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Sustainability of Blood Pressure Reduction in Black Barbershops

Editorial, see p 20

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BACKGROUND: We developed a new model of hypertension care for non-Hispanic black men that links health promotion by barbers to medication management by American Society of Hypertension–certified pharmacists and demonstrated efficacy in a 6-month cluster-randomized trial. The marked reduction in systolic blood pressure (BP) seen at 6 months warranted continuing the trial through 12 months to test sustainability, a necessary precondition for implementation research.

METHODS: We enrolled a cohort of 319 black male patrons with systolic BP ≥140 mm Hg at baseline. Fifty-two Los Angeles County barbershops were assigned to either a pharmacist-led intervention or an active control group. In the intervention group, barbers promoted follow-up with pharmacists who prescribed BP medication under a collaborative practice agreement with patrons' primary care providers. In the control group, barbers promoted follow-up with primary care providers and lifestyle modification. After BP assessment at 6 months, the intervention continued with fewer in-person pharmacist visits to test whether the intervention effect could be sustained safely for 1 year while reducing pharmacist travel time. Final BP and safety outcomes were assessed in both groups at 12 months.

RESULTS: At baseline, mean systolic BP was 152.4 mm Hg in the intervention group and 154.6 mm Hg in the control group. At 12 months, mean systolic BP fell by 28.6 mm Hg (to 123.8 mm Hg) in the intervention group and by 7.2 mm Hg (to 147.4 mm Hg) in the control group. The mean reduction was 20.8 mm Hg greater in the intervention (95% CI, 13.9–27.7; $P<0.0001$). A BP <130/80 mm Hg was achieved by 68.0% of the intervention group versus 11.0% of the control group ($P<0.02$). These new 12-month efficacy data are statistically indistinguishable from our previously reported 6-month data. No treatment-related serious adverse events occurred in either group over 12 months. Cohort retention at 12 months was 90% in both groups.

CONCLUSIONS: Among black male barbershop patrons with uncontrolled hypertension, health promotion by barbers resulted in large and sustained BP reduction over 12 months when coupled with medication management by American Society of Hypertension–certified pharmacists. Broad-scale implementation research is both justified and warranted.

CLINICAL TRIAL REGISTRATION: URL: https://www.clinicaltrials.gov. Unique identifier: NCT 02321618.

*The authors dedicate this article to Ronald G. Victor, MD, the study's architect and our beloved colleague, mentor, and friend who passed away shortly before publication.

Key Words: continental population groups ■ ethnic groups ■ hypertension

Sources of Funding, see page 18

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Clinical Perspective

What Is New?

- A new model of hypertension care for non-Hispanic black men that links health promotion by barbers to medication management by American Society of Hypertension–certified pharmacists demonstrated efficacy in a 6-month cluster-randomized trial.
- The marked blood pressure reduction observed at 6 months was sustained through 12 months with fewer pharmacist visits, which speaks to the portability of the model.
- Given that the results continued to favor the pharmacist-led intervention, broad-scale implementation is warranted.

What Are the Clinical Implications?

- Community-based trials aimed at chronic disease management can be successful in reaching traditionally hard-to-reach, high-risk populations.
- Pharmacists can be valuable members of the multidisciplinary healthcare team but at present are underused in chronic disease management.
- Fidelity to simple treatment algorithms and persistence in adjusting therapy when blood pressure is above goal can markedly improve control rates.

Uncontrolled hypertension is particularly devastating to non-Hispanic black men, who are underrepresented in pharmacist-intervention trials in traditional healthcare settings.[1–6] Health outreach to barbershops is common,[7] but programs have not evaluated efficacy with clinical trial methodology or linked barber-based interventions to a community-partnered, team-based approach.

We created a new model of hypertension care for non-Hispanic black men that links health promotion by barbers to medication management by American Society of Hypertension (ASH)–certified pharmacists and demonstrated efficacy in a 6-month cluster-randomized trial.[8]

In this trial, barbershops were randomized to either a pharmacist-led intervention or an active control group. In the intervention group, barbers promoted follow-up with pharmacists who met with intervention participants at least monthly in their barbershops and prescribed blood pressure (BP) medication under a collaborative practice agreement with primary care providers (PCPs). In the control group, barbers were trained to encourage lifestyle modification and PCP appointments.

The mean reductions in systolic and diastolic BPs (21.6 and 14.9 mm Hg, respectively) at 6 months were impressive for a community-based trial in a traditionally difficult-to-reach, mainly low-income male population. The intervention effect was also 3 times larger than the 7 mm Hg effect shown in other pharmacist-led hypertension intervention trials with similar baseline systolic BP levels (≈150 mm Hg).[1–6]

The results warranted a 6-month extension study as a means of testing sustainability, a necessary precondition for subsequent implementation research. Here, we executed the same protocol for an additional 6 months for all participants with complete data at the end of the initial 6-month trial. The primary hypothesis was that the systolic BP reduction achieved after 6 months would be sustained at 12 months and would continue to favor the pharmacist-led intervention.

METHODS

The data, analytical methods, and study materials will not be made available to other researchers for the purposes of reproducing the results or replicating the procedure.

