Sustainability of a 12-month lifestyle intervention delivered by community health workers in reducing blood pressure in Nepal: 5-year follow-up of the COBIN open-label, cluster randomised trial

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Summary

Background The sustainability and scalability of limited-duration interventions in low-income and middle-income countries remain unclear. We aimed to investigate the sustainability in reduction of blood pressure through a 12-month lifestyle intervention led by community health workers to reduce blood pressure in Nepal, 4 years after the intervention ceased.

Methods The Community-Based Intervention for Control of Hypertension in Nepal (COBIN) trial was a non-blinded, cluster-randomised trial done in Kaski, Nepal. Adults aged 25–65 years were eligible. People were excluded if they declined consent, were severely ill, unlikely to be in the community throughout the intervention, or pregnant. During the 12-month intervention, female community health volunteers (FCHVs) visited participants in the intervention groups and provided lifestyle counselling and blood pressure measurement every 4 months. At the end of the 12-month intervention, systolic blood pressure was significantly lower in the intervention group than in the usual care group in all cohorts, ranging from –2·3 mm Hg (95% CI –3·8 to –0·8) lower in those with normal blood pressure to –4·9 mm Hg (–7·8 to –2·0) in the hypertensive cohort. The primary outcome for this follow-up study was a mean change in systolic blood pressure from baseline to follow-up at 60 months. We did an intention-to-treat analysis.

Findings Between April 1, 2015, and Dec 31, 2015, 1638 participants were recruited in COBIN (939 [57·3%] assigned to intervention and 699 [42·7%] assigned to usual care). Of the 1468 (89·6%) who completed the 12-month assessments, we followed up 1352 (92·1%) participants at 60 months, between Oct 11, 2020, and May 5, 2022. 964 (71·3%) participants were women and 388 (28·7%) were men. From baseline to 60 months, the mean systolic blood pressure increased by 10·4 mm Hg (95% CI 9·1–11·6) in the intervention group and 6·0 mm Hg (4·6–7·5) in the usual care group (adjusted mean difference 4·1 mm Hg [2·2 to 5·8]).

Interpretation Lifestyle counselling and blood pressure monitoring by community health workers is effective in substantially reducing blood pressure while adults are being monitored in a trial but, following cessation of the intervention, this benefit is not maintained in the long term, with potential for harm. This finding could have important implications for funders and research communities to regularly target participants for education and follow-up at an optimal timepoint to reduce any likelihood of harm.

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For the Nepali translation of the abstract see **Online** for appendix 1

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Introduction

Evidence for the long-term benefits of lifestyle interventions on the control of blood pressure and diabetes is inconsistent.[1–5] Several studies in diverse settings have shown that interventions led by community health workers can significantly reduce blood pressure in many low-income and middle-income countries (LMICs).[6–9] To date, these reports mostly include short-term immediate outcomes of a trial. Few studies have provided evidence for the effectiveness of lifestyle interventions targeting blood pressure beyond 24 months following trial completion.[5,10] Importantly, the evidence from these trials remains inconclusive, with the design of the lifestyle interventions and duration of follow-up heterogeneous between trials. Furthermore, most, if not all, of this evidence is from high-income countries,[11] leaving a gap in LMICs where services differ. Thus, the sustainability and scalability of interventions of limited duration in LMICs remain unclear. It is important to address this gap in what happens after trials are completed to understand the process of behaviour change, factors leading to long-term effectiveness, and how to best design interventions for sustained effects.

In the Community Based Intervention for Control of Hypertension in Nepal (COBIN) trial, we investigated

Research in context

Evidence before this study

To investigate the effectiveness of community health workers in reducing blood pressure and controlling hypertension, we searched Ovid MEDLINE, including PUBMED, Cochrane Central Register of Controlled Trials, and EMBASE, for studies published between database inception and Feb 25, 2023. The key terms used were "community health workers" OR "health volunteers" or "health auxiliary" AND "hypertension" or "BP" or "blood pressure" or "elevated blood pressure" AND "trial" OR "randomised controlled trial" OR "RCT" or "randomized control trial". We found 34 relevant trials targeting blood pressure as the primary outcome. In most trials, the intervention duration was 12 months or less, with only five studies having interventions longer than a year. Most outcomes were assessed immediately after the intervention phase had been completed. Only three studies had outcomes that occurred at least 3 months after the intervention was ceased. The blood pressure changes after the cessation of the intervention were inconsistent and the follow-up period after the intervention was mostly short—ie, less than a year after cessation of the intervention.

Added value of this study

This is the first randomised trial on the sustainability of the benefit of a trial led by community health workers 4 years after the cessation of an intervention. Despite considerable evidence that lifestyle counselling and blood pressure monitoring by community health workers are effective in substantially reducing blood pressure while participants are being monitored in a trial, we provide evidence that once the intervention ceases this reduction might not continue, with potential concern for harm in the long term.

Implications of all the available evidence

Our findings provide impetus for researchers, funders, and ethics committees to seriously consider sustainability and scale-up as important aspects of every clinical intervention. Our concern about potential harm to occur after the cessation of the trial highlights an imperative that longer-term follow-up should be commonplace for similar behavioural interventions for hypertension and other chronic diseases.

the long-term effects (at 5 years) of a 12-month lifestyle intervention led by community health workers targeted at reducing blood pressure in individuals who were normotensive, prehypertensive, or hypertensive at baseline.[9] At the end of that trial, systolic blood pressure was significantly lower in the intervention group than in the usual care group in all cohorts, ranging from –2·3 mm Hg (95% CI –3·8 to –0·8) lower in those without hypertension to –4·9 mm Hg (–7·8 to –2·0) in the hypertensive cohort.[9] Our aim was to investigate whether the blood pressure reduction at 12 months remained evident at 60 months after baseline. This is a post-hoc analysis, incorporating the same outcome measure as in the main research protocol, but with outcome 4 years after the intervention ceased.

