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Sustainability of Blood Pressure Reduction in Black Barbershops

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Abstract

Background—We developed a new model of hypertension (HTN) care for non-Hispanic black men that links health promotion by barbers to medication management by specialty-trained pharmacists and demonstrated efficacy in a 6-month randomized trial (Victor et al., NEJM, 2018). 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 subsequent implementation research.

Methods—We enrolled a cohort of 319 black male patrons with systolic BP ≥ 140 mm Hg at baseline, in a cluster-randomized trial. 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 (PCPs). In the control group, barbers promoted follow-up with PCPs and lifestyle modification. After BP assessment at 6 months, the intervention continued with fewer in-person pharmacist visits to test if the intervention effect could be sustained safely for one year while reducing pharmacist travel time to and from barbershops. 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 with the intervention (95% confidence interval, 13.9 to 27.7; $p < 0.0001$). A goal BP < 130/80 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

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

DISCLOSURES

Dr. Florian Rader is a consultant for Recor Medical. All other authors have nothing to disclose.

events occurred in either group over 12 months. Cohort retention at 12 months was 90% in both groups.

Conclusion—Among black male barbershop patrons with uncontrolled HTN, health promotion by barbers resulted in large and sustained BP reduction when coupled with medication management by specialty-trained pharmacists. Broad-scale implementation research is both justified and warranted.

Clinical Trial Registration—ClinicalTrials.gov,

INTRODUCTION

Undertreatment of 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 nor linked barber-based interventions to a community-partnered, team-based approach.

We created a new model of hypertension (HTN) care for non-Hispanic black men that links health promotion by barbers to medication management by specialty-trained 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 (CPA) with primary care providers (PCP). In the control group, barbers were trained to encourage lifestyle modification and doctor's appointments.

The mean reductions in systolic and diastolic BP (−21.6 mm Hg 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 HTN intervention trials with similar baseline systolic blood pressure levels (~150 mmHg).[1–6]

The results warranted a 6-month extension study as a means of testing sustainability, a necessary pre-condition 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 blood pressure reduction achieved after 6-months would be sustained at 12-months and would continue to favor the pharmacist-led intervention.

METHODS

Study Design and Oversight

Barbershops were the unit of randomization. Participant arm was determined by barbershop (Fig. 1, Fig. S1 in Supplementary Appendix**, 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 (survey research company that conducted screening and enrollment and collected baseline and follow-up data), with an independent data safety and monitoring board.[9] All participants gave informed written consent.

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

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 35–79 years of age, regular patrons of participating barbershops (≥ 1 haircut every 6 weeks for ≥ 6 months) and had systolic blood pressure ≥140 mm Hg on two screening days at baseline (Fig. 1). Men who planned to relocate, 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 intra-class correlation (ICC).[10,11] At baseline, barbershops were randomized 1:1 to intervention and comparison groups. Shop randomization occurred in equally balanced blocks of four using a pre-specified 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.

Barbers in shops randomized to the intervention were trained to encourage pharmacist follow-up and measure blood pressure. Before pharmacist intervention, participant's PCP's signed a CPA (Section S3 in the Supplementary Appendix). Two fulltime doctoral-level pharmacists (C.A.B, K.L.) received specialized training and certification as hypertension clinicians and regularly reviewed each participant's treatment with physician hypertension specialists (R.G.V., J.H., J.B.). Pharmacists met regularly with participants in barbershops in the intervention arm and prescribed a combination antihypertensive drug regimen; measured blood pressure; encouraged lifestyle changes; and monitored plasma electrolytes and creatinine, with a CLIA-waived point-of-care device (i-STAT, Abbott Park, Illinois).[12] The protocol required pharmacists to first prescribe a two-drug regimen that insurance would approve—preferably a dihydropyridine calcium-channel blocker (e.g. amplodipine) combined with either a long-acting angiotensin-converting–enzyme inhibitor (ACE-I) or angiotensin-receptor blocker (ARB). 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. After each encounter with a participant, pharmacists sent progress notes with their contact information to the given participant's healthcare provider.