Study Design and Oversight

Barbershops were the unit of randomization. Participant arm was determined by barbershop (Figure 1, Figure I in the online-only Data Supplement, and protocol at NEJM.org) at baseline and did not change in the 6-month extension study. The study was approved by institutional review boards at Cedars-Sinai Medical Center, Kaiser-Permanente, and Westat (the survey research company that conducted screening and enrollment and collected baseline and follow-up data), with an independent data safety and monitoring board (Section I in the online-only Data Supplement).[9] All participants gave informed written consent.

Study Population

A cohort of 319 self-identified non-Hispanic black men who had complete data at the end of our initial 6-month study were eligible to continue on to the 6-month extension phase. All men were 35 to 79 years of age, were regular patrons of participating barbershops (≥1 haircut every 6 weeks for ≥6 months), and had systolic BP ≥140 mm Hg on 2 screening days at baseline (Figure 1). Men who planned to relocate or were on dialysis or chemotherapy and women were excluded.

Randomization and Interventions

Randomization and intervention methods have been described previously.[8] In brief, cluster randomization was necessary to avoid between-group contamination and to account for intraclass correlation.[10,11] At baseline, barbershops were randomized 1:1 to the intervention and comparison groups. Shop randomization occurred in equally balanced blocks of 4 with a prespecified random-number sequence. Neither participants nor field interviewers could be blinded to barbershop condition assignment. However, baseline and follow-up data were collected by independently contracted field interviewers who were not invested in study outcomes.

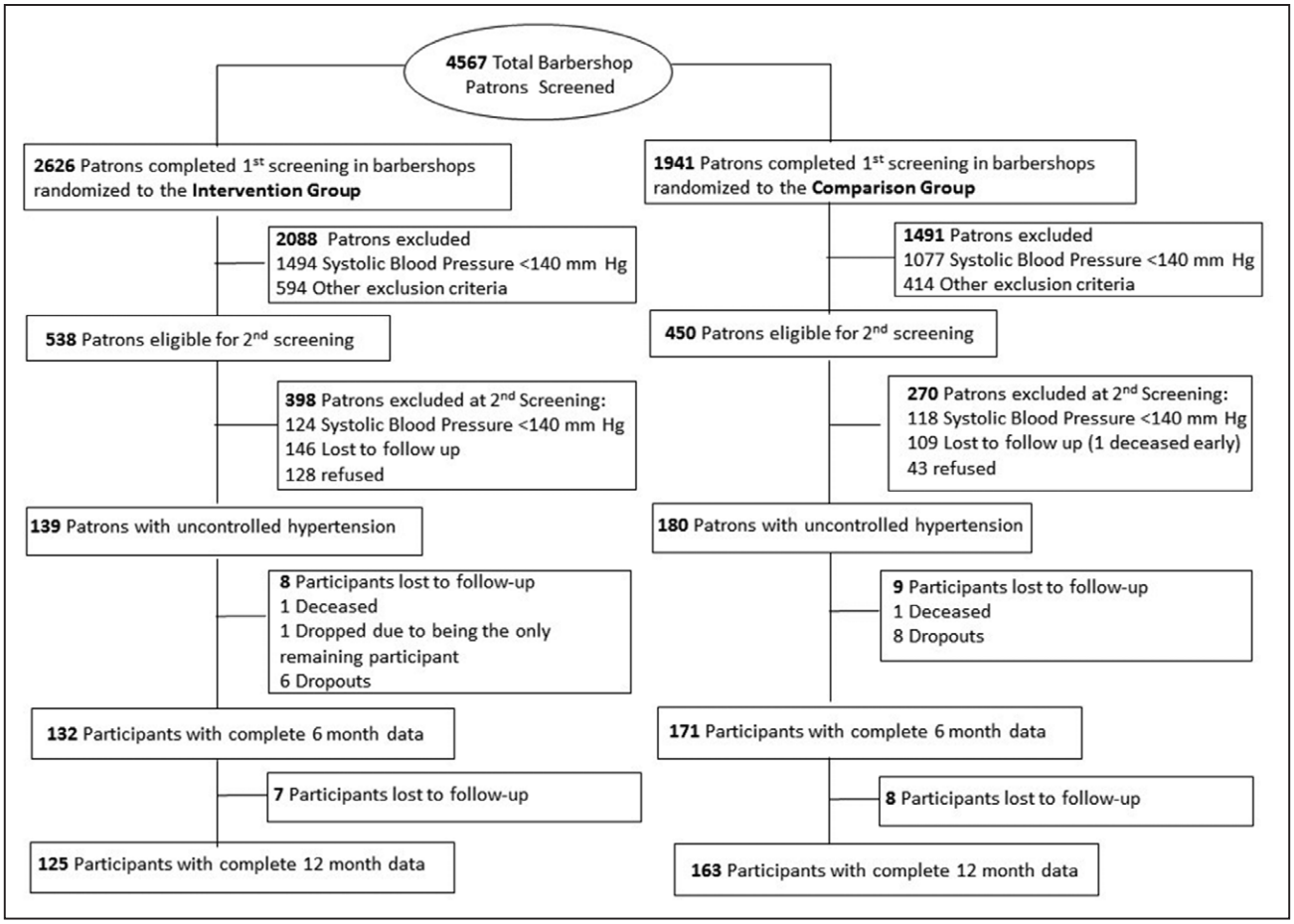

Figure 1. Screening, enrollment, and follow-up of barbershop patrons.
Other exclusion criteria included infrequent barbershop patronage (duration of <6 months or >6 weeks between visits), age <35 or >79 years, receiving either dialysis or cancer chemotherapy, plans to relocate, and incomplete 6-month data.

