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Community-Based Interventions to Promote Blood Pressure Control in a Developing Country

A Cluster Randomized Trial

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Background: Despite convincing evidence that lowering blood pressure decreases cardiovascular morbidity and mortality, the hypertension burden remains high and control rates are poor in developing countries.

Objective: To assess the effectiveness of 2 community-based interventions on blood pressure in hypertensive adults.

Design: Cluster randomized, 2 × 2 factorial, controlled trial. (ClinicalTrials.gov registration number: NCT00327574)

Setting: 12 randomly selected communities in Karachi, Pakistan.

Patients: 1341 patients 40 years or older with hypertension (systolic blood pressure ≥140 mm Hg, diastolic blood pressure ≥90 mm Hg, or already receiving treatment).

Measurements: Reduction in systolic blood pressure from baseline to end of follow-up at 2 years.

Intervention: Family-based home health education (HHE) from lay health workers every 3 months and annual training of general practitioners (GPs) in hypertension management.

Results: The age, sex, and baseline blood pressure–adjusted decrease in systolic blood pressure was significantly greater in the HHE and GP group (10.8 mm Hg [95% CI, 8.9 to 12.8 mm Hg]) than in the GP-only, HHE-only, or no intervention groups (5.8 mm Hg [CI, 3.9 to 7.7 mm Hg] in each; $P < 0.001$). The interaction between the main effects of GP training and HHE on the primary outcome approached significance (interaction $P = 0.004$ in intention-to-treat analysis and $P = 0.044$ in per-protocol analysis).

Limitations: Follow-up blood pressure measurements were missing for 22% of patients. No mechanism was detected by which interventions lowered blood pressure.

Conclusion: Family-based HHE delivered by trained lay health workers, coupled with educating GPs on hypertension, can lead to significant blood pressure reductions among patients with hypertension in Pakistan. Both strategies in combination may be feasible for upscaling within the existing health care systems of Indo-Asian countries.

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Cardiovascular disease has, in just a few decades, become the leading cause of death in adults worldwide, accounting for 1 in 5 deaths. Hypertension confers the highest attributable risk for death and disease associated with cardiovascular disease (1, 2).

Despite the demonstrated benefits of effective drug treatment (3, 4) and the existence of many clinical practice guidelines (5), hypertension prevention, treatment, and control rates remain suboptimal worldwide (6). The situation is particularly acute in developing countries, such as Pakistan, India, and China, where hypertension has reached epidemic proportions—affecting more than 20% of the adult population (7)—yet control rates are less than 6% (8). Poor health literacy and unhealthy lifestyles, compounded by lack of awareness of hypertension (7), are part of the cause. In addition, the health systems in these countries are often dysfunctional: More than 80% of the expenditure for chronic disease care is out-of-pocket; private care general practitioners (GPs), who primarily treat acute conditions, are the front-line service providers; and national programs for preventing and controlling hypertension are inadequate. Serious deficiencies in management of hypertension also have been identified in the knowledge and practice of health care providers. (9) However, evidence for public health interventions to improve hypertension control rates through patient or physician education in Indo-Asian countries is lacking.

We conducted the COBRA-1 (Control of Blood Pressure and Risk Attenuation-1) trial in Karachi, Pakistan, to test the effectiveness of 2 community-based strategies: family-based home health education (HHE), delivered by trained community health workers, to improve population-level health literacy and behaviors, and hypertension management training for GPs. We tested the effect of these interventions, alone and in combination, on blood pressure in adults with hypertension. We hypothesized that HHE

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Context

Physician education and community-based interventions to educate people with hypertension may improve hypertension care in resource-poor settings.

Contribution

Among 1341 patients living in 12 communities in Pakistan that were randomly assigned to general practitioner education, home health visits by trained lay workers, both, or neither, patients in communities assigned to both interventions had the greatest improvements in systolic blood pressure (10.8 mm Hg) after 2 years. Improvements were similar in all other groups (about 5 mm Hg).

Caution

Twenty-two percent of patients were lost to follow-up.

Implication

Home visits by trained lay workers plus physician education deserves further study as a way to improve hypertension control in resource-poor settings.

—The Editors

would be more effective than no education, that the specially trained GPs would provide more effective care than that usually received in Karachi, and that the combined interventions would provide additional benefit.

METHODS

Study Design and Setting

We performed a cluster randomized, controlled trial with a 2 × 2 factorial design to determine the effect of family-based HHE and special training for GPs on blood pressure in adults 40 years or older with hypertension. We used a cluster approach because our objective was to assess the effectiveness of both HHE and GP training as health system interventions at a population level, and an individual approach would be prone to contamination of interventions and biased outcomes (10). The Aga Khan University Ethics Review Committee granted ethical approval.

The sampling frame is described elsewhere (11). In brief, we used a multistage random sampling technique to select 12 of 4200 low- to middle-income, geographic census-based clusters (mean household monthly income, $70; about 250 households in each cluster) in Karachi, the most populous city in Pakistan (about 16 million inhabitants). We ensured at least a 10-km distance between clusters to minimize the risk for contamination by the intervention.