In the control group participants received instruction about blood pressure and lifestyle modification (Fig. S2 in the Supplementary Appendix). Barbers were trained to discuss the instructional information with participants and encourage follow-up with primary care providers.

In the extension phase of the study, both groups received the following cohort retention tools that also fostered blood pressure 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 questionnaire to participants in both arms at baseline, 6 and 12 months. These interviewers recorded blood pressure and structured response data on demographic characteristics, patient-reported outcomes, and prescription information transcribed from pill bottles.

All blood pressures were measured in barbershops using a validated oscillometric monitor (AccutorrV, Mindray, Mahwah, NJ).[15] To automate measurement and 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 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 second screening blood pressure was taken as the baseline value.[17]

For 12 months, pharmacists and some barbers measured blood pressure monthly to monitor drug therapy in only the intervention arm. The final 12-month blood pressures 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 pre-specified blood pressure goal was <130/80 mmHg – 5/5 mm Hg lower than the conventional out-of-office blood pressure goal of <135/85 mmHg[18] (prior to the release of the 2017 guidelines) – to account for blood pressure variability.

Study Outcomes

All study outcomes were taken as changes from baseline to 12 months. The pre-specified primary outcome was the change in systolic blood pressure. Secondary outcomes included the change in diastolic pressure, blood pressure 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 ICC of 0.01[16] — the initial design yielded 90% power to detect a −6.9 mmHg greater reduction in systolic blood pressure at 6 months in the intervention versus control arm with a 2-sided alpha level of 0.05. Due to the total number of patrons per barbershop being 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 (Fig. 1) and thus 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 intervention versus control arm. Given the sample size, the model included three baseline covariates – baseline blood pressure, a doctor for routine medical care, and high cholesterol. These were either strongly correlated with the dependent variable or showed baseline imbalance between arms.

The linear mixed effects model and its assumptions were as follows:

$$Y_{ij} = \beta_0 + \beta_1 arm_i + \beta_2 baseline\_BP_{ij} + \beta_3 routine\_doctor_{ij} + \beta_4 high\_cholesterol_{ij} + \beta_5 arm_i \times routine\ \ doctor_{ij} + \beta_6 arm_i \times high\_cholesterol_{ij} + b_i + \varepsilon_{ij},$$

where Y_{ij} was the change in systolic or diastolic blood pressure from baseline to 12 months for patient j in cluster i, β_1 was the main intervention effect with $arm_i = 1$ if the i-th cluster was in the intervention group and $arm_i = 0$ if in the comparison group, and β_2 to β_4 were fixed effects of the baseline patient-level covariates. We also included the interaction between intervention and each of the covariates, routine doctor and high cholesterol. The random cluster effect b_i was assumed to be $N\left(0, \sigma_b^2\right)$, and the measurement error ε_{ij} for the j-th individual in the i-th cluster was assumed to be $N\left(0, \sigma_\varepsilon^2\right)$. We further assumed that b_i was independent of the measurement error ε_{ij} and that ε_{ij}'s were mutually independent. The ICC was calculated as $\sigma_b^2/(\sigma_b^2 + \sigma_\varepsilon^2)$. For change in systolic blood pressure, the actual calculated ICC was 0.01. For binary secondary outcomes, we used generalized estimating equations with a compound symmetry working correlation matrix to estimate the invention effect while controlling for the above covariates.

Longitudinal analysis was performed for the repeated measurements of systolic blood pressure on patients in the intervention arm. The profile plot of systolic blood pressure with the loess curve suggested a more rapid decline in the early stage of the intervention (Fig. 2). This non-linear trend was characterized by piece-wise linear splines with a knot at t_0 in the following linear mixed effects model:

$$Y_{ij}(t) = \beta_0 + \beta_1 t_1 + \beta_2 t_2 + \beta_3 age_{ij} + b_i + b_{ij0} + b_{ij1} t_1 + b_{ij2} t_2 + \varepsilon_{ij}(t),$$