Methods

Study design and participants

COBIN was a community-based, open-label, two-group, cluster-randomised trial done between April 1, 2015, and Dec 25, 2016, the details of which have been described previously.[12] Briefly, adults aged 25–65 years, who were normotensive, prehypertensive, or hypertensive and resided in Lekhnath Municipality, Kaski, Gandaki Province, Nepal, were eligible for inclusion in the study. People were excluded if they declined consent, were severely ill, unlikely to be in the community throughout the intervention, or pregnant. Sample sizes were calculated separately for the normotensive, prehypertensive, and hypertensive groups to enable separate comparison, as presented elsewhere.[9,12]

A biostatistician who had no knowledge of the clusters used computer-generated codes to randomly assign (1:1) 14 clusters (wards) to either lifestyle intervention led by community health workers, herein referred to as female community health volunteers (FCHVs; known as *mahila swasthya swoyemsewika* in Nepal), or usual care. The FCHVs are supported by the Government of Nepal. FCHVs are primarily responsible for delivering maternal and child health services, for which they are provided training allowances, refresher training, annual clothing allowance, access to microcredit funds, and other incentives, but do not receive a fixed-rate remuneration.[13] Only those who participated in the 1-year trial were eligible for follow-up. Neither participants nor investigators were masked for practical reasons.

Among the 1638 participants recruited (939 [57·3%] in the intervention group and 699 [42·7%] in the usual care group) at baseline, 1468 participants (89·6%) were assessed at 12 months (855 intervention and 613 usual care). We followed up participants at 60 months after baseline (48 months after completion of the trial). Although most of the participants were followed up by early 2021, we undertook a further drive to May 5, 2022, to find those who could not initially be reached because of lockdowns and fear of COVID-19, and managed to find an additional 58 participants.

The COBIN trial was approved by the ethics review committee of the Nepal Health Research Council (NHRC; reference number 1065). The follow-up study was approved by the Monash University Human Research Ethics Committee (reference number 22854) and the NHRC (reference number 1363). Written informed consent was obtained from all participants in both the COBIN trial and the follow-up study.

Procedures

In the initial COBIN trial, the FCHVs in the intervention group had 5 days of training on risk factors for non-communicable diseases (NCDs), blood pressure measurement, and lifestyle counselling.[9] 43 FCHVs (four to nine per intervention cluster) were trained and mobilised for lifestyle counselling and blood pressure monitoring. During each visit, FCHVs in the intervention group delivered counselling for lifestyle modification, focusing on increasing physical activity, reducing consumption of salt, reducing alcohol, avoiding smoking, and reducing stress. Each FCHV visited a mean of 20 households (SD 11) three times a year. At each visit, FCHVs measured the participant's blood pressure, height, and bodyweight. Participants who had increased blood pressure were referred to the nearest health facility. FCHVs further assessed adherence in participants who were prescribed antihypertensive medications. During the trial, FCHVs were actively monitored by health-care workers employed by the research team as field supervisors.

After 12 months, the active intervention formally ended but the FCHVs retained the blood pressure devices as a tool to provide some passive screening if someone requested the service. But no monetary incentive or any other support was provided to continue the work, and no formal follow-up schedule was provided.

Usual-care clusters did not receive any intervention other than the services provided by the Government of Nepal for the usual management of hypertension during the intervention phase.

Outcomes

Our prespecified primary outcome was a mean change in systolic blood pressure from baseline to follow-up at 60 months. Data collection at follow-up was undertaken by research assistants who were not part of the initial intervention. These research assistants were public health graduates who received 3 days of basic training and 2 days of refresher training on risk factors for NCDs, measurement of blood pressure, and measurement of blood glucose concentrations, and electronic data collection procedures using an electronic tablet device with the REDCap software.[14] The research assistants were regularly monitored by field supervisors and the research coordinator. As in the baseline and 1-year follow-up, blood pressure was measured three times in each participant, at 5-min intervals, using the same device (HEM-7203 blood pressure monitor [Omron, Kyoto, Japan]). The first reading was discarded, and the mean of systolic blood pressure and diastolic blood pressure from the second and third readings was used for all analyses.[15] Normal blood pressure was defined as systolic blood pressure 120 mm Hg or lower and diastolic blood pressure 80 mm Hg or lower, in the absence of antihypertensive treatment. Participants were classified as having hypertension if their mean systolic blood pressure was 140 mm Hg or higher or their mean diastolic blood pressure was 90 mm Hg or higher, or if they reported being on regular antihypertensive therapy.[16] Prehypertension was defined as systolic blood pressure 120–139 mm Hg or diastolic blood pressure 80–89 mm Hg, in the absence of either hypertension or use of antihypertensive medications. Poorly controlled hypertension was defined as systolic blood pressure 160 mm Hg or higher or diastolic blood pressure 100 mm Hg or higher.

Secondary outcomes were mean change in diastolic blood pressure, the proportion of participants with a new diagnosis of hypertension, the proportion of those who were aware of their hypertension status (defined as self-report of being told by a doctor that they had hypertension), and change in the use of antihypertensive medication among those with hypertension. Other secondary outcomes included the change in proportion of those with diabetes (of any type), mean change in BMI, change in the proportion of current smokers, change in the proportion of those drinking excessive amounts of alcohol, change in physical activity, and difference in mean blood glucose concentration. Outcomes were measured using the same methods at baseline and at 60 months

