ORIGINAL ARTICLE

A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops

Ronald G. Victor, M.D., Kathleen Lynch, Pharm.D., Ning Li, Ph.D., Ciantel Blyler, Pharm.D., Eric Muhammad, B.A., Joel Handler, M.D., Jeffrey Brettler, M.D., Mohamad Rashid, M.B., Ch.B., Brent Hsu, B.S., Davontae Foxx-Drew, B.A., Norma Moy, B.A., Anthony E. Reid, M.D.,* and Robert M. Elashoff, Ph.D.

ABSTRACT

BACKGROUND

Uncontrolled hypertension is a major problem among non-Hispanic black men, who are underrepresented in pharmacist intervention trials in traditional health care settings.

METHODS

We enrolled a cohort of 319 black male patrons with systolic blood pressure of 140 mm Hg or more from 52 black-owned barbershops (nontraditional health care setting) in a cluster-randomized trial in which barbershops were assigned to a pharmacist-led intervention (in which barbers encouraged meetings in barbershops with specialty-trained pharmacists who prescribed drug therapy under a collaborative practice agreement with the participants' doctors) or to an active control approach (in which barbers encouraged lifestyle modification and doctor appointments). The primary outcome was reduction in systolic blood pressure at 6 months.

RESULTS

At baseline, the mean systolic blood pressure was 152.8 mm Hg in the intervention group and 154.6 mm Hg in the control group. At 6 months, the mean systolic blood pressure fell by 27.0 mm Hg (to 125.8 mm Hg) in the intervention group and by 9.3 mm Hg (to 145.4 mm Hg) in the control group; the mean reduction was 21.6 mm Hg greater with the intervention (95% confidence interval, 14.7 to 28.4; P<0.001). A blood-pressure level of less than 130/80 mm Hg was achieved among 63.6% of the participants in the intervention group versus 11.7% of the participants in the control group (P<0.001). In the intervention group, the rate of cohort retention was 95%, and there were few adverse events (three cases of acute kidney injury).

CONCLUSIONS

Among black male barbershop patrons with uncontrolled hypertension, health promotion by barbers resulted in larger blood-pressure reduction when coupled with medication management in barbershops by specialty-trained pharmacists. (Funded by the National Heart, Lung, and Blood Institute and others; ClinicalTrials.gov number, NCT02321618.)

From the Smidt Heart Institute at Cedars–Sinai Medical Center (R.G.V., K.L., C.B., E.M., M.R., B.H., D.F.-D., N.M., A.E.R.), the Department of Biomathematics, David Geffen School of Medicine, University of California, Los Angeles (N.L., R.M.E.), and Kaiser Permanente (J.H., J.B.) — all in Los Angeles. Address reprint requests to Dr. Victor at ronald.victor@cshs.org.

*Deceased.

This article was published on March 12, 2018, at NEJM.org.

N Engl J Med 2018;378:1291-301.
DOI: 10.1056/NEJMoa1717250

Non-Hispanic black men have the highest rate of hypertension-related death of any racial, ethnic, or sex group in the United States.[1,2] Black men have less physician interaction than black women[3] and lower rates of hypertension treatment and control,[2] necessitating community outreach.

Health outreach to barbershops is well-established but largely untested as to whether it improves hypertension management in black men. One previous randomized trial showed slightly better blood-pressure reduction in black men when barbers checked blood pressure and urged patrons with elevated readings to make doctor appointments than when barbers only distributed hypertension pamphlets.[4] The marginal intervention effect (between-group difference of −2.5 mm Hg in systolic blood pressure and −0.9 mm Hg in diastolic blood pressure) appeared due in part to design issues but also to the fact that clinicians rarely intensified drug therapy for these men,[5] a reportedly common occurrence (with notable exceptions)[6,7] in busy primary care practices in which doctors, patients, and health care systems have shared responsibility.[8-11]

Thus, we aimed to develop a potent — and convenient — blood-pressure control program for black men in which we linked health promotion by barbers to drug treatment by pharmacists and evaluated the resultant efficacy in a cluster-randomized trial. Although more than 40 randomized trials have provided evidence that hypertension control can be improved by the actions of pharmacists,[12-17] the traditional health care settings used in such trials included few black men.

Here we screened black men who were patrons of participating barbershops and enrolled a cohort with systolic blood-pressure levels of 140 mm Hg or higher. The barbershops were cluster-randomized; in some shops, barbers promoted follow-up with specialty-trained pharmacists (intervention group), whereas in other shops, barbers were trained to encourage lifestyle modification and doctor appointments (control group). In the intervention group, pharmacists met regularly with participants at the barbershops and prescribed and monitored a drug-intensification regimen and then sent notes on progress to the participants' providers. The primary hypothesis was that the reduction in systolic blood pressure after 6 months would be greater among participants at barbershops with the pharmacist-led intervention.

Methods

Trial Design and Oversight

In this trial, the barbershop was the unit of randomization. Participant group was determined according to barbershop (Fig. 1; and Fig. S1 in the Supplementary Appendix, available with the full text of this article at NEJM.org). The trial was approved by institutional review boards at Cedars–Sinai Medical Center, Kaiser Permanente, and Westat (a survey company that conducted screening and enrollment and collected baseline and follow-up data), and the conduct of the trial was periodically reviewed by an independent data and safety monitoring board.[18] Participants provided written informed consent. The authors vouch for the completeness and accuracy of the data and analyses and for the fidelity of the trial to the protocol, available at NEJM.org.

