ORIGINAL ARTICLE

# Home-Based Care for Hypertension in Rural South Africa

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## ABSTRACT

### BACKGROUND

Poorly controlled hypertension is a common problem worldwide, particularly in low-resource settings.

### METHODS

We conducted an open-label, randomized, controlled trial of a home-based model of hypertension care in South Africa. Adults with hypertension were assigned to receive home-based care, which consisted of patient monitoring of blood pressure, home visits from a community health worker (CHW) for data collection and medication delivery, and remote nurse-led decision making supported by a mobile application (CHW group); enhanced home-based care, which consisted of the same intervention but with blood-pressure machines transmitting readings automatically (enhanced CHW group); or standard care with clinic-based management (standard-care group). The primary outcome was the systolic blood pressure at 6 months. Secondary outcomes were the systolic blood pressure at 12 months and hypertension control at 6 and 12 months. Safety outcomes included adverse events, deaths, and retention in care.

### RESULTS

A total of 774 adults underwent randomization. The mean age was 62 years; 76.0% of the participants were women, 13.6% had diabetes mellitus, and 46.5% had human immunodeficiency virus infection. The mean systolic blood pressure at 6 months was lower in the CHW group than in the standard-care group (difference, –7.9 mm Hg; 95% confidence interval [CI], –10.5 to –5.3; P<0.001) and was also lower in the enhanced CHW group than in the standard-care group (difference, –9.1 mm Hg; 95% CI, –11.7 to –6.4; P<0.001). The percentage of participants with hypertension control at 6 months was 57.6% in the standard-care group, as compared with 76.9% in the CHW group (relative risk, 1.33; 95% CI, 1.18 to 1.51) and 82.8% in the enhanced CHW group (relative risk, 1.44; 95% CI, 1.28 to 1.62). The improvements in systolic blood pressure and hypertension control with home-based care appeared to persist at 12 months. Severe adverse events and deaths occurred in 2.7% and 1.0% of the participants, respectively, and occurred in a similar percentage of participants across trial groups. Retention in care was observed in more than 95% of the participants in the CHW and enhanced CHW groups.

### CONCLUSIONS

In South Africa, home-based hypertension care led to a significantly lower mean systolic blood pressure at 6 months than standard, clinic-based care. (Supported by the National Institutes of Health and others; IMPACT-BP ClinicalTrials.gov number, NCT05492955; South African National Clinical Trials Register number, DOH-27-112022-4895.)

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Elevated blood pressure is the leading risk factor for preventable death, resulting in approximately 10 million deaths each year.[1] Although numerous low-cost, effective therapies are available, poorly controlled hypertension is a common problem, particularly in populations with structural barriers to health care.[2-4] In the public sector of South Africa, patients' limited involvement in their care, overcrowded clinics, inconsistent availability of sphygmomanometers, and the costs of transportation to a clinic and missed work are commonly cited contributors to suboptimal outcomes.[5,6] Home-based blood-pressure management with remote monitoring has been proposed to address these barriers,[7] but data on the efficacy of such programs are scarce.

## Methods

### Intervention Development

The intervention tested in this trial was developed in partnership with people living with hypertension and the Department of Health in South Africa. Full details of the formative work that motivated intervention development and adaptation have been published previously.[6] In brief, input from partners resulted in three major design elements: direct provision of blood-pressure machines to patients to promote their involvement in their care; remote disease monitoring to reduce patient costs, decongest clinics, and support nurses with decision making; and the selection of community health workers (CHWs) to facilitate care that aligned with priorities of the South African Department of Health.[8] In South Africa, CHWs are lay health workers who reside in the community and serve as liaisons for the health system. Their primary roles include health promotion, health screening, referrals, and contact tracing.[9]

### Trial Design and Oversight

We conducted a parallel-group, open-label, randomized, controlled trial. The trial was designed and implemented as a superiority trial in which two intervention groups were individually compared with a control group. The trial protocol and the Supplementary Appendix, with information on the statistical analysis plan, are available with the full text of this article at NEJM.org. Detailed methods have been published previously.[10]

The trial was designed by the investigators with input from local colleagues at the South African Department of Health and from the Africa Health Research Institute community advisory board. The authors vouch for the accuracy and completeness of the data and for the fidelity of the trial to the protocol. The trial was approved by the University of KwaZulu-Natal biomedical research ethics committee, the institutional review board of Mass General Brigham, and the South African Health Products Regulatory Authority. All the participants provided written informed consent. A data and safety monitoring board conducted an interim analysis after 50% of the trial participants had completed 6 months of follow-up. After review of the data, the committee recommended continuation of the trial.