Barbers in shops randomized to the intervention were trained to encourage pharmacist follow-up and to measure BP. Before pharmacist intervention, participants' PCPs signed a collaborative practice agreement (collaborative practice agreement at NEJM.org) that granted the pharmacists prescriptive authority as per protocol. Two full-time doctoral-level pharmacists (C.A.B, K.L.) received clinical training and ASH certification as hypertension clinicians (Section II in the online-only Data Supplement). They regularly reviewed each participant's progress with physician hypertension specialists (R.G.V., J.H., J.B.), who also consulted on difficult-to-treat cases. Pharmacists met regularly with participants in barbershops in the intervention arm and prescribed a combination antihypertensive drug regimen, measured BP, encouraged lifestyle changes, and monitored plasma electrolytes and creatinine with a Clinical Laboratory Improvement Amendments–waived point-of-care device (i-STAT, Abbott Park, IL).[12] The protocol required pharmacists to first prescribe a 2-drug regimen that insurance would approve, preferably a dihydropyridine calcium channel blocker (eg, amlodipine) combined with either a long-acting angiotensin-converting enzyme inhibitor or an angiotensin receptor blocker. The long-acting thiazide-type diuretic indapamide was the preferred third-line drug,[13,14] followed by an aldosterone antagonist if a fourth drug was needed. Drug class substitutions were allowed when medically indicated. All patients treated at baseline were converted to the preferred regimen. After each encounter with a participant, pharmacists sent progress notes with their contact information to the given participant's healthcare provider to facilitate collaboration (Figure II in the online-only Data Supplement).

In the control group, participants received instruction about BP and lifestyle modification. Barbers were trained to discuss the instructional information with participants and to encourage follow-up with PCPs.

In the extension phase of the study, both groups received the following cohort retention tools that also fostered BP reduction: 9-month follow-up calls on interval health changes, culturally specific health lessons, and monthly haircut vouchers. In intervention shops only, participants received $25 per pharmacist visit to offset costs of generic drugs and pharmacy transportation.

Study Measurements

Field interviewers administered 30-minute structured in-person, computer-based health questionnaires to participants in both arms at baseline and 6 and 12 months. These interviewers recorded BP and structured response data on demographic characteristics, patient-reported outcomes, and prescription information transcribed from pill bottles.

All BPs were measured in barbershops with a validated oscillometric monitor (AccutorrV, Mindray, Mahwah, NJ).[15] To automate measurement and to minimize operator dependence, monitor readings were directly uploaded to a computer that electronically transmitted data to a secure website. Field interviewers, pharmacists, and barbers all used the same automated protocol, which required 5 sequential readings; the first 2 readings were discarded, and the last 3 readings produced a mean value.[16] All parties were trained in proper measurement technique (5 minutes of rest, arm at heart level, no conversation with participants, feet flat, back supported, and no urinary urgency). The correct arm cuff size was determined for each participant at the first screening and used throughout the trial. To reduce regression to the mean, the BP measured at the second screening was taken as the baseline value.[17]

For 12 months, pharmacists and some barbers measured BP monthly to monitor drug therapy in only the intervention arm. Because all BP measurements were attended, the final 12-month BPs were recorded by field interviewers in the control arm and by pharmacists in the intervention arm to minimize the alerting reaction evoked by an unfamiliar data collector.

The prespecified BP goal was <130/80 mm Hg, 5/5 mm Hg lower than the conventional out-of-office BP goal of <135/85 mm Hg[18] (before the release of the 2017 guidelines), to account for BP variability.

Study Outcomes

All study outcomes were taken as changes from baseline to 12 months. The prespecified primary outcome was the change in systolic BP. Secondary outcomes included the change in diastolic pressure, BP goal attainment rates, number of antihypertensive drugs prescribed, adverse drug reactions, self-rated health,[19] and patient engagement by a validated instrument.[20]

Statistical Analysis

With an enrollment target of 10 barbershop clusters per study arm—25 participants per cluster, 70% cohort retention, and an estimated intraclass correlation of 0.01[16]—the initial design yielded 90% power to detect a 6.9 mm Hg greater reduction in systolic BP at 6 months in the intervention versus control arm with a 2-sided α level of 0.05. Because the total number of patrons per barbershop was lower than anticipated, we increased the number of shops and grouped low-enrolling shops into clusters by both enrollment date and geographic proximity, yielding 10 shop clusters per arm with ≥10 participants per cluster.[21,22] The number of dropouts was very small (Figure 1); thus, dropouts were considered random after extensive analysis.[23]

The intervention effect at 12 months was estimated by a linear mixed-effects model, which included a random cluster effect. The primary predictor was an indicator for the intervention versus control arm. Given the sample size, the model included 3 baseline covariates: baseline BP, a PCP for routine medical care, and high cholesterol. These either were strongly correlated with the dependent variable or showed baseline imbalance between arms. The linear mixed-effects model and its assumptions are described in Section II of the online-only Data Supplement.