Trial Population

Field interviewers screened the clientele at participating black-owned barbershops to recruit self-identified regular patrons (≥1 haircut every 6 weeks for ≥6 months) who were non-Hispanic black men, 35 to 79 years of age, with systolic blood pressure of 140 mm Hg or more on two screening days (Fig. 1). Women and persons receiving dialysis or chemotherapy were excluded.

Randomization and Interventions

Cluster randomization was necessary to avoid between-group contamination and to account for intraclass correlation.[19,20] Barbershops were assigned to the intervention or to the active control approach in a 1:1 ratio in equally balanced blocks of four with the use of a prespecified random-number sequence. Participants and field interviewers were aware of the randomization assignments of the barbershops.

Barbers in shops assigned to the intervention were trained to encourage pharmacist follow-up and measure blood pressure. Before pharmacist intervention, providers signed a collaborative practice agreement. (See the Supplementary Appendix.) Two full-time doctoral-level pharmacists received specialized training and certification as

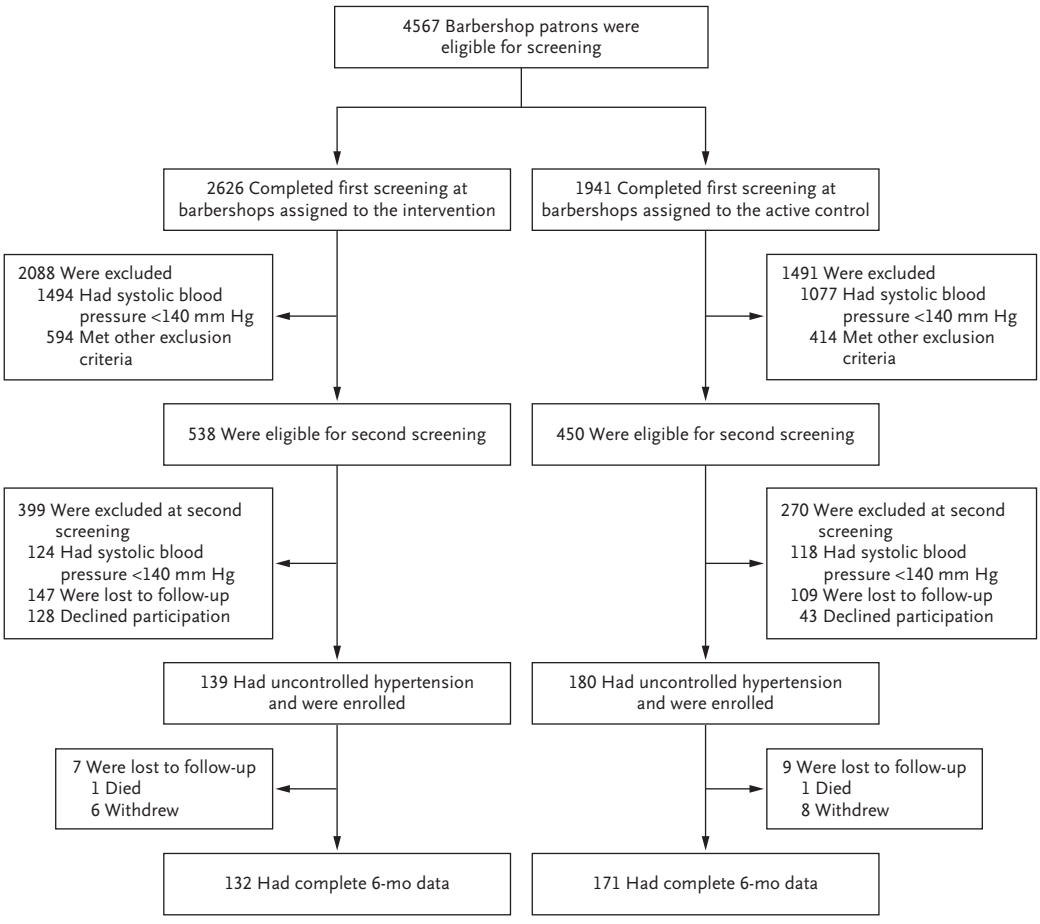

Figure 1. Screening, Enrollment, and Follow-up of Barbershop Patrons.

Other exclusion criteria included infrequent barbershop patronage (duration of <6 months or more than every 6 weeks between visits), an age younger than 35 years or older than 79 years, current treatment with dialysis or cancer chemotherapy, or plans to relocate.

hypertension clinicians and regularly reviewed each participant's treatment with physician hypertension specialists (the first, sixth, and seventh authors). Pharmacists met regularly with participants in barbershops assigned to the intervention; the pharmacists prescribed an antihypertensive drug regimen, measured blood pressure, encouraged lifestyle changes, and monitored plasma electrolyte levels. The protocol called for the pharmacists to prescribe two-drug therapy that insurance would approve — preferably amlodipine plus a long-acting angiotensin-receptor blocker (ARB) or angiotensin-converting–enzyme (ACE) inhibitor — and to use the long-acting thiazide-type diuretic indapamide as the preferred third drug.[21,22] Drug-class substitutions were allowed when medically indicated. After each encounter with a participant, pharmacists sent progress notes with their contact information to the given participant's health care provider. If a given participant did not have a provider to sign the collaborative practice agreement, a designated community physician served as the supervising doctor.