where $Y_{ij}(t)$ was the systolic blood pressure measured at time t for patient j in cluster i, $t_1 = t$ if $t \leq t_0$ and $t_1 = 0$ if otherwise, and $t_2 = 0$ if $t \leq t_0$ and $t_2 = t$ if otherwise, so that β_1 was the slope for $t \leq t_0$ and β_2 is the slope for $t > t_0$. The analysis was adjusted for baseline age which was found to be associated with intervention systolic blood pressure in our preliminary analysis ($p < 0.1$). The random cluster effect b_i was assumed to be $N\left(0, \sigma_b^2\right)$, and the measurement error $\varepsilon_{ij}(t)$ for the j-th individual in the i-th cluster was assumed to be $N\left(0, \sigma_\varepsilon^2\right)$. The random effects b_{ij0}, b_{ij1}, and b_{ij2} characterized individual-level heterogeneity in the intercept and two piece-wise linear time trends and were posited to be $N(0, \Sigma)$. Finally, we assumed b_i, $\varepsilon_{ij}(t)$, and $(b_{ij0}, b_{ij1}, b_{ij2})$ were mutually independent. We estimated the model for different locations of t_0 and compared the goodness of fit using AIC. The knot at 6 months provided the best fit and thus was chosen as the final model.

RESULTS

Study Sites and Study Participants

Fifty-two Los Angeles County barbershops completed 12-month participation between February 2015 to December 2017 (Fig. S1 in Supplementary Appendix). The primary statistical analysis is based on 125 participants in 28 intervention shops and 163 participants in 24 control shops that completed 12-month follow-up (Fig. 1). An intention-to-treat (ITT) analysis also was performed, using the last measured blood pressure 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 prior to 6 months in the control group who had only baseline data (Fig. 1).

The two 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 S1 in Supplementary Appendix). Cohort retention at the end of 12 months was 90% in both groups (Fig. 1).

Primary Outcome

At baseline, mean systolic blood pressure was similar between intervention and control groups (152.4 mmHg and 154.6 mm Hg respectively; Table 2). At 12 months, mean systolic pressure fell −28.6 mm Hg (to 123.8 mm Hg) in the intervention group versus −7.2 mmHg (to 147.4 mm Hg) in the control group; mean systolic blood pressure reduction was −20.8 mmHg greater in the intervention group (95% confidence interval [CI], −13.9 to −27.7 mmHg; P <0.0001; Table 2). Intervention effect size was similar by ITT analysis: −20.6 mmHg (95% [CI], −13.8 to −27.3 mmHg; P <0.0001; Table 3). The intervention effect was also consistent across barbershop clusters (Fig. 3). The change in systolic BP from 6 months

to 12 months was −1.9 ± 11.6 mm Hg in the intervention group and 2.2 ± 18.4 mm Hg the control group; the difference in mean change was 1.6 (95% confidence interval [CI], −6.6 to 9.8 mm Hg; P = 0.71; Table S2 in Supplementary Appendix). Longitudinal analysis of systolic BP in the intervention group estimated that the rate of change was −3.4 mmHg per month (95% [CI], −3.9 to −3.0 mmHg; p <0.0001) from baseline to 6 months and −2.0 mmHg per month (95% [CI], −2.2 to −1.8 mmHg; p <0.0001) after 6 months (Fig 2 and Table 4).

Secondary Blood Pressure Outcomes

Mean diastolic blood pressure reduction was −14.5 mm Hg greater in the intervention group (95% [CI], −9.5 to −19.5 mm Hg; P <0.0001), with similar values by ITT (Table 2 and Table 3, Fig. S4 in Supplementary Appendix). A higher percentage of intervention participants achieved blood pressure goal of <130/80 (68.0% intervention group versus 11.0% control group; Table 2).

Changes in Medication and Doctors Visits

The intervention led to a greater number of antihypertensive drug classes per regimen and higher percentages of participants treated with preferred first-line, add-on drugs (Table 5 and Table S3 in Supplementary Appendix), and long-acting drugs (e.g., indapamide versus hydrochlorothiazide) (Table S4 in Supplementary Appendix). 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 S4 in Supplementary Appendix).

Intervention and control groups reported similar mean numbers of doctor visits in the past 3 months at baseline (1.0 ± 1.2 and 1.2 ± 1.4), however at 12 months the intervention group reported a greater number of doctors' 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-doctor relationship and perhaps enhanced it.

