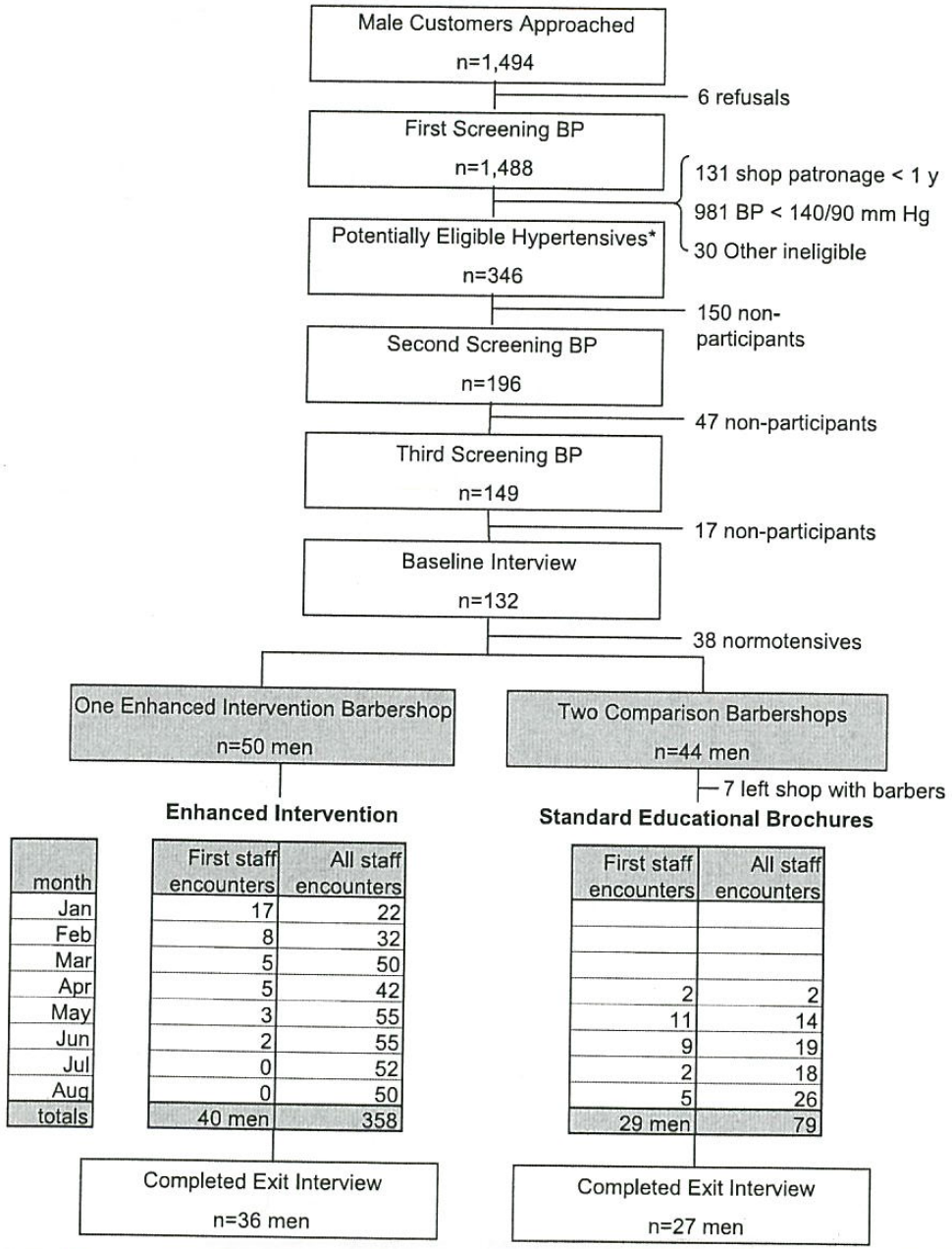
Hypertension African-American Males

1. African American Males (AAM) have a much higher HTN than other ethnic groups. The death rate from HTN is also higher.
2. In 2006, there were 2.
3. Nonrandomized Study I
    a) Participant attend a barbershop regular
    b) Phase IIa cohert study
    c) Selection of subjects



month	First staff encounters	All staff encounters
Jan	17	22
Feb	8	32
Mar	5	50
Apr	5	42
May	3	55
Jun	2	55
Jul	0	52
Aug	0	50
totals	40 men	358

First staff encounters	All staff encounters
2	2
11	14
9	19
2	18
5	26
29 men	79

Figure 1. Cohort recruitment and retention for study 1. *Eligibility criteria: first screening BP ≥140/90 mm Hg and barbershop patronage ≥1 year.