Longitudinal analysis was performed for all measurements of systolic BP on patients in the intervention arm. The profile plot of systolic BP with the locally estimated scatterplot smoothing curve suggested a more rapid decline in the early stage of the intervention (Figure 2). This nonlinear trend was characterized by piecewise linear splines with a knot at t_0 in

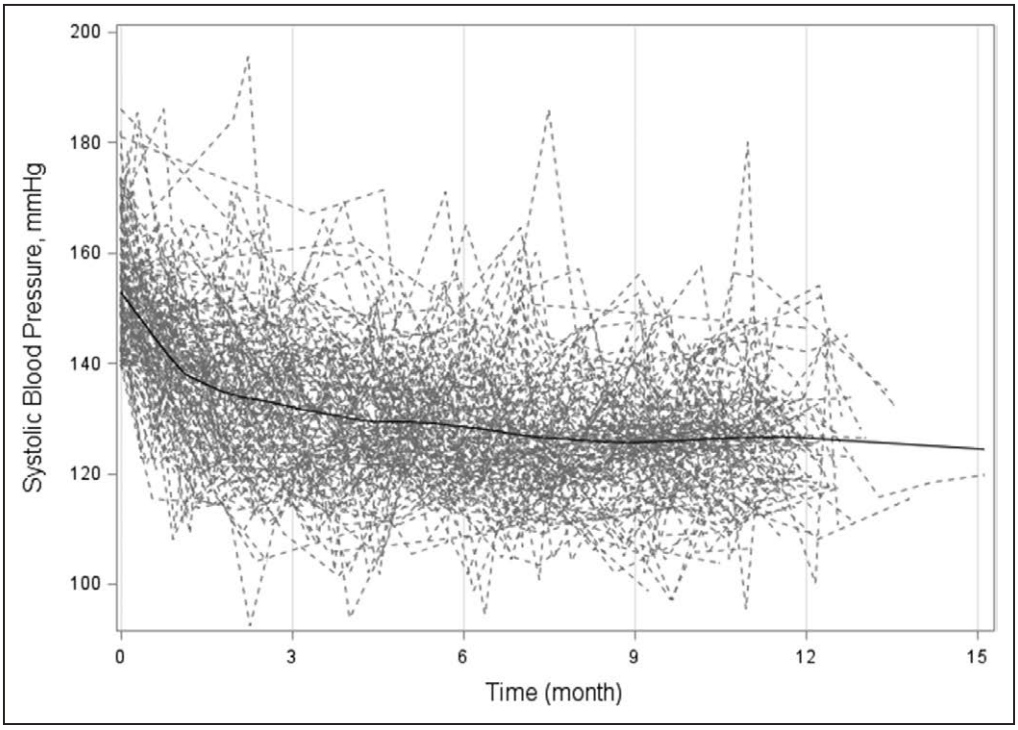

Figure 2. Longitudinal analysis of systolic blood pressure in the intervention group.
Shown is an individual profile plot and locally weighted polynomial regression (locally estimated scatterplot smoothing) curve of systolic blood pressure in the intervention group.

a linear mixed-effects model. The linear trend model and its assumptions are described in the online-only Data Supplement.

RESULTS

Study Sites and Study Participants

Fifty-two Los Angeles County barbershops completed 12-month participation between February 2015 and December 2017 (Figure I in the online-only Data Supplement). The primary statistical analysis is based on 125 participants in 28 intervention shops and 163 participants in 24 control shops that completed a 12-month follow-up (Figure 1). An intention-to-treat analysis also was performed using the last measured BP for 14 participants lost to follow-up in the intervention group and 8 participants lost to follow-up after 6 months in the control group; however, no adjustment for abbreviated treatment could be made for 9 participants lost to follow-up before 6 months in the control group who had only baseline data (Figure 1).

The 2 groups remained well balanced across most characteristics, except a higher percentage of participants in the intervention group had high cholesterol by self-report (Table 1 and Table I in the online-only Data Supplement). Cohort retention at the end of 12 months was 90% in both groups (Figure 1).

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

Characteristic	Intervention	Control
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
No. of patrons screened per shop	90±47	81±43
Participants		
No. of participants	139	180
Age, y	54.4±10.2	54.5±9.4
Married or living with a partner, n (%)	64 (46.4)	88 (48.9)
Highest education, n (%)		
Less than high school	6 (4.5)	15 (8.6)
High school graduate (includes equivalency)	30 (22.6)	51 (29.1)
Some college or associate's degree	68 (51.1)	76 (43.4)
Bachelor's degree	22 (16.5)	23 (13.1)
Graduate or professional degree	7 (5.3)	10 (5.7)
Household income, n (%)†		
<100% of Federal Poverty Level	41 (31.8)	43 (24.4)
100%–300% of Federal Poverty Level	36 (27.9)	48 (27.3)
301%–500% of Federal Poverty Level	26 (20.2)	49 (27.8)
>500% of Federal Poverty Level	26 (20.2)	36 (20.5)
Regular medical care provider, n (%)	106 (76.8)	137 (77.0)
Any health insurance, n (%)	118 (84.9)	155 (86.1)
Barbershop patronage		
Duration of patronage, y	10.4±9.9	11.4±8.8
Frequency of visits, every No. of weeks	2.0±0.9	2.1±1.1
Cardiac risk factors and history‡		
Body mass index, kg/m²§	30.7±5.5	31.2±6.1
Current smoker, n (%)	43 (31.4)	55 (30.6)
Diabetes mellitus, n (%)	31 (22.3)	38 (21.1)
High cholesterol, n (%)	49 (35.3)	44 (24.4)