Participants

Persons 40 years or older who resided in the 12 clusters and had known hypertension or consistently elevated blood pressure on 2 separate visits (mean of 2 of past 3 measurements of systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg) were eligible for inclusion. We excluded pregnant women, persons who could not give informed consent, and bed-bound persons.

Randomization and Intervention

We used computer-generated codes to randomly assign 3 clusters each to the following groups: HHE alone, GP alone, HHE and GP combined, and no intervention.

Home Health Education

We trained 6 community health workers (1 for each cluster) over 6 weeks in methods for using behavior-changing communication strategies to convey standardized health education messages to all households in clusters assigned to receive HHE. The education status of the workers we employed was consistent with the requirements of the government-sponsored Lady Health Workers Programme of Pakistan (8 or preferably 10 years of schooling) (12). Salary scales and assigned workload were similarly consistent. The health messages included information on the deleterious effects of hypertension and nonpharmacologic interventions for preventing and controlling hypertension and cardiovascular disease, as well as advice on the importance of engaging in moderate physical activity; maintaining normal body weight; reducing salt intake; consuming a diet rich in fruit, vegetables, and low-fat dairy products; reducing intake of saturated and total fat (including suggestions on sample recipes for culturally acceptable and economically feasible food products); and smoking cessation (**Appendix 1**, available at www.annals.org). The importance of achieving blood pressure targets and adhering to medication and physician follow-up was emphasized. The first HHE session, lasting 90 minutes, was held at a time when all members of the household could be present. Follow-up reinforcement visits of 30 minutes were made every 3 months.

General Practitioner Education

We invited all GPs in the 6 study areas assigned to this intervention to receive training, with the aim of training at least two thirds of the GPs in each area. We considered this proportion to be feasible both for future uptake of the strategy and for assessing the effectiveness of training. Training was a 1-day session that focused on standard treatment algorithms for the stepped-care management of hypertension, which were based on the seventh report of the Joint National Committee (3) and the Fourth Working Party of the British Hypertension Society guidelines (4) and modified for the Indo-Asian population (**Appendix 2**, available at www.annals.org). The course included components on nonpharmacologic (diet, exercise, weight loss, and smoking cessation) and pharmacologic interventions, prescription of low-cost and appropriate generic drugs, preferential use of single-dose drug regimens, scheduled follow-up visits guided by blood pressure, the stepped-care approach for titrating drugs to achieve target blood pressure, and satisfactory consultation sessions for patients, with explanations of treatment and use of appropriate communication strategies. For managing persons with known hypertension, GPs were advised to review medication and blood pressure; simplify regimens; and aim to return to a regimen that was in line, as reasonably as possible, with that recommended for those with newly diagnosed hypertension. The recommended target blood pressure was <140/90 mm Hg for all patients. Although this diverges from recent guidelines for special subgroups (such as diabetic persons or those with end-organ damage), we reasoned that we needed to keep the intervention, guidelines, and targets simple for both patients and practitioners in a setting where blood pressure control rates are less than 3% (7). The training sessions for GPs used a case-based curriculum and were interactive. We provided a certificate of training at the end of the course.

All study participants were advised to consult a local GP. If participants in the clusters randomly assigned to a trained GP group did not already have a preferred GP, we gave them a list of trained GPs in their cluster from which to choose. However, it remained the participant's choice whether they attended a physician on the list. We did not provide for medications or fee-for-health care services. Participants were blinded to intervention status (training of GP). Neither the patients nor the GPs received reimbursement for participation.

Screening and Recruitment

All households in each cluster were visited, and we obtained informed consent for screening from all adults 40 years and older, whose blood pressure was then measured 3 times with a calibrated automated device (Omron HEM-737 IntelliSense; Omron Healthcare, Vernon Hills, Illinois) in the sitting position after 5 minutes of rest. Those with known hypertension were invited to participate. Those with elevated blood pressure who were not receiving antihypertensive medication were visited again for remeasurement of blood pressure 1 to 4 weeks after the initial visit. If mean blood pressure remained elevated, these persons were also invited to participate.

A routine physical examination was performed, and the following information was collected: smoking status, food frequency, and physical activity by questionnaire, the latter by using the international physical activity questionnaire; blood pressure, measured as described above; anthropometric characteristics (height, weight, and waist and hip circumferences); and fasting blood glucose level (Synchron Cx-7/Delta, Beckman Coulter, Fullerton, California) and lipid profile (Hitachi-912, Roche, Basel, Switzerland) (11).

Follow-up Procedures

Trained outcomes assessors (who were not part of and had no relationship with the community health worker team) evaluated participants at 4-month intervals; the assessors obtained 3 consecutive blood pressure readings at each evaluation, according to the same protocol used at baseline. We planned on a 2-year median duration of follow-up. The assessors were blinded to the randomization status of each cluster. The home visits were scheduled during the first half of the day to minimize the effect of diurnal variations in blood pressure. The assessors also collected information on changes in lifestyle (diet, smoking, or physical activity) and use of antihypertensive medications.