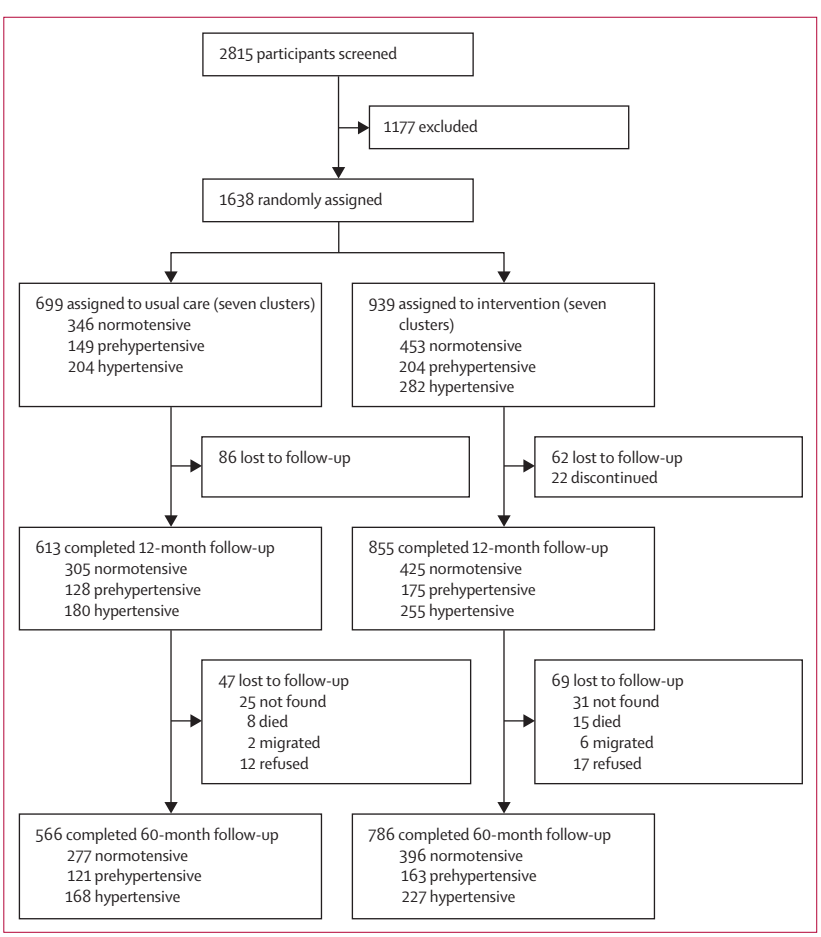

Figure 1: **Trial profile**

See Online for appendix 2

except for diabetes (appendix 2 p 2). At baseline, diabetes was considered present when participants self-reported being diagnosed with diabetes by a doctor or a health professional. At the 60-month follow-up, it was considered present if fasting blood glucose concentrations, measured by the capillary fingerpick method using a standardised digital glucometer (EasyGluco Auto-coding [Infopia, Anyang-si, Gyeonggi-do Province, South Korea), were 126 mg/dL or greater or if the participant reported taking anti-diabetic medication. Demographic information such as age, sex, occupation, and education were self-reported by participants. Sex included an option for male, female, and other.

Statistical analysis

All analyses were done by intention to treat. For the primary outcome (change in systolic blood pressure) and secondary outcomes that were continuous variables, we used generalised linear mixed models, including random effects for clusters and fixed effects for baseline systolic blood pressure, age, sex, trial group, and the interaction of the trial group with time. No imputation was done for missing data under the missing-at-random assumption.[17] The best-fitting model for both systolic blood pressure and diastolic blood pressure comprised unstructured means and an unstructured covariance matrix. We used contrasts to estimate change in blood pressure between groups from baseline to 60 months. The analysis of binary outcomes comprised generalised linear mixed models with a logit link, with random effects for clusters and fixed effects for the intervention group, age, sex, and intervention group by time interaction. We did separate analyses in participants who were normotensive, prehypertensive, and hypertensive at baseline.

We did subgroup analyses by sex, age, BMI, presence of diabetes, and use of antihypertensive medication to estimate the effect size on mean blood pressure. We further did subgroup analysis to assess any potential effects of exposure to other similar interventions after the 12-month intervention period had concluded. To explore the heterogeneity of the intervention by subgroup, we included an interaction term between the intervention assignment and subgroup in the models, and its significance was tested using the Wald test. All p values were deemed statistically significant at two-sided p≤0·05. We analysed data using Stata (version 16.2).

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Oct 11, 2020, and May 5, 2022, we followed up 1352 (92·1%) of 1468 participants at 60 months. Of the 1468 participants who completed 12-month follow-up,

	Overall		Normotensive at baseline		Prehypertensive at baseline		Hypertensive at baseline	
	Intervention (n=786)	Usual care (n=566)	Intervention (n=396)	Usual care (n=277)	Intervention (n=163)	Usual care (n=121)	Intervention (n=227)	Usual care (n=168)
Mean age, years (SD)	45·4 (9·8)	45·3 (9·6)	42·4 (9·6)	42·7 (9·3)	45·9 (9·6)	45·0 (10·1)	50·2 (8·9)	49·9 (8·0)
Sex								
Female	554 (70·5%)	410 (72·4%)	319 (80·6%)	217 (78·3%)	114 (70·0%)	84 (69·4%)	121 (53·3%)	109 (64·9%)
Male	232 (29·5%)	156 (27·6%)	77 (19·4%)	60 (21·7%)	49 (30·0%)	37 (30·6%)	106 (46·7%)	59 (35·1%)
No formal education	104 (13·2%)	76 (13·4%)	40 (10·1%)	27 (9·7%)	27 (16·6%)	19 (15·7%)	37 (16·3%)	30 (17·9%)
Mean BMI, kg/m²	24·9 (4·3)	25·1 (4·2)	24·2 (4·3)	23·8 (4·0)	25·5 (4·5)	26·1 (3·9)	25·7 (4·2)	26·4 (4·4)
Comorbidity of heart or kidney disease*	22 (2·9%)	21 (4·0%)	5 (1·4%)	6 (2·4%)	3 (1·9%)	4 (3·5%)	14 (6·3%)	11 (6·9%)
Systolic blood pressure, mm Hg	121·6 (18·4)	122·4 (18·8)	108·7 (6·8)	108·4 (6·9)	124·1 (7·1)	125·1 (7·0)	142·9 (17·2)	143·1 (18·3)
Diastolic blood pressure, mm Hg	79·7 (11·1)	80·4 (11·6)	71·8 (5·6)	72·0 (5·2)	82·1 (4·9)	82·6 (4·9)	91·9 (9·6)	92·8 (10·8)
Diabetes†	31 (8·9%)	25 (11·0%)	11 (7·3%)	6 (5·0%)	1 (1·4%)	5 (8·5%)	19 (15·3%)	14 (14·4%)
Current smoker	122 (15·5%)	80 (14·1%)	61 (15·4%)	41 (14·8%)	20 (12·3%)	17 (14·1%)	41 (18·1%)	22 (13·1%)
Harmful alcohol consumption‡	85 (10·8%)	56 (9·9%)	18 (4·5%)	13 (4·7%)	19 (11·7%)	15 (12·4%)	48 (21·1%)	28 (16·7%)
Salt intake >5 g/day	622 (79·1%)	481 (85·0%)	319 (80·6%)	243 (87·7%)	133 (81·6%)	103 (85·1%)	170 (74·9%)	135 (80·4%)
Low physical activity§	52 (6·6%)	19 (3·4%)	15 (3·8%)	10 (3·6%)	9 (5·5%)	3 (2·5%)	28 (12·3%)	6 (3·6%)
Low intake of fruit and vegetables¶	702 (89·3%)	521 (91·9%)	354 (89·4%)	255 (92·1%)	147 (90·2%)	109 (90·1%)	201 (88·6%)	156 (92·9%)
Use of anti-hypertensive medications‖	..	..	..	..	..	..	78 (34·4%)	59 (35·1%)
Poorly controlled hypertension‖	..	..	..	..	..	..	61 (7·8%)	54 (9·5%)