*Plus-minus values are mean±SD. There were no significant between-group differences ($P<0.05$).

†The 2015 US federal poverty guidelines are based on the total household income and family size. In 2015, the federal poverty threshold was $11,770 for a single person and $4,160 for each additional person.

‡Risk factors and history are by self-report.

§The body mass index is the weight in kilograms divided by the square of the height in meters; both height and weight were by self-report.

Primary Outcome

At baseline, mean systolic BP was similar between the intervention and control groups (152.4 and 154.6 mm Hg respectively; Table 2). At 12 months, mean systolic BP fell 28.6 mm Hg (to 123.8 mm Hg) in the intervention group versus 7.2 mm Hg (to 147.4 mm Hg) in the control group; mean systolic BP reduction was 20.8 mm Hg greater in the intervention group (95% CI, 13.9–27.7 mm Hg; $P<0.0001$; Table 2). Intervention effect size was similar by intention-to-treat analysis with a reduction of 20.6 mm Hg (95% CI, 13.8–27.3 mm Hg; $P<0.0001$; Table 3). The intervention effect was also consistent across barbershop clusters (Figure 3). The change in systolic BP from 6 to 12 months was −1.9±11.6 mm Hg in the intervention group and 2.2±18.4 mm Hg in the control group; the difference in mean change was 1.6 (95% CI, −6.6 to 9.8 mm Hg; $P=0.71$; Table II in the online-only Data Supplement). Longitudinal analysis of systolic BP in the intervention group estimated that the rate of change was −3.4 mm Hg per month (95% CI, −3.9 to −3.0 mm Hg; $P<0.0001$) from baseline to 6 months and −2.0 mm Hg per month (95% CI, −2.2 to −1.8 mm Hg; $P<0.0001$) after 6 months (Figure 2 and Table 4).

Secondary BP Outcomes

Mean diastolic BP reduction was 14.5 mm Hg greater in the intervention group (95% CI, 9.5–19.5 mm Hg; $P<0.0001$), with similar values by intention to treat (Tables 2 and 3 and Figure III in the online-only Data Supplement). A higher percentage of intervention participants achieved the BP goal of <130/80 mm Hg (68.0% of the intervention group versus 11.0% of the control group; $P=0.0177$; Table 2).

Changes in Medication and PCP Visits

The intervention led to a greater number of antihypertensive drug classes per regimen and higher percentages of participants treated with preferred first-line drugs, add-

Table 2. Primary and Secondary Blood Pressure Outcomes at 12 Months*

BP	Intervention (n=125)	Control (n=163)	Intervention Effect	
			Difference in Mean Change of BP (95% CI)	P Value†
Systolic BP, mm Hg‡				
Baseline	152.4±10.1	154.6±12.0		
At 12 mo	123.8±8.8	147.4±15.7		
Change	−28.6±12.7	−7.2±17.7	−20.8 (−27.7 to −13.9)	<0.0001
Diastolic BP, mm Hg				
Baseline	91.9±11.3	89.8±11.3		
At 12 mo	74.1±8.2	86.5±12.6		
Change	−17.8±11.9	−3.3±11.2	−14.5 (−19.5 to −9.5)	<0.0001
Hypertension control rate after 12 mo, n (%)			Odds Ratio (95% CI)	P Value§
BP <140/90 mm Hg	118 (94.4)	47 (28.8)	3.3 (1.8 to 6.1)	0.0001
BP < 135/85 mm Hg	110 (88.0)	24 (14.7)	6.7 (2.3 to 18.9)	0.0004
BP <130/80 mm Hg	85 (68.0)	18 (11.0)	9.1 (1.5 to 56.6)	0.0177

BP indicates blood pressure.

*Plus-minus values are mean±SD.

†*P* values calculated from linear mixed-effects models with random intercepts for clusters. The estimated intervention effect was controlled for baseline systolic BP (or diastolic BP), primary care provider, and high cholesterol.

‡Prespecified primary outcome. Intraclass correlation coefficient from the linear mixed-effects model for change in systolic BP is 0.01.

§*P* values 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 BP, primary care provider, and high cholesterol.

on drugs (Table 5 and Table III in the online-only Data Supplement), and long-acting drugs (eg, indapamide versus hydrochlorothiazide; Table IV in the online-only Data Supplement). After 12 months, antihypertensive medication use increased from 57% to 100% in the intervention group and from 53% to 65% in the control group (*P*<0.001; Table IV in the online-only Data Supplement).