Outcomes and Measurements

The primary outcome was change in systolic blood pressure from baseline to the last follow-up visit. The secondary outcome was proportion of participants with controlled blood pressure (<140 mm Hg for systolic blood pressure and <90 mm Hg for diastolic blood pressure) at the last follow-up visit.

Statistical Analysis

We planned a sample of 336 participants in each of the 4 trial groups (total of 1344) on the assumption of a 10% dropout rate, 80% power, and an α value of 0.05 to detect a 6.0 mm Hg–reduction in systolic blood pressure (SD, 11 mm Hg) in the trained GP versus usual GP intervention (13) and a significant interaction between HHE and GP training, with HHE enhancing this effect 2-fold. We assumed an intraclass correlation of 0.02 and applied a design effect of 2.5 (14).

We used SAS, version 9.13 (SAS Institute, Cary, North Carolina), for statistical analyses. For the main intention-to-treat analysis, we computed the intervention-specific cluster mean blood pressure values at last follow-up visit for the 1044 participants with available readings, and assigned it to the 297 participants who did not have final follow-up blood pressure readings in their respective clusters (15). In the initial analysis, we investigated clustering of participants at the family level. Because this was not significant, we only accounted for clustering by household at the census level as a random effect in the main analysis; this was also the unit of randomization (16). We compared the distribution of patient-related variables among those randomly assigned to each of the 4 groups (HHE-only, GP-only, HHE and GP, and no intervention) by using a nested mixed-factorial design analysis of variance for continuous variables and the chi-square test for discrete variables. We first tested for an interaction among treatment groups by using 1 degree of freedom. Because we detected a significant interaction, we then tested the difference among the 4 groups according to the principles of factorial study analysis (17). We considered a P value less than 0.050 to be statistically significant for the main effects and a value less than 0.100 to be significant for interactions. We report marginal adjusted means and 95% CIs for the treatment effects, adjusted to the mean values of the other variables in the model.

We also performed sensitivity analyses on our findings as per protocol (after excluding participants with missing readings at the last follow-up visit), after adjusting for proportion of participants with controlled blood pressure and diabetes prevalence at baseline (18), after imputing missing blood pressure readings by carrying the last available reading forward, and after replacing missing readings with the mean follow-up blood pressure of the 12 clusters.

In the analysis of the secondary outcome, we compared the proportion of participants with controlled blood pressure at the last visit among randomized groups by using a mixed-effects logistic regression model, accounting for clustering of households at the census level, age, sex, and baseline blood pressure control. We used the marginal adjusted probabilities to calculate the risk ratios and computed their 95% CI by bootstrapping (19, 20).

We also performed several additional secondary analyses. We used the Wilcoxon signed-rank test and Kruskal–Wallis (nonparametric) test to determine whether the significant improvements in lifestyle and treatment targets emphasized in the interventions were achieved during follow-up; we assessed this separately for the intervention and control clusters.

Role of the Funding Source

This investigator-initiated study was competitively funded by a research award from the Wellcome Trust. The design, conduct, analysis, interpretation, and presentation of the data are the responsibility of the investigators, with no involvement from the funding source.

RESULTS

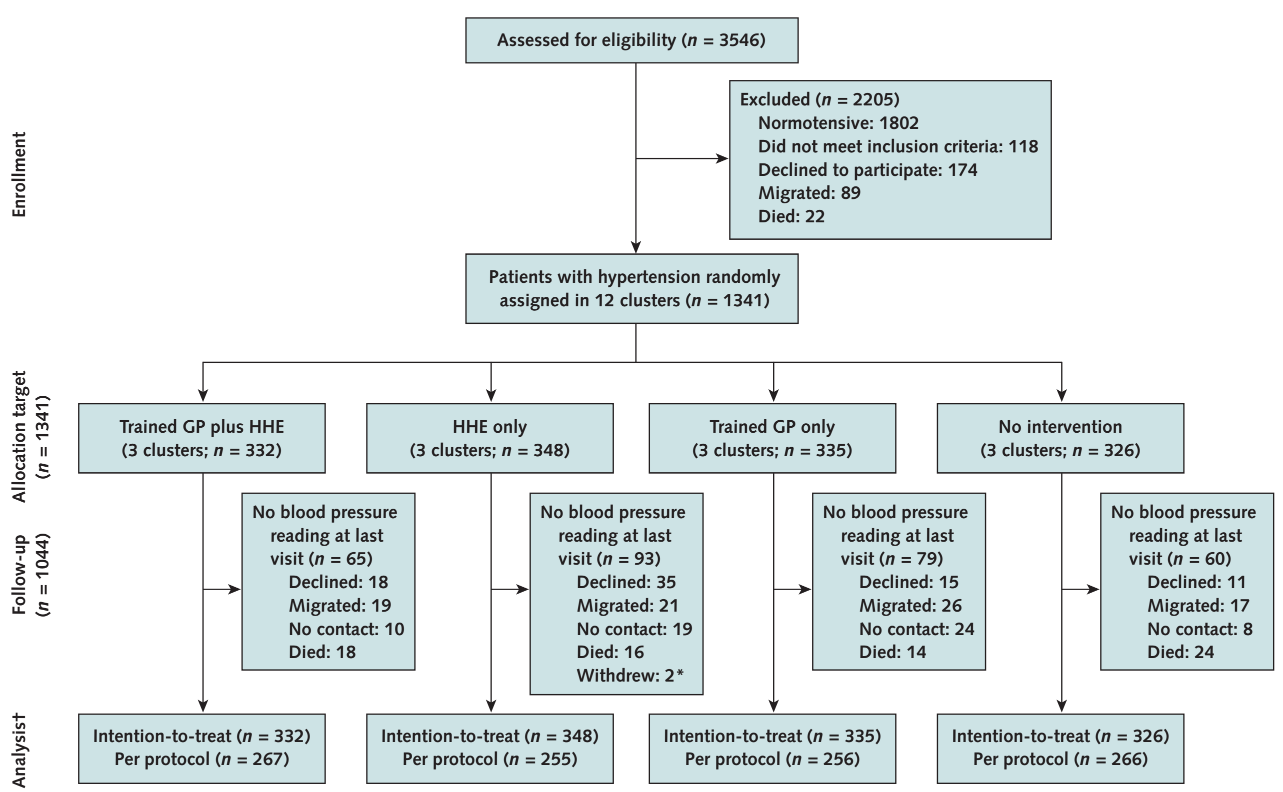
We randomly assigned 3 of the 12 clusters to each of the 4 study groups (**Figure**) (21, 22). The 12 clusters comprised 1341 adults 40 years or older with hypertension.