Design: Intervention Protocol

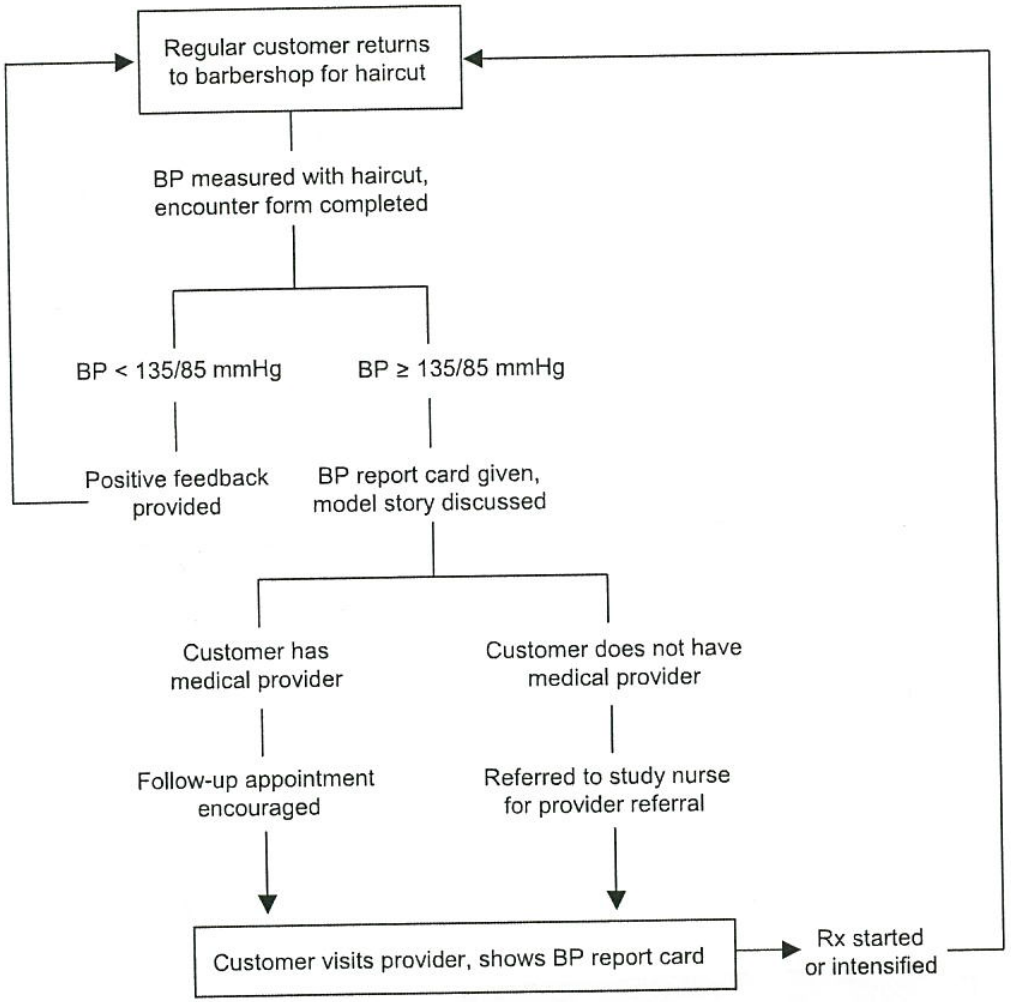


Figure 2. Intervention protocol for study 1 (and study 2). Rx indicates prescription BP medication. In study 2, the main differences were that the enhanced intervention was administered by barbers rather than research personnel and the BP report cards were to be signed by the healthcare providers and returned to the barber in return for a free haircut.

BP Measurement

Parkland Health and Hospital System.[20] Patients with undertreated HTN were referred back to their established providers.

The main intervention tools were "BP report cards" giving customers and their providers on-going feedback about the need to initiate or intensify antihypertensive therapy and role model stories depicting successful risk reduction strategies adopted by other members of the target community with whom study participants could readily identifyorreal hypertensive customers in the intervention barbershop (please see the data supplement for these materials, available online at http://hyper.ahajournals.org). Discounted haircuts ($6 off the regular price of $12) were provided as an incentive for continued intervention participation.

BP Measurement

All of the BPs were measured in the barbershops with validated electronic oscillometric monitors (Series 52 000, Welch Allyn)[21] after 10 minutes of rest using an appropriately sized arm cuff with the participant seated in a barber chair. At each encounter, 4 consecutive BP readings were taken, and the last 2 readings were averaged to calculate a BP value; 2 sets of readings on separate days were averaged to calculate initial and final BP values for each participant.

