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Effect of health extension workers-led home-based multicomponent intervention on blood pressure reduction among hypertensive patients in rural districts of northwest Ethiopia: a cluster-randomised controlled trial

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ABSTRACT

Objectives To evaluate effects of health extension workers-led home-based multicomponent intervention on blood pressure change in hypertensive patients in rural districts of northwest Ethiopia.

Design Two-arm cluster randomised controlled trial was conducted.

Participants Hypertensive patients' age ≥25 years were included. 20 clusters or kebeles with 456 participants were randomly assigned to the intervention group (10 clusters with 228 participants) and the control group (10 clusters with 228 participants).

Interventions Participants in the intervention kebeles received health extension workers-led home-based multicomponent interventions every other month for 40–60 min for 9 months.

Main outcome measures The primary outcomes were the differences in mean systolic blood pressure (SBP) and diastolic blood pressure (DBP) changes from baseline between patients in the intervention and control groups. Intention-to-treat analysis was used for the primary analyses. Linear mixed effect model was used to evaluate the intervention's effect on change in mean SBP and DBP. Effect sizes of mean difference and relative benefit increase were used.

Results At 9 months, the mean SBP decreased by 15.8 mm Hg (95% CI: 13.5, 18.1) in the intervention and 10.8 mm Hg (95% CI: 8.7, 12.9) in the control groups; with a 5.0 mm Hg (95% CI: 1.9, 8.1) greater reduction in the intervention group. The mean DBP decreased by 12.1 mm Hg (95% CI: 10.6, 13.5) in the intervention and 8.4 mm Hg (95% CI: 7.0, 9.8) in the control group. The proportion of optimal blood pressure control was higher in the intervention group (45.8%) than the control group (28.2%) with percentage difference of 17.6% (95% CI: 8.5, 26.7).

Conclusions Health extension workers-led home-based multicomponent intervention has resulted significant reduction of blood pressure and achieved a higher proportion of optimal blood pressure control. This strategy is effective, but further research is needed to determine its cost effectiveness for scaling up and integrating in primary care settings.

Trial registration The trial is registered with Pan African clinical trial registry (PACTR202102729454417).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The use of geographically separated kebeles reduced intervention contamination between intervention and control group participants.
⇒ Cluster randomisation stratified by the average distance of kebeles from the nearest health facility was used to reduce its effect on the outcome measures.
⇒ Sensitivity analysis was performed by changing any of the assumptions used in the primary analyses, and the analytic model was found to be robust.
⇒ Randomisation done at the cluster level and the implementers of the intervention were not masked.
⇒ The intervention effect might be underestimated because participants in the control group may lower their high blood pressure due to learning effects caused by repeated blood pressure measurements.

INTRODUCTION

Ethiopia has faced triple disease burden of infectious or communicable diseases, non-communicable diseases and injuries.[1 2] According to the 2018 Ethiopian Non-communicable Disease and Injury Commission Summery Report, non-communicable diseases, including cardiovascular disease (CVDs), 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,[4] is now recognised as a public health problem,[5–7] accounting for 62.3% of CVDs,[8] 36.3 to 69.3% of stroke cases[9–13] and 3.5%

of all deaths.[14] The pooled prevalence of hypertension in Ethiopia was 21.8% in 2020 with a slight difference between rural (18.45%) and urban (22.85%) populations.[4] However, a significant proportion of hypertensive patients in the country remain undiagnosed, untreated and uncontrolled their high blood pressure.[15] The 2018 Ethiopian Non-communicable Disease and Injury Commission summary report also revealed that less than 40% of hypertensive patients in Ethiopia were identified as having hypertension. Only 28% of those identified received antihypertensive treatment, and only 26% of those on treatment have adequate blood pressure control.[16] This indicates that there is an unmet need in the country for early detection, treatment and care of hypertension.

Patient education,[17] lifestyle modifications and behavioural counselling are all cost effective measures to improve the early treatment and control of high blood pressure.[18 19] However, limited access to healthcare and a scarcity of healthcare providers are major factors limiting hypertension care at the primary healthcare level, where most people receive their care.[20] 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 4.45/1000 population to meet the sustainable development goal health targets.[21] Health extension workers are frontline public health workers who act as a link between health and the community, bridging cultural and language barriers, increasing access and coverage of health services, and thus, improving the health outcomes of their community.[22]

One of the strategies found to be effective and feasible in other contexts to improve hypertension care and bridge the gap between the community and the health system is task sharing, in which specific tasks are shared from more qualified healthcare cadre to a lesser trained cadre such as community health workers (CHWs).[23 24] For instance, community-based health education and healthy lifestyle counselling interventions implemented by CHWs have shown promising results in mean blood pressure reduction[25–27] and optimal blood pressure control.[25 28 29]

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 so there is no evidence of how effective of the community-based health education and healthy lifestyle counselling intervention will be in this context.[30 31] Hence, this study aimed to evaluate the effect of HEWs-led home-based multicomponent interventions on blood pressure change and optimal blood pressure control in rural areas of northwest Ethiopia using a cluster randomised controlled trial.

Hypotheses

1. Health extension workers-led home-based multicomponent intervention reduces systolic and diastolic blood pressure of hypertensive patients
2. Health extension workers-led home-based multicomponent intervention significantly improve the proportion of optimal blood pressure control

METHODS AND ANALYSIS

Trial design

A two-arm parallel cluster randomised controlled trial using a 1:1 allocation ratio was used to evaluate the effects of HEWs-led home-based multicomponent intervention on lifestyle modification, change in mean blood pressure and optimal blood pressure control in hypertensive patients.

Study setting

The trial was conducted in rural areas of northwest Ethiopia (Dabat and Gondar Zuria districts) from 12 March 2021 to 18 January 2022. Dabat is one of the districts in the North Gondar Administrative Zone, and Gondar Zuria is found in the Central Gondar Zone of the Amhara National Regional State, Ethiopia. The districts are divided into urban and rural kebeles (lowest administrative levels). There were 31 and 41 rural kebeles in Dabat and Gondar Zuria districts, 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 to 25 000 people.[32] The details are described elsewhere.[33 34]

Health extension workers are the key players (backbone) of the health extension programme in Ethiopia.[35] They are female and are recruited based on nationally agreed-upon criteria that include residence in the village, age of at least 18 years, the ability to speak the local language, completion of 10th or 12th grade, and willingness to remain in the village and serve communities.[35] All HEWs received a year of theoretical training in training institutions and practical training in health centres.[36] Two HEWs are assigned to each health post to serve 3000 to 5000 people in a village 'kebele'.[37]

Health extension workers spend 50% of their time at health posts providing services such as immunisations, injectable contraception and limited basic curative services such as malaria treatment, first aid, and diarrheal diseases and intestinal parasite management.[37] They also provide community promotion and education programmes at the household level. During the usual home visit, HEW supports households in making behavioural changes and encourages them to use primary healthcare services. According to the 2018 district Public Health Office report, there were 77 and 102 rural HEWs in Dabat and Gondar Zuria districts, respectively.