In the clusters assigned to receive HHE, 1269 (95%) households received the intervention: 640 in the HHE-only group and 629 in the HHE and GP group. Of the 110 GPs in the clusters assigned to receive GP intervention, 78 (71%) received the training program—36 in clusters in the GP-only group and 42 in clusters in the HHE and GP group. The other clusters contained 130 GPs.

Baseline Characteristics

The mean age of participants ranged from 52.7 to 55.3 years. Approximately one third of the participants were male, one quarter to one third had known or newly diagnosed diabetes, and about three quarters were overweight. Mean systolic blood pressure was 151.7 mm Hg (SD, 24.6); blood pressure and percentage of patients with controlled hypertension did not differ among groups

Figure. **Study flow diagram.**



GP = general practitioner; HHE = home health education.
* One pregnant woman and 1 man withdrew because of target organ damage and severe debility.
† Participants who successfully completed 2 years of follow-up were included in the analyses.

Table 1. **Comparison of Clusters and Baseline Patient Characteristics**

Characteristic	Total	HHE and GP Group	GP-Only Group	HHE-Only Group	No Intervention Group	*P* Value
Clusters						
Clusters, *n*	12	3	3	3	3	
Households, *n*	2650	656	657	673	664	
Mean residents per household (SD), *n*	6.6 (3.0)	6.5 (3.0)	6.6 (3.0)	6.7 (3.0)	6.4 (3.1)	0.176
Patients						
Hypertension, *n*	1341	332	335	348	326	
Mean age (SD), *y*	53.8 (11.5)	54.0 (11.5)	55.3 (11.5)	52.7 (11.4)	53.3 (11.5)	0.026
Men, *n (%)*	501 (37.4)	112 (33.7)	138 (41.2)	133 (38.2)	118 (36.2)	0.34
Education level, *n (%)*						
Illiterate	554 (41.3)	131 (39.5)	151 (43.4)	110 (32.8)	162 (49.7)	0.72
Primary or higher	787 (58.6)	201 (60.5)	225 (67.1)	197 (56.6)	164 (50.3)	
Tobacco use, *n (%)**						0.51
Past	144 (10.7)	37 (11.1)	49 (14.6)	33 (9.5)	25 (7.7)	
Current	463 (34.5)	101 (30.4)	110 (32.8)	142 (40.8)	110 (33.7)	
Never	734 (54.7)	194 (58.4)	176 (52.5)	173 (49.7)	191 (58.6)	
Physical activity MET score ≥840, *n (%)*†	456 (34.0)	96 (28.9)	96 (28.7)	116 (33.3)	148 (45.4)	0.30
Low socioeconomic status, *n (%)*‡	932 (69.5)	232 (69.9)	188 (56.1)	246 (70.7)	266 (81.6)	0.36
Diabetes, *n (%)*§	370 (27.6)	76 (24.0)	105 (33.0)	95 (28.8)	94 (29.9)	0.100
Mean serum cholesterol level (SD)						0.46
mmol/L	5.04 (1.06)	5.10 (1.09)	4.91 (1.09)	4.99 (1.08)	5.18 (1.09)	
mg/dL	194.7 (40.9)	196.8 (42.2)	189.5 (42.2)	192.5 (41.6)	200.0 (42.1)	
Central obesity, *n (%)*‖	1008 (75.2)	269 (81.0)	244 (72.8)	254 (73.0)	241 (73.9)	0.40
Hyperlipidemia, *n (%)*¶	527 (39.3)	141 (44.5)	122 (38.7)	122 (37.3)	142 (45.5)	0.53
Overweight or obese, *n (%)***	1012 (75.7)	274 (82.5)	236 (70.7)	250 (72.0)	252 (77.8)	0.27
Mean blood pressure (SD), *mm Hg*						
Systolic	151.7 (24.6)	148.3 (24.7)	153.3 (24.62)	151.8 (24.5)	153.3 (24.6)	0.45
Diastolic	93.3 (13.0)	91.1 (13.0)	92.9 (12.9)	93.7 (12.9)	95.5 (12.5)	0.46
Controlled blood pressure, *n (%)*††	314 (23.4)	94 (28.3)	93 (27.8)	57 (16.4)	70 (21.5)	0.21
Receiving antihypertensive medication, *n (%)*	506 (37.7)	117 (35.2)	119 (35.5)	138 (39.7)	132 (40.5)	0.89

