ORIGINAL ARTICLE

A Community-Based Intervention for Managing Hypertension in Rural South Asia

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ABSTRACT

BACKGROUND

The burden of hypertension is escalating, and control rates are poor in low- and middle-income countries. Cardiovascular mortality is high in rural areas.

METHODS

We conducted a cluster-randomized, controlled trial in rural districts in Bangladesh, Pakistan, and Sri Lanka. A total of 30 communities were randomly assigned to either a multicomponent intervention (intervention group) or usual care (control group). The intervention involved home visits by trained government community health workers for blood-pressure monitoring and counseling, training of physicians, and care coordination in the public sector. A total of 2645 adults with hypertension were enrolled. The primary outcome was reduction in systolic blood pressure at 24 months. Follow-up at 24 months was completed for more than 90% of the participants.

RESULTS

At baseline, the mean systolic blood pressure was 146.7 mm Hg in the intervention group and 144.7 mm Hg in the control group. At 24 months, the mean systolic blood pressure fell by 9.0 mm Hg in the intervention group and by 3.9 mm Hg in the control group; the mean reduction was 5.2 mm Hg greater with the intervention (95% confidence interval [CI], 3.2 to 7.1; P<0.001). The mean reduction in diastolic blood pressure was 2.8 mm Hg greater in the intervention group than in the control group (95% CI, 1.7 to 3.9). Blood-pressure control (<140/90 mm Hg) was achieved in 53.2% of the participants in the intervention group, as compared with 43.7% of those in the control group (relative risk, 1.22; 95% CI, 1.10 to 1.35). All-cause mortality was 2.9% in the intervention group and 4.3% in the control group.

CONCLUSIONS

In rural communities in Bangladesh, Pakistan, and Sri Lanka, a multicomponent intervention that was centered on proactive home visits by trained government community health workers who were linked with existing public health care infrastructure led to a greater reduction in blood pressure than usual care among adults with hypertension. (Funded by the Joint Global Health Trials scheme; COBRA-BPS ClinicalTrials.gov number, NCT02657746.)

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Uncontrolled high blood pressure is the leading attributable risk factor for death globally.[1] Treatment of hypertension reduces risk, but less than one third of persons with hypertension have controlled blood pressure.[2-4] Asians have enhanced susceptibility to vascular disease.[5-7] Uncontrolled blood pressure is particularly prevalent in rural areas in low- and middle-income countries where health literacy and health systems are weakest and case fatality rates for cardiovascular disease are highest.[8,9]

Our previous trial in urban Pakistan suggested that a combined intervention of home health education delivered by community health workers, coupled with training of physicians, lowered blood pressure and was cost-effective.[10,11] However, the trial intervention used a privately contracted health care workforce, which was not integrated into the existing community infrastructure, and would not be sustainable or scalable. More than 30 trials on hypertension management in low- and middle-income countries have similar limitations.[12,13]

We conducted a cluster-randomized, controlled trial (Control of Blood Pressure and Risk Attenuation–Bangladesh, Pakistan, and Sri Lanka [COBRA-BPS]) in rural communities in three South Asian countries over a period of 2 years to evaluate the effectiveness of a scalable, multicomponent intervention designed specifically for hypertension management in rural areas.[14] The intervention was conceptually based on our previous intervention in urban Pakistan and was modified for delivery in rural settings in the three South Asian countries.[10,15] Additional components were added (blood-pressure monitoring by government community health workers, checklists, care coordinators, and compensation for additional services) in response to the results of a feasibility study.[10,14,15] We hypothesized that a low-cost, multicomponent intervention integrated into the existing public health system would be more effective than usual care in lowering blood pressure among adults with hypertension in rural communities.