### Enrollment and Randomization

Participants were recruited from two public-sector primary care clinics in KwaZulu-Natal, a rural region of South Africa. Nurses at the clinics obtained blood-pressure measurements that were used for screening. Persons 18 years of age or older were eligible for inclusion in the trial if they had evidence of uncontrolled hypertension, which in guidelines from the South African Department of Health is defined by two high blood-pressure measurements (>140 mm Hg systolic, >90 mm Hg diastolic, or both) obtained a minimum of 6 months apart, with diet and lifestyle advice provided in the interim.[11] The provision of diet and lifestyle advice was not recorded in patients' files and therefore was not used as an eligibility criterion for this trial.

Additional eligibility criteria included residence in the catchment area of the trial clinics, which enabled CHW home visits, as well as plans to remain in the area for at least 24 months. Exclusion criteria were as follows: an indication for immediate referral to a physician, on the basis of guidelines from the South African Department of Health, including pregnancy or breast-feeding; severely high blood pressure (>180 mm Hg systolic or >100 mm Hg diastolic) accompanied by symptoms; reduced renal function (an estimated glomerular filtration rate [eGFR] of <60 ml per minute per 1.73 $m^2$ of body-surface area); or the current use of three or more antihypertensive therapies at the maximal dose. The eGFR was calculated with the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation from the results of a

point-of-care creatinine test administered on the day of enrollment.[12]

Eligible patients who provided written informed consent were randomly assigned, in a 1:1:1 ratio, to one of the three trial groups. Randomization was performed in blocks of nine with the use of a module in REDCap.[10,13] Randomization was stratified according to clinic and use of antihypertensive therapy at enrollment. The trial statistician generated a locked randomization table, and only the data manager had access to the table. After randomization, the participants and clinic staff were aware of the trial-group assignments.

### TRIAL PROCEDURES

Participants were randomly assigned to receive home-based care from a CHW (CHW group), enhanced home-based care from a CHW (enhanced CHW group), or standard care with clinic-based management (standard-care group). Participants in all three groups were seen by a nurse on the day of enrollment for determination of initial antihypertensive therapy. Before the trial began, nurses involved in the program had received training on best practices for hypertension care in accordance with guidelines from the South African Department of Health.[14] The three principal antihypertensive therapies that were available in the public sector in South Africa and used in this trial were hydrochlorothiazide, lisinopril, and amlodipine. All the therapies were provided to the participants free of charge by the South African Department of Health.

In the standard-care group, participants were asked to return to the clinic approximately monthly for measurement of blood pressure, adjustment of antihypertensive therapy in accordance with the national guidelines, and collection of medication from the clinic pharmacy.

In the CHW group, participants received an automated blood-pressure machine (Omron M3), were trained on its use by CHWs, and were advised to take blood-pressure measurements daily. Those with an arm circumference of 42 cm or greater received a large cuff. CHWs visited participants within 1 week after enrollment and approximately monthly thereafter to record blood-pressure readings in a mobile health application on their phones (iMarketing Consultants; details on the application are provided in the Supplementary Appendix). Clinic nurses received monthly prompts from the application to review participant data and enter prescribing information. The application was programmed with the treatment algorithm from the national guidelines and made recommendations on the basis of the mean blood-pressure readings from the past 2 weeks. Once the nurse entered a decision, the application produced an electronic prompt for a clinic staff member to fill the prescription. Once the prescription was filled, a CHW received a prompt through the phone-based application to retrieve the medication and deliver it to the participant's home.

In the enhanced CHW group, participants received a blood-pressure machine with the capability of sending text messages (Blipcare, Carematix). These machines transmitted blood-pressure data directly to the application used by nurses for clinical decision making. CHWs visited participants to ensure that the blood-pressure machines were functional and to deliver the medicines that had been prescribed by nurses. Trial procedures in this group were otherwise similar to those in the CHW group.

### OUTCOMES AND ASSESSMENTS

The primary outcome was the systolic blood pressure at 6 months. Secondary outcomes were the systolic blood pressure at 12 months and hypertension control at 6 and 12 months. Hypertension control was defined by a systolic blood pressure of less than 140 mm Hg and a diastolic blood pressure of less than 90 mm Hg. Safety outcomes included adverse events, hospitalizations, deaths, and retention in care, which was defined as an interaction with a health care worker (nurse, physician, or CHW) for hypertension care within the past 3 months.