Participants in the control group received instruction about blood pressure (Fig. S2 in the Supplementary Appendix). Barbers were trained to discuss the instructional information with participants and encourage follow-up with a provider.

Participants in both groups received resources to promote cohort retention and blood-pressure reduction: the results of two blood-pressure screenings, with follow-up recommendations and identification cards (Figs. S3 and S4 in the Supplementary Appendix); follow-up calls at 3 months; culturally specific health sessions; and vouchers for monthly haircuts. In intervention-group shops only, pharmacists interviewed participants to generate peer-experience stories (posted on shop walls), reviewed blood-pressure trends (Figs. S5 and S6 in the Supplementary Appendix), and gave participants $25 per pharmacist visit to offset the costs of generic drugs and transportation to pharmacies.

TRIAL MEASUREMENTS

Field interviewers administered 30-minute, in-person, computer-based questionnaires in barbershops to participants in both groups at baseline and 6 months. These interviewers recorded blood pressure and structured response data on baseline characteristics, participant-reported outcomes, and prescription information transcribed from pill bottles.

All blood pressures were measured in barbershops with the use of a validated oscillometric monitor (Accutorr V, Mindray).[23] To automate measurement and minimize dependence on operators, monitor readings were directly uploaded to a computer that electronically transmitted data to a secure website. (See the protocol.) At each visit, five sequential blood-pressure readings were obtained; the first two readings were discarded, and the last three readings were averaged.[4] To reduce regression to the mean, the second screening blood pressure was taken as the baseline value.[24] Field interviewers, pharmacists, and barbers were trained in proper measurement technique (with the participant seated after 5 minutes of rest and the arm resting at heart level and with no conversation with participants). The correct arm-cuff size was determined for each participant at the first screening and used throughout the trial.

For 6 months, pharmacists and some barbers measured blood pressure monthly to monitor drug therapy in the intervention group but not in the control group. The final 6-month blood pressures were recorded by field interviewers in the control group and by pharmacists in the intervention group to minimize the alerting reaction evoked by an unfamiliar data collector. The prespecified blood-pressure goal was less than 130/80 mm Hg — 5/5 mm Hg lower than the conventional out-of-office blood-pressure goal of less than 135/85 mm Hg[25] — to account for blood-pressure variability. Pharmacists used a validated Clinical Laboratory Improvement Amendments–waived point-of-care device (i-STAT, Abbott Laboratories)[26] to monitor plasma levels of electrolytes and creatinine after each medication change.

TRIAL OUTCOMES

Outcomes were measured as changes from baseline to 6 months. The prespecified primary outcome was systolic blood pressure. Secondary outcomes included diastolic pressure, rates of meeting blood-pressure goals, numbers of antihypertensive drugs, adverse drug reactions, self-rated health,[3] and patient engagement according to a validated instrument.[27] Acute kidney injury was defined as an increase in the plasma creatinine level of at least 0.3 mg per deciliter (30 μmol per liter) or a level at least 1.5 times the baseline level.[28]

STATISTICAL ANALYSIS

With an enrollment target of 10 barbershop clusters per trial group — 25 participants per cluster, a rate of cohort retention of 70%, and an estimated intraclass correlation coefficient of 0.01[4] — the initial design yielded 90% power to detect a 6.9 mm Hg greater reduction in systolic blood pressure at 6 months in the intervention group than in the control group, with a two-sided alpha level of 0.05. Because the total number of patrons per barbershop was much lower than anticipated, we increased the number of shops and grouped low-enrolling shops into clusters according to both enrollment date and geographic proximity, yielding 10 shop-clusters per group with at least 10 participants per cluster.[29,30] The number of participants who withdrew from the trial was very small (Fig. 1) and was considered to be random after extensive analysis.[31]

The intervention effect was estimated by means of a linear mixed-effects model, which included a random cluster effect. The primary predictor was an indicator for intervention group

versus control group. Given the sample size, the model included three baseline covariates: baseline blood pressure, a doctor for routine medical care (yes vs. no), and high cholesterol level (yes vs. no). These were either strongly correlated with the dependent variable or showed baseline imbalance between the two groups. The linear mixed-effects model and its assumptions are described in the Supplementary Appendix.

RESULTS

TRIAL SITES AND TRIAL PARTICIPANTS

A total of 78 Los Angeles County barbershops completed 6 months of participation between February 2015 and July 2017; 26 shops that enrolled 0 or 1 participant were eliminated (Fig. S1 in the Supplementary Appendix). We enrolled a cohort of 319 participants with systolic blood pressure of 140 mm Hg or higher from 52 black-owned barbershops. The primary statistical analysis is based on 132 participants in 28 intervention shops and 171 participants in 24 control shops that completed a 6-month follow-up (Fig. 1). An intention-to-treat analysis that used the last measured blood pressure for 7 participants lost to follow-up in the intervention group was also performed; however, no adjustment for abbreviated treatment could be made in the control group, which had only baseline data on 9 participants lost to follow-up (Fig. 1).

