



Effectiveness of a lifestyle intervention led by female community health volunteers versus usual care in blood pressure reduction (COBIN): an open-label, cluster-randomised trial

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Summary

Introduction Elevated blood pressure greatly contributes to cardiovascular deaths in low-income and middle-income countries. We aimed to investigate the effectiveness of a population-level intervention led by existing community health workers in reducing the burden of hypertension in a low-income population.

Methods We did a community-based, open-label, two-group, cluster-randomised controlled trial in Nepal. Using computer-generated codes, we randomly assigned (1:1) 14 clusters to a lifestyle intervention led by female community health volunteers (FCHVs) or usual care (control group). In the intervention group, 43 FCHVs provided home visits every 4 months for lifestyle counselling and blood pressure monitoring. Eligible participants had been involved in a previous population-based survey, were aged 25–65 years, did not have plans to migrate outside the study area, and were not severely ill or pregnant. The primary outcome was mean systolic blood pressure at 1 year. We included all participants who remained in the trial at 1 year in the primary analysis. This trial is registered with ClinicalTrials.gov, number NCT02428075.

Findings Between April 1, 2015, and Dec 31, 2015, we recruited 1638 participants (939 assigned to intervention; 699 assigned to control). At 1 year, 855 participants remained in the intervention group (425 were normotensive, 175 were prehypertensive, and 255 had hypertension) and 613 remained in the control group (305 were normotensive, 128 were prehypertensive, and 180 had hypertension). The mean systolic blood pressure at 1 year was significantly lower in the intervention group than in the control group for all cohorts: the difference was -2.28 mm Hg (95% CI -3.77 to -0.79 , $p=0.003$) for participants who were normotensive, -3.08 mm Hg (-5.58 to -0.59 , $p=0.015$) for participants who were prehypertensive, and -4.90 mm Hg (-7.78 to -2.00 , $p=0.001$) for participants who were hypertensive.

Interpretation A simple, FCHV-led lifestyle intervention coupled with monitoring of blood pressure is effective for reduction of blood pressure in individuals with hypertension and ameliorates age-related increases in blood pressure in adults without hypertension in the general population of Nepal.

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Introduction

Elevated blood pressure is the biggest risk factor contributing to the global incidence of cardiovascular death.¹ In the past four decades, blood pressure has decreased in high-income countries (HICs), whereas it has increased in low-income countries (LICs) in southern Asia and sub-Saharan Africa.² Without interventions for elevated blood pressure, we are unlikely to meet the target of reducing by a third premature mortality from non-communicable diseases, as set in the 2015 UN Sustainable Development Goals.³ A 5 mm Hg reduction in systolic blood pressure in the population has been estimated to result in a 14% overall reduction in mortality due to stroke, a 9% reduction in mortality due to coronary heart disease, and a 7% reduction in all-cause mortality.⁴ Even modest population-wide reductions in systolic blood pressure (eg, 1 mm Hg) are

predicted to have substantial effects on cardiovascular death prevention.⁵ Hence, this strategy for reducing premature cardiovascular morbidity, mortality, and burden is cost-effective, with use of few health resources.⁶

WHO aims to achieve a 25% relative reduction in the prevalence of hypertension by 2025.⁷ To achieve this objective, population-level interventions focusing on low-income and middle-income countries (LMICs) are needed. One way to address the emerging hypertension burden in LMICs could be to involve community health workers, such as those in the Female Community Health Volunteer (FCHV) programme in Nepal.⁸ FCHVs are trained community health workers who provide basic health services in Nepal. They are selected by members of Mothers' Group for Health with the help of staff at local health facilities. FCHVs receive 18 days of basic training, in two phases, on selected primary health-care components.

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Research in context

Evidence before this study

We did a systematic review of randomised controlled trials assessing community health worker-led interventions for blood pressure reduction. To identify trials, we searched PubMed and the Cochrane Central Register of Controlled trials up to Dec 31, 2016, using the search terms “blood-pressure” OR “hypertension” OR “raised-blood-pressure” OR “high-blood-pressure” AND “community-health-worker”. We found 30 completed and 21 ongoing trials investigating involvement of community health workers in blood pressure management. Most of these studies were from Europe, North America, and Australia; only three studies were from low-income countries (LICs; two from Pakistan and one from Ghana). Of the completed trials, nine involved patients with diabetes, ten involved patients with hypertension, and four involved patients with coronary heart disease. None of the studies from LICs used community health workers to implement lifestyle interventions and to monitor blood pressure. The interventions used in these studies involved one or a combination of individualised or personalised health education delivered by community health workers (lifestyle

modification, drug reconciliations), clinic-based follow-up, home-based blood pressure monitoring, and pharmacological treatment. Evidence is conflicting on the effects of these interventions on blood pressure.

Added value of the study

This study is the first to assess the effectiveness of a community health worker-led lifestyle intervention and blood pressure monitoring in reduction of blood pressure in normotensive, prehypertensive, and hypertensive populations in an LIC. We showed that female community health volunteer (FCHV)-led health education (lifestyle intervention) and blood pressure screening over a 1 year period in Nepal led to a significantly lower mean systolic blood pressure in the intervention group than in the control group.