Data on demographic characteristics and medical history were obtained at enrollment.[15] Trial staff members who were not involved in the intervention program and were unaware of the trial-group assignments conducted home visits at 6 and 12 months after enrollment in all three groups to collect outcomes data. At these visits, trial staff members used automated sphygmomanometers to obtain three blood-pressure measurements, 5 minutes apart, with the participant in a seated position. The mean of the second and third measurements was used as the blood-pressure reading. At follow-up visits, data on adverse events and hospitalizations in the past 6 months were also collected. Chart reviews were conducted to determine retention in care, which

was indicated by a record of a clinic visit or a CHW home visit in the previous 3 months or by an active prescription for antihypertensive therapy.

### STATISTICAL ANALYSIS

On the basis of a recent population-based study of blood pressure in this geographic region, we anticipated a mean (±SD) systolic blood pressure at baseline of 150±19 mm Hg.[16] We estimated that a sample size of 774 participants (258 per trial group) would provide the trial with more than 80% power to detect a difference of at least 5 mm Hg in the mean systolic blood pressure at 6 months between each intervention group and the control group, allowing for 20% loss to follow-up, a correlation coefficient between baseline and follow-up measurements of 0.5, and a two-sided alpha level of 0.025 to account for multiple comparisons between each intervention group and the control group.

All analyses were performed in the modified intention-to-treat population, which included all participants who had undergone randomization and completed a 6-month follow-up visit. In the primary analysis, data from participants with missing data were censored. The primary analysis was performed with a linear regression model that included terms for trial group, the systolic blood pressure at baseline (enrollment), and stratification factors (clinic and use of antihypertensive therapy at enrollment). The same approach was used for the analysis of the systolic blood pressure at 12 months. Percentages of participants with hypertension control at 6 and 12 months were calculated in each trial group, and separate logistic regression models for each time point were used to estimate the odds ratio and derive the relative risk. Marginal standardization was used to estimate the effect of each intervention on hypertension control, as compared with standard care.[17]

In exploratory analyses, the treatment effect at 6 months was estimated in prespecified subgroups of interest by fitting an interaction term between the trial group and covariates, which included sex, age (<60 years vs. ≥60 years), the systolic blood pressure at enrollment (140 to <160 mm Hg vs. ≥160 mm Hg), and human immunodeficiency virus (HIV) status. In post hoc analyses, the treatment effect at 6 months was estimated in additional subgroups, including those defined according to body-mass index (BMI; the weight in kilograms divided by the square of the height in meters) (<30 vs. ≥30), renal function (eGFR <72 ml per minute per 1.73 $m^2$ [the cohort median] vs. eGFR ≥72 ml per minute per 1.73 $m^2$), and demographic characteristics, including employment status and whether participants had access to running water in their homes. Additional sensitivity analyses are described in the Supplementary Appendix.

Multiplicity control was applied only to the primary outcome and was performed with the Bonferroni adjustment, in which the prespecified alpha level of 0.05 was divided by two for the comparison of each intervention group with the control group. For all secondary and exploratory outcomes, point estimates and 95% confidence intervals are reported; the widths of the confidence intervals were not controlled for multiplicity and cannot be used to infer definitive treatment effects.

Finally, for the comparison of safety outcomes, total adverse events and severe adverse events were summarized according to trial group. Percentages of participants retained in care at 6 and 12 months were calculated.

## RESULTS

### PARTICIPANTS

From November 30, 2022, through June 25, 2024, a total of 910 patients with an elevated blood pressure and a record of at least one elevated reading 6 months earlier underwent screening. Of these patients, 136 did not meet the eligibility criteria (Fig. S1 in the Supplementary Appendix). The remaining 774 patients were randomly assigned to the CHW group (257 participants), the enhanced CHW group (258 participants), or the standard-care group (259 participants). A total of 762 participants (98.4%) completed the 6-month follow-up visit and were included in the primary analysis. All the participants in the CHW and enhanced CHW groups and no participants in the standard-care group were assigned to a CHW for home visits and received a blood-pressure cuff.

The demographic and clinical characteristics of the participants were generally similar among the trial groups and are summarized in Table 1. All the participants were of Black African descent, reflecting the population with hypertension in this rural region of South Africa (Table S1). At enrollment, the mean age was 62±12 years, and

588 participants (76.0%) were women. The mean systolic blood pressure was 147±17 mm Hg, and 156 participants (20.2%) had a systolic blood pressure of 160 mm Hg or higher. A total of 360 participants (46.5%) were living with HIV; 105 (13.6%) had diabetes mellitus and 351 (45.3%) had a BMI of 30 or higher. In addition, 87 participants (11.2%) were employed, and 112 (14.5%) had access to running water in their homes.