The two cluster-randomized groups were well balanced across most characteristics, except that a higher percentage of participants in the intervention group than in the control group reported having a high cholesterol level (Table 1, and Table S1 in the Supplementary Appendix). The rate of cohort retention was 95% in both groups (Fig. 1).

PRIMARY OUTCOME

At baseline, the mean systolic blood pressure was 152.8 mm Hg in the intervention group and 154.6 mm Hg in the control group (Table 2). At 6 months, the mean systolic pressure fell 27.0 mm Hg (to 125.8 mm Hg) in the intervention group versus 9.3 mm Hg (to 145.4 mm Hg) in the control group; the mean reduction in systolic blood pressure was 21.6 mm Hg greater in the intervention group than in the control group (95% confidence interval [CI], 14.7 to 28.4; P<0.001) (Table 2). The size of the intervention effect was similar in the intention-to-treat analysis: the mean reduction was 21.0 mm Hg greater in the intervention group than in the control group (95% CI, 14.0 to 28.0; P<0.001) (Table S2 in the Supplementary Appendix). The intervention effect was consistent across clusters (Fig. 2).

SECONDARY BLOOD-PRESSURE OUTCOMES

The mean reduction in diastolic blood pressure was 14.9 mm Hg greater in the intervention group than in the control group (95% CI, 10.3 to 19.6; P<0.001), with similar values in the intention-to-treat analysis (Table 2, and Table S2 and Fig. S7 in the Supplementary Appendix). Blood-pressure goals were met by a higher percentage of participants in the intervention group than in the control group (Table 2, and Table S2 in the Supplementary Appendix).

CHANGES IN DOCTOR VISITS AND MEDICATION

The mean (±SD) number of doctor visits that participants reported for the 3 months before baseline was similar in the intervention and control groups (1.0±1.2 and 1.2±1.4, respectively), as was the mean number of visits between 3 months and 6 months after enrollment (1.2±1.5 and 1.1±1.3, respectively). After 6 months, the use of antihypertensive medication increased from 55% to 100% in the intervention group and from 53% to 63% in the control group (P<0.001).

The intervention led to a greater number of antihypertensive drug classes per regimen and higher percentages of participants treated with preferred first-line and add-on drugs than did the active control (Table 3, and Table S3 in the Supplementary Appendix). In addition, participants in the intervention group were more likely than those in the control group to be treated with long-acting drugs such as amlodipine, irbesartan or telmisartan (ARBs), and indapamide (Table S4 in the Supplementary Appendix).

SAFETY OUTCOMES

There were no treatment-related serious adverse events in either group. There was one death per group that was adjudicated by physician monitors to be unrelated to trial participation. Changes in medication side effects were similar in the two groups, with few exceptions (Table S5 in the Supplementary Appendix).

Table 1. Baseline Characteristics of the Barbershops and Trial Participants.*

Characteristic	Intervention Group	Control Group
Barbershops		
No. of barbershops	28	24
Years in business	17.3±14.2	18.1±8.3
No. of barbers per shop	4±2	4±2
Participants		
No. of participants	132	171
Age — yr	54.4±10.2	54.6±9.5
Married or living with a partner — no./total no. (%)	61/131 (46.6)	86/171 (50.3)
Highest educational level — no./total no. (%)		
Not a high school graduate	6/131 (4.6)	13/171 (7.6)
High school graduate or GED equivalent	30/131 (22.9)	49/171 (28.7)
Some college or associate's degree	67/131 (51.1)	76/171 (44.4)
Bachelor's degree	21/131 (16.0)	23/171 (13.5)
Graduate or professional degree	7/131 (5.3)	10/171 (5.8)
Annual household income — no./total no. (%)		
$0–$15,999	31/123 (25.2)	34/168 (20.2)
$16,000–$24,999	20/123 (16.3)	15/168 (8.9)
$25,000–$39,999	9/123 (7.3)	19/168 (11.3)
$40,000–$49,999	14/123 (11.4)	21/168 (12.5)
$50,000–$74,999	20/123 (16.3)	34/168 (20.2)
$75,000–$99,999	16/123 (13.0)	21/168 (12.5)
≥$100,000	13/123 (10.6)	24/168 (14.3)
Regular medical care provider — no./total no. (%)	101/131 (77.1)	134/170 (78.8)
Any health insurance — no. (%)	112 (84.8)	150 (87.7)
Barbershop patronage		
Duration of patronage — yr	10.2±9.6	11.5±9.0
Frequency of visits — every no. of wk	2.0±0.9	2.1±1.1
Cardiovascular risk factors†		
Body-mass index‡	30.8±5.4	31.2±6.0
Current smoker — no./total no. (%)	43/130 (33.1)	51/171 (29.8)
Diabetes — no. (%)	28 (21.2)	38 (22.2)
High cholesterol level — no. (%)	46 (34.8)	41 (24.0)

* Plus–minus values are means ±SD. There were no significant between-group differences ($P<0.05$), except for high cholesterol level ($P=0.04$). All data are unadjusted. GED denotes General Educational Development.
† Risk factors were reported by the participants.
‡ The body-mass index is the weight in kilograms divided by the square of the height in meters. Both height and weight were reported by the participants.

In the intervention group, transient acute kidney injury developed in three participants. In each case, the regimen included indapamide; the acute kidney injury resolved when indapamide was stopped (Table S6 in the Supplementary Appendix). We had no data on acute kidney injury in the control group.