Methods

Trial Design

The trial was a multicountry, cluster-randomized, controlled trial in 30 rural villages (communities) of the districts Tangail and Munshiganj in Bangladesh, Thatta in Pakistan, and Puttalam in Sri Lanka. Because the intervention was delivered through the health systems in the rural areas of these countries, a cluster-randomized, controlled trial design was chosen to minimize contamination (i.e., to prevent participants in the control group from actively or passively receiving some or all of the multicomponent intervention). The trial protocol and statistical analysis plan were published previously[14,16] and are available with the full text of this article at NEJM.org. The authors vouch for the completeness and accuracy of the data and for the fidelity of the trial to the protocol. The ethics review committee at each participating institution approved the trial. All the participants provided written informed consent before screening. The conduct of the trial was independently reviewed by the trial steering committee and the data and safety monitoring committee. The funders had no role in the design, conduct, analysis, or reporting of the trial.

Participants

The main eligibility criteria were an age of 40 years or older and hypertension, defined as current use of antihypertensive medications or persistently elevated blood pressure (systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg) based on each set of the last two of three measurements from 2 separate days. Pregnant women and persons with advanced illness (e.g., those receiving dialysis or with liver failure), terminal illness, or an inability to travel to the clinic were excluded. (Additional details are provided in the protocol.)

Randomization

The unit of randomization was a cluster of 250 to 300 households served by one or two community health workers and one government clinic.[14,16] A total of 30 clusters were randomly selected from designated districts in the three countries (10 per country). Randomization was stratified according to country and distance from the government clinic (near [≤2 km] or far [>2 km]), and clusters were assigned in a 1:1 ratio to either the multicomponent intervention (intervention group) or usual care (control group) with the use of a computer-generated program (Table S1 in the Supplementary Appendix, available at NEJM.org).

TRIAL GROUPS

Multicomponent Intervention

The details of the intervention components are described in the trial protocol; a condensed description is provided here. The first component was blood-pressure monitoring and the use of checklists to guide monitoring and referral to physicians. Government community health workers were trained in measuring blood pressure with the use of a digital blood-pressure monitor. They monitored participants' blood pressures at home visits every 3 months. On the basis of a checklist (see the Supplementary Appendix), participants with very poorly controlled blood pressure (systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥100 mm Hg) or those at high risk for cardiovascular disease were referred to a physician at the government primary care facility.

The second component was home health education by government community health workers. Community health workers were trained in a curriculum regarding home health education and in strategies regarding behavior-change communication over a period of 5 days (see the Supplementary Appendix), followed by retraining in 2 months and then annually. Details of the training curricula are provided in the protocol. Home health education was delivered to all the participants and their family members at home visits every 3 months. All the participants were encouraged to adhere to antihypertensive medications and to follow up with their physicians. A checklist was completed by the community health workers and submitted to their supervisors.

The third component was training of physicians in blood-pressure monitoring, management of hypertension, and use of the checklist. A treatment algorithm was based on the Joint National Committee and 2013 European Society of Cardiology guidelines.[17] Generic antihypertensive medications (thiazide-like diuretics, angiotensin-converting–enzyme inhibitors or angiotensin-receptor blockers, and calcium-channel blockers) and statins (for patients at high risk for cardiovascular disease) were used as indicated.[17,18] The target blood pressure was a systolic blood pressure of less than 140 mm Hg and a diastolic blood pressure of less than 90 mm Hg (see the treatment algorithm in the Supplementary Appendix). Physicians were retrained in 2 months and annually thereafter.

The fourth component was a designated hypertension triage reception desk and hypertension care coordinator at the government clinics. A hypertension triage reception desk to reduce waiting time was established at the intervention clinics. A hypertension care coordinator was appointed to track participants with very poorly controlled blood pressure.

The fifth component was compensation for additional health services and targeted subsidies. Compensation was paid to the community health workers at the discretion of the local district health office. The cost of medications and diagnostics was borne primarily by the patients in Bangladesh and Pakistan and by publicly funded clinics in Sri Lanka, in accordance with the local norms.

Usual Care

Usual care consisted of existing services in the community, with routine home visits by community health workers for maternal and child care only. The clinics did not have designated triage reception desks or care coordinators for hypertension.

TRIAL ASSESSMENTS

Trained research staff who were unaware of randomization status visited all households and invited adults 40 years of age or older to participate. Written informed consent was obtained before assessment for trial eligibility. Blood pressure was measured with an Omron HEM-7300 automatic digital monitor (Omron Healthcare) with the person in a sitting position according to the standard protocol.[19] Three blood-pressure readings were taken consecutively 3 minutes apart with the use of a cuff of the appropriate size. Persons with consistently elevated blood pressure (systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg based on the last two of three readings) were visited again after 2 weeks for remeasurement. Those with persistently elevated blood pressure at the second screening visit were invited for enrollment. Persons who were using antihypertensive medications were also invited to enroll.