The intervention and control groups reported similar mean numbers of PCP visits in the past 3 months at baseline (1.0±1.2 and 1.2±1.4); however, at 12

Table 3. Intention-to-Treat Analysis: Primary and Secondary Blood Pressure Outcomes at 12 Months*

BP	Intervention (n=139)	Control (n=171)	Intervention Effect	
			Difference in Mean Change of BP (95% CI)	P Value†
Systolic BP, mm Hg‡				
Baseline	153.1±10.6	154.6±12.0		
At 12 mo	125.1±9.9	147.5±16.0		
Change	−28.1±13.7	−7.2±17.6	−20.6 (−27.3 to −13.8)	<0.0001
Diastolic BP, mm Hg				
Baseline	92.6±11.8	89.8±11.2		
At 12-month	77.5±17.1	89.4±18.4		
Change	−15.2±17.9	−0.4±17.5	−18.9 (−27.2 to −10.7)	<0.0001
Hypertension control rate after 12 mo, n (%)			Relative Risk (95% CI)	P Value§
BP <140/90 mm Hg	118 (84.9)	55 (32.2)	3.2 (2.3 to 4.4)	<0.0001
BP < 135/85 mm Hg	109 (78.4)	32 (18.7)	5.2 (2.4 to 11.3)	<0.0001
BP <130/80 mm Hg	84 (60.4)	20 (11.7)	5.4 (2.4 to 12.3)	<0.0001

BP indicates blood pressure.

*Plus-minus values are mean±SD.

†*P* values calculated from linear mixed-effects models with random intercepts for clusters. The estimated intervention effect was controlled for baseline systolic BP (or diastolic BP), primary care provider, and high cholesterol.

‡Prespecified primary outcome. Intraclass correlation coefficient from the linear mixed-effects model for change in systolic BP is 0.02.

§*P* values 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 BP, primary care provider, and high cholesterol.