Data are n (%) or mean (SD). Poorly controlled hypertension was defined as systolic blood pressure 160 mm Hg or greater or diastolic blood pressure 100 mm Hg or greater. COBIN=Community-Based Intervention for Management of Hypertension in Nepal. *Based on self-report and medication history; for comorbidity of heart or kidney disease there were the following missing values: overall (n=37 intervention; n=38 usual care); normotensive (n=27 intervention; n=24 usual care); prehypertensive (n=7 intervention; n=6 usual care); and hypertensive (n=3 intervention; n=8 usual care). †Diabetes at baseline was based on the self-report of having been told of having diabetes; for diabetes there were the following missing values: overall (n=439 intervention; n=289 usual care); normotensive (n=246 intervention; n=156 usual care); prehypertensive (n=90 intervention; n=62 usual care); and hypertensive (n=103 intervention; n=71 usual care). ‡Eight standard drinks per week for women and 15 per week for men. §Less than 3000 metabolic equivalents of activity. ¶Fewer than five servings of fruits and vegetables combined. ||The denominator for this figure is participants with hypertension.

Table 1: **Baseline characteristics of participants followed up at 60 months in the COBIN trial**

	Overall		Normotensive at baseline		Prehypertensive at baseline		Hypertensive at baseline	
	Intervention (n=786)	Usual care (n=566)	Intervention (n=396)	Usual care (n=277)	Intervention (n=163)	Usual care (n=121)	Intervention (n=227)	Usual care (n=168)
Age, years	51·1 (10·1)	50·7 (9·9)	47·9 (9·7)	47·9 (9·7)	51·7 (9·6)	50·8 (10·2)	56 (8·9)	55·1 (8·3)
No formal education	72 (9·2%)	87 (15·4%)	22 (5·6%)	38 (13·7%)	22 (13·5%)	17 (14·0%)	28 (12·3%)	32 (19·0%)
Mean BMI, kg/m²	26·4 (4·7)	26·3 (4·2)	26·1 (4·6)	25·7 (4·1)	27·0 (4·5)	26·9 (3·8)	26·6 (4·8)	27·0 (4·7)
Heart disease*†	32 (4·1%)	33 (5·8%)	5 (1·3%)	5 (1·8%)	4 (2·5%)	4 (3·3%)	23 (10·2%)	24 (14·3%)
Chronic kidney disease*†	7 (0·9%)	8 (1·4%)	2 (0·5%)	3 (1·1%)	0	3 (2·5%)	5 (2·2%)	2 (1·2%)
Chronic obstructive pulmonary disease*‡	16 (2·0%)	16 (2·8%)	5 (1·3%)	10 (3·6%)	6 (3·7%)	1 (0·8%)	5 (2·2%)	5 (3·0%)
Systolic blood pressure, mm Hg	132·8 (20·9)	129·2 (20·7)	123·0 (14·8)	119·7 (14·2)	136·0 (18·7)	131·9 (15·1)	147·9 (21·9)	143·1 (24·1)
Diastolic blood pressure, mm Hg	84·9 (11·1)	83·2 (11·5)	80·0 (9·5)	78·4 (8·1)	86·2 (9·5)	85·4 (9·7)	91·1 (11·7)	89·6 (13·8)
Diabetes§	112 (14·2%)	105 (18·6%)	35 (8·8%)	21 (7·6%)	16 (9·8%)	25 (20·7%)	61 (27·0%)	59 (35·1%)
Mean fasting blood glucose, mg/dL	106·3 (26·5)	110·0 (27·5)	103·2 (22·5)	105·3 (20·1)	103·8 (22·4)	110·6 (26·8)	113·4 (33·6)	118·3 (35·7)
Current smoker	200 (25·4%)	131 (23·1%)	72 (18·2%)	50 (18·1%)	46 (28·2%)	33 (27·3%)	82 (36·1%)	48 (28·5%)
Harmful alcohol consumption¶	203 (25·8%)	87 (15·4%)	71 (17·9%)	34 (12·3%)	47 (28·8%)	17 (14·1%)	85 (37·4%)	36 (21·4%)
Salt intake >5 g/day‖	675 (86·6%)	488 (87·6%)	344 (87·5%)	246 (90·1%)	148 (91·4%)	105 (88·2%)	183 (81·7%)	137 (82·5%)
Inadequate physical activity**	110 (13·9%)	114 (20·1%)	47 (11·9%)	46 (16·6%)	18 (11·0%)	26 (21·5%)	45 (19·8%)	42 (25·0%)
Low intake of fruit and vegetables††	551 (70·1%)	390 (68·9%)	283 (71·5%)	198 (71·5%)	109 (66·9%)	73 (60·3%)	159 (70·0%)	119 (70·8%)
Anti-diabetic medication among diabetic‡‡	60 (53·6%)	50 (47·6%)	16 (45·7%)	8 (36·1%)	7 (43·8%)	11 (44·0%)	37 (60·7%)	31 (52·5%)
Hypertensive at 60 months	372 (47·3%)	250 (44·2%)	92 (23·2%)	43 (15·5%)	79 (48·5%)	62 (51·2%)	201 (88·5%)	145 (86·3%)
Awareness of hypertension status§§	199 (53·5%)	161 (64·4%)	31 (33·7%)	20 (46·5%)	30 (38·0%)	31 (50·0%)	138 (68·7%)	110 (75·9%)
Anti-hypertensive drugs among participants with hypertension§§	155 (42·0%)	123 (49·2%)	16 (17·4%)	11 (25·6%)	18 (22·8%)	20 (32·3%)	121 (60·2%)	92 (63·4%)