GP = general practitioner; HHE = home health education; MET = metabolic equivalent.
* Current users either smoked or chewed tobacco at the time of survey. Past users smoked ≥100 cigarettes or chewed ≥100 pieces in their lifetime. Never-users smoked <100 cigarettes or chewed <100 pieces in their lifetime.
† Calculated as total MET minutes/wk = walk (MET minutes × days) + moderate (MET minutes × days) + vigorous (MET minutes × days).
‡ Monthly household income <$70 as reported by the Federal Bureau of Statistics.
§ Use of antidiabetic medications or a fasting blood glucose level ≥7.0 mmol/L (≥126 mg/dL). Blood samples were missing for 62 participants.
‖ Waist circumference ≥80 cm in women and ≥90 cm in men.
¶ Fasting serum cholesterol level ≥5.18 mmol/L (≥200 mg/dL). Blood samples were missing for 70 participants.
** Body mass index ≥23 kg/m^2 (Asian-specific criterion).
†† Systolic blood pressure <140 mm Hg and diastolic blood pressure <90 mm Hg.

(**Table 1**). More than 1 participant was recruited from the same household in 16.9% of cases.

Missing Data

During follow-up, blood pressure readings were not available at 2 years for 297 participants (22%), of whom 80 had died (**Figure 1**). A total of 1044 (78%) participants (255 in the HHE-only group, 256 in the GP-only group, 267 in the HHE and GP group, and 266 in the no intervention group) successfully completed 2 years of follow-up.

The distribution of participants with missing final blood pressure readings did not differ significantly by group allocation. Participants with and without a blood pressure reading at the last visit did not differ in such baseline characteristics as mean age (53.6 years [SD, 11.5] vs. 54.8 years [SD, 12.4]; $P = 0.131$), sex (64% vs. 58% women; $P = 0.078$), mean baseline systolic blood pressure (153.9 mm Hg [SD, 26.6] vs. 151.4 mm Hg [SD, 24.7]; $P = 0.143$), or blood pressure control rate (24% vs. 23%; $P = 0.78$).

Blood Pressure and Hypertension Control

Systolic blood pressure decreased in all treatment groups (**Table 2**). We detected a significant interaction on change in systolic blood pressure ($P = 0.004$ for intention-to-treat analysis and 0.04 for per-protocol analysis) between the main effects of GP training and HHE. We then compared the 4 intervention groups according to the principles of factorial study design analysis (17). At 10 mm Hg, the decrease in systolic blood pressure (adjusted for age, sex, and baseline blood pressure) in the intention-to-treat analysis was significantly greater in the HHE and GP group ($P = 0.001$) than in the other 3 groups (about 5 mm Hg in each) (**Table 2**). None of the variables except baseline systolic blood pressure ($P < 0.001$) was significantly associated with

Table 2. **Mean Blood Pressure at Follow-up and Change in Systolic Blood Pressure**

Variable	Total (*n* = 1341)	HHE and GP Group (*n* = 332)	HHE-Only Group (*n* = 348)	GP-Only Group (*n* = 335)	No Intervention Group (*n* = 326)	*P* Value
Mean systolic blood pressure (95% CI)*	144.8 (143.7–145.9)	139.5 (137.3–141.7)	146.2 (144.0–148.3)	147.0 (144.8–149.2)	146.7 (144.5–148.9)	<0.001
Mean diastolic blood pressure (95% CI)*	88.4 (87.7–89.0)	86.4 (85.1–87.6)	88.9 (87.7–90.1)	88.4 (87.2–89.7)	89.8 (88.5–91.0)	0.197
Decrease in systolic blood pressure (95% CI)†	–	10.8 (8.9–12.8)	5.6 (3.7–7.4)	5.6 (3.7–7.5)	5.8 (3.9–7.7)	<0.001

GP = general practitioner; HHE = home health education.
* Adjusted for clustering.
‡ Adjusted for clustering, age, sex, and baseline systolic blood pressure. Interaction *P* value for trained GP and HHE = 0.004.

the primary outcome in the multivariable model. The intraclass correlation for change in systolic blood pressure for this model was 0.004. Of note, intercluster variation in change in blood pressure was not significant.