Information on sociodemographic characteristics, health-seeking behavior, and associated costs was collected. Adherence to antihypertensive medications and statins was assessed by

means of the Morisky Medication Adherence Scale (MMAS-8; scores range from 0 to 8, with higher scores indicating better adherence).[20-22] Body-mass index (BMI) and waist circumference were measured.

All persons in both the intervention group and the control group with uncontrolled hypertension (systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg) were asked by the research staff to consult their local physicians. Persons with very high blood pressure (systolic blood pressure ≥180 mm Hg or diastolic blood pressure ≥120 mm Hg) or those with acute associated symptoms (e.g., chest pain or breathlessness) were referred urgently to the district hospital.

Follow-up assessments of blood pressure were conducted at home visits every 6 months in both the intervention group and the control group. Adverse events including falls, hypotension, coronary heart disease, stroke, and heart failure were reported. Hospitalizations and deaths were tracked extensively (details are provided in the protocol). Fasting blood and random urine samples were collected at baseline and 24-month visits.

TRIAL OUTCOMES

The prespecified primary outcome was the mean change in systolic blood pressure from baseline to 24 months. The mean of the second and third blood-pressure readings was used for all analyses, and the first was discarded.

Prespecified secondary outcomes included diastolic blood pressure, the percentage of participants with blood-pressure control (systolic blood pressure <140 mm Hg and diastolic blood pressure <90 mm Hg), blood-pressure response (blood-pressure control or decline in systolic blood pressure by 5 mm Hg), very poorly controlled blood pressure (systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥100 mm Hg), use of and mean MMAS-8 scores for adherence to antihypertensive medications and statins, and participant-reported health status according to the mean score on the visual-analogue scale of the EuroQol 5-Dimension 5-Level questionnaire (EQ-5D-5L; range, 0 to 100, with higher scores indicating better health) and the mean score on the EQ-5D-5L utility index calculated with the use of the Indonesian value set (range, −0.865 to 1, with higher scores indicating better health).[23]

Other prespecified secondary outcomes were BMI, waist circumference, physical activity, smoking status, intake of fruits and vegetables, dietary sodium intake (urinary sodium excretion), laboratory measures (plasma glucose level, lipid levels, estimated glomerular filtration rate, and urinary albumin-to-creatinine ratio), adverse events, new-onset diabetes, death from any cause, and hospitalizations for cardiovascular disease. Because information on secondhand smoking was missing at baseline, the prespecified measure of the INTERHEART score for the risk of cardiovascular disease was replaced with the Framingham score for the 10-year risk of cardiovascular disease.[24] Although not prespecified, the daily dose of antihypertensive medications and the causes of death were evaluated. A prespecified cost-effectiveness analysis[14] is being conducted, but costs of the intervention are reported below.

STATISTICAL ANALYSIS

The estimated sample size was 2550 participants, under the assumptions of 85 participants per cluster, 10 clusters per country, an intraclass correlation coefficient of 0.02,[10,15] 80% retention, and a two-sided type I error rate of 5%. The trial had more than 99% power to detect a difference of 5 mm Hg in the change in systolic blood pressure between the two groups at 24 months.[16]

All analyses were performed with the use of the intention-to-treat principle. As prespecified in the statistical analysis plan, for the primary outcome analysis, the changes from baseline measurements were modeled with the use of a generalized linear mixed-effects model for repeated measures based on a participant-level analysis.[25] The primary outcome model included fixed effects for baseline systolic blood pressure, country, distance of the cluster from the clinic, age, sex, trial group, time, and the interaction of trial group with time. No imputation technique was used because the analysis model accounts for missing data and is valid under the missing-at-random assumption. Similar analyses were used for secondary outcomes.[25] We also conducted post hoc sensitivity and exploratory analyses, as explained in the Supplementary Appendix.