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 developed the research questions and study design, which were approved by the institutional review board of

the University of Gondar. After the findings have been translated into the local language (Amharic), community members such as religious leaders and women's development groups will be involved in disseminating the main findings to participants in collaboration with HEWs.

Clusters and participants eligibility

A cluster was defined as a kebele with a single health post that serves up to 1000 households.[38] Kebeles that had at least two working HEWs at the health post were eligible for the study. Adults aged ≥25 years who reside in the 20 kebeles, who had a diagnosis of hypertension (≥130/80 mm Hg) both in the home-based hypertension screening study[34] and at another measurement made before recruitment and were willing to participate in the study were eligible. However, patients who migrated out and critically ill patient were excluded.

Intervention package

The intervention package was developed after reviewing various literatures, hypertension management guidelines, and consulting experts. Content experts validated the package for validity. First, seven experts with more than 10 years of work experience in the field (one internal medicine specialist, four nutritionists, one expert in health policy and one MSc in medical nursing) evaluated the documents for content validity. The opinions of the experts were incorporated and presented to another group of experts. Accordingly, eight experts from various departments (one internal medicine specialist, two nutritionists, two health policy expert, two health education and behavioural science experts, and one MSc in medical nursing) evaluated the package. These experts' feedback was incorporated, and a panel discussion was held to reach a consensus. The intervention for this study was then named 'Health Extension Workers-led Home-Based Multicomponent Intervention.' This intervention package included four components: patient home health education about hypertension, behavioural counselling, medication adherence counselling and referral to a nearby health facility. It aimed to reduce high blood pressure, improve lifestyle modification and achieve optimal blood pressure control in hypertensive patients.

20 HEWs in the intervention group received 3 days of the intervention package training to teach hypertensive patients and family members. The HEWs conducted a 60 min family-based health education session during the first visit to go over general information about hypertension and treatment options. The HEWs then conducted three 40–60 min follow-up home visits every other month to provide home health education about hypertensive disease, behavioural counselling, medication adherence counselling and linkage to hypertension care-S1Table-.

Component 1: home health education about hypertensive disease

The HEWs provided brief hypertension health education about hypertension, its symptoms and major modifiable risk factors to hypertensive patients and their families, with the goal of increasing patients' knowledge of the disease and the importance of attending chronic care appointments. This session also included information about the chronic nature of the disease, the potential complications of untreated and uncontrolled hypertension, and the possibility of the need for lifelong medications.[39]

Component 2: behavioral counseling

Health extension workers used the Health Belief Model approach to counsel patients on healthy dietary habits (consuming a diet rich in fruits and vegetables, low-fat dairy products, low salt diet, use of vegetable cooking oil and use of whole grains), alcohol moderation, increasing physical activity and weight reduction for those participants who are overweight or obese. Health extension workers used motivational and effective communication, goal setting and family support to encourage participants to change unhealthy lifestyle behaviours. They used the five A's approach: ask, advise, agree, assist and arrange to provide intensive counselling for patients on healthy lifestyle modification.[40]

Poor health beliefs about hypertension may lead to less optimal blood pressure control through poor linkage to hypertension care and treatment and less engagement in healthy lifestyle practices. In order to provide behavioural counselling intervention, HEWs assessed participants' beliefs using the Health Belief Model, which has dimensions of perceived susceptibility to hypertension complications, perceived severity of hypertension complications, perceived benefit, barrier and self-efficacy to take action. The HEWs asked patients about the benefits of reducing salt intake, moderate alcohol consumption, reducing saturated fats, increasing fruit and vegetable consumption, increasing physical activity and losing weight on blood pressure control. The HEWs also asked hypertensive patients about perceived barriers or reasons for not taking the recommended amount of salt, alcohol, fruits and vegetables, and exercising. The potential conditions for reducing salt and alcohol intake, increasing fruit and vegetable consumption, and increasing physical activity were also asked.

Following that, the HEWs counselled hypertensive patients on the benefits of lowering salt and alcohol consumption, lowering cholesterol and saturated fats, increasing fruit and vegetable consumption, increasing physical activity and losing weight to lower blood pressure. The HEWs and hypertensive patients then agreed on the benefits of the aforementioned intervention components, and the HEWs assisted patients to take the appropriate measures (online supplemental additional file 1).

Component 3: referral for linkage to a health facility

The HEWs educated patients on the importance of regular blood pressure checks and gave them a referral slip that explained the nature of the disease, the reason for the referral and the importance of starting treatment

as soon as possible if they were eligible. Furthermore, during a home visit, they reminded participants who had not previously started antihypertensive medication to seek treatment and care at a nearby health facility.

Component 4: medication adherence counseling

Health extension workers taught participants about the purpose of using medications, the positive effects of treatment and the negative effects of non-adherence. The HEWs reinforced key points of the medication regimen, including how the medication works, the proper dosage schedule and administration, what to do if doses are missed and proper storage.

Control group

These groups of HEWs were not involved in the intervention and were not informed about the study's goal. Hence, they did not provide any of the above-mentioned intervention components to study participants. They delivered 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, participants in both the intervention and control groups who were already on treatment can continue to take antihypertensive medications as prescribed by the healthcare providers.

Intervention Fidelity

The following measures were implemented to improve intervention fidelity: a manual of operating procedures was developed, intensive training for interventionists was provided, routine communication with interventionists was established and the supervisory team conducted a spot check when the HEWs delivered the intervention to study participants. The fidelity of the intervention was assessed at the end of the intervention using a fidelity checklist that included the frequency, duration and intensity of the intervention (online supplemental table S2).

Outcome measures

The primary outcomes of this trial were the differences in mean systolic and diastolic blood pressure changes at 3, 6 and 9 months from baseline between the intervention and control groups. The secondary outcomes were the proportion of hypertensive patients who had optimal blood pressure control at 3, 6 and 9 months after the intervention and change in the proportion of lifestyle modifications (alcohol intake, high salt intake, low fruit and vegetable consumption, and low level of physical activity) at the end of the intervention from baseline. This trial also assessed intervention process measures such as change from baseline in the sum score of hypertensive disease knowledge and change from baseline in the mean score of health beliefs about hypertension among hypertensive patients.