In the analysis of the secondary outcome, we detected a significant interaction in the proportion of patients with controlled blood pressure ($P < 0.001$) between the main effects of GP training and HHE (**Table 3**). Thus, a substantially greater proportion of patients (56.9%) achieved controlled blood pressure in the HHE and GP group than in the other groups (GP-only, 29.0%; HHE-only, 23.0%; no intervention, 27.3%; *P* for difference among groups = 0.003).

Diastolic blood pressure decreased markedly in the 4 groups per intention-to-treat analysis (by 6 mm Hg in the HHE and GP group and 4 mm Hg in the HHE-only, GP-only, and no intervention groups), but we detected no significant interaction among the groups ($P = 0.27$). In 2-way comparisons, those who did and did not receive HHE (5 vs. 4 mm Hg, respectively; $P = 0.146$) or did and did not receive trained GP care (4 mm Hg in both groups; $P = 0.199$) did not differ significantly after we accounted for clustering, age, sex, and baseline diastolic blood pressure.

Sensitivity analyses conducted per protocol yielded consistent results for systolic blood pressure (**Appendix Table 1**, available at www.annals.org).

Behavior Change

The proportion of current smokers decreased from baseline to the last follow-up visit in all 4 groups ($P < 0.001$ in each). We found a 12.3% decrease in the HHE and GP group, an 11.9% decrease in the HHE-only and GP-only groups, and a 9.5% decrease in the no intervention group ($P < 0.001$ for difference among groups).

Median metabolic equivalent scores for physical activity increased in the HHE and GP group (84 [25th, 75th percentiles: −501, 323]), remained unchanged in the GP-only (0 [25th, 75th percentiles: −950, 347]) and HHE-only (0 [25th, 75th percentiles: −495, 297]) groups, and decreased (−231.0 [25th, 75th percentiles: −1666.0, 326.5]) in the no intervention group ($P = 0.030$ for difference among groups).

We observed a nonsignificant increase in mean body mass index in all 4 groups. This was most marked in the no intervention group (0.20 [CI, −0.13 to 0.53] vs. 0.04 [CI, −0.38 to 0.05] in the HHE and GP group, 0.04 [CI, −0.19 to 0.28] in the GP-only group, and 0.09 [CI, −0.16 to 0.34] in the HHE-only group; $P = 0.89$ for difference among groups).

The number of prescribed antihypertensive medications increased from baseline in all 4 groups ($P < 0.001$ in each): 20.8% in the HHE and GP group, 17.6% in the HHE-only group, 13.1% in the GP-only group, and 12.9% in the no intervention group ($P < 0.001$ for difference among groups).

DISCUSSION

We show that among adults in Pakistan with hypertension, a 2-year strategy that combined family-based HHE delivered by community health workers and GP education with a case-based curriculum for blood pressure management significantly reduced systolic blood pressure and increased the proportion of adults with controlled blood pressure by nearly 2-fold compared with either intervention alone or with no intervention. This combined strategy is simple, is easy to scale up in a developing country, and does not require access to specialist services.

We designed our trial to assess the combined effect of GP training and HHE on lowering blood pressure, not to

Table 3. **Adjusted Risk Ratio for Controlled Blood Pressure***

Treatment Group	Patients, *n*	Adjusted Risk Ratio (95% CI)†	*P* Value
HHE and GP	332	2.2 (1.3–3.6)	<0.001
HHE-only	348	0.8 (0.7–1.1)	0.25
GP-only	335	1.0 (0.8–1.4)	0.93
No intervention	326	1	

GP = general practitioner; HHE = home health education.
* Control was defined as achieving systolic blood pressure <140 mm Hg and diastolic blood pressure <90 mm Hg on last follow-up visit at 2 years after random assignment.
† We computed adjusted risk ratios from adjusted marginal probabilities by using a mixed-effects logistic regression model. Analysis is adjusted for clustering, age, sex, and baseline blood pressure control. Interaction *P* for HHE and GP group < 0.001 (20).

determine the mechanisms by which a reduction in blood pressure was achieved. We speculate that the synergistic benefit of HHE and GP training on lowering blood pressure was due to mutual reinforcement of health care messages. Beneficial trends in smoking, physical activity, and use of antihypertensive agents were also more marked in the combined intervention group. In addition, we report in a nested substudy (23) that adherence to medication was significantly higher in those randomly assigned to receive trained GP care versus untrained GP care, and that those with enhanced adherence had greater blood pressure reduction.

A MEDLINE review of English-language randomized, controlled trials on either physician education or patient education from 1966 to 2008 shows heterogeneous results (**Appendix Table 2**, available at www.annals.org [24–44]), with at best marginal benefits on hypertension control. In contrast to single interventions, multifaceted approaches to restructuring organizational hypertension care, including provider and patient education and automated reminder systems, have had promising results in developed countries (45, 46).