The incremental cost of intervention delivery was prospectively estimated for each country with the use of an activity-based costing approach that quantified all nonrecurring labor, rental space, materials, supplies, and services required to deliver the intervention. Further details are presented in the Supplementary Appendix.

RESULTS

PARTICIPANTS

Of 11,510 persons who were screened for the trial, 2645 (23.0%) were enrolled from April 2016 through February 2017, with follow-up ending in March 2019. The 24-month follow-up ended with retention of 92.1% of the participants in the intervention group and 89.3% of those in the control group (Figs. S1 through S4). The baseline characteristics were generally balanced between the intervention group and the control group. The mean (±SD) age of the participants was 58.8±11.5 years, 64.3% were women, 25.8% had diabetes, and 41.9% had chronic kidney disease. Blood pressure was uncontrolled in 69.6% of the participants and very poorly controlled in 29.6% (Table 1 and Table S2).

Table 1. Baseline Characteristics of the Participants.*

Characteristic	Intervention (N=1330)	Control (N=1315)
Age — yr	58.5±11.2	59.0±11.8
Female sex — no. (%)	877 (65.9)	824 (62.7)
Formally educated — no. (%)	834 (62.7)	725 (55.1)
Overweight or obese — no. (%)†	814 (61.2)	683 (51.9)
Participant-reported heart disease — no. (%)	177 (13.3)	167 (12.7)
Participant-reported stroke — no. (%)	165 (12.4)	159 (12.1)
Diabetes — no. (%)‡	374 (28.1)	308 (23.4)
Chronic kidney disease — no. (%)§	558 (42.0)	549 (41.7)
Blood pressure — mm Hg		
Systolic	146.7±22.4	144.7±21.0
Diastolic	89.1±14.7	87.8±13.8
Uncontrolled blood pressure — no. (%)¶	934 (70.2)	907 (69.0)
Very poorly controlled blood pressure — no. (%)‖	416 (31.3)	366 (27.8)
Current smoker — no. (%)	138 (10.4)	132 (10.0)
No. of antihypertensive medications — no. (%)		
0	404 (30.4)	422 (32.1)
1	607 (45.6)	552 (42.0)
2	257 (19.3)	258 (19.6)
≥3	62 (4.7)	83 (6.3)

* Plus–minus values are means ±SD. A total of 30 rural communities in Bangladesh, Pakistan, and Sri Lanka were randomly assigned to either a multicomponent intervention (intervention group) or usual care (control group).
† Overweight or obesity was defined as a body-mass index (the weight in kilograms divided by the square of the height in meters) of 23.5 or more.
‡ Diabetes was defined as a fasting plasma glucose level of 126 mg or more per deciliter, the use of antidiabetes medications, or a previous diagnosis of diabetes.
§ Chronic kidney disease was defined as an estimated glomerular filtration rate (calculated with the Chronic Kidney Disease Epidemiology Collaboration equation on the basis of Pakistan data) of less than 60 ml per minute per 1.73 m^2 of body-surface area or a urinary albumin-to-creatinine ratio of 30 or more (with albumin measured in milligrams and creatinine in grams).
¶ Uncontrolled blood pressure was defined as a systolic blood pressure of 140 mm Hg or more or a diastolic blood pressure of 90 mm Hg or more.
‖ Very poorly controlled blood pressure was defined as a systolic blood pressure of 160 mm Hg or more or a diastolic blood pressure of 100 mm Hg or more.

IMPLEMENTATION AND INTERVENTION ADHERENCE

In the intervention clusters during 2 years, 92.5% of the planned home health education checklists were completed; 91.5% of the participants received at least 80% of planned home visits (up to eight visits every 3 months over a period of 24 months) by community health workers for blood-pressure monitoring and home health education; and 76.8% of physician management checklists were completed for participants referred to clinics (Table S3).