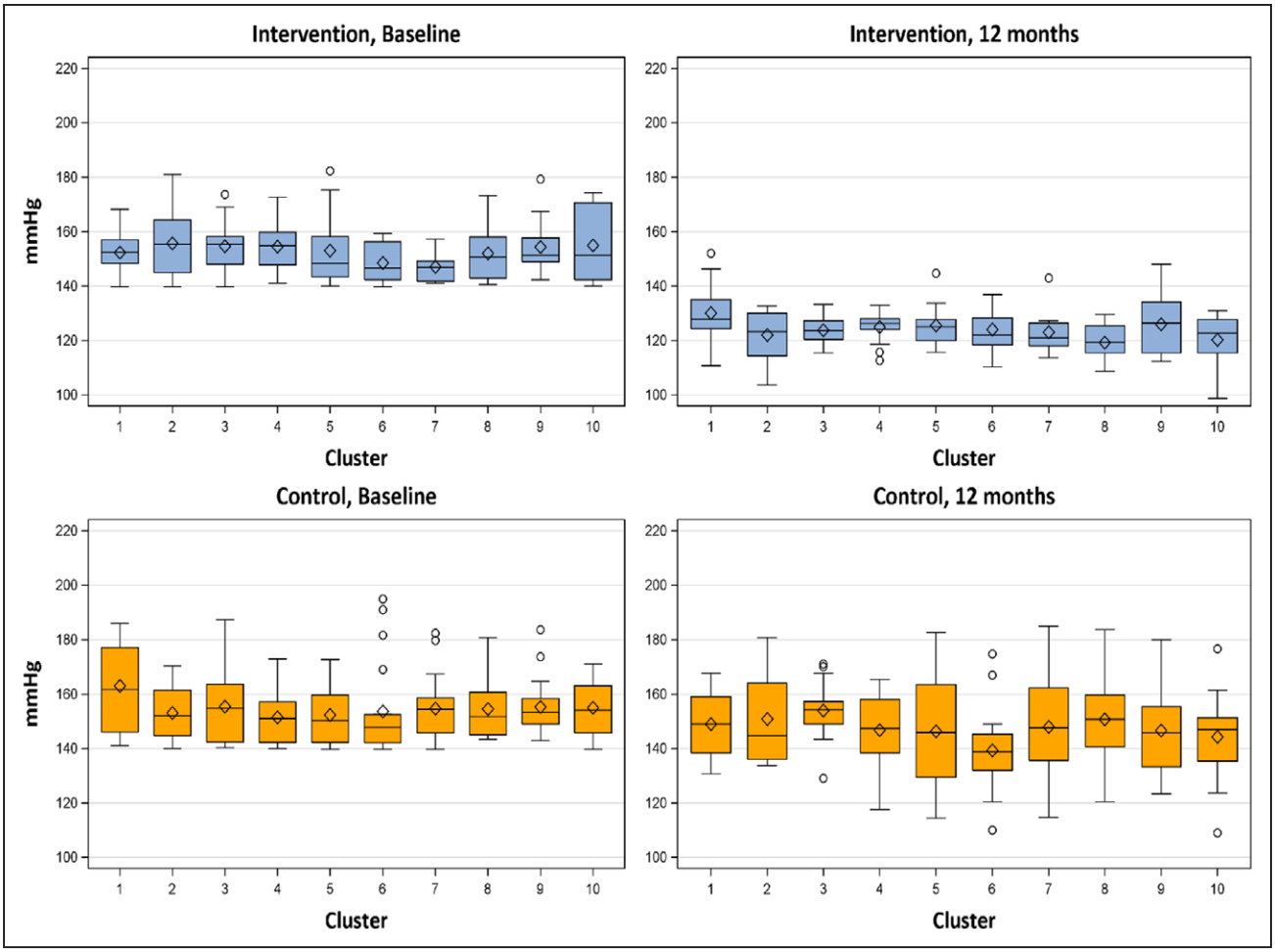

Figure 3. Systolic blood pressure at baseline and 12 months according to barbershop cluster.
Shown are box plots for systolic blood pressure according to barbershop cluster. The horizontal line inside each box indicates the median; the diamond indicates the mean; and the bottom and top of each box indicate the 25th 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 indicate outliers.

months, the intervention group reported a greater number of PCP visits (1.5±1.8 and 1.1±1.5; *P*=0.0329). This suggests that the pharmacist intervention did not interfere with the patient-PCP relationship and perhaps influenced the increase in PCP visits.

Safety Outcomes

There were no treatment-related serious adverse events or deaths related to trial participation in either group. Changes in medication side effects were similar across groups, with few exceptions (Table V in the online-only Data Supplement). There were no cases of acute kidney injury in the extension phase of the study compared with the 3 reversible cases documented in the first 6 months. We had no control group data on acute kidney injury.

Patient-Reported Outcomes

Self-rated health and patient engagement scores increased more in the intervention group (Tables VI and VII in the online-only Data Supplement) as judged by validated instruments.[19,20]

Process Data

Time from baseline to study completion was 12.0±1.0 months in the control group and 11.5±0.9 months in the intervention group. In that time, each intervention participant received an average of 11 in-person pharmacist visits (7 in months 0–6 and 4 in months 7–12). Barbers checked BP in 6 of 28 intervention shops (4 checks per participant) and discussed health

Table 4. Longitudinal Analysis of Systolic Blood Pressure in the Intervention Group (Baseline to 12 Months)

Effect	Estimate	95% CI	P Value
Rate of change (per month) from baseline to 6 mo	−3.4	−3.9 to −3.0	<0.0001
Rate of change (per month) after 6 mo	−2.0	−2.2 to −1.8	<0.0001
Age	−0.1	−0.2 to 0.01	0.09

Table 5. Blood Pressure Medications at 12 Months*

No. of BP Medications per Participant	Intervention (n=125)	Control (n=163)	Difference at 12 mo (95% CI)	P Value†
Mean	2.7±0.9	1.4±1.3	2.0 (1.4 to 2.6)	<0.0001
Drug class, n (%)			Odds Ratio at 12 mo (95% CI)	P Value‡
First-line drugs				
ACE inhibitor or ARB	122 (97.6)	70 (42.9)	62.0 (19.2 to 200.0)	<0.0001
Calcium channel blocker	118 (94.4)	59 (36.2)	39.2 (17.4 to 88.2)	<0.0001
Diuretic	60 (48.0)	48 (29.5)	2.5 (1.5 to 4.0)	0.0002
Add-on drugs				
Aldosterone antagonist	15 (12.0)	2 (1.2)	15.5 (4.7 to 51.1)	<0.0001
β-Blocker	15 (12.0)	31 (19.0)	0.6 (0.4 to 0.9)	0.0183
α-Blocker	2 (1.6)	8 (4.9)	0.3 (0.1 to 1.2)	0.0981
Central sympatholytic	1 (0.8)	6 (3.7)	‖	‖
Direct vasodilator§	0 (0)	7 (4.3)	‖	‖

ACE indicates angiotensin-converting enzyme; ARB, angiotensin-receptor blocker; and BP, blood pressure.

*Plus-minus values are mean±SD.

†*P* values calculated from linear mixed-effects models with random intercepts for clusters. The estimated between-group difference was controlled for baseline systolic BP (or diastolic BP), primary care provider, and high cholesterol.

‡*P* values calculated from generalized estimating equations with a compound symmetry working correlation to account for cluster effects. The estimated between-group difference was controlled for baseline systolic BP, primary care provider, and high cholesterol.

§The direct vasodilator was hydralazine.

‖Odds ratio and *P* value not available because of very low or zero counts.

lessons in 10 of 24 comparison shops (4 lessons per participant).

DISCUSSION

Among black male barbershop patrons with uncontrolled hypertension, health promotion by barbers resulted in large and sustained BP reduction when coupled with medication management conveniently delivered in their barbershops by ASH-certified pharmacists. The mean reductions in systolic and diastolic BPs observed at 12 months are statistically indistinguishable from our previously reported 6-month data[8] despite fewer interactions with the pharmacists in the second 6 months of the trial (7±2 versus 4±2 visits). The observed 90% cohort retention, few treatment-related adverse events, and improved patient satisfaction and self-rated health strongly suggest sustainability of our hypertension detection and treatment model.