### EFFICACY OUTCOMES

The mean systolic blood pressure at 6 months was similar to that at enrollment in the standard-care group (difference, –1.9 mm Hg; 95% confidence interval [CI], –4.2 to 0.4) (Table 2 and Fig. 1A). By contrast, the mean systolic blood pressure at 6 months was lower than that at enrollment in the CHW group (difference, –9.1 mm Hg; 95% CI, –11.3 to –6.8) and in the enhanced CHW group (difference, –10.5 mm Hg; 95% CI, –12.8 to –8.2). The mean systolic blood pressure at 6 months was lower in the CHW group than in the standard-care group (difference, –7.9 mm Hg; 95% CI, –10.5 to –5.3; P<0.001) and was also lower in the enhanced CHW group than in the standard-care group (difference, –9.1 mm Hg; 95% CI, –11.7 to –6.4; P<0.001).

The percentage of participants with hypertension control at 6 months, in accordance with the definition from the South African Department of Health, was 76.9% (95% CI, 71.2 to 81.7) in the CHW group, 82.8% (95% CI, 77.7 to 87.0) in the enhanced CHW group, and 57.6% (95% CI, 51.5 to 63.6) in the standard-care group (Fig. 1B). The reduction in the mean systolic blood pressure and the increase in hypertension control in the CHW and enhanced CHW groups appeared to be sustained at 12 months. Results were similar in sensitivity analyses that were adjusted for confounders and used the last blood-pressure measurement carried forward for participants with missing data (Tables S2 and S3). A similar pattern was observed for diastolic blood pressure in a post hoc analysis (Table S4).

In terms of the reduction in the mean systolic blood pressure at 6 months, the magnitude of benefit observed in the CHW and enhanced CHW groups as compared with the standard-care group was similar in most subgroups. The effect appeared to be greater among participants with a systolic blood pressure of 160 mm Hg or higher at enrollment than among those with a systolic blood pressure of 140 to less than 160 mm Hg at enrollment (Fig. 2).

### SAFETY OUTCOMES

A total of 21 severe adverse events occurred in 20 participants, including 8 deaths and 13 hospitalizations (Table 2 and Table S5). The percentage of participants with an event was similar across trial groups, and no adverse events were deemed by investigators to be related to trial procedures. Retention in care was observed in more than 95% of the participants in the CHW and enhanced CHW groups at 6 and 12 months.

## DISCUSSION

In a rural, low-resource region of South Africa, a home-based model of hypertension care — consisting of patient monitoring of blood pressure, CHW home visits, and remote nurse-led decision making supported by a mobile health application — led to a significantly lower mean systolic blood pressure at 6 months than standard, clinic-based care. The percentage of participants with hypertension control at 6 and 12 months appeared to be higher in the intervention groups than in the standard-care group. A reduction of 8 to 10 mm Hg in the mean systolic blood pressure, which was observed in the intervention groups in our trial, has been associated with a reduction of 15 to 25% in the risk of heart attack, stroke, and heart failure.[18] The improvements appeared to persist at 12 months and were evident regardless of demographic or clinical characteristics. These results, in a historically disadvantaged community, support home-based hypertension care in similar low-resource settings and are consistent with findings from trials of community-based models for other chronic diseases[19] and with recommendations made by the South African Department of Health and the World Health Organization.[2,8]

Our results differ from those of many previous studies of interventions that used mobile health applications to enhance hypertension care in resource-limited settings. For example, a meta-analysis of nine randomized, controlled trials conducted in resource-limited settings that compared in-person care with remote care for hypertension estimated a difference between groups in the mean systolic blood pressure of 1 mm Hg.[20] Interventions in that review included text-