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 S5 in Supplementary Appendix). There were no cases of acute kidney injury in the extension phase of the study, as compared to 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 S6, S7 in Supplementary Appendix) 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 to 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 to 6 and 4 in months 7

to 12). Barbers checked blood pressure in 6 of 28 intervention shops (4 checks /participant) and discussed health lessons in 10 of 24 comparison shops (4 lessons/participant).

DISCUSSION

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

Major strengths of this study are the large intervention effect and notable cohort retention in both groups. We attribute the intervention potency to several factors. More intensive drug therapy using more combination regimens, more first-line blood pressure drugs, and more long-acting drugs largely explains the enhanced blood pressure reduction observed in our intervention group compared with standard treatment by community physicians. In a departure from most guidelines[24,25] that recommend thiazide-type diuretics as first-line for black men, our starting regimen of amlodipine plus an ARB or ACE-I was well-tolerated and proved very effective with only 50% of regimens requiring three or more drugs.

Unlike other pharmacist intervention trials[1–6] that required travel to traditional healthcare settings like 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 non-traditional setting. Our model was tailor-made for black men by addressing gender-specific issues of black men (i.e. underutilization of healthcare due to longstanding issues related to distrust of the medical profession) and enlisting barbers (trusted community members) to deliver health messages. Our trial differs from other NHLBI-funded hypertension trials that consider black men and women as one group.[26] 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 vs. 65% in the control group) and drug-regimen intensity (2 more antihypertensive drug classes per intervention participant than control-group participant bolster the validity of our primary outcome.[27,28] Condition assignment could not be blinded; however, the intervention was evaluated by an independent survey research company and blood pressure was measured using an validated automated monitor and data capture software that eliminated human transcription error. The multiple reading blood pressure 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 blood pressure measurement became routine. Financial incentives were used to off-set the cost of generic drugs used in the intervention. However, published data suggest that financial incentives have little effect on medication adherence.[29] Finally, our blood pressure goal of <130/80 (which was influenced by the Systolic Blood Pressure Intervention Trial – SPRINT[30]) was likely lower than the <140/90 goal most community physicians would have targeted prior to the release of the 2017 ACC/AHA guidelines.[25]

The results presented herein successfully demonstrate both efficacy and sustainability, and now warrant broad scale implementation research. Towards that end, cost-effectiveness is being assessed to determine fiscally viable business models and to assess potential savings to public and private payors. 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 in this trial was the amount of time pharmacists spent traveling to and from barbershops. While we found that the initial in-person visits between the pharmacist, barber, and patron were essential for establishing trust, once rapport was established and blood pressure control 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 one trial involving exclusively black participants[31–34], may constitute an appropriate means of maintaining/sustaining the intervention effect whilst also addressing this logistical inefficiency.

Perhaps the most critical first step towards 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 UK)[35]. While team-based care models that include pharmacists have proven an effective way to manage chronic disease, many states have been slow to adopt broad collaborative practice authorities for pharmacists.

In conclusion, intensive medication management delivered in barbershops by specialty-trained pharmacists, as compared to standard management afforded by primary care practices, resulted in large and sustained blood pressure reduction in the shops' hypertensive black male patrons. Our results indicate that our new model of HTN 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 blood pressure remains above goal.[36]