We attribute the intervention potency to several factors. More intensive drug therapy with more combination regimens, more first-line BP drugs, and more long-acting drugs largely explain the enhanced BP reduction observed in our intervention group compared with standard treatment by community physicians. In a departure from most guidelines[24] that recommend thiazide-type diuretics and calcium channel blockers as first-line treatment for black men, our starting regimen of an angiotensin receptor blocker or angiotensin-converting enzyme inhibitor plus amlodipine was well tolerated and proved very effective, with only 50% of regimens requiring ≥3 drugs.

Unlike other pharmacist intervention trials[1–6] that required travel to traditional healthcare settings such as clinics or pharmacies, our pharmacists made treatment more convenient by bringing drug therapy and monitoring to the patrons in their barbershops, a uniquely personal and readily accessible nontraditional setting. Our model was tailor-made for black men by addressing sex-specific issues of black men (ie, underuse of health care resulting from long-standing issues related to distrust of the medical profession) and enlisting barbers (trusted community members) to deliver health messages. Our trial differs from other National Heart, Lung, and Blood Institute–funded hypertension trials that consider black men and women as 1 group.[25] Finally, the participants' loyal patronage (with average barbershop visit every 2 weeks for over a decade) facilitated frequent follow-up and contributed to cohort retention.

As previously reported,[8] the study has several limitations. The lower participation rate in the intervention group may reflect lay misgivings about prescription drugs, but treatment rates were similar at baseline, and the large effect on rates of antihypertensive drug treatment at 12 months (100% in the intervention group versus 65% in the control group) and the drug-regimen intensity (2 more antihypertensive drug classes per intervention participant than control-group participant) bolster the validity of our primary outcome.[26,27] Assignment through cluster randomization could not be blinded; however, the intervention was evaluated by an independent survey research company, and BP was measured with a validated automated monitor and data capture software that eliminated human transcription error. The multiple-reading BP protocol was designed to reduce falsely high readings by habituation of the alerting reaction to arm cuff inflation; however, habituation was likely greater among the intervention participants, for whom barbershop BP measurement became routine. End-of-study BP measurements were not recorded by individuals blinded to treatment condition but instead by pharmacists in the intervention group and field interviewers in the control group in an effort to minimize the alerting reaction evoked by an unfamiliar data collector. Financial incentives were used in both groups for cohort retention ($25 monthly haircut vouchers) and in the intervention group to offset the cost of generic drugs ($25 reimbursement for pharmacist visits). Although we cannot discount any effect of financial incentives on the

outcome of our multifaceted intervention, data suggest they have a small (but not insignificant) effect on medication adherence.[28] Finally, our BP goal of <130/80 mm Hg (which was influenced by the SPRINT trial [Systolic Blood Pressure Intervention Trial[29]]) was likely lower than the goal of <140/90 mm Hg that most community physicians would have targeted before the release of the 2017 American College of Cardiology/American Heart Association guidelines.[24]

The results presented here successfully demonstrate both efficacy and sustainability and now warrant broad-scale implementation research. Toward that end, cost-effectiveness is being assessed to determine fiscally viable business models and to assess potential savings to public and private payers. An initial pilot study is also underway to assess whether these results can be replicated in a different city and with a different pharmacist-led team.

Beyond that, scalability will depend on our ability to adapt the model to create operational efficiencies while maintaining intervention potency. One of the most significant time-consuming aspects of this trial was the amount of time that pharmacists spent traveling to and from barbershops. Although we found that the initial in-person visits between the pharmacist, barber, and patron were essential for establishing trust, once rapport was established and BP control was achieved, the need for in-person pharmacist intervention decreased (as evidenced by the drop in number of visits in the extension phase of the study). Telemonitoring, which has worked well in trials involving predominantly nonblack participants and shown some success in 1 trial involving exclusively black participants,[30–33] may constitute an appropriate means of maintaining/sustaining the intervention effect while also addressing this logistical inefficiency.

Perhaps the most critical first step toward widespread dissemination of our model is the expansion of collaborative practice between pharmacists and physicians or the elimination of the requirement altogether (as in Canada and the United Kingdom).[34] Although team-based care models that include pharmacists have proved to be an effective way to manage chronic disease, many states have been slow to adopt broad collaborative practice authorities for pharmacists. Board certification and other credentialing opportunities (ie, ASH certification) that prepare pharmacists for advanced patient care may help allay concerns about pharmacist readiness for an expanded scope of practice.

CONCLUSIONS

Intensive medication management delivered in barbershops by ASH-certified pharmacists compared with standard management afforded by primary care practices resulted in large and sustained BP reduction in the shops' hypertensive black male patrons. Our results indicate that our new model of hypertension care can succeed in reaching high-risk hypertensive populations and markedly improve control rates with simple treatment algorithms, frequent follow-up, and persistence in adjusting therapy when BP remains above goal.[35]

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R.G.V. and R.M.E. designed the study and trained field interviewers. C.A.B. and K.L. gathered data. R.M.E., N.L., L.C.C., and R.G.V analyzed the data. R.G.V. and R.M.E. vouch for the data and analysis. R.G.V. and C.A.B. wrote the paper. All coauthors decided to publish.

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Dr Rader is a consultant for Recor Medical. The other authors report no conflicts.

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