Our combined intervention may be scalable to the needs of many developing countries. As in Pakistan, private physicians provide ambulatory care for most patients with hypertension. Trained community health workers are gaining popularity as a method of delivering primary health care in several underresourced countries worldwide (47–52). The Lady Health Workers Programme of Pakistan has been established for about 2 decades and provides immunization and basic maternal and preventive child care services (47). Thus, existing health care infrastructures can easily be modified to implement this effective strategy to combat hypertension.

Obvious differences between developing and developed countries include standardized GP training and regulation, better opportunities for continued medical education, and higher health awareness and literacy in the general population (9, 53–59). However, despite the introduction of such schemes as pay-for-performance for physicians, blood pressure control remains disappointingly poor in the United States and United Kingdom (60–63). A structured program like ours, modified to the developed world setting through training for suitable nonhealth professionals coupled with efforts to enhance GP performance, may be particularly effective for high-risk populations (for example, African-American persons, Hispanic persons, other ethnic minorities, and low-income communities).

Our study has limitations. First, it was short and not sufficiently powered to determine the effect of the interventions on cardiovascular outcomes. However, data from the United States (64) suggest that a sustained systolic blood pressure reduction of about 5 mm Hg is projected to equate to a nearly 20% reduction in absolute risk for cardiovascular death over 2 decades—a substantial effect. Second, blood pressure readings from the last follow-up visit were missing for 297 (22%) participants. However, these missing visits were balanced among intervention groups. Third, although our analysis accounted for clustering of households at the census level, additional variance in individual blood pressure could have occurred because observations on individuals within clusters may be correlated (that is, persons who visit the same GP or live in the same household [20%] may be more similar than those in different practices or households, respectively). However, our aim was to assess the overall effect of mass training of GPs and HHE on groups within geographic areas (population health), as opposed to at the individual level alone. Moreover, accounting for clustering within households did not have a significant effect on our results. Fourth, our study was not designed to assess which elements of GP education or HHE drove the beneficial effect, although our substudy and the other lifestyle and behavioral changes we measured offer clues. Finally, the outcome assessors could have become unblinded to the random assignment status of participants. However, we kept the outcome assessment team separate from those who delivered the intervention, and the key outcome (blood pressure) was measured by using an automated device, which minimized the risk for biased outcome assessment.

Our study has several strengths. To our knowledge, this is the first population-based randomized, controlled trial of its kind on strategies to enhance hypertension control in the Indo-Asian region, where the burden of hypertension is high. Our sampling strategies ensured the recruitment of representative clusters. Our use of standardized, reproducible evaluation techniques and training methods (both for the GPs and by the health workers) are strong elements. The distance between study clusters (10 kilometers) minimized the chances of cross-contamination of interventions. We performed several sensitivity analyses, all of which yielded consistent results. Thus, we believe our findings are robust. Finally, our proposed strategy is simple and lacks the logistic complexities that preclude integration into existing health care systems of developing countries—1 GP training session per year coupled with HHE that can be provided through an infrastructure that is already in place in several countries in Indo-China and Africa. Such an integrated model of chronic disease care delivery within the primary health care framework is consistent with the Alma-Ata Declaration of the World Health Organization (65) and is being strongly advocated (66). Our findings indicate that this model will probably be effective in controlling hypertension.

We suggest that suitably modified forms of this intervention be tested in other resource-poor settings and that their effect on other measures of chronic disease, such as lipid profiles and glucose levels, as well as their more distal effect on cardiovascular events, be examined.

In conclusion, our findings provide robust evidence that the combined strategy of GP training and family-based HHE can effectively reduce blood pressure and increase blood pressure control in patients with hypertension who live in a poorly resourced developing country. These findings have substantial potential global health implications.

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Appendix Table 1. **Sensitivity Analyses**

Analysis and Treatment Group	Patients, *n*	Decrease in Systolic BP (95% CI), *mm Hg**	*P* Value
Per-protocol analyses			
Unadjusted (*n* = 1044)†			0.002
HHE and GP	267	10.5 (8.2–12.9)	
HHE only	255	5.5 (3.2–7.8)	
GP only	256	5.4 (3.1–7.7)	
No intervention	266	5.0 (2.8–7.3)	
Adjusted for baseline BP control rate (*n* = 1044)‡			0.002
HHE and GP	267	10.2 (8.0–12.4)	
HHE only	255	5.5 (3.4–7.6)	
GP only	256	5.4 (3.2–7.5)	
No intervention	266	4.6 (2.5–6.7)	
Adjusted for diabetes (*n* = 1014)§			0.002
HHE and GP	261	10.5 (8.1–13.0)	
HHE only	246	5.5 (3.0–7.9)	
GP only	248	5.1 (2.7–7.5)	
No intervention	259	5.0 (2.6–7.3)	
Intention-to-treat analyses			
With missing values replaced by last BP measurement (*n* = 1341)‖			0.001
HHE and GP	332	10.2 (8.0–12.4)	
HHE only	348	5.5 (3.4–7.6)	
GP only	335	5.4 (3.2–7.5)	
No intervention	326	4.6 (2.5–6.7)	
With missing values replaced by overall mean follow-up BP (*n* = 1341)¶			0.014
HHE and GP	332	9.5 (7.6–11.4)	
HHE only	348	5.8 (4.0–7.6)	
GP only	335	5.9 (4.0–7.8)	
No intervention	326	6.0 (4.1–7.9)	