Sample size determination

The sample size required to evaluate the effect of HEWs-led home-based multicomponent intervention on change in mean systolic blood pressure (SBP) was calculated using a double population mean formula accounted for the design effect of clusters. $n\ (in\ each\ group) = \left(z_{1-\alpha/2} + z_{\beta}\right)^2 \frac{\left(\delta_1^2+\delta_2^2\right)}{\left(\mu_1-\mu_2\right)^2}$, where δ_1 and δ_2 were the SD for the intervention and control groups, respectively, and μ_1 and μ_2 were the endline SBPs for the intervention and control groups, respectively. The design effect is defined as 1+ (m −1) ρ, where m is the average cluster size and ρ is the intracluster correlation coefficient for the specific outcome. Assumptions of a mean SBP reduction in the intervention group from 151.7 mm Hg baseline to 132.4 mm Hg (μ_1) end line and a mean SBP reduction in the control group from 149.8 mm Hg baseline to 137.7 mm Hg (μ_2) end line, yielding a mean difference of (d) 5.3 mm Hg. An SD of 10 mm Hg in both the intervention (δ_1) and control groups (δ_2), an intracluster correlation of 0.077,[25] and a 20% loss to follow-up were used, resulting a final sample size of 132 hypertensive patients in each group. On the other hand, a sample size of 456 participants was calculated using double population proportion formula to evaluate linkage to hypertension care, one of the outcomes of the trial. Because the sample size required to evaluate linkage to hypertension care is greater than the change in SBP, we used the larger sample size.

Cluster and participant recruitment

A simple random sampling method was used to select 10 kebeles from each district among the 70 eligible kebeles. A community-based cross-sectional study was conducted in the study setting between September and November 2020 to determine the proportion of undiagnosed hypertension. Hypertensive screening was performed on 2423 study participants in the selected kebeles, and 758 were found to have hypertension. The research team re-measured the blood pressure of adults who were identified as potentially hypertensive in a previous home-based hypertension screening study for the second time to recruit participants. Adults diagnosed with hypertension for the second time were evaluated for eligibility. An average of 23 hypertensive patients per cluster were enrolled using a simple random sampling method. An epidemiologist from the research team completed the participants' eligibility forms and enrolled them in the follow-up study.

Randomization and implementation

The unit of randomisation was clusters or kebeles. Cluster randomisation stratified by physical distance from the kebele to the nearest healthcare facility was used to achieve balance across geographic healthcare access. We have two distance strata: close distance (within 5 km) and far distance (greater than 5 km). We randomly assigned 10 kebeles (four from Dabat and six from Gondar Zuria district) within 5 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. Computer-generated random numbers were used to produce randomisation codes. Randomisation at the kebele level ensured that only patients in the intervention group received home-based multicomponent interventions from HEWs. A biostatistician, a member of the research team who did not interact with the study participants, used a 1:1 allocation ratio and randomly assigned 20 kebeles with pre-identified hypertensive cases to either the intervention (10 kebeles with 228 hypertensive patients) or control group (10 kebeles with 228 hypertensive patients).

Awareness of assignment

Neither the participants nor the HEWs were masked with respect to the participants' group assignment. The risk of contamination was minimised using buffering kebele/s, whereby the intervention and control kebeles geographically separated (5–15 km) and the chance of intervention cluster participants meeting control cluster participants was insignificant. The trainers taught the HEWs in the intervention clusters not to share information about the study with those in the control group. The outcome assessors were masked from the intervention allocation of participants.

Study visits and data collection procedures

The baseline survey was conducted prior to randomisation to reduce selection bias during the allocation of kebeles to either the intervention or control groups. The WHO Stepwise Approach to Surveillance of Non-communicable Diseases Questionnaire[41] was adapted and used to collect data regarding sociodemographic factors, behavioural risk factors and the history of non-communicable diseases. Participants' knowledge and beliefs about hypertension, the distance to the nearby health facility, health insurance coverage and access to healthcare were collected. Physical measurements such as height, weight and blood pressure were measured.

The data collection tool was prepared in English and translated into the local language (Amharic) by two bilingual experts. An expert panel consisted of two translators, methodologists and subject experts 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 took 3 days of training on how to conduct interviews with patients and measure blood pressure, weight and height. Data were 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 visited participants' homes and collected the data.

A follow-up survey was conducted at 3, 6 and 9 months in both the intervention and control groups. Blood pressure was measured at each visit, twice at a 5 min interval. At the end of the intervention, outcome data on lifestyle modification, knowledge about hypertension and health beliefs towards hypertension were collected in both the intervention and control groups. Compliance with the intervention during the follow-up period was collected only in the intervention group.

Variable measurement and definition

The rural community's household assets were used to calculate the wealth of the families.[42] These were combined into a single wealth index and divided into three equal-sized groups based on their relative position on the household wealth index. The question 'Does your household have community-based health insurance membership?' determined the health insurance status of the participants. Those who respond 'no' were categorised as uninsured. Those who respond 'yes' then asked the question, 'Does the insurance cover all healthcare costs?' Participants who respond 'no' to this question were categorised as underinsured. Participants who respond 'yes' to this question were categorised as adequately insured.

The lifestyle modifications of the study participants were measured using the following behavioural risk factors: alcohol consumption, fruit and vegetable consumption, salt consumption and level of physical activity. Weekly alcohol consumption was defined as consuming at least one alcoholic drink per week. The international physical activity questionnaire short form was used to assess the participants' physical activity. A low level of physical activity was defined as any combination of walking, moderate or vigorous intensity activity <600 metabolic equivalent tasks (MET)-minutes per week.[43] The salt used in cooking was 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 was defined as always or almost always adding salt to a plate or while cooking. Low intake of fruit and vegetable was defined as eating less than five servings of fruit and vegetables per day.

Participants' hypertension knowledge was assessed using closed-ended questions with 'yes, no, or don't know' responses. The items were recoded, and correct responses were assigned a value of one, while incorrect or don't know responses were assigned a value of zero. The sum score for hypertension knowledge was computed. The health belief model, which has six subdomains, was used to assess participants' beliefs about hypertension. Each item was rated on a 5-point Likert scale ranging from strongly disagree to strongly agree. Total scores were computed for each subdomain, and mean scores were computed for each subdomain by dividing the total scores of the subdomain items by the total number of subdomain items.