Evaluation

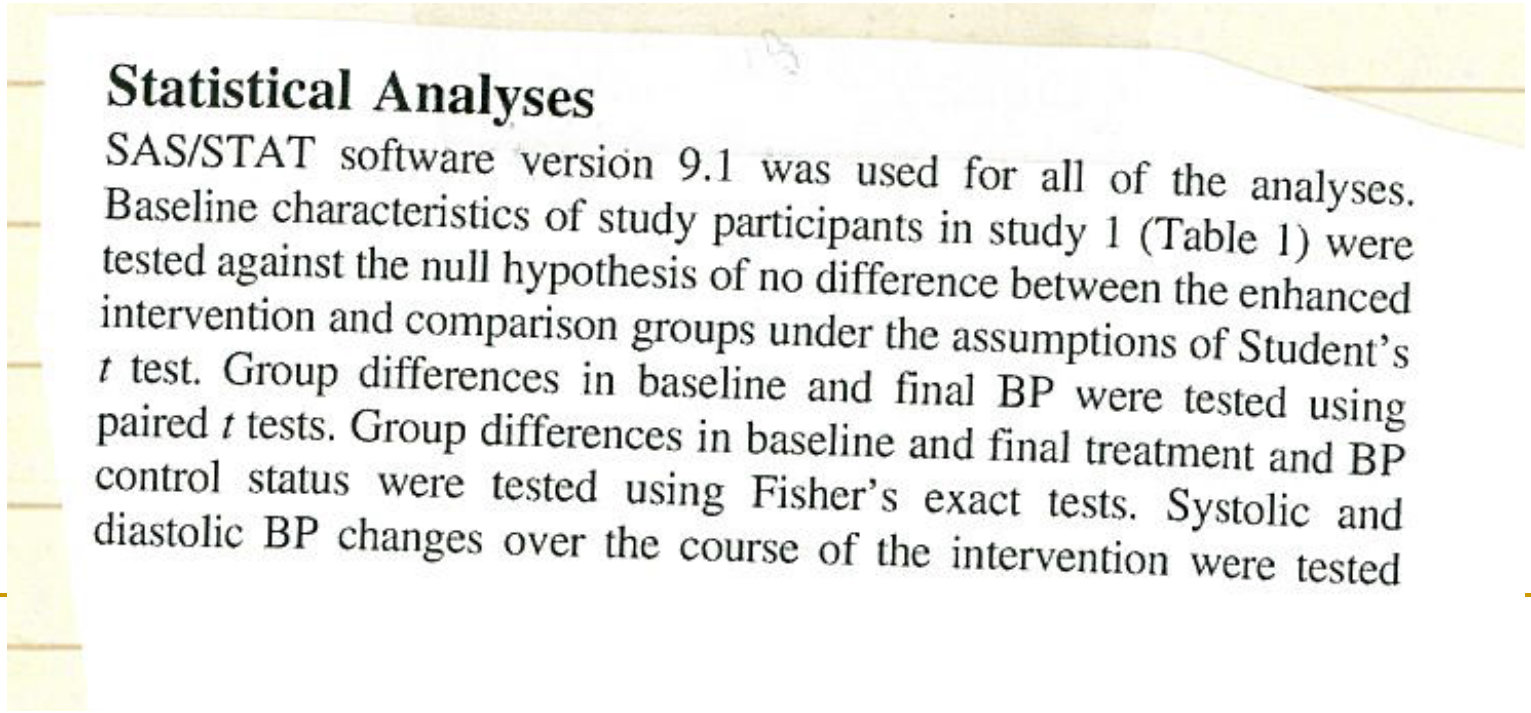
Serial cross-sectional face-to-face structured interviews were conducted by black surveyors to measure group differences in the BP change over the intervention period (the prespecified primary end point), as well as changes in HTN treatment rate (percentage of hypertensive subjects receiving prescription BP medication) and HTN control rate (percentage achieving BP <140/90 mm Hg). Data also were collected on numerous other individual characteristics shown in Table 1. Treatment status was validated by inspection of prescription pill bottles brought to the barbershop.

- BP readings were carried out by barbers.
- There were 3 time patients evaluated: for each eligible patient (HTN)

Nonrandomized Treatment Groups

1. Enhanced Intervention

   One barbershop had medical students take blood pressure and generally show up occasionally at that shop.
2. The other 2 shops student did not participate. These shops use the computer.