BLOOD-PRESSURE OUTCOMES

At baseline, the mean systolic blood pressure was 146.7±22.4 mm Hg in the intervention group and 144.7±21.0 mm Hg in the control group. At 24 months, the mean systolic blood pressure fell by 9.0 mm Hg (95% confidence interval [CI], 7.7 to 10.4) in the intervention group and by 3.9 mm Hg (95% CI, 2.5 to 5.3) in the control group. The mean reduction in systolic blood pressure was 5.2 mm Hg greater in the intervention group than in the control group (95% CI, 3.2 to 7.1; P<0.001). The between-group differences in systolic blood pressure increased over time (Fig. 1A and Table 2).

At baseline, the mean diastolic blood pressure was 89.1±14.7 mm Hg in the intervention group and 87.8±13.8 mm Hg in the control group. From baseline to 24 months, the mean reduction in diastolic blood pressure was 2.8 mm Hg greater in the intervention group than in the control group (95% CI, 1.7 to 3.9) (Table 2). Controlled blood pressure was achieved in 53.2% of

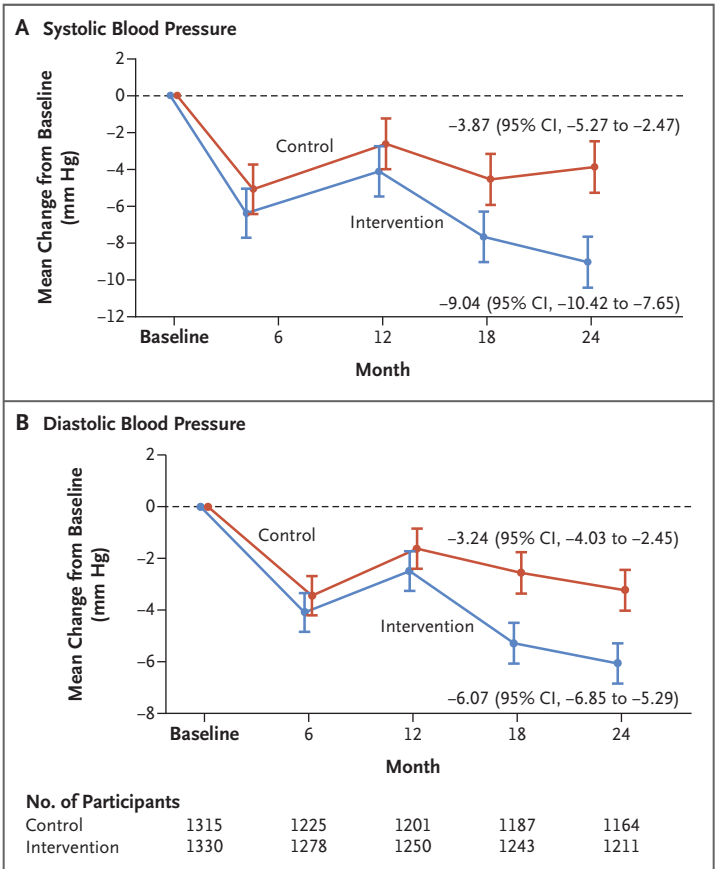

Figure 1. Mean Change in Systolic Blood Pressure and Diastolic Blood Pressure over Time.

Mean changes from baseline were estimated with a generalized linear mixed-effects model for repeated measures for change in systolic blood pressure (Panel A) or diastolic blood pressure (Panel B), with fixed effects for baseline systolic or diastolic pressure, country, distance of the cluster from the clinic, age, sex, time, and interaction of time with trial group and with random effects for clusters. The I bars indicate 95% confidence intervals.

the participants in the intervention group, as compared with 43.7% in the control group (relative risk, 1.22; 95% CI, 1.10 to 1.35) (Table 2).

USE OF ANTIHYPERTENSIVE MEDICATION

At 24 months, the mean number of antihypertensive medications per participant increased more in the intervention group than in the control group (mean difference, 0.11) (Table 2), and the mean increase in the daily dose was greater by 6.3 mg (95% CI, 2.7 to 9.8). The mean MMAS-8 score for adherence to antihypertensive medications increased more in the intervention group than in the control group (mean difference, 0.60; 95% CI, 0.24 to 0.96). (Detailed results regarding adherence to antihypertensive medications and other secondary outcomes are provided in Table S4.)