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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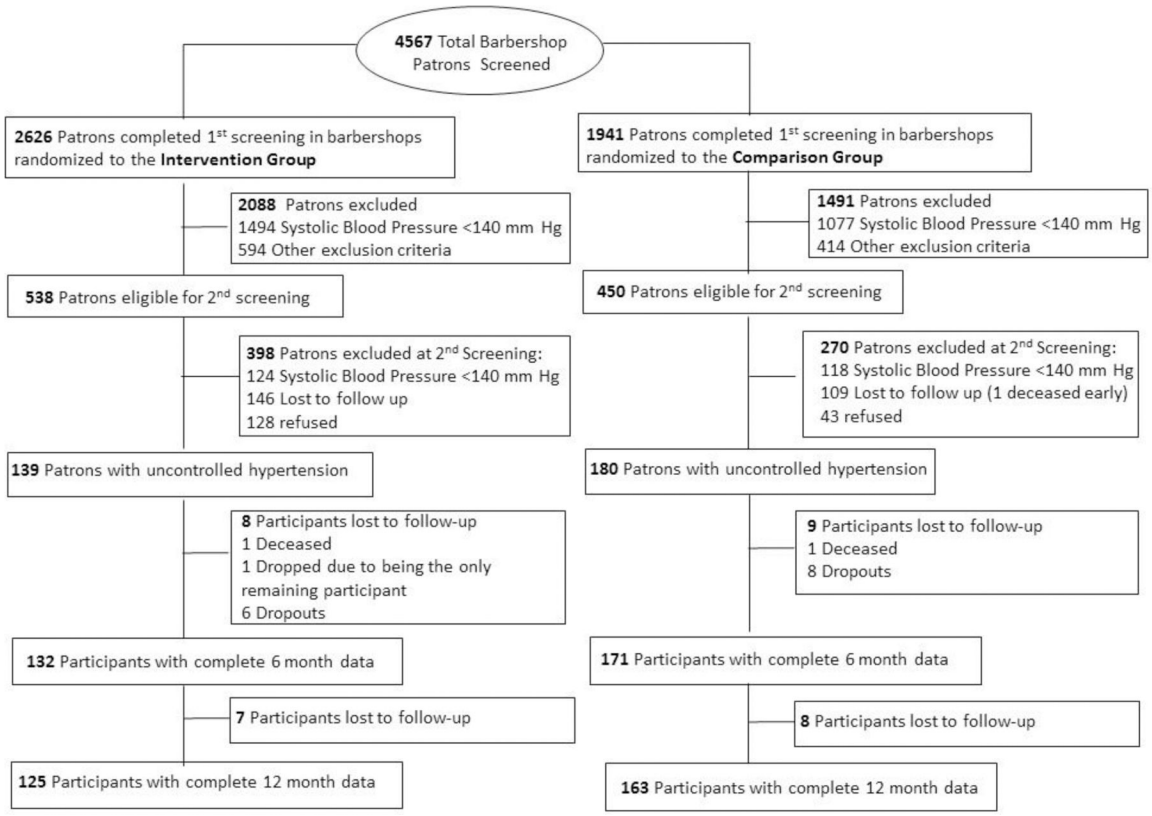

Figure 1. Screening, Enrollment, and Follow-Up of Barbershop Patrons.

Other exclusion criteria included: infrequent barbershop patronage (duration of less than 6 months or longer than every 6 weeks in between visits), age < 35 or >79 years old, receiving either dialysis or cancer chemotherapy, plans to relocate and incomplete 6-month data.