Statistical Analyses

SAS/STAT software version 9.1 was used for all of the analyses. Baseline characteristics of study participants in study 1 (Table 1) were tested against the null hypothesis of no difference between the enhanced intervention and comparison groups under the assumptions of Student's *t* test. Group differences in baseline and final BP were tested using paired *t* tests. Group differences in baseline and final treatment and BP control status were tested using Fisher's exact tests. Systolic and diastolic BP changes over the course of the intervention were tested

Results Study

TABLE 1. Participant Characteristics at Baseline for Study 1

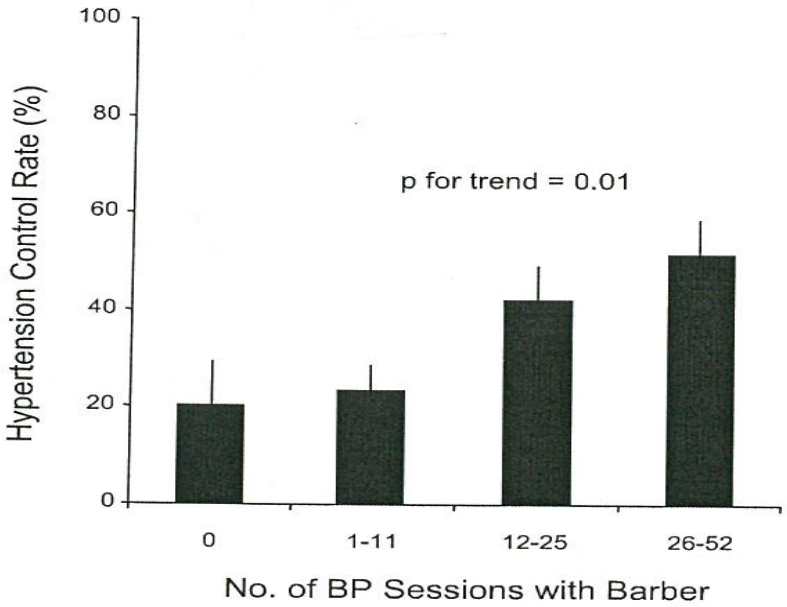
Baseline Characteristics	Completed Baseline Interview			Completed Baseline and Exit Interviews		
	Enhanced Intervention Group (n=50)	Comparison Group (n=44)	*P*	Enhanced Intervention Group (n=36)	Comparison Group (n=27)	*P*
Biological Characteristics						
Age, y	49.5±1.7	49.0±1.7	0.83	49.9±2.4	53.0±1.8	0.32
BMI, kg/m^2	30.7±0.8	30.6±0.8	0.91	30.7±0.8	30.1±0.9	0.63
Systolic BP, mm Hg	149.2±2.0	146.8±1.7	0.38	148.8±2.6	145.8±2.5	0.42
Diastolic BP, mm Hg	87.8±1.3	87.5±1.1	0.84	87.2±1.6	86.7±1.7	0.84
Demographic data, %						
Married or living with partner	58	66	0.44	59	74	0.24
Education beyond high school	64	75	0.25	66	85	0.09
Employed full time	76	77	0.89	69	74	0.66
Healthcare characteristics, %						
Has a primary source of health care	68	72	0.67	75	73	0.87
Has health insurance	88	80	0.27	88	89	0.87
Aware of hypertension	68	66	0.83	66	67	0.93
Seeing a physician for hypertension	46	52	0.31	44	52	0.46
Taking antihypertensive medication	40	43	0.69	38	44	1.00
Controlled to BP <140/90 mm Hg	16	16	0.84	19	22	1.00
Self-reported diabetes	16	27	0.19	19	30	0.34
Barbershop patronage						
Years at current barbershop	12.8±1.4	11.8±1.2	0.59	11.8±1.7	11.7±1.4	0.96
Haircuts per month	2.8±0.2	2.4±0.2	0.26	3.0±0.3	2.1±0.2	0.03

Baseline characteristics of the special intervention and comparison groups both for all of the subjects who completed the baseline interview and for only those subjects who completed the entire study including the exit interview. Expressed as mean±SE for continuous and percentage of discrete variables. BMI indicates body mass index.

TABLE 2. Hypertension Outcomes for Study 1

Hypertension Outcomes	Enhanced Intervention Group (n=36)			Comparison Group (n=27)		
	Initial	Final	*P*	Initial	Final	*P*
Systolic BP, mm Hg	149.1±2.2	133.4±2.2	<0.001	146.4±2.4	146.7±2.5	0.89
Diastolic BP, mm Hg	87.4±2.6	78.8±2.6	<0.001	87.9±2.2	88.0±2.2	0.94
Treated with BP medication, %	47	92	<0.001	56	67	0.60
BP controlled to <140/90 mm Hg, %	19	58	0.002	26	22	1.0

Initial and final hypertension outcomes for the enhanced intervention and comparison groups. Expressed as mean±SE for continuous and percentage for discrete variables.