Blood pressure measurements were taken in the sitting position on the left arm and values recorded to the nearest 2 mm Hg using an aneroid sphygmomanometer and stethoscope. Participants who drank caffeinated

beverages (tea or coffee) or had been working within 30 min waited for 30 min before blood pressure measurements. The data collectors make the 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. The first reading was taken after resting for at least 5 min, and the second was measured 5 min after the first measurements. The averages of the two were taken to define blood pressure control. According to the new American College of Cardiology and American Heart Association guideline,[44] hypertension (high blood pressure) is defined as a mean SBP of ≥130 mm Hg or a diastolic blood pressure (DBP) of ≥80 mm Hg. Stage 1 hypertension was defined as an SBP ranging from 130 to 139 mm Hg or a DBP ranging from 80 to 89 mm Hg, while stage 2 hypertension was defined as an SBP of ≥140 mm Hg or a DBP of ≥90 mm Hg. Optimally controlled blood pressure was defined as an average blood pressure <130/80 mm Hg for all adults.[44] Linkage to hypertension care was defined as visiting a healthcare facility for hypertension care and/or treatment within 9 months of the follow-up period.

Participants' weight was measured using a digital weighting scale by placing it on a flat surface and stepping onto it while wearing light clothing to the nearest 0.1 kg. The participants' heights were measured with a tape measure to the nearest 0.1 cm. Participants were asked to stand up straight, without shoes, with their heels together, and their eyes directed forward. The Body Mass Index (BMI) was 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).[45]

Trial management

A manual of operating procedures was developed and used to describe the procedures for staff training, participant recruitment, instructions for all forms and procedures, patient education, behavioural and medication adherence counselling, blood pressure measurement and other operational aspects of the study. The research team monitored the data collection process using telephone and onsite supervision. Efforts were made to retain study participants throughout the trial period to ensure the success of the study. The names and contact information of individuals closely related to the participant were obtained during enrollment.

Statistical analysis

The data was entered into Epidata 4.6 and transferred to Stata 16 for further analysis. The data were cleaned, coded and recoded. An intent-to-treat analysis was applied to all primary analyses. The baseline characteristics of participants were described using means and SD for continuous variables and frequencies and proportions for categorical variables. The baseline characteristics of the study participants between the intervention and control groups were compared for uniformity using a two-tailed independent t-test for the continuous variables and a chi-square ($\chi 2$) test for categorical variables. The McNemar test was used to test within-group differences between baseline and endline data on lifestyle modifications. The mean profile plot was used to investigate the change in mean SBP and DBP of the intervention groups over time.

A linear mixed-effect model was 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 was used to model the within-subject variance-covariance structure. We used Y_{ij} to represent the SBP and/or DBP measurements for subject i at visit j, which had a normal distribution with an identity link function. Thus: $Y_{ij}=\beta_0 + b_{oi}+ \beta_1 Int_i + (\beta_2+ b_{1i})\ time_{ij} +\beta_3 Int_i x time_{ij}+ \varepsilon_{ij}$. Where β_0 is the fixed intercept, Int_i is the intervention variable for subject i, β_1 is the regression coefficient for the intervention variable, β_2 is the regression coefficient for the 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 the time variable and ε_{ij} is the measurement error for subject i at time j and is normally distributed with a mean of 0 and a variance σ^2. In addition, the random effect coefficients and the measurement error are assumed to be independent.

A generalised estimating equation was used to model the proportion of optimal blood pressure control at 3, 6 and 9 months, taking repeated measures into account. A robust variance estimator was used to estimate standard errors. The effect sizes, such as the mean difference with 95% CI, were used to evaluate the intervention effect on blood pressure change from baseline, whereas, the relative benefit increase (RBI), absolute benefit increase or percentage difference, and attributable proportion were used to evaluate the intervention effect on optimal blood pressure control. A two-sided p value of <0.05 was used to indicate statistical significance for all outcome measures.

Subgroup analyses

Subgroup analyses were performed for the primary outcome measures to investigate the heterogeneity of the intervention effect based on baseline characteristics such as age, sex and stage of hypertension. We computed the rates of loss to follow-up for each group, and the difference in attrition between the intervention and control groups was calculated. Differential attrition is considered when the absolute value of the attrition difference is ≥0.05 SD.

Sensitivity analysis

A sensitivity analysis was performed for the primary outcome measures to determine the robustness of the primary analysis by changing any of the assumptions made in the primary analyses. Outliers were identified using a z-score and sensitivity analysis with and without outliers was performed. Complete-case analysis, single imputation (replacing missing data with the mean of the outcome) and multiple imputation based on the assumption that

missing data are missing at random were used to handle missing data. An adjusted analysis for age, sex and stage of hypertension was performed for each outcome using the same regression model as the primary analyses.

RESULTS

Participants' recruitment and follow-up

758 adults with high blood pressure who were identified during the hypertension screening study were re-checked and assessed for eligibility from 20 February 2021 to 10 March 2021. Accordingly, 456 of 620 eligible hypertensive patients were enrolled. At 9 months, 425 (93.2%) participants completed the trial, 216 (94.7%) in the intervention group and 209 (91.7%) in the control group. At the end of the intervention, data were not available for 31 (6.8 %) participants, of whom 6 had died, 9 moved out from their residence kebeles, 8 were not found during the data collection date and 8 declined the intervention