OTHER SECONDARY OUTCOMES

Participants in the intervention group reported better overall health status than those in the control group: the mean increase in the score on the EQ-5D-5L visual-analogue scale was greater by 2.41 with the intervention (95% CI, 0.15 to 4.66). Similar results were observed for the EQ-5D-5L utility index. The mean MMAS-8 score for adherence to statins increased more in the intervention group than in the control group (mean difference, 0.42; 95% CI, 0.15 to 0.68).

SAFETY AND MORTALITY

There was no intervention-related serious adverse event in either group. All-cause mortality was 2.9% (39 deaths) in the intervention group and 4.3% (56 deaths) in the control group (P=0.06). The number of deaths from cardiovascular events was lower in the intervention group (8 deaths, 0.6%) than in the control group (23 deaths, 1.7%), (P=0.006) (Table S5).

SENSITIVITY AND SUBGROUP ANALYSES

The results with respect to the intervention effect were consistent in sensitivity analyses that used models for each time point separately (Table S6). The cluster-level analysis, which takes a summary measure for each cluster (as opposed to the primary analysis, which is at patient level but accounts for clustering), also showed consistent results (Table S7). The results with respect to the intervention effect were also consistent in the prespecified subgroups (Fig. 2 and Table S8), post hoc subgroups (Fig. S5), and country-specific analyses (Tables S9 through S11).

COST OF INTERVENTION

The estimated cost of scale-up per eligible patient with hypertension in rural areas in Bangladesh, Pakistan, and Sri Lanka was $10.70, $10.50, and $4.70 (U.S. dollars), respectively (Table S12).

DISCUSSION

In a cluster-randomized trial involving adults with hypertension in villages in Bangladesh, Pakistan, and Sri Lanka, blood-pressure control was improved by a multicomponent intervention, which included community health workers,

Table 2. Intervention Effect on Blood-Pressure Outcomes and Use of Antihypertensive Medications.*

Variable	Intervention		Control		Difference or Relative Risk (95% CI)†
	No. of Participants	Mean or Percentage (95% CI)	No. of Participants	Mean or Percentage (95% CI)	
Change in mean systolic blood pressure (mm Hg) from baseline‡					
At mo 6	1278	−6.38 (−7.71 to −5.05)	1225	−5.08 (−6.43 to −3.74)	−1.30 (−3.19 to 0.59)
At mo 12	1250	−4.11 (−5.47 to −2.74)	1201	−2.61 (−3.99 to −1.24)	−1.50 (−3.43 to 0.44)
At mo 18	1243	−7.66 (−9.03 to −6.29)	1187	−4.54 (−5.93 to −3.16)	−3.12 (−5.07 to −1.17)
At mo 24	1211	−9.04 (−10.42 to −7.65)	1164	−3.87 (−5.27 to −2.47)	−5.17 (−7.13 to −3.20)§
Change in mean diastolic blood pressure (mm Hg) from baseline					
At mo 6	1278	−4.10 (−4.85 to −3.35)	1225	−3.45 (−4.21 to −2.69)	−0.65 (−1.72 to 0.42)
At mo 12	1250	−2.49 (−3.26 to −1.73)	1201	−1.63 (−2.40 to −0.85)	−0.87 (−1.96 to 0.23)
At mo 18	1243	−5.29 (−6.07 to −4.50)	1187	−2.56 (−3.37 to −1.76)	−2.72 (−3.85 to −1.60)
At mo 24	1211	−6.07 (−6.85 to −5.29)	1164	−3.24 (−4.03 to −2.45)	−2.83 (−3.94 to −1.72)
Percentage of participants with controlled blood pressure¶					
At mo 6	1278	48.4 (45.1 to 52.0)	1225	45.7 (42.4 to 49.2)	1.06 (0.96 to 1.17)
At mo 12	1250	42.2 (39.1 to 45.5)	1201	42.1 (39.0 to 45.5)	1.00 (0.90 to 1.12)
At mo 18	1243	48.7 (45.4 to 52.2)	1187	44.3 (41.0 to 47.8)	1.10 (0.99 to 1.22)
At mo 24	1211	53.2 (49.7 to 56.9)	1164	43.7 (40.4 to 47.3)	1.22 (1.10 to 1.35)
Change in mean no. of antihypertensive medications from baseline					
At mo 6	1281	−0.01 (−0.05 to 0.04)	1233	0.00 (−0.05 to 0.04)	0.00 (−0.07 to 0.06)
At mo 12	1268	0.08 (0.03 to 0.12)	1212	0.02 (−0.03 to 0.07)	0.06 (−0.01 to 0.13)
At mo 18	1251	0.15 (0.10 to 0.20)	1194	0.05 (0.00 to 0.10)	0.10 (0.03 to 0.17)
At mo 24	1224	0.15 (0.10 to 0.20)	1174	0.05 (−0.01 to 0.10)	0.11 (0.04 to 0.18)