Implications of all the available evidence

The potential for FCHVs to control blood pressure in this population might lead to scaling up of the intervention to the national level. The strategy might also be replicated in other low-income and middle-income countries that have a strong network of community health workers.

The main role of an FCHV is to promote health and healthy behaviours in the community to improve safety of motherhood, child health, and family planning.⁹ Generally, health-seeking practice for non-communicable diseases is low in Nepal. Hypertension remains undiagnosed because it is often asymptomatic and most of the population are never screened for elevated blood pressure. People only visit the doctor when they are feeling seriously ill.

Although many studies¹⁰ have investigated the role of community health workers in improving maternal and child health, reports of lifestyle interventions led by community health workers for blood pressure control are scarce. Previous randomised trials investigating mobilisation of community health workers for reduction of blood pressure have mostly been confined to HICs and focused on patients diagnosed with hypertension.¹¹ A study¹² in children and young adults in Pakistan showed a small but significant difference in blood pressure between children and young adults in the intervention group and those in the control group. Another study¹³ in Pakistan by the same group did not yield conclusive results for an effect of mobilisation of community health workers on blood pressure reduction in patients with hypertension.

We aimed to assess the effectiveness of an FCHV-led lifestyle intervention and screening of blood pressure in reducing blood pressure in individuals who are normotensive, prehypertensive, or hypertensive in Nepal.

Methods

Study design and participants

The community-based management of hypertension in Nepal (COBIN) trial was an open-label, two-group,

cluster-randomised controlled trial designed to establish the effectiveness of FCHV-led home-based health education and screening of blood pressure in adults in Nepal.¹⁴ The trial was approved by the ethics review committee of Nepal Health Research Council (reference number 1065). Participants gave written informed consent.

The sampling frame and study design has been described previously.¹⁴ Feasibility studies^{15,16} before implementation of the trial have been published. Briefly, we did a community-based survey to estimate the prevalence of hypertension in Lekhnath municipality, Nepal.¹⁷ The total population of the municipality in a 2011 census¹⁸ was 58816. The municipality is divided into 15 smaller units called wards. Each ward—with the exception of one ward that was excluded because it was different from the other wards in terms of geographical accessibility and service availability—was considered one cluster in the study. The municipality health services comprised one primary health-care centre, three sub-health posts, and two urban health-care centres. During the survey, individuals were asked whether they would like to participate in this study. Eligible participants were aged 25–65 years, consented to participate in the study, did not have plans to migrate outside the study area, and had participated in the prevalence study. People were excluded if they declined consent or were severely ill, unlikely to be in the community throughout the intervention, or pregnant.

Randomisation and masking

A biostatistician, who had no previous knowledge of the clusters, used computer-generated codes to randomly

assign (1:1) 14 clusters to the intervention group or control group. Participants and investigators were not masked to group assignment for practical reasons.

Procedures

After randomisation, 46 FCHVs were invited to a 5 day intensive training course on blood pressure (FCHVs did not receive any training in blood pressure monitoring before this study). They were trained in burden of non-communicable diseases or hypertension; identification of blood pressure risk factors with a checklist comprising salt intake, physical inactivity, smoking, and alcohol consumption; blood pressure screening with digital sphygmomanometers; height and weight measurements; referral procedures for participants with blood pressures of higher than 140/90 mm Hg; personalised health promotion counselling on major risk factors; and recording, reporting, and follow-up procedures. The training materials were developed after consultation with experts and stakeholders and with guidance from the Health Belief Model.¹⁹ The materials were pretested in FCHVs in another municipality. At the end of training, three FCHVs withdrew from the study because they could not properly read blood pressure measurements.

FCHVs visited selected households three times a year (every 4 months) to provide health promotion counselling and to measure blood pressure. On average, one FCHV visited 20 households three times a year. When visiting a household, an FCHV measured the blood pressure, height, and weight of the participant according to standard procedures. During the visit, the FCHV delivered the lifestyle counselling intervention, focusing on increasing physical activity, lowering salt consumption, reducing alcohol consumption, avoiding smoking, and decreasing stress. If a participant had a high blood pressure, they were referred to the nearest health facility and, if on antihypertensive medication, were also followed up for adherence to their medication during the FCHV visit.

One field supervisor was responsible for supervising the 43 FCHVs. All participants in the control group received usual care pertaining to current practices for hypertension management at the community level.

To establish whether the intervention was implemented as planned, a register developed for the purpose of this trial was used by FCHVs to record dates, times, and activities. The FCHV activities were cross-verified by the field supervisor and were confirmed during the follow-up survey by asking participants whether FCHVs had adhered to the protocol. We also used a supervision checklist to track and update the knowledge and skill levels of FCHVs.

After 1 year of intervention, a follow-up survey was done by trained professional health workers (eg, nurses and health assistants) who were not involved in the baseline survey. To reduce the effects of diurnal variation and seasonality on blood pressure measurements, all baseline and follow-up home visits and blood pressure measure-

ments were taken in the first half of the day at the same time of year. Three blood pressure measurements were taken with the Omron HEM-7203 blood pressure monitor (Omron, Kyoto, Japan) in 5 min intervals for precision, and the mean of the last two readings was included in the analyses.