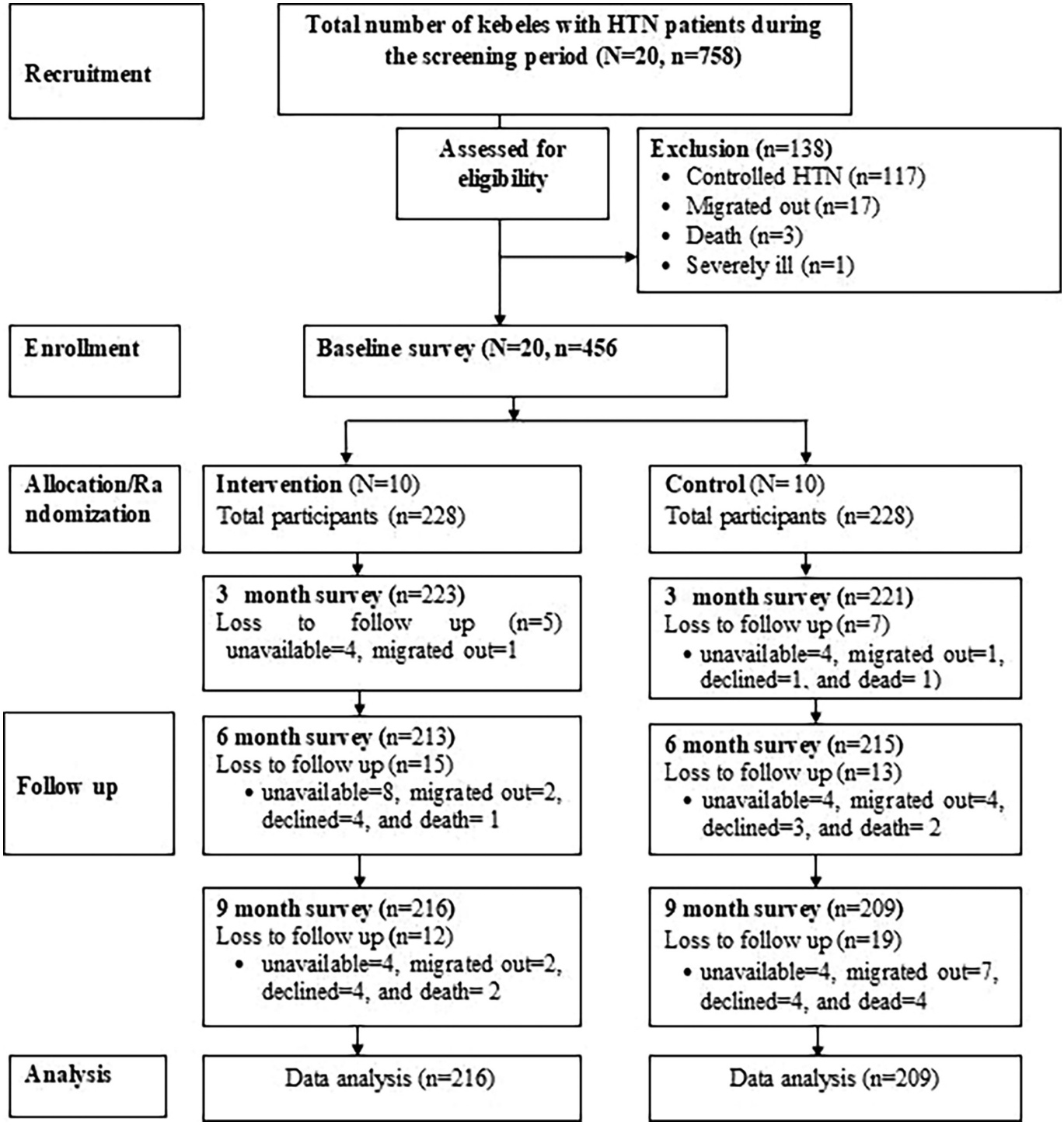

Figure 1 The CONSORT flow diagram of participant allocation, follow-up and analysis.

(figure 1). The dropout rates were 5.3% and 8.3% for intervention and control groups, respectively. The difference in attrition between the intervention and control groups was not of statistical significance (p=0.19).

Participants' baseline characteristics

A total of 456 (228 in intervention group and 228 in the control group) hypertensive patients enrolled in this trial. The mean age of participants was 54.2±15.2 years in the intervention group and 54.5±14.8 years in the control groups. Of the participants, 135 (59.2%) in the intervention group and 123 (53.9%) in the control group were female. 169 (74.1%) participants in the intervention group and 180 (78.9%) participants in the control group could not read and write. The baseline mean SBP for the intervention group was 145.45 (SD±14.04) mm Hg and 146.17 (SD±13.75) mm Hg for the control group. Participants in the intervention and control groups had baseline mean DBP of 86.83 (SD±7.68) and 87.39 (SD±7.15) mm Hg, respectively. 186 (81.6%) participants in the intervention group and 194 (85.1%) in the control group had stage 2 hypertension. 47 (20.6%) of the study participants in the intervention and 43 (18.9%) of the study participants in the control group have had family history of hypertension. All the study participants' baseline characteristics were uniformly distributed between the intervention and control groups (table 1).

Intervention Fidelity

Intervention fidelity was assessed among 216 study participants in the intervention group. 207 (95.8%) of the participants attended all of the planned HEWs-led home-based interventions visits, with the intervention being carried out with high fidelity.

Primary outcomes: change in mean systolic and diastolic blood pressure

Three months following the intervention, the mean SBP reduction was 8.6 mm Hg (95% CI: 6.7, 10.5 mm Hg) in the intervention group and 2.1 mm Hg (95% CI: 0.32, 3.9 mm Hg) in the control group, whereas 6 months later, the mean SBP reduction was 13.5 mm Hg (95% CI: 11.4, 15.6 mm Hg) in the intervention group and 7.8 mm Hg (95% CI: 5.9, 9.6 mm Hg) in the control group. At the end of the intervention, the mean SBP reduction was 15.8 mm Hg (95% CI: 13.5, 18.1 mm Hg) in the intervention group and 10.8 mm Hg (95% CI: 8.7, 12.9 mm Hg) in the control group. The intervention group experienced a mean SBP reduction of 5.0 mm Hg (95% CI: 2.0, 8.0 mm Hg) greater than the control group.

At the end of the intervention, the mean DBP in the intervention group decreased by 12.1 mm Hg (95% CI: 10.6, 13.5 mm Hg) and 8.4 mm Hg (95% CI: 7.0, 9.8 mm Hg) in the control group. The difference in DBP reduction was 3.5 mm Hg (95% CI: 1.6, 5.5 mm Hg) greater in the intervention group than the control group. The overall mean change in SBP and DBP after adjusting for age, sex and baseline hypertension stage was 5.0 mm

Table 1 Baseline characteristics of hypertensive patients in northwest Ethiopia (n=456)

Characteristics	Intervention group (n=228)	Control group (n=228)	P value
Sex			
Male	93 (40.8)	105 (46.1)	
Female	135 (59.2)	123 (53.9)	0.257
Age group, in years			
25–34	23 (10.1)	18 (7.9)	0.888
35–44	37 (16.2)	41 (18.0)	
45–54	49 (21.5)	53 (23.3)	
55–64	52 (22.8)	48 (21.0)	
≥65	67 (29.4)	68 (29.8)	
Marital status			
Single	6 (2.6)	3 (1.3)	0.556
Married	176 (77.2)	183 (80.3)	
Divorced	16 (7.0)	11 (4.8)	
Widowed	30 (13.2)	31 (13.6)	
Educational status			
Unable to read and write	169 (74.1)	180 (78.9)	0.475
Able to read and write	40 (17.5)	33 (14.5)	
Primary school and above	19 (8.3)	15 (6.6)	
Household Wealth Index			
Poor	78 (34.2)	74 (32.5)	0.11
Medium	66 (29.0)	86 (37.7)	
Rich	84 (36. 8)	68 (29. 8)	
Family size			
<5 members	87 (38.2)	105 (46.1)	0.088
≥5 members	141 (61.8)	123 (53.9)	
Behavioural risk factors			
Weekly alcohol drinking, number (%)	114 (50.0)	116 (50.9)	0.851
Low intake of fruit and vegetables	228 (100.0)	227 (99.6)	0.317
Added salt while cooking	179 (78.2)	185 (81.1)	0.484
Low physical activity	45 (19.7)	56 (24.6)	0.436
Body Mass Index, mean(SD)	20.06 (2.50)	20.13 (2.76)	0.8027
Community-based health insurance			
Adequately insured	69 (30.3)	51 (22.3)	0.06
Partially insured	32 (14.0)	25 (11.0)	
Not insured	127 (55.7)	152 (66.7)	
Blood pressure, mm Hg			
SBP, mean (SD)	145.45 (14.04)	146.17 (13.8)	0.5831
DBP, mean (SD)	86.83 (7.68)	87.39 (7.15)	0.4268
Hypertension			