PATIENT-REPORTED OUTCOMES

Self-rated health and patient engagement increased more in the intervention group than in the control group (Tables S7 and S8 in the Supplementary Appendix). These patient-reported outcomes were assessed by means of validated instruments.[3,27]

Table 2. Primary and Secondary Blood-Pressure Outcomes.*

Outcome	Intervention Group (N=132)	Control Group (N=171)	Intervention Effect	P Value†
Blood pressure				
Systolic blood pressure — mm Hg‡				
At baseline	152.8±10.3	154.6±12.0		
At 6 mo	125.8±11.0	145.4±15.2		
Change	−27.0±13.7	−9.3±16.0	−21.6 (−28.4 to −14.7)§	<0.001
Diastolic blood pressure — mm Hg				
At baseline	92.2±11.5	89.8±11.2		
At 6 mo	74.7±8.3	85.5±12.0		
Change	−17.5±11.0	−4.3±11.8	−14.9 (−19.6 to −10.3)§	<0.001
Hypertension control at 6 mo — no. (%)				
Blood pressure <140/90 mm Hg	118 (89.4)	55 (32.2)	3.4 (2.5 to 4.6)¶	<0.001
Blood pressure <135/85 mm Hg	109 (82.6)	32 (18.7)	5.5 (2.6 to 11.7)¶	<0.001
Blood pressure <130/80 mm Hg	84 (63.6)	20 (11.7)	5.7 (2.5 to 12.8)¶	<0.001

* Plus–minus values are means ±SD.
† For systolic blood pressure and diastolic blood pressure, P values were calculated from linear mixed-effects models with random intercepts for clusters. The estimated intervention effect was controlled for baseline systolic or diastolic blood pressure, routine doctor, and high cholesterol level. For hypertension control at 6 months, P values were calculated from generalized estimating equations with a compound symmetry working correlation to account for cluster effects. The estimated intervention effect was controlled for baseline systolic blood pressure, routine doctor, and high cholesterol level.
‡ The prespecified primary outcome was the change in systolic blood pressure from baseline to 6 months. The intraclass correlation coefficient from the linear mixed-effects model for change in systolic blood pressure was 0.05. Degrees of freedom for the estimated intervention effect=276.
§ Shown is the difference in mean change in blood pressure and 95% confidence interval.
¶ Shown is the relative risk and 95% confidence interval.

PROCESS DATA

A total of 83 peer-experience stories were generated and posted in intervention shops (Fig. S5 in the Supplementary Appendix). In 6 months, each participant in the intervention group received on average seven in-person pharmacist visits and four follow-up telephone calls from the pharmacist and messaged or called the pharmacist six times. Barbers checked blood pressure in 6 of the 28 intervention shops (average of four checks per participant in these 6 shops) and discussed health lessons in 10 of the 24 control shops (average of four lessons per participant in these 10 shops).

DISCUSSION

Among black men who were barbershop patrons with uncontrolled hypertension, health promotion by barbers resulted in larger reductions in blood pressure when coupled with drug therapy prescribed by specialty-trained pharmacists. The mean reductions in systolic and diastolic blood pressure were 21.6 and 14.9 mm Hg greater, respectively, in participants assigned to the pharmacist-led intervention than in those assigned to the active control. In the intervention group, the rate of cohort retention was 95%, there were few adverse events, and self-rated health and patient engagement increased.

The major strengths of the trial are the intervention effect itself and the high cohort retention. For a community-level trial with a traditionally difficult-to-reach, mainly low-income male population, the net intervention effect on systolic blood pressure was large — an order of magnitude larger than the −2.5 mm Hg effect in our previous barbershop trial[4] and 3 times larger than the average −7 mm Hg effect in pharmacist intervention trials[12-17] involving men with similar baseline systolic blood-pressure levels (approximately 150 mm Hg).[14-17]

The intervention increased the use of antihypertensive drugs. The interventional pharmacists prescribed more combination drug therapy with long-acting first-line drugs than did com-