**Table 1. Demographic and Clinical Characteristics of the Participants at Enrollment.***

| Characteristic | CHW (N=257) | Enhanced CHW (N=258) | Standard Care (N=259) | Total (N=774) |
|---|---|---|---|---|
| Age — yr | 63±12 | 62±11 | 62±12 | 62±12 |
| Female sex — no. (%) | 202 (78.6) | 192 (74.4) | 194 (74.9) | 588 (76.0) |
| Education level — no. (%) | | | | |
| None | 110 (42.8) | 90 (34.9) | 103 (39.8) | 303 (39.1) |
| Primary education | 61 (23.7) | 65 (25.2) | 57 (22.0) | 183 (23.6) |
| Higher than primary education | 85 (33.1) | 103 (39.9) | 99 (38.2) | 287 (37.1) |
| Missing data | 1 (0.4) | 0 | 0 | 1 (0.1) |
| Employment status — no. (%) | | | | |
| Employed | 28 (10.9) | 31 (12.0) | 28 (10.8) | 87 (11.2) |
| Unemployed | 226 (87.9) | 225 (87.2) | 227 (87.6) | 678 (87.6) |
| Missing data | 3 (1.2) | 2 (0.8) | 4 (1.5) | 9 (1.2) |
| Asset index quintile — no. (%) | | | | |
| Most deprived | 43 (16.7) | 55 (21.3) | 64 (24.7) | 162 (20.9) |
| Deprived | 54 (21.0) | 51 (19.8) | 42 (16.2) | 147 (19.0) |
| Moderately deprived | 51 (19.8) | 42 (16.3) | 58 (22.4) | 151 (19.5) |
| Less deprived | 46 (17.9) | 53 (20.5) | 54 (20.8) | 153 (19.8) |
| Least deprived | 57 (22.2) | 55 (21.3) | 40 (15.4) | 152 (19.6) |
| Missing data | 6 (2.3) | 2 (0.8) | 1 (0.4) | 9 (1.2) |
| Access to running water — no. (%) | | | | |
| Yes | 34 (13.2) | 38 (14.7) | 40 (15.4) | 112 (14.5) |
| No | 222 (86.4) | 220 (85.3) | 218 (84.2) | 660 (85.3) |
| Missing data | 1 (0.4) | 0 | 1 (0.4) | 2 (0.3) |
| Travel time to clinic — min | 52±187 | 41±33 | 47±43 | 47±112 |
| Cost of travel to clinic — South African rand† | 30.58±27.17 | 29.11±24.93 | 26.21±16.14 | 28.68±23.37 |
| Systolic blood pressure — mm Hg | 146.6±18.0 | 146.8±17.2 | 147.4±16.4 | 147.0±17.2 |
| Systolic blood pressure ≥160 mm Hg — no. (%) | 53 (20.6) | 53 (20.5) | 50 (19.3) | 156 (20.2) |
| Use of antihypertensive therapy — no. (%) | 249 (96.9) | 251 (97.3) | 251 (96.9) | 751 (97.0) |
| Body-mass index‡ | 29.8±7.1 | 30.0±7.1 | 29.3±7.5 | 29.7±7.2 |
| Estimated glomerular filtration rate — ml/min/1.73 $m^2$§ | 74.5±14.1 | 78.2±15.7 | 75.5±14.9 | 76.1±15.0 |
| Diabetes mellitus — no. (%) | 32 (12.5) | 41 (15.9) | 32 (12.4) | 105 (13.6) |
| HIV status — no. (%) | | | | |
| Negative | 133 (51.8) | 149 (57.8) | 131 (50.6) | 413 (53.4) |
| Positive | 123 (47.9) | 109 (42.2) | 128 (49.4) | 360 (46.5) |
| Unknown | 1 (0.4) | 0 | 0 | 1 (0.1) |

* Plus–minus values are means ±SD. Participants were randomly assigned to receive home-based care, which consisted of patient monitoring of blood pressure, home visits from a community health worker (CHW) for data collection and medication delivery, and remote nurse-led decision making supported by a mobile application (CHW group); enhanced home-based care, which consisted of the same intervention but with blood-pressure machines transmitting readings automatically (enhanced CHW group); or standard care with clinic-based management (standard-care group). Percentages may not total 100 because of rounding. HIV denotes human immunodeficiency virus.
† At the time of the trial, 1 U.S. dollar was equivalent to approximately 18 South African rand.
‡ Body-mass index is the weight in kilograms divided by the square of the height in meters.
§ The estimated glomerular filtration rate was calculated with the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation from creatinine measurements obtained on the day of enrollment.[12]