BP = blood pressure; GP = general practitioner; HHE = home health education.
* Adjusted for clustering, age, sex, and baseline systolic BP.
† Interaction *P* for HHE and GP group = 0.044.
‡ Also adjusted for baseline systolic BP control rate; interaction *P* for HHE and GP group = 0.045.
§ Also adjusted for diabetes (data missing for 30 patients); interaction *P* for HHE and GP group = 0.044.
‖ Interaction *P* for HHE and GP group = 0.073.
¶ Interaction *P* for HHE and GP group = 0.048.

Appendix Table 2. Studies of the Effect of Physician Education or Patient Education on BP Control

Study, Year (Reference)	Patients, *n*	Duration of Follow-up, *mo*	Difference in Mean Change in BP (95% CI)		Weighted Odds Ratio of BP Control (95% CI)*	Conclusion
			Systolic	Diastolic		
Physician education versus control						
Coe et al, 1977 (24)	116	5 to 8	−1.20 (−10.06 to 7.66)	1.10 (−3.63 to 5.83)	NR	Not superior
Dickinson et al, 1981 (25)	111	7	1.00 (−8.35 to 10.35)	−1.00 (−6.89 to 4.89)	0.95 (0.24 to 3.78)	Not superior
Evans et al, 1986 (26)	183	12	0.80 (−4.23 to 5.83)	0.30 (−2.00 to 2.60)	0.83 (0.46 to 1.50)	Not superior
McAlister et al, 1986 (27)	602	6	NR	NR	1.05 (0.67 to 1.64)	Not superior
Hetlevik et al, 1999 (28)	1839	24	−1.50 (−3.22 to 0.22)	−0.60 (−1.42 to 0.22)	NR	Not superior
Montgomery et al, 2000 (29)	229	12	−4.00 (−8.30 to 0.30)	1.00 (−1.19 to 3.19)	1.05 (0.67 to 1.64)	Not superior
Sanders and Satyvavolu, 2002 (30)	261	< or >1	−6.80 (−11.34 to −2.26)	−2.10 (−4.81 to 0.61)	NR	Not superior
Current study	5005		NR	NR	0.99 (0.88 to 1.10)	Not superior
Ornstein et al, 2004 (31)	7772	24	NR	NR	0.77 (0.70 to 0.84)	Intervention better
Fahey et al, 2006 (45)			−2.03 (−3.45 to −0.62)	−0.43 (−1.12 to 0.27)	0.85 (0.80 to 0.91)	May be marginally superior
Patient education versus control						
Sackett et al, 1975 (32)	112	6	NR	NR	0.74 (0.27 to 2.07)	Not superior
Webb, 1980 (33)	92	6	NR	−3.30 (−6.95 to 0.35)	NR	
Tanner and Noury, 1981 (34)	30	4	NR	0.20 (−4.74 to 5.14)	NR	
Earp et al, 1982 (35)	121	12	NR	NR	1.00 (0.42 to 2.43)	Not superior
Zismer et al, 1982 (36)	39	6	−15.70 (−26.00 to −5.40)	−8.70 (−15.54 to −1.86)	NR	Intervention better
Morisky et al, 1983 (37)	84	24 and 60	NR	NR	0.34 (0.14 to 0.84)	Intervention better
Pierce et al, 1984 (38)	86	12	NR	NR	0.41 (0.14 to 1.17)	Intervention better
Fahey et al, 2005 (53)	16	8	−7.40 (−22.50 to 7.70)	7.10 (−5.16 to 19.39)	NR	
Watkins et al, 1987 (39)	414	12	0.60 (−2.98 to 4.18)	0.40 (−1.39 to 2.19)	NR	Not superior
Roca-Cusachs et al, 1991 (40)	195	6	1.30 (−4.34 to 6.94)	1.90 (−1.08 to 4.88)	NR	Not superior
Mühlhauser et al, 1993 (41)	160	18	−5.00 (−9.26 to −0.74)	−3.00 (−5.42 to −0.58)	1.08 (0.44 to 2.61)	Intervention better
Fielding et al, 1994 (42)	145	12	−8.50 (−14.82 to −2.18)	−3.90 (−7.07 to −0.73)	NR	Intervention better
Billault et al, 1995 (43)	167	12	−1.10 (−5.83 to 3.63)	1.40 (−1.52 to 4.32)	NR	Not superior
Fahey et al, 2006 (45)			−2.54 (−4.55 to −0.53)	−0.81 (−1.83 to 0.21)	0.66 (0.44 to 1.01)	May be marginally superior
McKinstry et al, 2006 (44)	294	12	0.00 (−3.70 to 1.90)	0.00 (−5.2 to 4.50)	NR	Not superior

BP = blood pressure; NR = not reported.
* Ratio <1 favors treatment.