Data are n (%) or mean (SD). COBIN=Community-Based Intervention for Management of Hypertension in Nepal. *Based on self-report and history of medication use. †Missing values: overall (n=2 intervention; n=1 usual care); normotensive (n=1 usual care); prehypertensive (n=1 intervention); and hypertensive (n=1 intervention). ‡Missing values: overall (n=2 intervention; n=3 for usual care); normotensive (n=2 usual care); prehypertensive (n=1 intervention); and hypertensive (n=1 intervention; n=1 usual care). §Diabetes was defined as fasting blood glucose 126 mg/dL or greater or taking anti-diabetic medication. ¶Eight standard drinks per week for women and 15 per week for men. ||Missing values: overall (n=7 intervention; n=9 usual care); normotensive (n=3 intervention; n=5 usual care); prehypertensive (n=1 intervention; n=2 usual care); and hypertensive (n=3 intervention; n=2 usual care). **Less than 3000 metabolic equivalents of activity. ††Fewer than five servings of fruits and vegetables combined per day. ‡‡The denominator for the figure is participants with diabetes at 60 months. §§The denominator for the figure is participants with hypertension at 60 months.

Table 2: **Characteristics of followed-up participants at 60 months in the COBIN trial**

116 (7·9%) participants could not be followed up; 56 (48·3%) of 116 could not be found, 23 (19·8%) had died, eight (6·9%) had migrated, and 29 (25·0%) refused to participate (figure 1). The baseline characteristics of those remaining in the follow-up study were generally balanced between the intervention and usual care groups (table 1). The mean age of participants at baseline was 45·3 years (SD 9·8); 554 (70·5%) of 786 in the intervention group and 410 (72·4%) of 566 in the usual care group were women and 232 (29·5%) of 786 in the intervention group and 156 (27·6%) of 566 in the usual care group were men (table 1). The mean systolic blood pressure was 121·6 mm Hg (18·4) in the intervention group and 122·4 mm Hg (18·8) in the usual care group (table 1). 673 (49·8%) were normotensive, 284 (21·0%) were prehypertensive, and 395 (29·2%) were hypertensive at baseline (table 1). 115 (8·5%) participants had poorly controlled hypertension, and 137 (35%) of those who were hypertensive were receiving medication (table 1).

The overall prevalence of hypertension increased from 29·2% (395/1352) at baseline to 46·0% (622/1352) at follow-up at 60 months (table 2). The mean systolic blood pressure increased from 121·6 mm Hg (SD 18·4) at baseline to 132·8 mm Hg (20·9) at 60 months in the intervention group, and from 122·4 mm Hg (18·8) to 129·2 mm Hg (20·7) in the usual care group. 141 (49·6%) of 284 participants who were prehypertensive at baseline developed hypertension (79 [48·5%] of 163 in the intervention group and 62 [51·2%] of 121 in the usual care group). Similarly, 92 (23%) of 396 participants in the intervention group and 43 (16%) of 277 in the usual care group who were normotensive at baseline developed hypertension at 60 months (table 2). The mean fasting blood glucose concentration was 106·3 mg/dL (26·5) in the intervention group and 110·0 (27·5) mg/dL in the usual care group (table 2).

The increase in systolic blood pressure was consistent among those who were initially normotensive, prehypertensive, and hypertensive (figure 2). The overall mean systolic blood pressure increased by 10·4 mm Hg (95% CI 9·1–11·6) in the intervention group and 6·0 mm Hg (4·6–7·5) in the usual care group (table 3). The mean systolic blood pressure increased by 4·1 mm Hg (95% CI 2·2–5·8) more in the intervention group than in the usual care group between baseline and 60 months (table 3). In those who had hypertension, the net increase in mean systolic blood pressure was 4·9 mm Hg (0·8–9·1) more in the intervention group than in the usual care group (table 3).

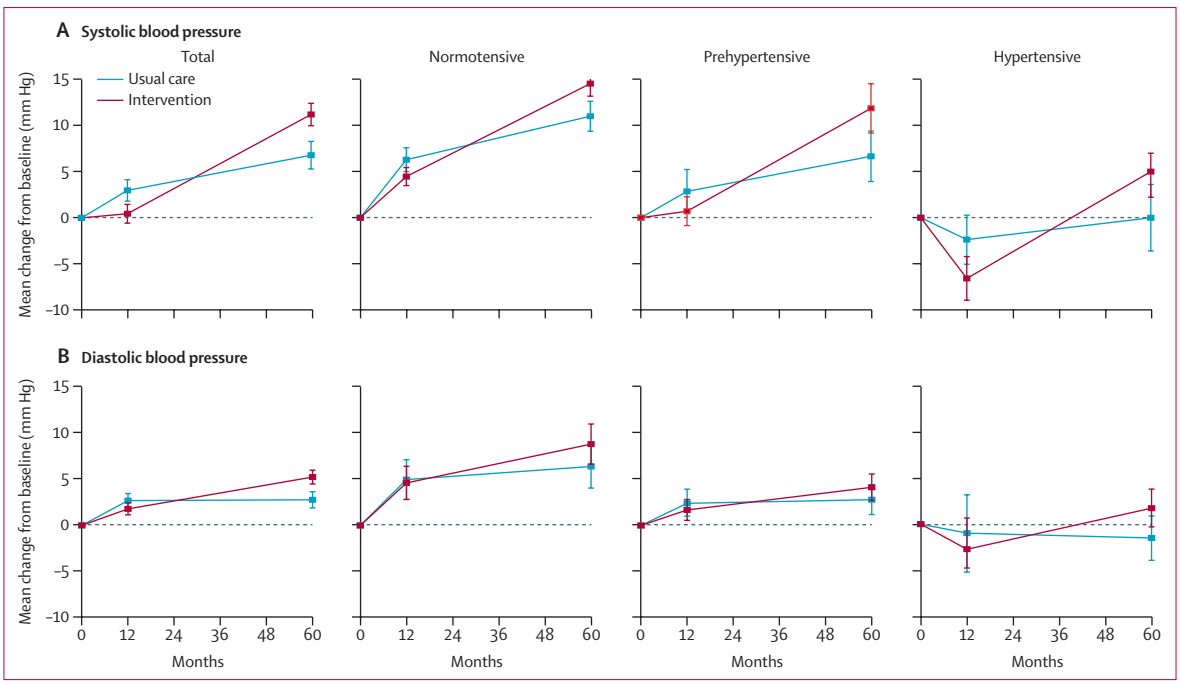

Figure 2: **Change in blood pressure from baseline to 12 and 60 months**
(A) Systolic blood pressure. (B) Diastolic blood pressure. Mean change from baseline was estimated using generalised mixed models for repeated measures for the outcome variable, with fixed effects for baseline value, age, sex, and interaction of time with trial group, and with random effects for clusters.