**Table 2. Efficacy and Safety Outcomes.***

| Outcome | CHW (N=257) | Enhanced CHW (N=258) | Standard Care (N=259) |
|---|---|---|---|
| Systolic blood pressure — mm Hg | | | |
| Enrollment | | | |
| Mean (95% CI) | 146.6 (144.4 to 148.8) | 146.8 (144.7 to 149.0) | 147.4 (145.4 to 149.4) |
| 6 Mo | | | |
| Mean (95% CI) | 137.5 (135.6 to 139.4) | 136.5 (134.8 to 138.1) | 145.8 (143.4 to 148.2) |
| Difference vs. enrollment (95% CI) | −9.1 (−11.3 to −6.8) | −10.5 (−12.8 to −8.2) | −1.9 (−4.2 to 0.4) |
| Difference vs. standard-care group (95% CI) | −7.9 (−10.5 to −5.3) | −9.1 (−11.7 to −6.4) | — |
| P value vs. standard-care group | <0.001 | <0.001 | — |
| 12 Mo | | | |
| Mean (95% CI) | 134.1 (132.6 to 135.7) | 134.0 (132.6 to 135.4) | 144.8 (142.6 to 147.1) |
| Difference vs. enrollment (95% CI) | −12.4 (−14.7 to −10.1) | −12.8 (−15.1 to −10.5) | −3.0 (−5.1 to −0.9) |
| Difference vs. standard-care group (95% CI) | −10.3 (−12.6 to −8.0) | −10.5 (−12.8 to −8.2) | — |
| Hypertension control | | | |
| 6 Mo | | | |
| % (95% CI) | 76.9 (71.2 to 81.7) | 82.8 (77.7 to 87.0) | 57.6 (51.5 to 63.6) |
| Relative risk vs. standard-care group (95% CI) | 1.33 (1.18 to 1.51) | 1.44 (1.28 to 1.62) | — |
| 12 Mo | | | |
| % (95% CI) | 82.8 (77.6 to 87.0) | 85.7 (80.7 to 89.5) | 57.7 (51.5 to 63.7) |
| Relative risk vs. standard-care group (95% CI) | 1.43 (1.27 to 1.62) | 1.48 (1.32 to 1.67) | — |
| Adverse events during observation period — no. (%) | | | |
| Total adverse events | 7 (2.7) | 10 (3.9) | 4 (1.6) |
| Severe adverse events | 7 (2.7) | 10 (3.9) | 4 (1.6) |
| Adverse events related to trial procedures | 0 | 0 | 0 |
| Deaths | 1 (0.4) | 4 (1.6) | 3 (1.2) |
| Retention in care — % (95% CI) | | | |
| 6 Mo | 98.1 (95.4 to 99.2) | 99.6 (97.3 to 99.9) | 76.4 (70.9 to 81.2) |
| 12 Mo | 97.3 (94.4 to 98.7) | 97.7 (94.9 to 99.0) | 72.6 (66.8 to 77.7) |

* Participants were randomly assigned to receive home-based care from a CHW (CHW group), enhanced home-based care from a CHW (enhanced CHW group), or standard care with clinic-based management (standard-care group). Blood-pressure measurements were available for 774 participants at enrollment, 762 participants at 6 months, and 752 participants at 12 months. The estimated differences in systolic blood pressure between time points within each trial group were based on data from participants who had measurements available at both enrollment and the given time point (i.e., 6 or 12 months). The estimated differences in systolic blood pressure between trial groups were derived from a multivariable adjusted model that accounted for stratification factors and thus may not be identical to the unadjusted differences.

messaging communication platforms, clinical decision support tools, and in one study in China, provision of home-based blood-pressure devices to participants. Yet, in contrast to our trial, no study in that review combined multiple strategies to address the multifactorial barriers to chronic disease care.

A separate meta-analysis of nonpharmaceutical strategies to improve hypertension care showed substantial improvements with health-systems approaches and more modest improvements with patient-focused approaches.[21] Most of the data in that review were not derived from low-resource settings. In the Control of Blood Pressure and Risk Attenuation–Bangladesh, Pakistan, and Sri Lanka (COBRA-BPS) study, which evaluated a CHW-engaged model of care, the mean systolic blood pressure was 5 mm Hg lower with the intervention than with usual care.[22] However, in that study, CHW involvement was limited to

home-based blood-pressure measurement. After the initial visit, participants traveled to the clinic for ongoing care. An alternative approach that used group-based care in Kenya resulted in lowering of the systolic blood pressure, but the reductions observed (3.3 to 3.9 mm Hg) were not statistically different from those in the standard-care group.[23]