No. of Hypertensive Customers	15	30	31	31	
Age, y, mean (SE)	50.9 (3.3)	50.1 (1.9)	50.8 (2.1)	51.4 (2.1)	p=ns
HMO/Private Insurance, % (SE)	80.0 (0.1)	76.7 (0.1)	90.0 (0.1)	71.0 (0.1)	p=ns
Hypertension Awareness Rate, % (SE)	73.3 (11.8)	70.0 (8.5)	80.6 (7.2)	90.3 (5.4)	p=0.06
Hypertension Treatment Rate, % (SE)	53.3 (0.1)	54.3 (0.1)	75.0 (0.1)	78.4 (0.1)	p=0.01
Hypertension Control Rate, % (SE)	20.0 (10.7)	23.3 (7.9)	41.9 (9.0)	51.6 (9.1)	p=0.01

Figure 3. HTN control as a function of intervention exposure for study 2. Intervention exposure is measured as the total number of BP monitoring and interpretation sessions with a barber. In the first level (no exposure), customers participated in the exit interview for a monetary incentive, but they did not allow the barbers to measure their BP during the intervention; the other 3 levels represent tertiles of exposure. HMO indicates health maintenance organization.

to 78.8±2.6 mm Hg) but remained unchanged in the comparison group (systolic: 146.4±2.4 to 146.7±2.4 mm Hg; diastolic: 87.9±2.2 to 88.0±2.2 mm Hg; Table 2). The intervention effect remained significant ($P<0.0001$) after adjustment for age and body mass index. With the enhanced intervention, HTN treatment increased from 47% to 92% ($P<0.001$), and HTN control increased from 19% to 58% ($P<0.001$), whereas both remained unchanged in the comparison group (Table 2 and Figure S3 from data supplement 1).

Study 2: Barber Intervention

The barbers recorded 8953 BP checks during 11 066 haircuts (Figure S3 from data supplement 2). They correctly staged 8237 of 8953 BPs (92%) recorded on the encounter forms as "normal" (<135/85 mm Hg), "high" (135/85 to 179/109 mm Hg), or "very high" (≥180/110 mm Hg).

After the intervention, 308 of 321 regular male customers completed the exit interview. Of these, HTN was present in 107 men. HTN control rate increased progressively with increasing levels of intervention exposure ($P=0.01$), from 20±10.7% in those who did not participate in the intervention to 51±9% in those with maximum intervention exposure (Figure 3). The relationship between intervention exposure and HTN control remained significant after controlling for insurance status ($P=0.01$).

Discussion

The principal new findings are 2-fold. First, in a cohort of hypertensive barbershop customers, an enhanced intervention program of continuous on-site BP monitoring and peer-based health messaging was more effective than intermittent BP screening and standard educational brochures for increasing treatment rates and lowering BP. Second, with nurse supervision, much of the responsibility for administering the intervention could be shifted from research personnel to barbers, who demonstrated a high degree of sustained intervention fidelity.

We are not the first to propose barbershops for HTN surveillance in black men, but the existing peer-reviewed literature is scant.[14,15] Black barbers and stylists have been taught previously to measure BP, enabling screening and referral in low-income neighborhoods.[14,15] Our work confirms and extends these earlier studies by providing quantitative data on barbershop patronage,

Perspectives

If these positive findings can be replicated in a randomized multicenter trial, this innovative biobehavioral approach could serve as a new model to help manage other cardiovascular risk factors and other chronic diseases that disproportionately affect black men. If a fall in systolic BP of 10 to 20 mm Hg could be sustained for 5 years, the risk of fatal myocardial infarction could be reduced by ≈30% and the risk of fatal stroke by ≈40%.[28] The potential public health impact of this community-based research is high, with thousands of black-owned barbershops nationwide.[12]

Factors Associated With Hypertension Awareness, Treatment, and Control in Dallas County, Texas

Ronald G. Victor, MD; David Leonard, PhD; Paul Hess, MD; Deepa G. Bhat, ME; Jennifer Jones, PhD; Patrice A. C. Vaeth, DrPH; Joseph Ravenell, MD, MS; Anne Freeman, MSPH; Ruth P. Wilson, PhD; Robert W. Haley, MD

Background: Hypertension (HTN) control rates in the United States remain lower in black than white persons, particularly before 65 years of age. Potential sociocultural factors have not been sufficiently addressed.

Methods: We analyzed data from structured interviews and blood pressure measurements in a population-based sample of 1514 hypertensive (1194 non-Hispanic black and 320 non-Hispanic white) subjects aged 18 to 64 years in Dallas County, Texas, from 2000 to 2002 to identify sociocultural factors associated with low rates of HTN control. We calculated adjusted odds ratios (aORs) and 95% confidence intervals (CIs) using multivariate logistic regression.

