{c(t=0)}]$, where, $Y_{i(t=9)}$ is the mean score of hypertension knowledge and/or hypertension health belief in the intervention group at the 9 months, $Y_{i(t=0)}$ is the baseline mean scores in the intervention group, $Y_{c(t=9)}$ is the mean score of hypertension knowledge and/or hypertension health belief in the control group at the 9 months, and $Y_{c(t=0)}$ is the baseline mean scores in the control group.

The effect size, such as mean difference with 95% CI will be used for each follow-up period to evaluate the intervention effect on blood pressure change from baseline, whereas relative risk, attributable risk and population AR with percent and 95% CI will be used to evaluate the intervention effect on clinical linkage, lifestyle modification, medication adherence and optimal blood pressure control. For the process outcomes, the effect size will be reported as the mean difference with a 95% CI. A two-sided $p<0.05$ will be used to indicate statistical significance for all outcome measures.

Additional analyses

Subgroup analyses will be performed for all outcome measures to investigate the heterogeneity of the intervention effect based on the baseline characteristics such as age, sex, alcohol consumption, salt intake and stage of hypertension. Moreover, a randomisation or balance check will be performed on the baseline characteristics of the study participants to ensure that the intervention and control groups are comparable at baseline. As a result, if the p values are less than a predefined threshold ($p<0.05$), a post hoc subgroup analysis for the baseline characteristics will be performed.

Adjusted analyses for age, sex, baseline blood pressure and educational level, level of salt and alcohol consumption, and study site will be performed if appropriate for each outcome using the same regression model as the primary analyses. In addition, we will compute the rates of loss to follow-up for each group, and the difference in attrition between the intervention and control groups will be calculated. Differential attrition will be considered when the absolute value of the attrition difference is ≥0.05 SD. We will also examine the baseline characteristics of participants who were lost to follow-up and those who remained to see if the outcomes were influenced by attrition bias. If the baseline characteristics of those who participated differ from those who were lost at follow-up, this may indicate bias, and additional adjusted analysis will be performed to account for covariates that did not have similar baseline characteristics.

Sensitivity analysis

The robustness of the intervention effect in this trial will be assessed by changing any of the assumptions made in the primary analyses, such as outliers, missing data, different methods of analysis and controlling potential confounders. Outliers will be identified using a z-score or boxplot. If outliers are present, a sensitivity analysis with and without outliers will be performed. A sensitivity analysis for all outcome measures will be performed to determine how robust the primary analysis is to the chosen missing data handling mechanism. To do this, we will use a variety of missing data handling mechanisms, including complete-case analysis after excluding missing data, single imputation (replacing missing data with the mean of the outcome), and multiple imputation based on the assumption that missing data are missing not at random. Sensitivity analysis with and without adjustment for the baseline characteristics, as well as different methods of analysis, will be carried out.

Safety reporting

In this trial study, there are no a reasonably foreseeable risks associated with the intervention for the study participant. The intervention will have no negative consequences or adverse effects. However, the disease has the potential to cause complications in the long run.

DISCUSSION

Community-based interventions implemented by community health workers have shown promising results in terms of early detection of hypertension, linkage to healthcare facilities, improved medication adherence and optimal blood pressure control. In Ethiopia, community health workers or HEWs have been effective in managing infectious diseases and improving maternal and child health. However, there has been no involvement of HEWs in the management of non-communicable diseases including hypertension. This study will evaluate whether a home-based intervention led by HEWs enhances clinical linkage to healthcare facilities, lifestyle modification, medication adherence, optimal blood pressure control and reducing the blood pressure of patients with hypertension.

The study will provide timely and credible information about the effects of HEWs' led home-based intervention on hypertension management. This study will provide evidence for effective, practical and sustainable intervention programmes for lowering blood pressure, controlling hypertension and preventing cardiovascular disease. It will provide evidence to the Ministry of Health and policy-makers in order for them to develop a strategy to control the hidden burden of hypertension.

Ethics and dissemination

This study has been approved by the Institutional Review Board (IRB) of the University of Gondar (Ref. No: V/P/RCS/05/2293/2020 on the date of 31 August 2020). Informed consent for participation in the form of a signature or thumb print will be obtained from each study participant prior to enrolment. Consent for randomisation to either of the intervention or control groups will be obtained from the district health officer before randomisation. Potential participants will be given detailed information about the study's objectives, procedures, importance, risks and benefits. Confidentiality of data will be assured by using identification numbers and limiting access to the data. Participant participation in the study will be on a voluntary basis. The chance to ask any question about the study, as well as the right to refuse or terminate the interview, will be provided.

Trial status

The trial began in March 2021 and will continue until end-line data is collected. We recruited 20 kebeles with 456 hypertensive cases. The intervention has begun, and the follow-up is ongoing.

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Contributors DFT is the principal investigator of the study. DFT is involved in the conception, designing research questions, developing the intervention and writing the manuscript. SA, TAA, AA and KAG participated in selecting an appropriate research design, critical revised the manuscript and approved the protocol.

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