Outcomes

The primary outcome was 1 year mean systolic blood pressure in participants who were normotensive, prehypertensive, or hypertensive. Normotension was defined as a systolic blood pressure of less than 120 mm Hg and a diastolic blood pressure of less than 80 mm Hg, in the absence of antihypertensive treatment. Prehypertension was defined as a systolic blood pressure of 120–139 mm Hg and a diastolic blood pressure of 80–89 mm Hg, in the absence of antihypertensive treatment. Hypertension was defined as a systolic blood pressure of 140 mm Hg or higher, a diastolic blood pressure of 90 mm Hg or higher, or use of antihypertensive medication.²⁰ Secondary outcomes were change in mean diastolic blood pressure and percentage change in proportion of risk factors (smoking, alcohol consumption, high salt intake, and low physical activity). Information about smoking, alcohol consumption, fruit and vegetable intake, and physical activity was self-reported, whereas salt intake was measured by dividing the amount of table salt used in the past 24 h by the number of people who consumed salt. In our study setting, the diet of participants was such that salt intake other than table salt was minimal. Low physical activity was defined as less than 3000 metabolic equivalent of tasks (METs) of vigorous or moderate activity each week.^{21,22} Daily tobacco users were respondents who reported smoking cigarettes, bidi, kankat, or hukka or using other forms of smokeless tobacco on a daily basis. We defined harmful alcohol use as 15 or more standard drinks a week for men and eight or more standard drinks a

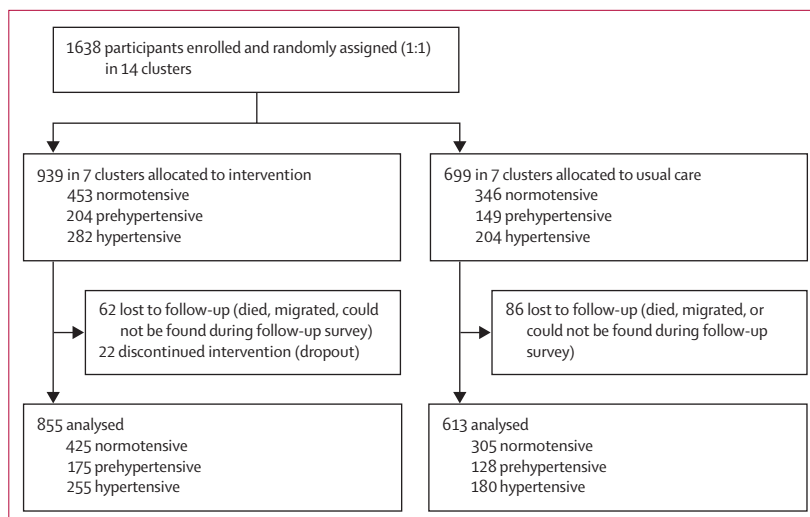


Figure 1: Trial profile

	Normotension		Prehypertension		Hypertension	
	Intervention (n=425)	Control (n=305)	Intervention (n=175)	Control (n=128)	Intervention (n=255)	Control (n=180)
Age (years)	42.17 (9.79)	42.25 (9.52)	46.02 (9.73)	45.15 (9.92)	50.12 (8.99)	50.28 (8.14)
Sex						
Female	335 (79%)	238 (78%)	122 (70%)	88 (69%)	134 (53%)	115 (64%)
Male	90 (21%)	67 (22%)	53 (30%)	40 (31%)	121 (47%)	65 (36%)
Body-mass index (kg/m ²)	24.09 (4.22)	23.70 (3.98)	25.44 (4.53)	26.22 (3.89)	25.58 (4.23)	26.23 (4.44)
Systolic blood pressure (mm Hg)	108.24 (6.93)	108.54 (6.89)	124.27 (7.07)	125.50 (7.09)	142.71 (16.96)	144.19 (19.19)
Diastolic blood pressure (mm Hg)	71.75 (5.56)	71.95 (5.19)	81.76 (4.98)	82.44 (5.13)	91.83 (9.57)	93.08 (10.83)
Current smoker	70 (16%)	46 (15%)	23 (13%)	17 (13%)	51 (20%)	27 (15%)
Harmful alcohol consumption*	19 (4%)	18 (6%)	21 (12%)	16 (13%)	55 (22%)	35 (19%)
High salt intake†	342 (80%)	267 (88%)	144 (82%)	109 (85%)	189 (74%)	144 (80%)
Low physical activity‡	17 (4%)	10 (3%)	11 (6%)	5 (4%)	31 (12%)	6 (3%)
Low fruit and vegetable intake§	382 (90%)	280 (92%)	156 (89%)	115 (90%)	224 (88%)	167 (93%)
Diabetes	8 (2%)	5 (2%)	2 (1%)	4 (3%)	19 (7%)	16 (9%)
Family history of hypertension	159 (37%)	110 (36%)	68 (39%)	50 (39%)	93 (36%)	81 (45%)
Receiving antihypertensive medication	88 (35%)	62 (34%)

Data are mean (SD) or n (%). *Eight standard drinks per week for women and 15 per week for men. †More than 5 mg per day. ‡Less than 3000 metabolic equivalent of tasks. §Fewer than five servings per day.