Results: Awareness, treatment, and control of HTN were negatively associated with a common perception of good health, with aORs (95% CIs) of 0.37 (0.27-0.50) for awareness, 0.47 (0.36-0.62) for treatment, and 0.66 (0.51-0.86) for control. They were positively associated with having a regular physician, with aORs (95% CIs) of 3.81 (2.86-5.07) for awareness, 8.36 (5.95-11.74) for treatment, and 5.23 (3.30-8.29) for control. Among untreated hypertensive subjects, lack of perceived need for a regular physician was associated with perceived good health (aOR [95% CI], 2.2 [1.2-4.0]), male gender (aOR [95% CI], 2.4 [1.4-4.1]), and black race/ethnicity (aOR [95% CI], 2.1 [1.0-4.4]). The HTN outcomes were unrelated to perceived racism or lay beliefs about the causes, consequences, and treatment of HTN.

Conclusions: Among young to middle-aged hypertensive subjects, a perception of good health and the lack of perceived need for a regular physician remain major factors associated with untreated and uncontrolled HTN at the community level—particularly among black men. These factors merit greater emphasis in professional education and public health programs on HTN.

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Design of a Randomized Group Randomization with Repeated Measures

1. This is a Phase III trial in HTM for African American males who are hypertensive.
2. Participants will be recruited from 16 sites. Each site is a barber owned shop.
3. Recall

formally

In 2 non-randomized feasibility trials, we recently found that an enhanced intervention program of continuous blood pressure (BP) monitoring and peer-based health messaging in a barbershop can (1) increase medical referrals and lower BP more than standard screening and health education, and (2) be implemented by barbers rather than research personnel.[10] Based on these encouraging feasibility data, we subsequently designed a group randomized trial. This report describes the novel community-based intervention administered by barbers and the rigorous study design that will be used to formally evaluate its effectiveness.

4. Design Elements

Study objectives

The study is designed to critically evaluate the effectiveness of a barber-based intervention for HTN utilizing state-of-the-art clinical trial methodology. The primary objective is to test whether HTN control rates will increase more in barbershops randomized to an enhanced HTN detection, referral, and follow-up program administered by barbers than in barbershops randomized to standard HTN screening and health education. An additional objective is to test for an intervention effect on the customers' healthcare-seeking attitudes and behaviors leading to HTN control.

5. Study Participants

All participants will be African American men, 18 years of age or older, who patronize any participating barbershop. The study has been approved by the Institutional Review Boards of both UT Southwestern and the Temple University Institute for Survey Research, which will conduct the field interviews.

6. Study Design

The study design is depicted in Figure 1. A cohort of 16 previously unstudied barbershops will go through a pre-test/post-test group-randomization protocol. Serial cross-sectional data collection periods (each lasting 10 weeks) will be conducted by trained African American field interviewers to obtain accurate snap-shots of HTN control in each of the 16 barbershops before and after 10 months of either barber-based intervention (n=8 shops) or a contemporaneous inactive control period (n=8 shops).

During each data collection period, interviewers will screen all adult male customers in each barbershop for HTN. Men meeting preset screening criteria will receive an incentive for returning on a separate day to complete a second set of BP measurements, a computer-assisted health questionnaire, and a detailed prescription medication list.

With this design, the barbershop (not the individual customer) is the unit of randomization. Shops will be enrolled in blocks of 4, stratified by their baseline HTN control rates, and then randomly allocated to either intervention or control conditions for a balanced design.

Group randomization is necessitated by the infeasibility of isolating the intervention to specific customers within the barbershop as well as the expectation that barbershop customers selected from the same barbershop will be more similar than customers selected at random.[18–21] The group randomization design also neatly handles attrition and addition of customers during the trial, unavoidable complications of cohort designs.