Continued

Table 1 Continued

Characteristics	Intervention group (n=228)	Control group (n=228)	P value
Stage 1	42 (18.4)	34 (14.9)	0.315
Stage 2	186 (81.6)	194 (85.1)	
Family history of hypertension			
Yes	47 (20.6)	43 (18.9)	0.638
No	181 (79.4)	185 (81.1)	
Chronic respiratory diseases			
Yes	6 (2.6)	3 (1.3)	0.312
No	222 (97.4)	225 (98.7)	

DBP, diastolic blood pressure; SBP, systolic blood pressure.

Hg (95% CI: 1.9, 8.0) and 3.5 mm Hg (95% CI: 1.6, 5.4), respectively, which was consistent with the primary analysis (table 2 and figure 2).

Linear mixed effect model showed that individuals in the intervention group had a 2.80 mm Hg (95% CI: 0.40, 5.22 mm Hg) greater reduction in mean SBP than those in the control group; and individuals in the intervention group had a 1.43 mm Hg (95% CI: 0.46, 2.40) greater reduction in mean SBP over time than the control group. The intervention group also had a 2.52 mm Hg (95% CI: 1.25, 3.78 mm Hg) greater reduction in mean DBP than the control group. The intervention group also had a 1.01 mm Hg (95% CI: 0.39, 1.63 mm Hg) reduction of mean DBP over time than the control group. The adjusted analysis also revealed individuals in the intervention group had a 2.4 (95% CI: 0.35, 4.45) greater reduction in mean SBP than those in the control group. The intervention group also had a 2.4 (95% CI: 1.16, 3.53) greater reduction in mean DBP than the control group. The intraclass correlation coefficient was 0.38 for systolic blood pressure and 0.24 for DBP (online supplemental table S3).

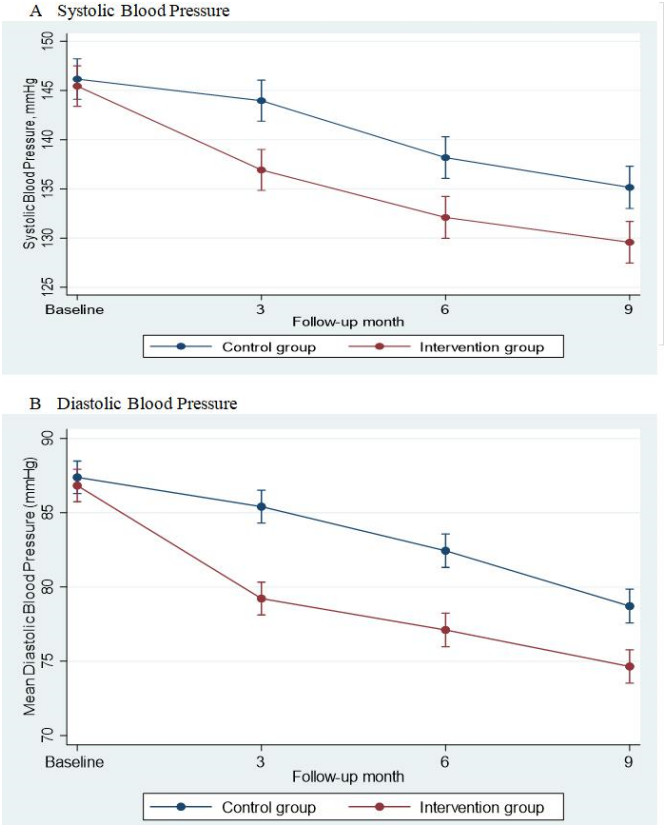

Figure 2 Mean systolic blood pressure (A) and diastolic blood pressure (B) in intervention and control groups of hypertensive ptaients.

Secondary outcomes

Proportions of blood pressure control

Three months after the intervention, 45 (20.2%) of participants in the intervention group and 15 (6.8%) of participants in the control group had optimal blood pressure control, while 6 months later, 76 (35.7%) of participants in the intervention group and 28 (13.0%) of participants in the control group had optimal blood pressure control. At the end of the intervention, the proportion

Table 2 Effect of intervention on blood pressure outcome among hypertensive patients in northwest Ethiopia

Month measured	Intervention		Control		Net mean difference (95% CI)	Adjusted net mean difference (95% CI)*
	Number of patients	Mean difference (95% CI)	Number of patients	Mean difference (95% CI)		
Change in mean systolic blood pressure (mm Hg) from baseline						
3	223	−8.6 (−10.5 to 6.7)	221	−2.1 (−3.9, −0.32)	−6.5 (−9.1 to 3.9)	−6.5 (−9.1 to 3.9)
6	213	−13.5 (−15.6 to 11.4)	215	−7.8 (−9.6, −5.9)	−5.6 (−8.4 to 2.8)	−5.6 (−8.4 to 2.8)
9	216	−15.8 (−18.1 to 13.5)	209	−10.8 (−12.9, −8.7)	−5.0 (−8.0 to 2.0)	−5.0 (−8.0 to 1.9)
Change in mean diastolic blood pressure (mm Hg) from baseline						
3	223	−7.5 (−8.7 to 6.3)	221	−1.9 (−2.9, −0.9)	−5.6 (−7.3 to 3.9)	−5.6 (−7.3 to 3.9)
6	213	−9.7 (−11.1 to 8.3)	215	−4.8 (−6.0, −3.6)	−4.8 (−6.6 to 3.0)	−4.8 (−6.7 to 3.0)
9	216	−12.1 (−13.5 to 10.6)	209	−8.4 (−9.8, −7.0)	−3.5 (−5.5 to 1.6)	−3.5 (−5.4 to 1.6)

*Adjusted for age, sex and baseline hypertension stage.