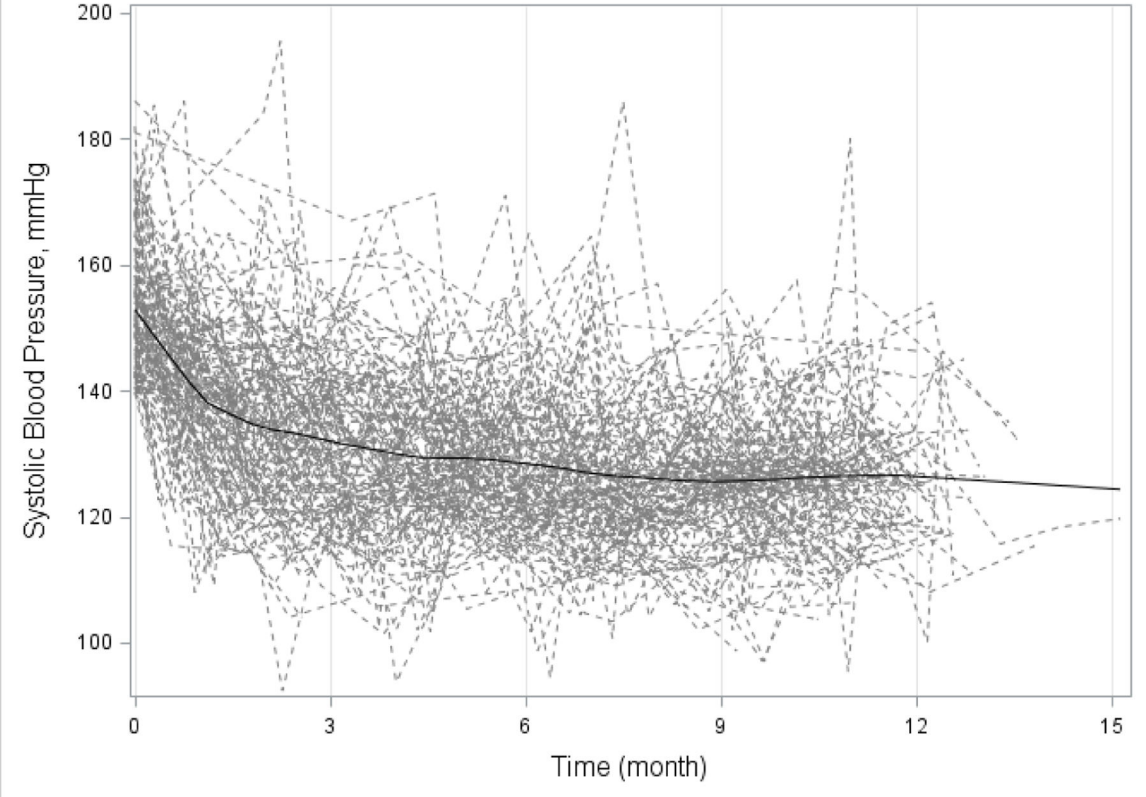

Figure 2.
Individual Profile Plot and Locally Weighted Polynomial Regression (LOESS) Curve of Systolic Blood Pressure in Intervention Group