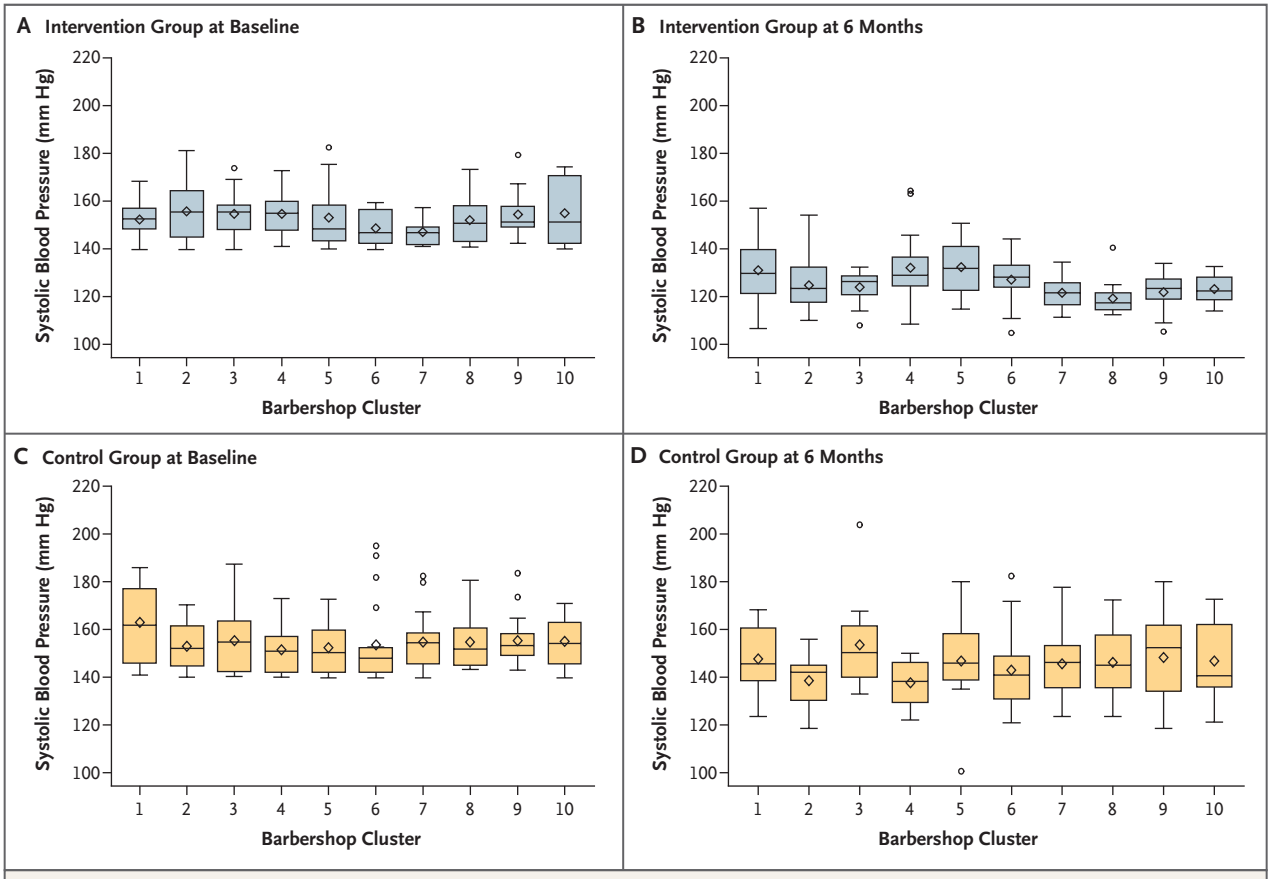

Figure 2. Systolic Blood Pressure at Baseline and 6 Months According to Barbershop Cluster.

Shown are box plots for systolic blood pressure according to barbershop cluster. The horizontal line inside each box indicates the median, the diamond indicates the mean, and the bottom and top of each box indicate the 25th percentile and 75th percentile, respectively. I bars indicate the upper adjacent value (75th percentile plus 1.5 times the interquartile range) and the lower adjacent value (25th percentile minus 1.5 times the interquartile range), and the circles outliers.

munity practitioners treating men in the control group. The starting combination of amlodipine–ARB or amlodipine–ACE inhibitor in the present trial was effective; fewer than half of individual patient regimens involved three or more drugs.

The effectiveness of the intervention was probably multifaceted. Pharmacists made drug therapy convenient by bringing it to the barbershop. The intervention was tailored to black men and endorsed by the involved barbers — trusted community members (as evidenced in the peer-experience stories). That loyal patrons of barbershops are consistent in their visits (every 2 weeks for a decade) facilitated hypertension management in the present trial. Because most patrons in the present trial lived alone, we speculate that peer support at the barbershop facilitated health promotion.

The intervention was implemented largely as intended, but specific elements evolved to meet unexpected challenges. Regimen intensification showed pharmacist fidelity to the medication protocol. The 83 peer-experience posters showed fidelity to the behavior theory (peer learning).[4,32] Because the total clientele size of the barbershops was much smaller than expected, one barbershop owner (the fifth author) recruited approximately 4 times the originally planned number of barbershops. Because barbers did not consistently check blood pressure, pharmacists assumed this role. Because 40% of the participants did not have a doctor to sign the collaborative practice agreement, one main community physician (the next-to-last author) served as their supervising doctor. To avoid delays in laboratory testing, our pharmacists monitored

Table 3. Blood-Pressure Medications at 6 Months.*

Variable	Intervention Group (N=132)	Control Group (N=171)	Mean Difference or Relative Risk (95% CI)†	P Value‡
Mean no. of blood-pressure medications per participant	2.6±0.9	1.4±1.4	1.9 (1.3–2.4)	<0.001
Drug class				
First-line drugs — no. (%)				
ACE inhibitor or ARB	130 (98.5)	71 (41.5)	2.4 (2.0–2.8)	<0.001
Calcium-channel blocker	125 (94.7)	56 (32.7)	3.0 (2.4–3.6)	<0.001
Diuretic	61 (46.2)	49 (28.7)	1.6 (1.3–2.1)	<0.001
Add-on drugs — no. (%)				
Aldosterone antagonist	14 (10.6)	2 (1.2)	7.0 (2.5–19.2)	<0.001
Beta-blocker	14 (10.6)	33 (19.3)	0.5 (0.3–0.8)	0.008

* Plus–minus values are means ±SD. ACE denotes angiotensin-converting enzyme, and ARB angiotensin-receptor blocker.
† Mean difference is shown for number of blood-pressure medications per participant, and relative risk is shown for drug class.
‡ For number of blood-pressure medications per participant, the P value was calculated from linear mixed-effects models with random intercepts for clusters. For drug class, P values were calculated from generalized estimating equations with a compound symmetry working correlation to account for cluster effects. For all P values, the estimated between-group difference was controlled for baseline systolic blood pressure, routine doctor, and high cholesterol level.

plasma electrolyte levels at the point of care — the barbershop.