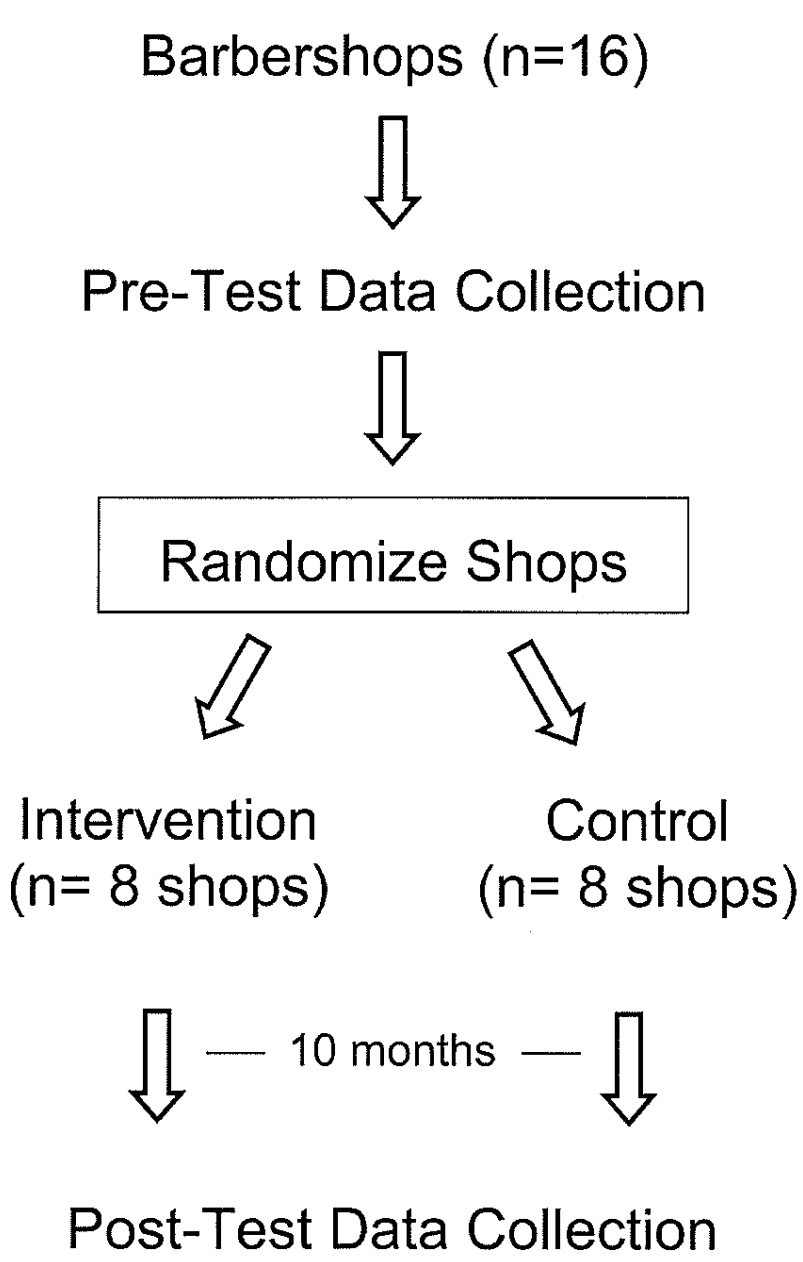

Figure 1.
Overall study design.