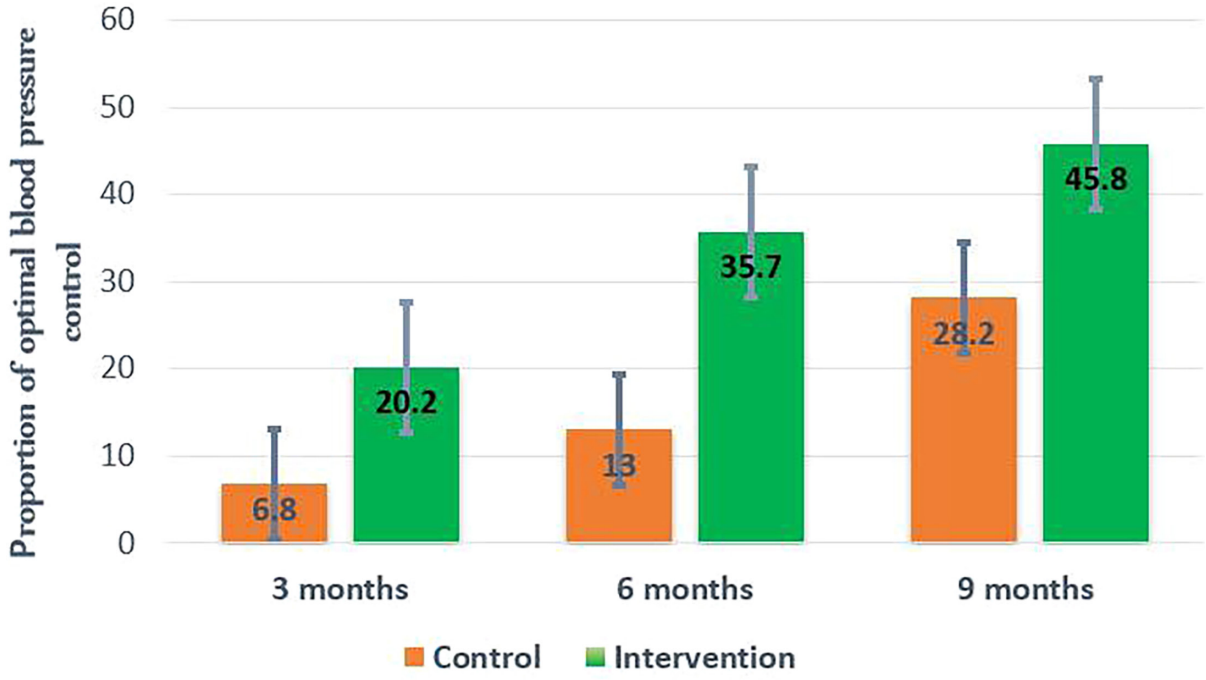

Figure 3 Proportion of optimal blood pressure control among hypertensive patients in northwest Ethiopia, March 2021–January 2022.

of hypertensive patients with optimally controlled blood pressure was significantly higher in the intervention group than in the control group. The intervention group achieved optimal blood pressure control of 45.8% (95% CI: 38.7, 52.9) while the control group achieved 28.2% (95% CI: 21.6, 34.8), with a 17.6% (95% CI: 8.5, 26.7) attributable difference (figure 3). The attributable proportion of optimal blood pressure control was 46.2%.

The generalised estimating equation/GEE revealed that the HEWs-led home-based multicomponent intervention was associated with a twofold increase in optimal blood pressure control (RBI=1.86; 95% CI: 1.48, 2.35). After adjusting for age, sex and baseline hypertension staging, the rate of blood pressure control in the intervention group was nearly two times higher than the control group (adjusted relative benefit increase (ARBI)=1.81, 95% CI: 1.44, 2.27), which was consistent with the primary analysis.

Change in the proportion of Lifestyle modification

The trial found a significant difference between the intervention and control groups in high salt and alcohol consumption reduction. The proportion of high salt consumption in the intervention group decreased from 78.2% at baseline to 30% at end line (p<0.001), while in the control group, it decreased from 81.3% to 79.4% (p value=0.68), with a 49.4% (95% CI: 39.5, 56.7) attributable difference. However, the intervention did not show significant differences between the intervention and control groups at the end of the intervention in terms of proportions of hypertensive patients who ate less than five servings of fruit and vegetables each day and low physical activity.

Process outcomes

At baseline, the intervention and control groups did not differ significantly in terms of knowledge of common hypertensive symptoms, knowledge of hypertension complications, mean score of perceived susceptibility to hypertension complications, perceived severity of hypertension, perceived benefits and self-efficacy to take action (p>0.05). The intervention significantly increased the sum scores of knowledge of common hypertensive symptoms, complications, preventive and treatment measures, and the mean scores of perceived susceptibility to hypertension complications, perceived severity of hypertension, perceived benefits, perceived self-efficacy, and cues to action in the intervention group compared with the control group. The intervention also significantly reduced the perceived barriers to take corrective measures (p<0.001) (online supplemental table S4).

Subgroup analysis

The reduction of mean SBP in male participants was 8.8 (95% CI: 4.1, 13.6) mm Hg higher in the intervention group than the control group, while mean DBP changes were consistent in both groups. The reduction in mean SBP was 12.1 (95% CI: 5.8, 18.4) mm Hg higher in the intervention group compared with the control group in hypertensive patients aged 65 years of age and older; and the change in mean DBP was 4.1 (95% CI: 0.2, 8.1) mm Hg higher in the intervention group compared with the control group. The intervention group experienced a 5.7 (95% CI: 2.2, 9.1) mm Hg greater change in SBP than the control group among stage 2 hypertensive patients. The corresponding changes in DBP were 3.9 (95% CI:

1.7, 6.2) mm Hg greater in the intervention group than the control group (online supplemental table S5).

Sensitivity analysis

Sensitivity analysis was performed for the primary outcomes including adjusted analysis for baseline characteristics (online supplemental table S3); handling missing data using complete case analysis (online supplemental table S6), single imputation (online supplemental table S7) and multiple imputations (online supplemental table S8); different analytic methods such as generalised estimating equations (online supplemental table S9); and data analysis without outliers. The findings revealed that the intervention had consistent effects on change inmean systolic and diastolic blood pressure. As a result, we believe our findings are robust.

Safety reporting

There are no reasonably foreseeable risks associated with the intervention for study participants in this trial study. The intervention has no negative consequences or side effects. However, the disease has the potential to cause long-term complications.

DISCUSSION

This randomised controlled trial in rural northwest Ethiopia demonstrates that the HEWs-led home-based multicomponent intervention is effective in lowering blood pressure and significantly increasing the proportion of adults with controlled blood pressure. Participants in the intervention group had shown significant reductions of SBP/DBP by 15.8/12.1 mm Hg. Blood pressure declined an average of 5.0/3.5 mm Hg more in the intervention group than the control group. The use of a health belief model to deliver the intervention may explain why the intervention group experienced greater blood pressure reduction and better blood pressure control. The intervention helps patients in improving their perceived susceptibility and severity of hypertension, which may lead to blood pressure reduction and better blood pressure control via improved healthy lifestyle practices. Participants in the control group also showed significant reductions of both systolic and diastolic blood pressure. This could be due to the period effects, in which participants may learn and modify their behaviour and lower their blood pressure, as a result of repeated measurements of the outcome variables over the 9-month follow-up period.