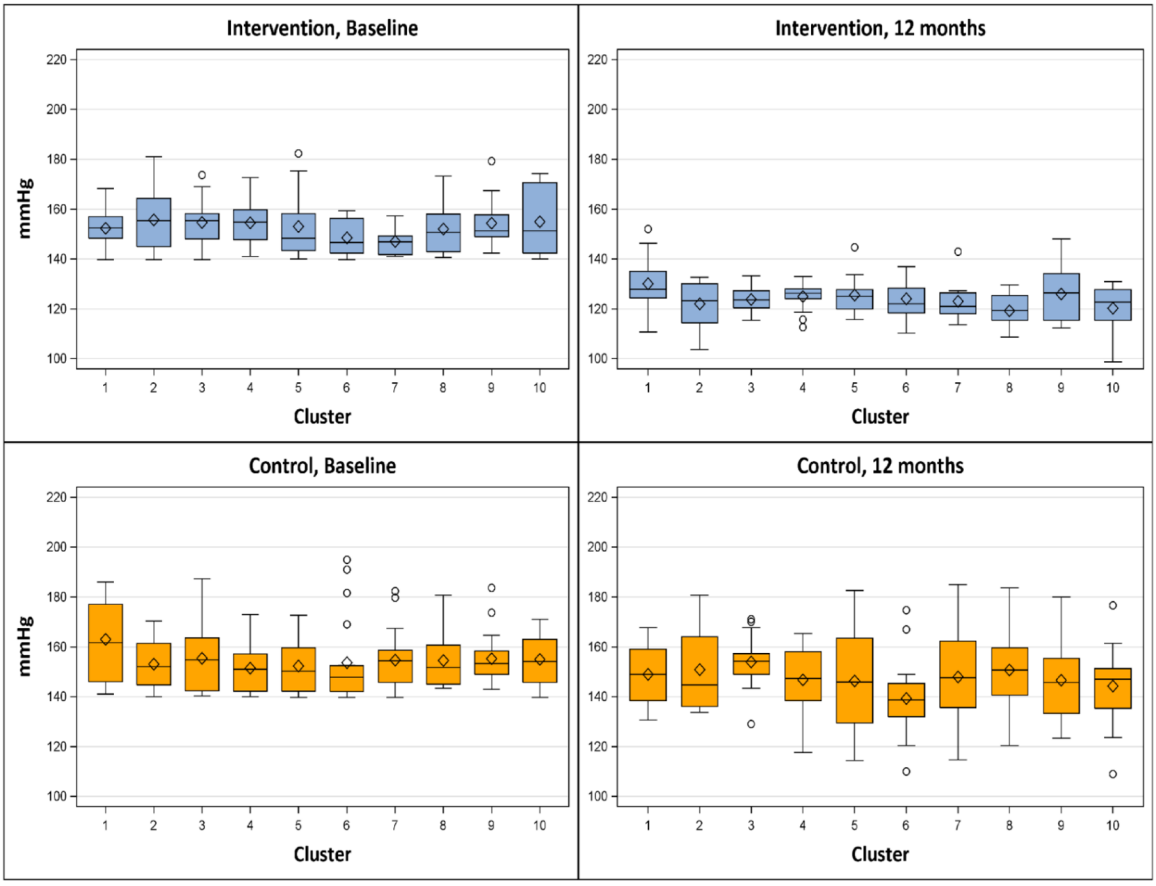

Figure 3. Systolic Blood Pressure at Baseline and 12 months According to Barbershop Cluster.

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 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.

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 - yr	54.4 ± 10.2	54.5 ± 9.4
Married or living with a partner - no. (%)	64 (46.4)	88 (48.9)
Highest education - no. (%)		
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, % of the federal poverty level - no. (%) †		
<100% of Federal Poverty Limit	41 (31.8)	43 (24.4)
100–300% of Federal Poverty Limit	36 (27.9)	48 (27.3)
301–500% of Federal Poverty Limit	26 (20.2)	49 (27.8)
>500% of Federal Poverty Limit	26 (20.2)	36 (20.5)
Regular medical care provider - no. (%)	106 (76.8)	137 (77.0)
Any health insurance - no. (%)	118 (84.9)	155 (86.1)
Barbershop patronage		
Duration of patronage - yr	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 §	30.7 ± 5.5	31.2 ± 6.1
Current smoker- no. (%)	43 (31.4)	55 (30.6)
Diabetes- no. (%)	31 (22.3)	38 (21.1)
High cholesterol - no. (%)	49 (35.3)	44 (24.4)

Note: Unadjusted Data

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

† The 2015 United States 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 dived by the square of the height in meters, both height and weight were by self-report.

Table 2.

Primary and Secondary Blood Pressure Outcomes at 12 months*

	Intervention, N = 125	Control, N =163	Intervention Effect	
Blood Pressure			**Difference in Mean Change of BP (95% CI)**	**p-value**†
Systolic Blood Pressure - mm Hg ‡				
Baseline	152.4 ± 10.1	154.6 ± 12.0		
12-months	123.8 ± 8.8	147.4 ± 15.7		
Change	−28.6 ± 12.7	−7.2 ± 17.7	−20.8 (−27.7, −13.9)	<0.0001
Diastolic Blood Pressure - mm Hg				
Baseline	91.9 ± 11.3	89.8 ± 11.3		
12-month	74.1 ± 8.2	86.5 ± 12.6		
Change	−17.8 ± 11.9	−3.3 ± 11.2	−14.5 (−19.5, −9.5)	<0.0001
Hypertension Control Rate after 12 months - no. (%)			Odds Ratio (95% CI)	p-value§
Blood Pressure <140/90 mm Hg	118 (94.4%)	47 (28.8%)	3.3 (1.8, 6.1)	0.0001
Blood Pressure < 135/85 mm Hg	110 (88.0%)	24 (14.7%)	6.7 (2.3, 18.9)	0.0004
Blood Pressure <130/80 mm Hg	85 (68.0%)	18 (11.0%)	9.1 (1.5, 56.6)	0.0177

*Plus-minus values are means ± SD

†p-values calculated from linear mixed effects models with random intercepts for clusters. The estimated intervention effect was controlled for baseline systolic blood pressure (or diastolic), routine doctor, and high cholesterol.

‡Pre-specified primary outcome. Intraclass Correlation Coefficient from the linear mixed effects model for change in SBP 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 SBP, routine doctor, and high cholesterol.

Table 3.

ITT analysis.