Table 1: Baseline characteristics

	Normotension		Prehypertension		Hypertension	
	Intervention (n=425)	Control (n=305)	Intervention (n=175)	Control (n=128)	Intervention (n=255)	Control (n=180)
Systolic blood pressure (mm Hg)	112.63 (10.87)	115.15 (12.07)	124.69 (10.31)	128.38 (13.35)	136.24 (15.46)	141.34 (20.07)
Diastolic blood pressure (mm Hg)	76.33 (7.49)	77.07 (7.72)	83.24 (7.25)	84.96 (8.01)	88.93 (10.55)	91.97 (13.01)
Current smoker	68 (16%)	48 (16%)	22 (13%)	19 (15%)	53 (21%)	31 (17%)
Harmful alcohol consumption*	38 (9%)	32 (10%)	20 (11%)	10 (8%)	58 (23%)	35 (19%)
High salt intake†	331 (78%)	261 (86%)	129 (74%)	98 (77%)	187 (73%)	135 (75%)
Low physical activity‡	22 (5%)	28 (9%)	11 (6%)	17 (13%)	33 (13%)	26 (14%)
Low fruit and vegetable intake§	417 (98%)	300 (98%)	169 (97%)	124 (97%)	245 (96%)	175 (97%)
Receiving antihypertensive medication	4 (1%)	5 (2%)	7 (4%)	9 (7%)	91 (36%)	70 (39%)

Data are mean (SD) or n (%). *Eight standard drinks per week for women and 15 per week for men. †More than 5 mg per day. ‡Less than 3000 metabolic equivalent of tasks. §Fewer than five servings per day.

Table 2: Characteristics at 1 year

week for women.²³ Participants consuming fewer than five servings of fruit or vegetables a day were categorised as low fruit and vegetable consumers.²⁴ One serving of vegetables was defined as one cup of raw, leafy green vegetables; half a cup of other cooked or raw vegetables; or half a cup of vegetable juice. One serving of fruit was defined as one medium-sized piece of fruit; half a cup of raw, cooked, or canned fruit; or half a cup of juice from a fruit (not artificially flavoured).¹⁹

Statistical analysis

We assumed a mean difference in systolic blood pressure of 5 mm Hg between the control group and the intervention group after 1 year, with SDs of 18.8 for participants who were normotensive, 13.6 for participants who were prehypertensive, and 15.7 for participants

who were hypertensive, and an intraclass correlation coefficient of 0.01.²⁵ Thus, the sample size required for 80% power was 1638 (812 in the normotensive cohort, 336 in the prehypertensive cohort, and 490 in the hypertensive cohort). 2815 eligible participants were available from the community-based prevalence survey.¹⁷ To establish the number of participants that should be recruited from each ward, for each ward we multiplied the required sample size (ie, 1638) by the proportion of eligible participants in that ward. We then selected participants from each ward using systematic random sampling. Because of different size clusters, the total number of participants in the intervention group and the control group was not matched.

All quantitative analyses were done with Stata version 14. We included all participants who remained in

the trial at 1 year in the primary analysis. Analyses were adjusted for age, sex, cluster, and baseline blood pressure. We excluded missing data ($n=170$) from the analyses. We modelled systolic blood pressure at follow-up using random-effects mixed regression. The effect size of the primary outcome is reported as mean difference with 95% CI. We calculated relative risk (RR) to estimate the incidence of hypertension after adjusting for age, sex, and cluster.

This trial is registered with ClinicalTrials.gov, number NCT02428075.

Role of the funding source

The funders had no role in study design, participant selection, data collection, and data analyses. The corresponding author had full access to the data in the study and final responsibility for the decision to submit for publication.

Results

Between April 1, 2015, and Dec 31, 2015, 1638 participants in 14 clusters were randomly assigned to the intervention group ($n=939$) or control group ($n=699$; figure 1). At 1 year of intervention, nine people had died, 39 had migrated, 100 had been lost to follow-up, and 22 had discontinued the intervention.

Table 1 shows the baseline characteristics of the 1468 (90%) participants who remained in the study at 1 year. At baseline, the mean systolic blood pressure was 122 mm Hg and the mean diastolic blood pressure was 80 mm Hg. 234 (16%) participants were smokers, 164 (11%) were drinking alcohol in amounts harmful to their health, and 80 (5%) had low physical activity.

Table 2 shows the follow-up characteristics of the participants who remained in the study at 1 year. 59 (10%) of 600 participants who were normotensive or prehypertensive in the intervention group and 66 (15%) of 433 participants who were normotensive or prehypertensive in the control group had newly developed hypertension at 1 year. Four times the number of participants who were prehypertensive at baseline as those who were normotensive at baseline had progressed to hypertension at 1 year (22 [5%] of 425 vs 37 [21%] of 175 in the intervention group and 25 [8%] of 305 vs 41 [32%] of 128 in the control group). At 1 year, the risk of participants who were normotensive or prehypertensive at baseline developing hypertension (adjusted for baseline age, sex, and cluster) was 53% higher in the control group than in the intervention group (RR 1.53, 95% CI 1.05–2.23).