At 60 months, the increase in diastolic blood pressure was 2·1 mm Hg (95% CI 0·9–3·4) higher in the intervention group than in the usual care group (p<0·0001; table 3). Diastolic blood pressure had increased by 5·7 mm Hg in the intervention group (p<0·0001) and 3·2 mm Hg in the usual care group (p<0·0001; table 3).

Regarding secondary outcomes, awareness of hypertension, control of hypertension, and use of antihypertensive agents were better in the usual care than in the intervention groups at 60 months, although these findings were not statistically different (appendix 2 pp 2–3). By contrast, diabetes appeared to occur less often in the intervention group than in the usual care group at 60 months (appendix 2 pp 2–3). The risk factors of smoking, alcohol use, salt intake, and physical inactivity increased, with a statistically significant greater increase in harmful alcohol consumption in the intervention groups compared with in the usual care group (appendix 2 p 4).

Subgroup analysis revealed that the increase in systolic blood pressure was consistent for the effect of intervention across different sample characteristics (figure 3). We found a decrease in blood pressure among individuals who had poorly controlled hypertension, but this decline appeared to be similar between intervention and usual care groups (figure 3).

128 participants (23%) in the usual care and 286 (36%) in the intervention group received counselling and at least one blood pressure measurement by FCHVs in the year before the final interview through a diabetes prevention programme that commenced 2 years before our survey and was ongoing in both intervention and usual care clusters at the time of the survey (appendix 2 p 5). This programme involved blood pressure measurement, glucose monitoring, and lifestyle counselling, but was needs-based and, unlike the three predefined target-driven visits by FCHVs in the 12-month intervention period, had passive monitoring. In a post-hoc analysis to assess whether this other trial[18] might have affected our findings, the larger increase in systolic blood pressure that we observed in the intervention group than in the usual care group was evident irrespective of whether or not participants were included in the other trial (appendix 2 p 5).

Discussion

The mean reduction in systolic blood pressure that was observed in the COBIN trial following a 12-month intervention involving lifestyle counselling and blood pressure measurement led by community health workers was not sustained at 60 months. Indeed, we found a larger increase in mean systolic blood pressure in the intervention group than in the usual care group. These results support the notion that although time-limited interventions involving community health workers improve control of hypertension while participants are being monitored in a trial, this reduction might not continue, with concern of potential harm in the long term when the intervention ceases.

	Intervention (n=786)		Usual care (n=566)		Adjusted difference between groups, mm Hg (95% CI)*
	Mean (SD), mm Hg	Adjusted change from baseline, mm Hg (95% CI)*	Mean (SD), mm Hg	Adjusted change from baseline, mm Hg (95% CI)*	
Total					
Systolic blood pressure					
Baseline	121·6 (17·4)	Ref	122·4 (18·8)	Ref	Ref
12 months†	122·1 (15·9)	–0·1 (–0·6 to 1·6)	125·4 (18·5)	2·4 (0·4 to 4·4)	–2·8 (–4·7 to –0·9)
60 months	132·9 (20·9)	10·4 (9·1 to 11·6)	129·2 (20·7)	6·0 (4·6 to 7·5)	4·1 (2·2 to 5·8)
Diastolic blood pressure					
Baseline	79·7 (11·1)	Ref	80·4 (11·6)	Ref	Ref
12 months†	81·5 (10·1)	1·9 (1·0 to 2·7)	83·1 (11·5)	2·8 (1·8 to 3·8)	–1·3 (–2·5 to 0·0)
6 months	84·9 (11·1)	5·7 (4·8 to 6·6)	83·2 (11·5)	3·2 (2·2 to 4·2)	2·1 (0·9 to 3·4)
Normotensive at baseline‡					
Systolic blood pressure					
Baseline	108·7 (6·8)	Ref	108·4 (6·9)	Ref	Ref
12 months†	112·9 (11·0)	4·2 (2·7 to 5·7)	115·0 (11·7)	6·1 (4·3 to 7·8)	–2·0 (–4·0 to 0·1)
60 months	122·9 (14·8)	13·6 (12·2 to 15·0)	119·7 (14·2)	10·1 (8·5 to 11·7)	3·5 (1·7 to 5·3)
Diastolic blood pressure					
Baseline	71·8 (5·6)	Ref	71·9 (5·2)	Ref	Ref
12 months†	76·4 (7·6)	4·6 (3·7 to 5·5)	76·9 (7·5)	4·9 (3·8 to 6·1)	–0·3 (–1·7 to 1·1)
60 months	80·6 (8·7)	8·7 (7·7 to 9·7)	78·4 (8·2)	6·3 (5·2 to 7·4)	2·4 (1·0 to 3·8)
Prehypertensive at baseline§					
Systolic blood pressure					
Baseline	124·1 (7·4)	Ref	125·2 (7·1)	Ref	Ref
12 months†	124·8 (10·3)	0·6 (–1·9 to 3·1)	128·1 (13·4)	2·8 (–0·1 to 5·6)	–3·5 (–6·4 to –0·5)
60 months	135·9 (18·7)	10·6 (8·7 to 13·8)	131·9 (15·9)	5·4 (2·2 to 8·6)	4·9 (2·1 to 7·6)
Diastolic blood pressure					
Baseline	82·1 (4·7)	Ref	82·6 (4·9)	Ref	Ref
12 months†	83·8 (7·0)	0·5 (–2·2 to 3·2)	85·1 (7·9)	2·6 (0·8 to 4·2)	–0·9 (–2·5 to 0·8)
60 months	86·2 (9·5)	4·3 (2·9 to 5·8)	85·4 (9·6)	2·9 (1·3 to 5·8)	1·28 (–0·4 to 2·9)
Hypertensive at baseline¶					
Systolic blood pressure					
Baseline	142·9 (17·2)	Ref	143·1 (18·3)	Ref	Ref
12 months†	136·3 (15·5)	–6·7 (–9·5 to –3·8)	140·7 (19·6)	–2·5 (–5·7 to 0·8)	–4·7 (–9·1 to –0·2)
60 months	147·9 (21·9)	3·9 (0·3 to 7·5)	143·1 (24·1)	–1·0 (–5·2 to 3·2)	4·9 (0·8 to 9·1)
Diastolic blood pressure					
Baseline	91·9 (9·6)	Ref	92·8 (10·8)	Ref	Ref
12 months†	88·8 (10·4)	–2·7 (–4·8 to –0·7)	91·9 (12·9)	–0·6 (–2·9 to 1·8)	–3·0 (–5·9 to –0·2)
60 months	91·1 (12·3)	1·7 (–0·3 to 3·8)	89·6 (13·8)	–1·5 (–3·9 to 0·9)	2·3 (–0·5 to 5·2)