Our trial has several limitations. The assignment through cluster randomization could not be blinded; however, the intervention was evaluated by independently contracted field interviewers, and blood-pressure measurement and transmission of the values obtained were automated and standardized to minimize interobserver variability. Confounding may have led to overestimation of the effect size of the intervention. Pharmacists targeted an in-barbershop blood pressure of less than 130/80 mm Hg for the participants in the intervention group, whereas primary care providers probably targeted an in-office blood pressure of less than 140/90 mm Hg[33,34] for most participants in the control group. Normotensive office readings that mask high out-of-office blood pressure (masked hypertension) are common in black patients.[35] The number of participants was higher in the control group than in the intervention group, so the control group may have had more patrons who were reluctant to try prescription drugs. Transient blood-pressure elevation with inflation of the arm cuff may have been minimized in participants in the intervention group, who underwent more frequent blood-pressure measurements than participants in the control group. However, the magnitude of the intervention effect appeared substantially larger than that in a previous trial that we conducted in which similar confounding was present,[4] and, in the present trial, the finding was not attenuated in the intention-to-treat analysis.

Sustainability beyond 6 months is being examined in an ongoing extension study. Because this was an efficacy trial, large-scale implementation would require broader inclusion criteria and cost-effective business models. Several aspects of our intervention (blood-pressure measurement and medication protocols) could be adopted by other health care professionals and organizations. We believe that the relatively large intervention effect indicates that such implementation research is warranted.[11]

Our prespecified blood-pressure goal of less than 130/80 mm Hg is consonant with the new 2017 American blood-pressure guidelines, which are more stringent than previous guidelines.[2] Under these new guidelines, approximately 3.5 million more black men in the United States would be considered to have hypertension. If the guidelines are correct, such men might benefit from this intervention.[2] Because currently 58.4% of U.S. black men with hypertension have a blood pressure of 140/90 mm Hg or more, our intervention offers an evidence-based model for implementing these new, more stringent guidelines,[2]

which were influenced by the Systolic Blood Pressure Intervention Trial (SPRINT).[36] Because black men with hypertension often have multiple cardiovascular risk factors,[37] marked reductions in blood pressure — if sustained with the use of our approach and then initiated more widely — might reduce the high rates of hypertension-related disability and death among black men with hypertension in the United States.[11]

In conclusion, medication management that was delivered in barbershops by specialty-trained pharmacists, as compared with standard management afforded by primary care practices, resulted in much larger blood-pressure reductions in black male patrons of those shops who had hypertension.

Supported by the National Institutes of Health (NIH) National Heart, Lung, and Blood Institute (R01HL117983), the NIH National Center for Advancing Translational Sciences UCLA Clinical and Translational Science Institute (UL1TR001881), the California Endowment (grant numbers 20131872 and 20162257), the Lincy Foundation, the Harriet and Steven Nichols Foundation, the Burns and Allen Chair in Cardiology Research at the Smidt Heart Institute, and the Division of Community Relations and Development at Cedars–Sinai Medical Center.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

We dedicate this article to Anthony E. Reid, M.D., the invaluable community cardiologist for the trial, who died shortly before the trial was completed.