This significant reduction in SBP has important clinical implications for hypertensive patients, as each 5 mm Hg decrease in SBP reduces the risk of developing CVDs events[46 47] and deaths[47] by 10% and 5%, respectively. A 10 mm Hg reduction in SBP also reduces the risk of major CVDs events by 20%, stroke by 27%, heart failure by 28%, coronary heart disease by 17% and death from all causes by 13%.[48] A 2 mm Hg reduction in DBP would result in a 17% reduction in hypertension prevalence, a 6% reduction in the risk of coronary heart diseases, and a 15% reduction in the risk of stroke and transient ischaemic attacks.[49]

The mean systolic and diastolic blood pressure reduction in this trial was consistent with a meta-analysis conducted in low-income and middle-income countries, which found that CHWs-led interventions for blood pressure management reduce mean SBP and DBP by 3.67 and 2.29 mm Hg,[50] respectively. In an 18-month cluster randomised trial conducted in Argentina among low-income uninsured hypertensive patients, a CHWs-led home-based multicomponent intervention including health coaching, home blood pressure monitoring and audit delivered for 60–90 min monthly or bimonthly reduced SBP by 6.6 mm Hg and DBP by 5.4 mm Hg when compared with usual care.[25] A cluster randomised controlled trial of lifestyle intervention led by female community health volunteers and delivered home visits every 4 months for a year in Nepal found that the intervention group had a 4.9 and 2.63 mm Hg greater reduction in mean systolic and diastolic blood pressure than the control group.[51] Another community-based open-level cluster randomised controlled trial in Surkhet, Nepal, community health volunteers-led community-based health education and home support resulted a significant reduction of SBP by 7.5 mm Hg and DBP by 5.42 mm Hg.[52] Our findings were also consistent with the findings of a cluster randomised controlled trial conducted in rural India, where trained CHWs delivered a group-based intervention and revealed that the intervention group had a 5.0 and 2.1 mm Hg greater reduction in SBP and DBP than the usual care group.[53] A 2-month multicomponent exercise programme consisting of functional mobility, balance, muscle strength and flexibility exercises resulted in a 7.25 mm Hg decrease in SBP.[54] This finding is also consistent with a community-based intervention for hypertension management in rural South Asia, where trained community health workers for blood-pressure monitoring and counselling, as well as physician training, resulted in 5.2 mm Hg and 2.8 mm Hg greater reductions in SBP and DBP, respectively, in the intervention group.[55] A cluster randomised controlled trial in India also found that CHW-led hypertension management reduced mean SBP by 12.2 mm Hg in the intervention group compared with 6.4 in the control group after 2 years.[56]

The HEWs-led home-based multicomponent intervention achieved 45.8% of optimal blood pressure control compared with 28.2% in the control group. The study found an attributable proportion of 46.2%, which means that 46.2% of optimal blood pressure control in the intervention group could be due to the HEWs-led home-based multicomponent intervention. This suggests that integrating community HEWs in hypertension management could help with management and control of hypertension. This trial finding provides an insight for policymakers and implementers as starting point on how to integrate hypertension management into existing health extension programme. They will help to achieve the national blood pressure control target of 41%–60%

by 2025.[57] This finding is also very helpful to save millions of hypertensive patients from developing CVDs such as ischaemic heart disease, heart failure and stroke, leading cause of death from hypertension.

In this trial, the effect of a home-based multicomponent intervention led by HEWs on optimal blood pressure control was consistent with findings from trials in low and middle-income countries, where optimal blood pressure control in the intervention group was 44.1% in rural district in Bangladesh[58] and 38.3% in Nepal.[52] The positive outcomes of the intervention on optimal blood pressure control may be attributable in part to the HEWs ability to form frequent contact and positive relationships with patients, making the patients feel cared for, esteemed and part of a network of mutual obligations. However, the effect of a home-based multicomponent intervention led by HEWs on blood pressure control rates in this trial was lower than in previous trials, where optimal blood pressure control in the intervention group was 53.2% in rural South Asia,[55] 69.7% in rural India[53] and 72.9% in Argentina.[25 53] This could be because previous trials, such as one in Argentina that lasted 18 months and another in South Asia that included physician training as part of the intervention, both of which improved optimal blood pressure control. Furthermore, the higher percentage of optimal blood pressure found in India was due to the fact that optimal blood pressure control was 49.5% at baseline.

This trial findings indicate HEWs are an important resource, and task sharing using these groups gives an insight into the management and control of hypertension in rural settings where trained health professionals are scarce. The interventions focusing on behaviour change communication and lifestyle counselling should be prioritised in order to bring behaviour change in hypertensive patients, followed by blood pressure reduction and control. Standard curricula for HEW training in hypertension control and management are required to guide the translation of such interventions across the country. To scale up this HEWs-led task sharing strategy in Ethiopia, future studies should investigate the cost-effectiveness in the management and control of hypertension.

However, the use of self-reported measures to assess behavioural risk factors such as physical activity, salt, alcohol, and fruit and vegetable consumption may be a limitation of this study, making it susceptible to recall bias. Additionally, since this was a cluster randomisation trial, the interventionist delivering the intervention was not blinded. Though we planned to evaluate the interventions effect on one of the secondary outcome measures-medication adherence, we found that only a small proportion of hypertensive patients started treatment, which was inadequate to properly assess medication adherence as an outcome.

CONCLUSIONS

Health extension workers-led home-based multicomponent intervention reduces both systolic and diastolic blood pressure and improves the proportion of optimal blood pressure control in hypertensive patients in underserved rural areas of Ethiopia. It can be integrated with the existing health extension programme in the primary healthcare unit at the health post levels to reduce the overall risk of CVDs. However, more research is needed to identify the barriers to implementing HEWs-led home-based multicomponent interventions and address the long-term effects of the intervention on CVDs reductions.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Ethics approval This study involves human participants and 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). Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available upon reasonable request. This manuscript contains all of the data generated or analyzed during the course of the trial. Individual participant data, the study protocol, and the consent form are available from the corresponding author and can be obtained by directing your proposal to destaw.fetene@gmail.com. Individual participant data that underlie the results reported in this article, after deidentification of participant names and kebeles, will be shared with anyone who wishes to access the data from 9 months after the manuscript's publication until 36 months later.

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