The mean systolic blood pressure (adjusted for age, sex, and baseline systolic blood pressure) increased between baseline and follow-up by 4.39 mm Hg in the intervention group and 6.61 mm Hg in the control group for participants who were normotensive and by 0.42 mm Hg in the intervention group and 2.88 mm Hg in the control group for participants who were prehypertensive

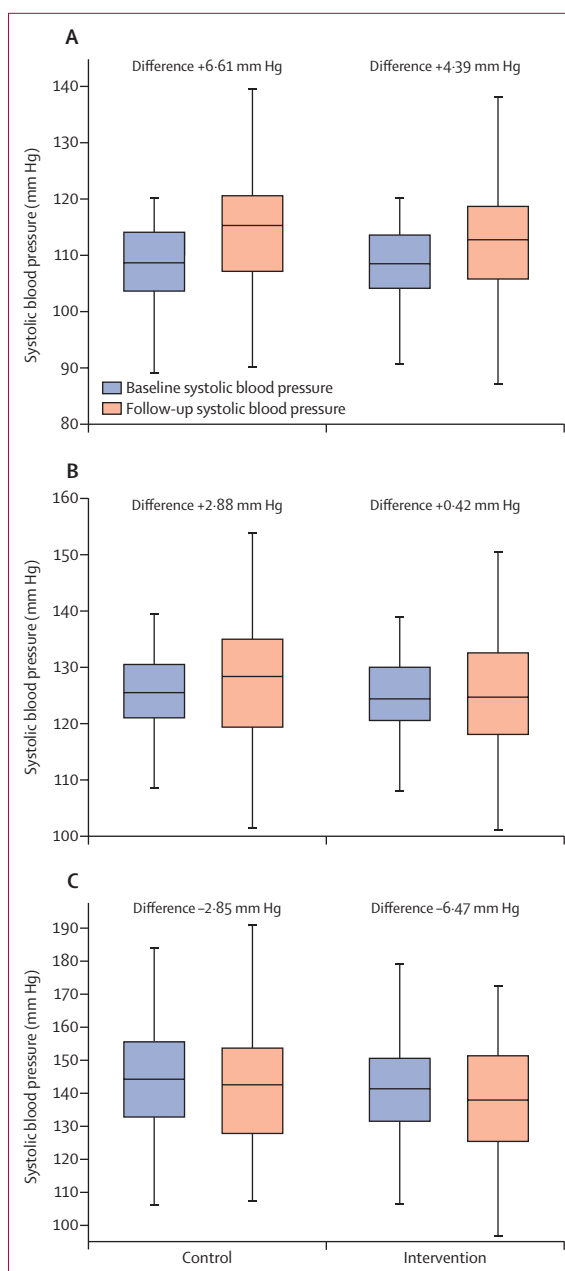


Figure 2: Change in systolic blood pressure from baseline to follow-up for participants who were normotensive (A), prehypertensive (B), or hypertensive (C)

(figure 2 and table 3). For participants who were hypertensive at baseline, the mean systolic blood pressure decreased by 6.47 mm Hg in the intervention group and 2.85 mm Hg in the control group (figure 2 and table 3).

The mean diastolic blood pressure of participants who were normotensive increased between baseline and follow-up by 4.58 mm Hg in the intervention group and 5.12 mm Hg in the control group. For participants who were prehypertensive, mean diastolic blood pressure

	Normotension		Prehypertension		Hypertension	
	Intervention (n=425)	Control (n=305)	Intervention (n=175)	Control (n=128)	Intervention (n=255)	Control (n=180)
Systolic blood pressure (mm Hg)	4.39	6.61	0.42	2.88	-6.47	-2.85
Diastolic blood pressure (mm Hg)	4.58	5.12	1.48	2.52	-2.90	-1.11
Current smoker	-0.47%	0.66%	-0.57%	1.56%	0.78%	2.22%
Harmful alcohol consumption*	4.47%	4.59%	-0.57%	-4.69%	1.18%	0.00%
High salt intake†	-2.59%	-1.97%	-8.57%	-8.59%	-0.78%	-5.00%
Low physical activity‡	1.18%	5.90%	0.00%	9.38%	0.78%	11.11%
Receiving antihypertensive medication§	18.20%	20.00%	19.00%	21.95%	1.18%	4.44%

*Eight standard drinks per week for women and 15 per week for men. †More than 5 mg per day. ‡Less than 3000 metabolic equivalent of tasks. §For patients who were normotensive or prehypertensive at baseline, only patients who were hypertensive at follow-up were included in calculation.