REFERENCES

1. Benjamin EJ, Blaha MJ, Chiuve SE, et al. Heart disease and stroke statistics — 2017 update: a report from the American Heart Association. Circulation 2017; 135(10):e146-e603.
2. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2017 November 7 (Epub ahead of print).
3. Victor RG, Leonard D, Hess P, et al. Factors associated with hypertension awareness, treatment, and control in Dallas County, Texas. Arch Intern Med 2008; 168:1285-93.
4. Victor RG, Ravenell JE, Freeman A, et al. Effectiveness of a barber-based intervention for improving hypertension control in black men: the BARBER-1 study: a cluster randomized trial. Arch Intern Med 2011;171:342-50.
5. Rader F, Elashoff RM, Niknezhad S, Victor RG. Differential treatment of hypertension by primary care providers and hypertension specialists in a barber-based intervention trial to control hypertension in Black men. Am J Cardiol 2013;112: 1421-6.
6. Jaffe MG, Lee GA, Young JD, Sidney S, Go AS. Improved blood pressure control associated with a large-scale hypertension program. JAMA 2013;310:699-705.
7. Zullig LL, Bosworth HB. Behavioral interventions to improve hypertension control in the Veterans Affairs healthcare system. J Clin Hypertens (Greenwich) 2014;16:827-37.
8. Khanna RR, Victor RG, Bibbins-Domingo K, Shapiro MF, Pletcher MJ. Missed opportunities for treatment of uncontrolled hypertension at physician office visits in the United States, 2005 through 2009. Arch Intern Med 2012;172: 1344-5.
9. Fontil V, Pletcher MJ, Khanna R, Guzman D, Victor R, Bibbins-Domingo K. Physician underutilization of effective medications for resistant hypertension at office visits in the United States: NAMCS 2006-2010. J Gen Intern Med 2014;29:468-76.
10. Pavlik VN, Chan W, Hyman DJ, et al. Designing and evaluating health systems level hypertension control interventions for African-Americans: lessons from a pooled analysis of three cluster randomized trials. Curr Hypertens Rev 2015;11: 123-31.
11. Whelton PK, Einhorn PT, Muntner P, et al. Research needs to improve hypertension treatment and control in African Americans. Hypertension 2016;68:1066-72.
12. Santschi V, Chiolero A, Colosimo AL, et al. Improving blood pressure control through pharmacist interventions: a meta-analysis of randomized controlled trials. J Am Heart Assoc 2014;3(2):e000718.
13. Cheema E, Sutcliffe P, Singer DR. The impact of interventions by pharmacists in community pharmacies on control of hypertension: a systematic review and meta-analysis of randomized controlled trials. Br J Clin Pharmacol 2014;78:1238-47.
14. Carter BL. Primary care physician-pharmacist collaborative care model: strategies for implementation. Pharmacotherapy 2016;36:363-73.
15. Tsuyuki RT, Houle SK, Charrois TL, et al. Randomized trial of the effect of pharmacist prescribing on improving blood pressure in the community: the Alberta Clinical Trial in Optimizing Hypertension (RxACTION). Circulation 2015; 132:93-100.
16. Anderegg MD, Gums TH, Uribe L, Coffey CS, James PA, Carter BL. Physician-pharmacist collaborative management: narrowing the socioeconomic blood pressure gap. Hypertension 2016;68:1314-20.
17. Svarstad BL, Kotchen JM, Shireman TI, et al. Improving refill adherence and hypertension control in black patients: Wisconsin TEAM trial. J Am Pharm Assoc (2003) 2013;53:520-9.
18. Carter BL, Ardery G. Avoiding pitfalls with implementation of randomized controlled multicenter trials: strategies to achieve milestones. J Am Heart Assoc 2016;5(12):e004432.
19. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. Int J Surg 2011;9:672-7.
20. Eldridge SM, Ashby D, Feder GS, Rudnicka AR, Ukoumunne OC. Lessons for cluster randomized trials in the twenty-first century: a systematic review of trials in primary care. Clin Trials 2004;1:80-90.
21. Roush GC, Ernst ME, Kostis JB, Tandon S, Sica DA. Head-to-head comparisons of hydrochlorothiazide with indapamide and chlorthalidone: antihypertensive and metabolic effects. Hypertension 2015; 65:1041-6.
22. Kaplan NM. Indapamide: is it the better diuretic for hypertension? Hypertension 2015;65:983-4.
23. Anwar YA, Tendler BE, McCabe EJ, Mansoor GA, White WB. Evaluation of the Datascope Accutorr Plus according to the recommendations of the Association for the Advancement of Medical Instrumentation. Blood Press Monit 1997;2: 105-10.
24. Hess PL, Reingold JS, Jones J, et al. Barbershops as hypertension detection, referral, and follow-up centers for black men. Hypertension 2007;49:1040-6.
25. Mancia G, Fagard R, Narkiewicz K, et al. 2013 ESH/ESC guidelines for the management of arterial hypertension: the

Task Force for the management of arterial hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). J Hypertens 2013;31:1281-357.
26. Dashevsky M, Bernstein SL, Barsky CL, Taylor RA. Agreement between serum assays performed in ED point-of-care and hospital central laboratories. West J Emerg Med 2017;18:403-9.
27. Glasgow RE, Wagner EH, Schaefer J, Mahoney LD, Reid RJ, Greene SM. Development and validation of the Patient Assessment of Chronic Illness Care (PACIC). Med Care 2005;43:436-44.
28. Khwaja A. KDIGO clinical practice guidelines for acute kidney injury. Nephron Clin Pract 2012;120(4):c179-c184.
29. Hayes RJ, Moulton LH. Cluster randomised trials. Boca Raton, FL: Chapman & Hall/CRC, 2009.
30. Everitt BS, Landau S, Leese M, Stahl D. Cluster analysis. 5th ed. Chichester, England: John Wiley, 2011.
31. Elashoff RM, Li G, Li N. Joint modeling of longitudinal and time-to-event data. Boca Raton, FL: Chapman & Hall/CRC, 2017.
32. Merzel C, D'Afflitti J. Reconsidering community-based health promotion: promise, performance, and potential. Am J Public Health 2003;93:557-74.
33. Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. JAMA 2003;289:2560-72.
34. James PA, Oparil S, Carter BL, et al. 2014 Evidence-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the Eighth Joint National Committee (JNC 8). JAMA 2014;311:507-20.
35. Franklin SS, O'Brien E, Staessen JA. Masked hypertension: understanding its complexity. Eur Heart J 2017;38:1112-8.
36. The SPRINT Research Group. A randomized trial of intensive versus standard blood-pressure control. N Engl J Med 2015;373:2103-16.
37. Carnethon MR, Pu J, Howard G, et al. Cardiovascular health in African Americans: a scientific statement from the American Heart Association. Circulation 2017;136(21):e393-e423.