Finally, a study among predominantly Black men in the United States compared clinic-based care with a pharmacist-led program in barbershops. The mean systolic blood pressure was 20 mm Hg lower with the intervention than with standard care.[24] Our trial was similar in its focus on a population with historical inequities in health care access and its use of an intervention targeting structural and sociobehavioral barriers. Our trial differed in its use of a home-based care model and its inclusion of both men and women. Our trial was unique in the evaluation of a home-based intervention in which participants performed blood-pressure monitoring and had home visits with lay health care workers. As in our trial, previous work has suggested that patient monitoring of blood pressure is more effective when paired with health-system support.[25]

This trial was strengthened by the use of an effectiveness evaluation design to enhance the generalizability to other remote and low-resource settings. For example, CHWs who participated in the program had the educational equivalent of high-school diplomas and were recruited from local villages, as recommended by the South African CHW recruitment policy. Clinical care for participants in the program was provided by nurses employed at public-sector primary care clinics. Moreover, the trial population was typical of that in many other resource-constrained settings: approximately one in three participants had completed more than a primary education, only one in five had in-home access to water, and the mean transportation time to the nearest clinic was 45 minutes.

Our trial is limited by its conduct in two clinics in one region of a single country. Studies in urban areas and in settings without CHW programs will be needed to determine the effect in such locations. We also studied a population with established hypertension, and many of the patients were already receiving treatment. Although we found benefits of the intervention in both men and women, the trial population was predominantly composed of women. Interventions

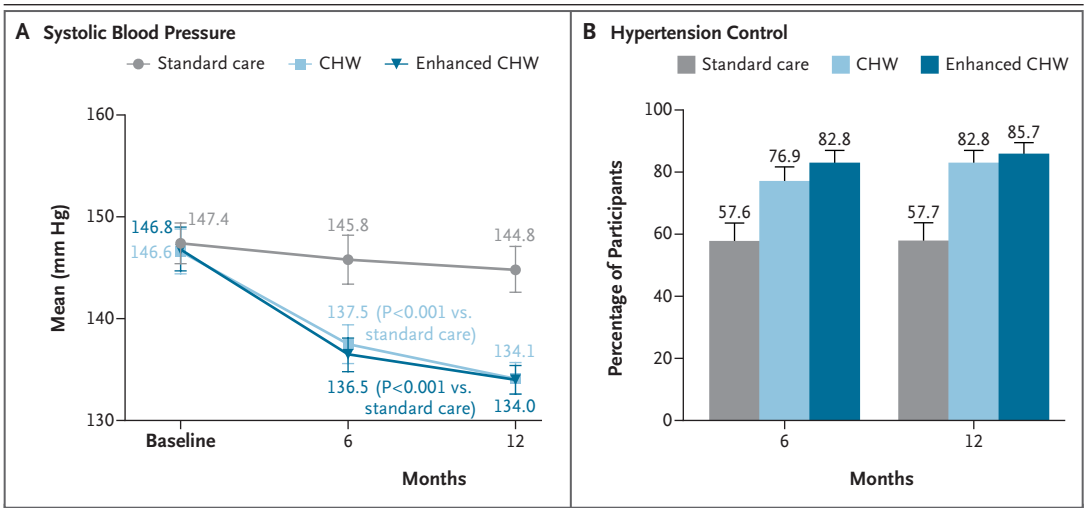


**Figure 1. Systolic Blood Pressure and Hypertension Control at 6 and 12 Months.**

Panel A shows the mean systolic blood pressure, and Panel B shows the percentage of participants with hypertension control. Participants were randomly assigned to receive home-based care, which consisted of patient monitoring of blood pressure, home visits from a community health worker (CHW) for data collection and medication delivery, and remote nurse-led decision making supported by a mobile application (CHW group); enhanced home-based care, which consisted of the same intervention but with blood-pressure machines transmitting readings automatically (enhanced CHW group); or standard care with clinic-based management (standard-care group). I bars indicate 95% confidence intervals.