*Mean change from baseline was estimated using a generalised linear mixed model for repeated measures of the outcome variable, with fixed effects for baseline value, age, sex, time, and interaction of time with trial group, and with random effects for clusters. †By contrast with the data previously reported, these analyses comprise those who were followed up at 60 months.[9] ‡Normotensive, systolic blood pressure below 120 mm Hg and diastolic blood pressure below 80 mm Hg and not using antihypertensive medication. §Prehypertensive, systolic blood pressure of 120–139 mm Hg or a diastolic blood pressure of 80–89 mm Hg, in the absence of antihypertensive medications. ¶Hypertensive, systolic blood pressure was 140 mm Hg or greater or mean diastolic blood pressure was 90 mm Hg or greater, or being on regular anti-hypertensive therapy.

Table 3: **Change in blood pressure over time**

Although there was initial benefit of the intervention in the COBIN trial, for how long this benefit would have been maintained following cessation of the intervention is unclear. Similar to our study, in a study done in the USA, Margolis and colleagues[5] reported that a programme of home blood pressure telemonitoring and pharmacist management in people with uncontrolled blood pressure resulted in a greater reduction of systolic blood pressure in the intervention group than in the usual care group (–11 mm Hg between groups) at the end of the intervention period (12 months) and a year after completion of the trial (24 months), but not at 54 months.[5] In the Systolic Blood Pressure Intervention Trial (SPRINT), USA,[19] an intensive treatment target (systolic blood pressure <120 mm Hg) was compared with a standard treatment target (systolic blood pressure

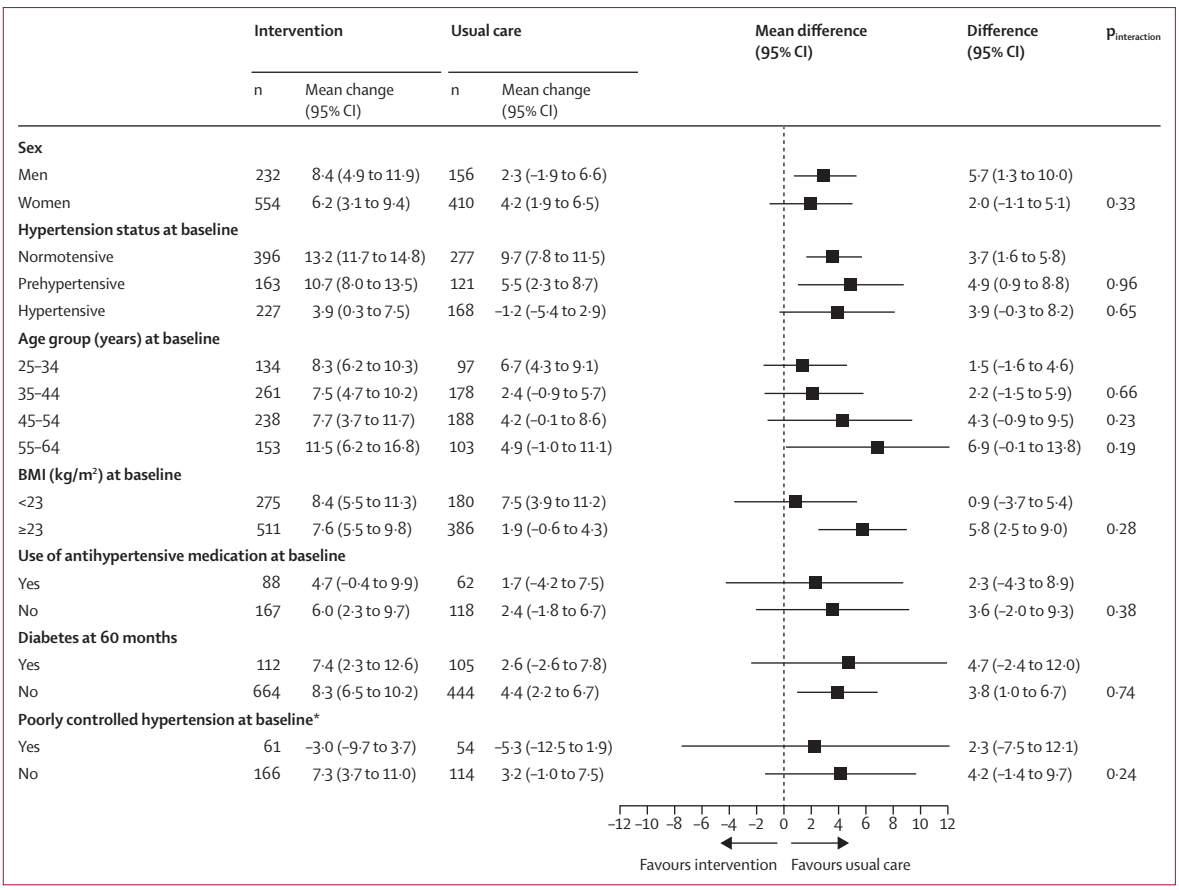

Figure 3: **Subgroup analysis for change in systolic blood pressure at 60 months by participant characteristics**
*Poorly controlled hypertension at baseline was defined as systolic blood pressure 160 mm Hg or greater or diastolic blood pressure 100 mm Hg or greater.