* Mean changes from baseline and percentages were estimated from a generalized linear mixed-model for repeated measures for the outcome variable, with fixed effects for baseline value of the outcome (if a quantitative outcome), country, distance of the cluster from the clinic, age, sex, time, and interaction of time with trial group and with random effects for clusters.
† Difference (intervention − control) is shown for mean changes from baseline. Relative risk (intervention:control) is shown for percentages.
‡ The mean intraclass correlation coefficient for systolic blood pressure was 0.0115 (range, 0.0111 to 0.0123).
§ P<0.001.
¶ Controlled blood pressure was defined as a systolic blood pressure of less than 140 mm Hg and a diastolic blood pressure of less than 90 mm Hg.

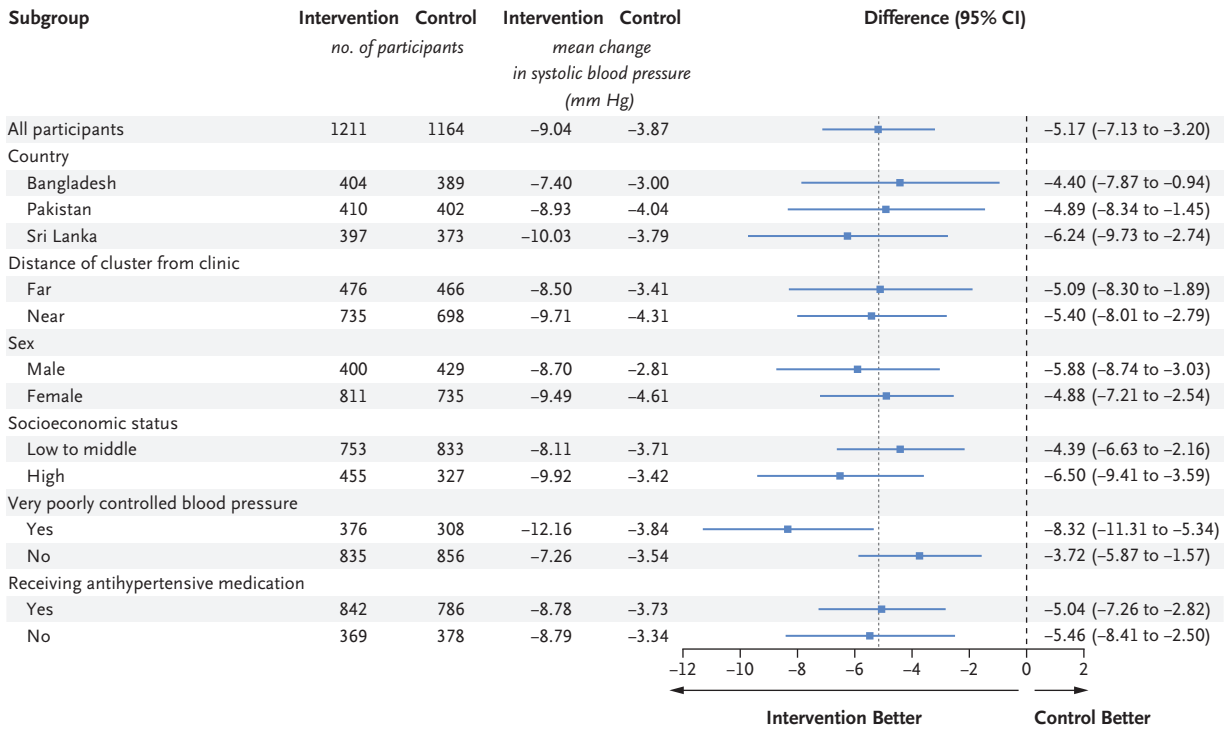

Figure 2. Subgroup Analyses for Change in Systolic Blood Pressure at 24 Months, According to Participant Characteristics at Baseline.