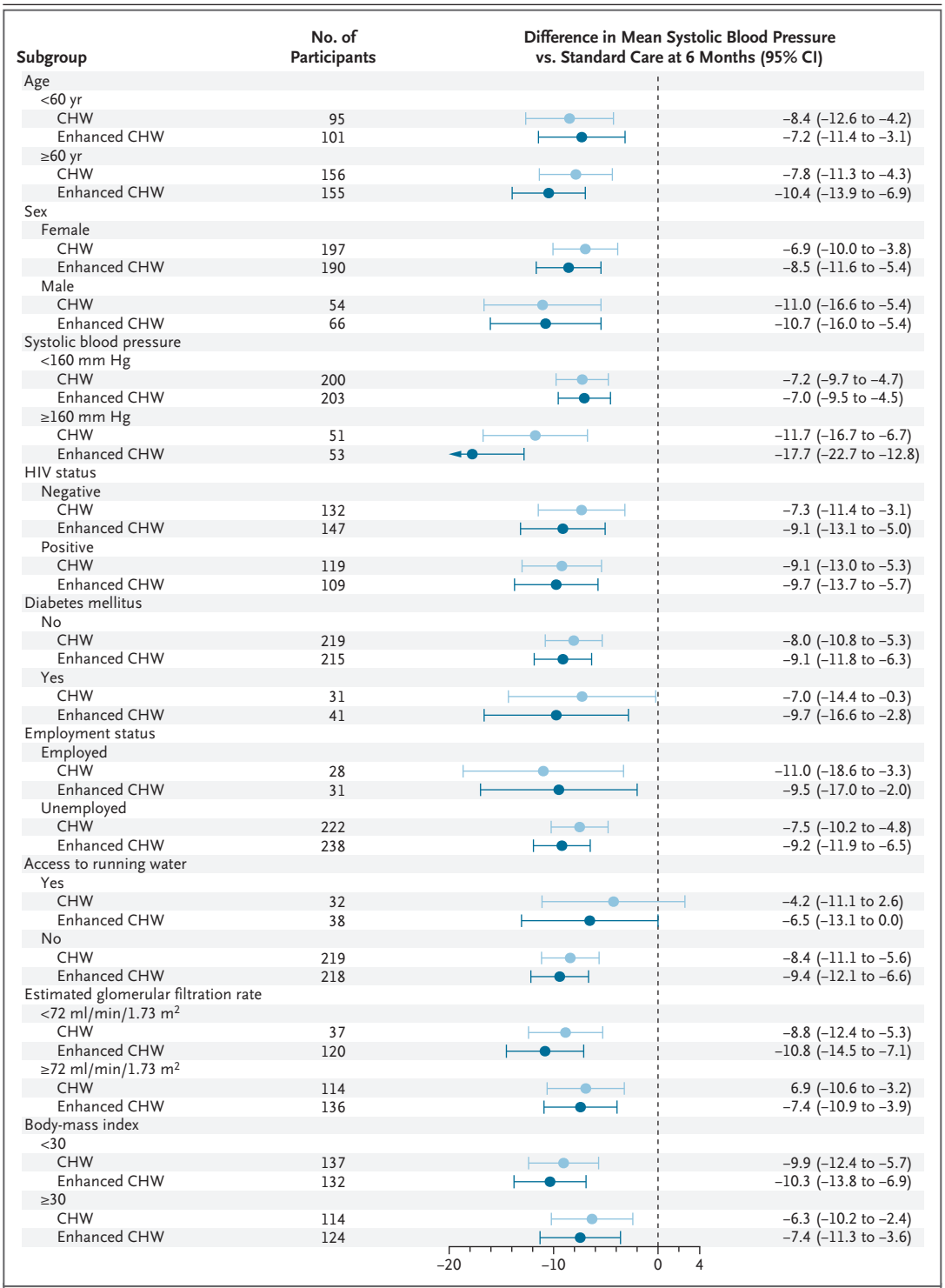


**Figure 2. Subgroup Analysis of Systolic Blood Pressure at 6 Months.**

Participants were randomly assigned to receive home-based care from a CHW (CHW group), enhanced home-based care from a CHW (enhanced CHW group), or standard care with clinic-based management (standard-care group). The body-mass index is the weight in kilograms divided by the square of the height in meters. HIV denotes human immunodeficiency virus.

that better engage and retain men in hypertension care remain a high priority in South Africa.[26] In addition, we studied only one disease. Future work could consider the feasibility of expanding such programs to address coexisting conditions. Information on adverse events was collected by recall at home visits conducted every 6 months, which may have led to underreporting of minor adverse events and medication side effects. Finally, the cost implications of the program for individual patients and health systems are not yet known. Future work may include comparisons of health-resource allocations and benefits between the CHW and enhanced CHW groups, the latter of which uses more costly blood-pressure machines but fewer human resources owing to the automated transfer of blood-pressure data.

In South Africa, a home-based model of hypertension care led to a lower mean systolic blood pressure than standard, clinic-based care. Primary care programs with poor performance may consider similar remote models of care that address structural barriers to improve hypertension control.

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