Table 3: Change in outcome variables from baseline to follow-up

	Systolic blood pressure		Diastolic blood pressure	
	Regression coefficient (95% CI)	p value	Regression coefficient (95% CI)	p value
Normotension	-2.28 (-3.77 to -0.79)	0.003	-0.56 (-1.72 to 0.59)	0.341
Prehypertension	-3.08 (-5.58 to -0.59)	0.015	-1.34 (-2.96 to 0.28)	0.104
Hypertension	-4.90 (-7.78 to -2.00)	0.001	-2.63 (-4.59 to -0.67)	0.008

Table 4: Multilevel mixed-effects linear regression adjusted for age, sex, and baseline blood pressure

increased by 1.48 mm Hg in the intervention group and 2.52 mm Hg in the control group. The mean diastolic blood pressure of participants who were hypertensive decreased by 2.90 mm Hg in the intervention group and 1.11 mm Hg in the control group. The differences in change in systolic blood pressure between the intervention group and the control group for normotensive, prehypertensive, and hypertensive cohorts were significant; however, the differences in change in diastolic blood pressure were only significant for participants with hypertension (table 4).

We did not find significant differences between the intervention and control groups at follow-up in terms of proportions of people who smoked daily (odds ratio 0.79, 95% CI 0.46–1.37), consumed 5 g or more of salt each day (0.80, 0.56–1.14), ate less than five servings of fruit and vegetables each day (1.09, 0.38–3.13), consumed harmful amounts of alcohol (1.07, 0.61–1.90), had low physical activity (0.77, 0.24–2.45), and were not taking antihypertensive medication (1.44, 0.69–3.00).

Discussion

We showed that an FCHV-led lifestyle intervention could effectively reduce mean systolic blood pressure in patients with hypertension and ameliorate the usual age-related increase in mean systolic blood pressure in individuals who were normotensive or prehypertensive in a general population in Nepal. A study²⁶ from the Framingham Heart Study showed a consistent linear increase in systolic blood pressure with age in normotensive and prehypertensive groups. We found that the

RR of developing hypertension was higher in the control group than in the intervention group. This finding might explain the higher use of medication in the control group than in the intervention group because successful lifestyle interventions in individuals who were prehypertensive might have postponed the development of hypertension and the need for antihypertensive medication.

The high incidence of hypertension in our study might have been due to various biological and behavioural risk factors. A review²⁷ reported that the incidence of hypertension in south Asia ranges between 3% and 18%. A multicountry study²⁸ from southern Asia also reported a high incidence (8.3%) of hypertension. The study²⁸ also reported that the rate of progression to hypertension in individuals with prehypertension was three times the rate in individuals with normal blood pressure, which was similar to our results.

We assessed the combined effect of home-based blood pressure monitoring and an FCHV-led lifestyle intervention, and did not assess the mechanisms by which the reduction in blood pressure was achieved. Although we could not find any significant difference in individual risk factors between the intervention and control groups, change in behavioural risk factors in the intervention group, compared with the control group, probably had synergistic beneficial effects. The personalised counselling delivered by FCHVs through home visits might have encouraged participants to adopt healthy lifestyles. Despite civil war, political instability, and natural disasters, the FCHV programme has continued to deliver essential health services in maternal and child health, in which health-promotion counselling is a major element.²⁹

Studies in HICs have mainly assessed the role of community health workers in patients with hypertension and have had positive results.¹¹ The characteristics (such as education, training, and recruitment) of community health workers in LMICs are different from, and cannot be compared to, those in HICs. In Nepal, FCHVs have a low level of education

and are semi-literate; in some other low-income settings, community health workers are often illiterate. Thus, the educational materials and training methods used for these interventions, and the strategies for implementation, will vary depending on the context of the health service. Robust research in different contexts is needed to fully understand the efficacy and effectiveness of these interventions.

Some community-based programmes have effectively reduced cardiovascular risk factors in LMIC settings.³⁰ A study³¹ in India showed that a community health worker-based personalised intervention for acute coronary syndrome improved adherence to healthy lifestyles. A study³² to reduce dietary salt intake in sub-Saharan Africa by mobilisation of community health workers lowered blood pressure levels in the short term. Another study³³ in children and young adults (5–39 years) in Pakistan showed that the change in systolic blood pressure (1.5 mm Hg) in the intervention group compared with the control group (0.1 mm Hg) was significant ($p=0.02$). Compared with these previous studies, we achieved a greater decline in systolic blood pressure, which might be because we used FCHVs trained under the Ministry of Health's FCHV programme and included older participants (25–65 years) who are more likely to be responsive to lifestyle interventions than younger individuals.^{33,34} Another study³⁵ in Pakistan concluded that a community health worker-led intervention for hypertension management in patients with hypertension was effective when combined with education of patients by general practitioners' (GPs) but not when used alone. Considering the shortage of GPs at the community level in many LMICs, provision of training in blood pressure screening and health promotion counselling to community health workers is a viable alternative to GP training in hypertension management. In this study, FCHVs under the Ministry of Health provided health promotion counselling during home visits and regularly monitored the blood pressure of participants. Further studies are needed to explore the effectiveness of using community health workers to treat patients with hypertension at the community level.