<140 mm Hg). Systolic blood pressure in this trial increased in both the intervention group and usual care group after the intervention ceased, potentially attributable to differential changes in the use of some blood pressure-lowering medications between groups. Similar to SPRINT, in the post-intervention phase, we observed a greater increase in the use of anti-hypertensive medication in the usual care group than in the intervention group. As we did not measure blood pressure serially over time, when the benefits of the FCHV-led intervention began to diminish is unclear.

We found that the usual care groups had a lesser increase in blood pressure than that of the intervention groups in each subgroup of those who were normotensive, prehypertensive, and hypertensive at baseline, indicating not only loss of benefit but also concern for potential harm. The cessation of active intervention might have led to decreased motivation among participants to continue using medications or seeking health care, thereby attenuating the benefits of the 12-month intervention. The risk profile of participants also changed considerably in both groups from baseline to 60 months. Differential health-seeking behaviour following the 12-month intervention, changes in the risk profile of participants both in the intervention and usual care groups at 60 months, and potential unmeasured confounders might at least partly explain the differences in change in blood pressure between groups. The treatment effect would be expected to be generated by behaviour changes such as a reduction in unhealthy lifestyle habits and increased access to drugs. The behaviours could have changed in the short term, but once the active intervention stopped, participants in the intervention groups might perceive that no further intervention is required and might have reduced self-efficacy[20] while ignoring their own self-management. Other studies have reported diminishing reductions in risk factors over time after an intervention ceases.[3,11,21,22] However, why this apparent harm has occurred is unclear and future work is required to investigate whether the intervention might have caused participants to neglect their own management.

Only a few studies have shown the long-term effectiveness of lifestyle interventions on blood pressure, and these are all from high-income countries. For example, in the Look Action for Health in Diabetes (Look AHEAD) study,[23] the effects of an intensive lifestyle intervention with diabetes support and education on

cardiovascular metabolic risk factors were compared with those of a diabetes support and education group. Although the difference between the intervention and control groups declined over time, the reduction in systolic blood pressure between groups was sustained until the end of the 4-year intervention.[23] However, the fact that the Look AHEAD intervention continued for 4 years probably explains the difference with our own findings because our intervention ceased at 12 months.

Our concerns about potential harm provide an imperative that longer follow-up periods for similar behavioural interventions for hypertension and other chronic diseases should be more commonplace because it would be useful to know whether similar potential concerns might arise in other settings. Such studies would be best undertaken with regular, potentially yearly, follow-up to enable assessment of the duration of the benefit, the timing of potential harm, and clarity on the dose, intensity, and frequency of monitoring required for ongoing sustainability of such proven cost-effective interventions.[24] Elucidating the timing of the decline in benefit would also enable targeting of people for education and follow-up at an optimal time to reduce any likelihood of harm. Furthermore, qualitative research might provide crucial data on how to engage with community health workers in NCD management and their integration with health systems, and barriers and facilitators of scaling-up, and to identify how such proven cost-effective interventions and their benefits can be continued for sustained effects.[25]

Our sample size did not enable us to assess outcomes according to different socioeconomic statuses and across three blood pressure groups, but the equitable distribution of risk and benefits of any intervention should be considered in any future effectiveness studies. Furthermore, intervention effects did not vary by sex, diabetes status, or use of antihypertensive medication in subgroup analyses. Importantly, the study was not powered to detect changes within subgroups and our findings do not signify definitive evidence of no difference between groups.

This study has some limitations. Some participants in the usual care group took part in a similar intervention during the follow-up period, thus potentially reducing the effects of the initial intervention. Such contamination is a feature of most trials done in real-world settings. Another limitation is that we did not have serially timed surveys after the trial was completed. Such surveys would be useful in understanding how the benefits of an intervention attenuate over time and when the best time to intervene is. Furthermore, data collection was done during the COVID-19 pandemic, which might have led to increases in blood pressure simply by having close contact with staff involved in the study, but this increase would probably have affected both intervention and usual care groups in a similar way.

Despite the limitations, this study is thus far the first long-term follow-up study of an intervention led by community health workers in a resource-poor setting. The follow-up rate was large, and we were able to assess changes in blood pressure in a diverse group of participants, including those who were normotensive, prehypertensive, and hypertensive at baseline. We used home-based blood pressure monitoring and interviews to facilitate increased participation. Mobilisation of local research assistants and community-based organisations enabled identification of ongoing festivals, the timing of which could be used to contact people who had migrated for work and were likely to return to celebrate with their families, and flexible work hours that included evening or morning visits, further maximised participation.

Despite considerable evidence that lifestyle counselling and blood pressure monitoring by community health workers is effective in substantially reducing blood pressure while patients are being monitored in a trial, we provide evidence that such reduction is not sustained, with potential concern for adverse effects in the long term if monitoring ceases. These findings could have important implications for funders and research communities to regularly target participants for education and follow-up at optimal timepoints to reduce any likelihood of harm.

Contributors

RT, AGT, DN, SRM, PK, and AZ conceptualised the study. AGT, RT, and DN were responsible for funding acquisition. RT, SK, AGT, and AZ performed the investigation. RT, AGT, DN, PK, and SRM finalised the methods. RT, AGT, DN, and AZ performed the formal analysis. SK and RT ensured the project administration. RT and DN have directly assessed the data and verified the data. RT drafted the manuscript and undertook data visualisation. AGT and AZ supervised the overall study. AGT, PK, AZ, DN, and SRM critically reviewed and revised the manuscript. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication. All authors read and approved the final version of the manuscript.

Declaration of interests

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Data sharing

COBIN data are not publicly available. Participant consent allows for data to be shared for future analyses with appropriate ethics approval. Non-identifiable data and analysis code can be made available to researchers on submission of a reasonable request to the corresponding author.

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