Primary and Secondary Blood Pressure Outcomes at 12 months*

	Intervention, N = 139	Control, N =171	Intervention Effect	
Blood Pressure			**Difference in Mean Change of BP (95% CI)**	**p-value†**
Systolic Blood Pressure - mm Hg ‡				
Baseline	153.1 ± 10.6	154.6 ± 12.0		
12-months	125.1 ± 9.9	147.5 ± 16.0		
Change	−28.1 ± 13.7	−7.2 ± 17.6	−20.6 (−27.3, −13.8)	<0.0001
Diastolic Blood Pressure - mm Hg				
Baseline	92.6 ± 11.8	89.8 ± 11.2		
12-month	77.5 ± 17.1	89.4 ± 18.4		
Change	−15.2 ± 17.9	−0.4 ± 17.5	−18.9 (−27.2, −10.7)	<0.0001
Hypertension Control Rate after 12 months - no. (%)			Relative Risk (95% CI)	p-value§
Blood Pressure <140/90 mm Hg	118 (84.9%)	55 (32.2%)	3.2 (2.3, 4.4)	<0.0001
Blood Pressure < 135/85 mm Hg	109 (78.4%)	32 (18.7%)	5.2 (2.4, 11.3)	<0.0001
Blood Pressure <130/80 mm Hg	84 (60.4 %)	20 (11.7%)	5.4 (2.4, 12.3)	<0.0001

*Plus-minus values are means ± SD

†p-values calculated from linear mixed effects models with random intercepts for clusters. The estimated intervention effect was controlled for baseline systolic blood pressure (or diastolic), routine doctor, and high cholesterol.

‡Pre-specified primary outcome. Intra-class Correlation Coefficient from the linear mixed effects model for change in SBP 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 SBP, routine doctor, and high cholesterol.

Table 4.

Longitudinal Analysis of Systolic Blood Pressure in Intervention Group (Baseline to 12 months)

Effect	Estimate	95% CI	p-value
Rate of change (per month) from baseline to 6 months	−3.4	(−3.9, −3.0)	<.0001
Rate of change (per month) after 6 months	−2.0	(−2.2, −1.8)	<.0001
age	−0.1	(−0.2, 0.01)	0.09

Table 5.

Blood Pressure Medications at 12 months*

No. of Blood Pressure Medications per Participant	Intervention (N = 125	Control (N = 163)	Difference at 12 months (95% CI)	p-value†
Mean	2.7 ± 0.9	1.4 ± 1.3	2.0 (1.4, 2.6)	<0.0001
Drug Class			**Odds Ratio at 12 months (95% CI)**	**p-value‡**
First Line Drugs				
ACE inhibitor or ARB - no. (%)	122 (97.6%)	70 (42.9%)	62.0 (19.2, 200.0)	<0.0001
Calcium-channel blocker - no. (%)	118 (94.4%)	59 (36.2%)	39.2 (17.4, 88.2)	<0.0001
Diuretic - no. (%)	60 (48.0%)	48 (29.5%)	2.5 (1.5, 4.0)	0.0002
Add On Drugs				
Aldosterone Antagonist - no. (%)	15 (12.0%)	2 (1.2%)	15.5 (4.7, 51.1)	<0.0001
Beta-blocker - no. (%)	15 (12.0%)	31 (19.0%)	0.6 (0.4, 0.9)	0.0183
Alpha-blocker - no. (%)	2 (1.6%)	8 (4.9%)	0.3 (0.1, 1.2)	0.0981
Central Sympatholytic- no. (%)	1 (0.8%)	6 (3.7%)	§	§
Direct Vasodilator - no. (%)¶	0 (0%)	7 (4.3%)	§	§

*Plus-minus values are means ± SD. ACE denotes angiotensin-converting enzyme, ARB angiotensin-receptor blocker.

†p-values calculated from linear mixed effects models with random intercepts for clusters. The estimated between-group difference was controlled for baseline SBP (or DBP), routine doctor, 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 SBP, routine doctor, and high cholesterol.

§odds ratio and p-value not available due to very low or zero counts.

¶The direct vasodilator was Hydralazine.