Long-term trials with hard clinical outcomes, such as myocardial infarction and stroke, as primary endpoints are needed to confirm the effect of these interventions on cardiovascular morbidity and mortality. A large randomised trial with longer-term follow-up in the future might provide more robust results. However, we expect that the observed blood pressure reductions, if maintained over time, will lead to reductions in cardiovascular morbidity and mortality. Development of automatic blood pressure monitoring devices, delivering audible blood pressure readings and displaying different colour signals for blood pressure classification, might help community health workers who are illiterate or semi-literate in low-resource settings such as Nepal. To ensure sustainability of the strategy, monitoring devices connected to solar panels could be more appropriate

than traditional devices, which need recharging. Further studies of cost-effectiveness would be needed before the strategy could be scaled up and replicated.

Our study has some limitations. First, the duration of the trial was limited to 12 months, so we could not determine to what extent changes in blood pressure could be sustained, nor could we predict the effect of the intervention after 12 months. Second, use of clusters within the same municipality might have introduced some contamination, with the possibility of exchange of information between clusters. However, we assigned all FCHVs in one cluster to either provide or not provide the intervention. Furthermore, only FCHVs of clusters assigned to the intervention received training in blood pressure monitoring and provision of health promotion counselling. These precautions helped to minimise the risk of contamination. Third, the intervention was not designed to assess which elements of the intervention caused the beneficial effect, although our risk-factor analyses offered several clues. Fourth, the high incidence of hypertension in our study could be partly due to regression to the mean effect. Fifth, although we adjusted for sex in our analysis, because of the highly skewed sex distribution of the participants, the results might not be generalisable to men, especially working men who are not always available for home-based visits.

Our study has several strengths. To our knowledge, this study is the first cluster-randomised controlled trial to report systolic blood pressure among normotensive, prehypertensive, and hypertensive populations through an existing network of community health workers. We mobilised existing health-care resources in real-life settings. Our sampling strategies ensured the recruitment of representative clusters. Furthermore, we used standardised, reproducible, and low-cost tools and techniques and we trained FCHVs using standard training materials. The baseline and follow-up surveys were done by different data enumerators and the key outcome (blood pressure) was measured with an automated device, which minimised the risk of assessor's bias.

Our intervention is simple in terms of design and logistics and, therefore, is ready for integration into existing health-care systems in LICs such as Nepal, where FCHVs have been part of the primary health-care system for the past 60 years. The findings resonate the call to action in the *Lancet* Commission on hypertension,³⁵ which recommended expansion of the workforce engaged in management of blood pressure through task sharing and use of endorsed education in collaboration with community health workers. We found that a simple, community health worker-led lifestyle intervention coupled with monitoring of blood pressure was effective for blood pressure reduction in a general population in Nepal. This strategy is potentially feasible to scale up in countries with a strong network of community health workers.

Contributors

DN conceived and designed the study; collected, analysed, and interpreted data; wrote the first draft; incorporated coauthors' suggestions; and prepared the final version for submission. PK conceived and designed the study, interpreted the data, contributed to all drafts, and approved the final version for submission. CSM, SRM, MHO, HBP, and AK contributed to all drafts and approved the final version for submission.

Declaration of interests

We declare no competing interests.