Mean changes and differences (intervention – control) were estimated with a generalized linear mixed-effects model for repeated measurements for change in systolic blood pressure, with fixed effects for baseline systolic pressure, country, distance of the cluster from the clinic, age, sex, time, and interaction among time, trial group, and subgroup and with random effects for clusters. Socioeconomic status was defined as low to middle and high on the basis of an International Wealth Index range of the 67th percentile or lower and higher than the 67th percentile, respectively, for each country sample separately. Participants with a systolic blood pressure of 160 mm Hg or more or a diastolic blood pressure of 100 mm Hg or more were considered to have very poorly controlled blood pressure.

was tailored to the rural setting, and was delivered through the existing public health care infrastructure. The intervention also increased adherence to antihypertensive medication and improved some aspects of participant-reported health at an annual cost of less than $11 per patient. The major strengths of our trial are a cluster design; rural settings in three countries, with stratification according to the distance from the clinic; the inclusion of all adults with hypertension (uncontrolled and controlled); excellent recruitment and retention rates; and a prespecified and prepublished statistical analysis plan.[16]

During this 24-month trial, the benefit of the intervention with respect to blood-pressure lowering increased with a longer duration of follow-up, which suggests potential longevity of the intervention effect. Although our trial was not designed to dissect the relative contributions of each component of the intervention on the effect, our previous work indicated synergies among the components[10,11]; the current trial suggests that appropriate use of medications may have played a substantial role. For example, participants with elevated blood pressure were referred to clinics in which trained physicians prescribed a greater number and a higher dose of antihypertensive medications than in the control group, coordinators facilitated tracking, and community health workers monitored blood pressure and reinforced messages about adherence during repeated home visits. The annual retraining of community health workers and physicians may have enhanced their competencies over time.

Many systematic reviews largely from high-income countries have shown the benefit of multicomponent strategies on hypertension control.[26] Our trial is different from previous studies

that have either focused primarily on urban populations[12,13,27] or used technology to deliver interventions in rural environments with conflicting results on blood-pressure reduction.[27-30]

Community health workers are an integral part of the primary care infrastructure for the successful delivery of maternal and child health care in South Asia,[31] as well as in China, Mexico, and Africa.[32-34] Our findings show that community health workers who are employed in the public sector can have an important role in managing hypertension.

Our trial has limitations. First, the intervention effect could have been underestimated because participants in the usual-care group may have modified their behavior in response to blood-pressure measurements performed by researchers to assess outcomes. Second, the trial was underpowered to detect changes in many secondary outcomes. Third, the short duration meant that there was insufficient power to assess cardiovascular events. However, a reduction of 2 mm Hg in systolic blood pressure has been associated with a reduction of 7 to 10% in the risk of coronary heart disease, stroke, and related death.[35-37]

Our findings have public health implications. Cardiovascular mortality continues to rise in low- and middle-income countries, especially in rural areas with a high burden of poverty and fragmented health systems.[9] There is ample evidence of the benefit of blood-pressure reduction on cardiovascular mortality; however, affordable strategies for blood-pressure control are lacking. Our low-cost intervention (<$11 per patient annually), if scaled up, might translate into substantial reductions in premature deaths and disability, as well as social and economic returns.[38,39] Discussions with provincial health departments and national advisory committees are ongoing to facilitate the scale-up of the intervention in the three countries, with the same fidelity as implemented in the trial.

We found that a multicomponent intervention for hypertension care, which centered on proactive home visits by trained government community health workers who were linked with existing public health care infrastructure, led to a clinically meaningful reduction in blood pressure in rural communities in Bangladesh, Pakistan, and Sri Lanka.

A data sharing statement provided by the authors is available with the full text of this article at NEJM.org.

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