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References

- Lim SS, Vos T, Flaxman AD, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 2012; **380**: 2224–60.
- NCD Risk Factor Collaboration (NCD-RisC). Worldwide trends in blood pressure from 1975 to 2015: a pooled analysis of 1479 population-based measurement studies with 19·1 million participants. *Lancet* 2017; **389**: 37–55.
- UN. Transforming our world: the 2030 Agenda for Sustainable Development. <https://sustainabledevelopment.un.org/post2015/transformingourworld> (accessed Oct 25, 2017).
- Whelton PK, He J, Appel LJ, et al. Primary prevention of hypertension: clinical and public health advisory from The National High Blood Pressure Education Program. *JAMA* 2002; **288**: 1882–88.
- Hardy ST, Loehr LR, Butler KR, et al. Reducing the blood pressure-related burden of cardiovascular disease: impact of achievable improvements in blood pressure prevention and control. *J Am Heart Assoc* 2015; **4**: e002276.
- Elliott WJ. The economic impact of hypertension. *J Clin Hypertens* 2003; **5**: 3–13.
- WHO. Noncommunicable diseases global monitoring framework: indicator definitions and specifications. http://www.who.int/nmh/global_monitoring_framework/en (accessed Oct 25, 2017).
- Neupane D, Kallestrup P, McLachlan CS, Perry H. Community health workers for non-communicable diseases. *Lancet Glob Health* 2014; **2**: e567.
- Government of Nepal, Ministry of Health and Population, Department of Health Services. Annual report: Department of Health Services 2070/71 (2013/2014). http://dohs.gov.np/wp-content/uploads/2014/04/Annual_Report_2070_71.pdf (accessed Oct 25, 2017).
- Lewin S, Munabi-Babigumira S, Glenton C, et al. Lay health workers in primary and community health care for maternal and child health and the management of infectious diseases. *Cochrane Database Syst Rev* 2010; **17**: CD004015.
- Brownstein JN, Chowdhury FM, Norris SL, et al. Effectiveness of community health workers in the care of people with hypertension. *Am J Prev Med* 2007; **32**: 435–47.
- Jafar TH, Islam M, Hatcher J, et al. Community based lifestyle intervention for blood pressure reduction in children and young adults in developing country: cluster randomised controlled trial. *BMJ* 2010; **340**: c2641.
- Jafar TH, Hatcher J, Poulter N, et al. Community-based interventions to promote blood pressure control in a developing country: a cluster randomized trial. *Ann Intern Med* 2009; **151**: 593–601.
- Neupane D, McLachlan CS, Christensen B, Karki A, Perry HB, Kallestrup P. Community-based intervention for blood pressure reduction in Nepal (COBIN trial): study protocol for a cluster-randomized controlled trial. *Trials* 2016; **17**: 292.
- Neupane D, McLachlan CS, Gautam R, et al. Literacy and motivation for the prevention and control of hypertension among female community health volunteers: a qualitative study from Nepal. *Glob Health Action* 2015; **8**: 28254.
- Neupane D, McLachlan CS, Mishra SR, Kallestrup P. Identifying female community health volunteers' understanding and motivations about blood pressure as a prerequisite for developing a community-based intervention for hypertension in Nepal. *Global Heart* 2017; published online March 13. DOI:10.1016/j.ghheart.2016.09.003.
- Neupane D, Shrestha A, Mishra SR, et al. Awareness, prevalence, treatment, and control of hypertension in western Nepal. *Am J Hypertens* 2017; **30**: 907–13.
- Government of Nepal, National Planning Commission Secretariat, Central Bureau of Statistics. National population and housing census 2011 (national report). <https://unstats.un.org/unsd/demographic/sources/census/wphc/Nepal/Nepal-Census-2011-Vol1.pdf> (accessed Oct 25, 2017).
- Janz NK, Becker MH. The Health Belief Model: a decade later. *Health Educ Q* 1984; **11**: 1–47.
- Chobanian AV, Bakris GL, Black HR, et al. The seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. *JAMA* 2003; **289**: 2560–72.
- WHO. Global recommendations on physical activity for health. Geneva: World Health Organization, 2010.
- WHO. The WHO STEPwise approach to noncommunicable disease risk-factor surveillance. <http://www.who.int/chp/steps/manual/en> (accessed April 19, 2016).
- CDC. Alcohol and public health. 2016. <https://www.cdc.gov/alcohol/faqs.htm> (accessed Oct 25, 2017).
- WHO. Healthy diet. 2015. <http://www.who.int/mediacentre/factsheets/fs394/en> (accessed April 19, 2016).
- Killip S, Mahfoud Z, Pearce K. What is an intraclass correlation coefficient? Crucial concepts for primary care researchers. *Ann Fam Med* 2004; **2**: 204–08.
- Franklin SS, Gustin W, Wong ND, et al. Hemodynamic patterns of age-related changes in blood pressure. *Circulation* 1997; **96**: 308.
- Hajjar I, Kotchen JM, Kotchen TA. Hypertension: trends in prevalence, incidence, and control. *Annu Rev Public Health* 2006; **27**: 465–90.
- Prabhakaran D, Jeemon P, Ghosh S, et al. Prevalence and incidence of hypertension: results from a representative cohort of over 16 000 adults in three cities of South Asia. *Indian Heart J* 2017; **69**: 434–41.
- Glenton C, Scheel IB, Pradhan S, Lewin S, Hodgins S, Shrestha V. The female community health volunteer programme in Nepal: decision makers' perceptions of volunteerism, payment and other incentives. *Soc Sci Med* 2010; **70**: 1920–27.
- van de Vijver S, Oti S, Addo J, de Graft-Aikins A, Agyemang C. Review of community-based interventions for prevention of cardiovascular diseases in low- and middle-income countries. *Ethn Health* 2012; **17**: 651–76.
- Xavier D, Gupta R, Kamath D, et al. Community health worker-based intervention for adherence to drugs and lifestyle change after acute coronary syndrome: a multicentre, open, randomised controlled trial. *Lancet Diabetes Endocrinol* 2016; **4**: 244–53.
- Cappuccio FP, Kerry SM, Micah FB, Plange-Rhule J, Eastwood JB. A community programme to reduce salt intake and blood pressure in Ghana [ISRCTN88789643]. *BMC Public Health* 2006; **6**: 13.
- Tibebu A, Mengistu D, Negesa L. Adherence to recommended lifestyle modifications and factors associated for hypertensive patients attending chronic follow-up units of selected public hospitals in Addis Ababa, Ethiopia. *Patient Prefer Adherence* 2017; **11**: 323–30.
- Fang J, Moore L, Loustalot F, Yang Q, Ayala C. Reporting of adherence to healthy lifestyle behaviors among hypertensive adults in the 50 states and the District of Columbia, 2013. *J Am Soc Hypertens* 2016; **10**: 252–62.
- Olsen MH, Angell SY, Asma S, et al. A call to action and a lifecourse strategy to address the global burden of raised blood pressure on current and future generations: the Lancet Commission on hypertension. *Lancet* 2016; **388**: 2665–712.