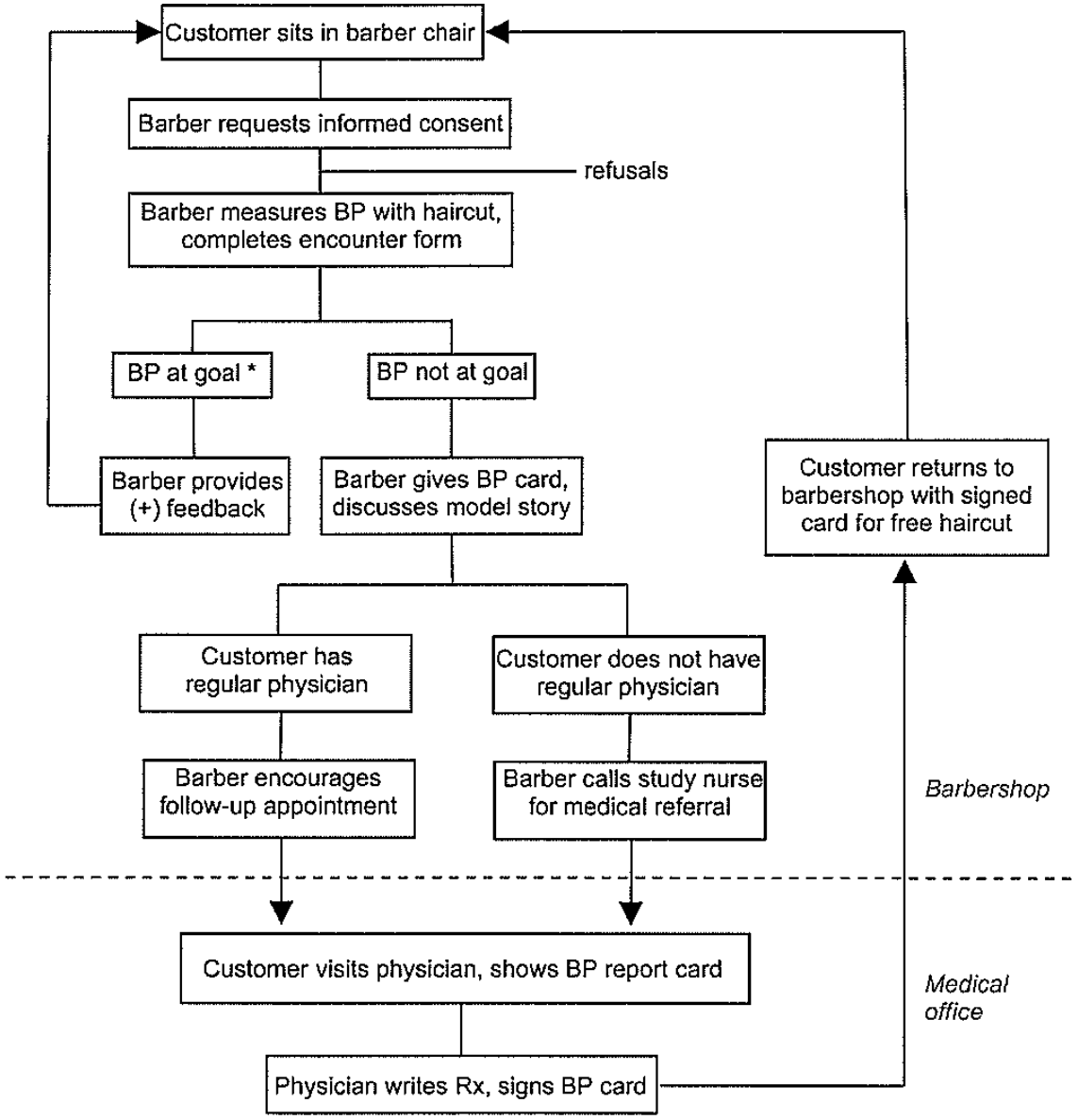

Figure 2. Overview of barber-based intervention protocol

BP, blood pressure; Rx, prescription for antihypertensive medication

* BP at goal is defined as < 135/85 mmHg (for non-diabetics) and < 130/80 mmHg (for diabetics).

Table I

Minimum Detectable Improvements in HTN Control Rate

over-time correlation*	8 barbershops per study-arm	12 barbershops per study-arm
0	15.5%	12.3%
0.1	15.0%	11.9%
0.2	14.6%	11.6%
0.3	14.1%	11.2%
0.4	13.6%	10.8%
0.5	13.1%	10.4%

Percentages are mean differences in HTN control rates between intervention and control barbershops in an experimentally controlled nested cross-sectional design. Calculations assume 100 hypertensive customers per barbershop, 80% power, and 2-sided 5% significance level.

* Over-time correlation refers to repeat-measure correlation of HTN control rate in a given barbershop

7. Study Measures

BP measurement

All BPs will be measured in the barbershops with a validated electronic oscillometric monitor (Welch Allyn, Series #52,000, Arden, N.C.)[27] using an appropriately-sized arm cuff with the participant seated comfortably in a barber chair. During the 10-week data collection periods, the field interviewers will try to obtain 2 sets of BP measurements on separate days on each hypertensive male customer. Each time they will measure 6 consecutive readings after 5 minutes of rest; the last 5 readings will be averaged to obtain a mean value, which will be used in calculation of the primary outcome.

During the intervention, the participating barbers will measure 3 consecutive readings toward the end of a haircut and enter the 3rd reading on an encounter form as process data.

Survey Instrument

During each 10-week data collection period, the field interviewers will administer a structured computer-assisted face-to-face health interview in 2 parts. The first part, a brief screening module, will be administered to all adult male patrons to identify potential hypertensive subjects. The second part, a more comprehensive health interview, will be administered to those who are hypertensive at screening. This ~15 minute interview will provide detailed information on each hypertensive participant about numerous factors that might influence HTN awareness, treatment, and control. These will include demographic characteristics, barbershop patronage, health care access and utilization, medical history, HTN knowledge, family history, smoking history, alcohol use, stages of change related to key behavioral outcomes, perceived discrimination in the healthcare setting, and perceived health. The instrument will be adapted from that used in the Dallas Heart Study[22] with modifications informed by pilot data.[10] The instrument will include validated scales to assess medication adherence, health-related quality of life, and perceived stress.[23,28–30] It also will include comprehensive medication lists—with detailed information about medication type, dosage and frequency—compiled by direct inspection of prescription drug labels rather than relying on self-report. Subjects who are hypertensive at screening will be asked to bring all their prescription pill bottles to the field interviewers during their next visit to the barbershop.

Primary Outcome

The primary outcome will be the change in HTN control rate. Using the currently recommended cutoff values for out-of-office BP,[31] HTN will be defined as having a current prescription for antihypertensive medication or having a measured BP ≥ 135/85 mmHg (BP ≥ 130/80 mmHg for men with diabetes) on 2 separate days. At each end of the study, the HTN control rate will be calculated for each barbershop as the percentage of hypertensive customers with BP < 135/85 mm Hg (BP < 130/80 mmHg for those with diabetes).

8. Separate Protocols for Intervention Barbershops and Control Barbershops
9. Further Measurement Comment

Protocol for the Intervention Barbershops

Barbers will be trained, equipped, and paid to conduct the intervention protocol depicted in Figure 2. All of their adult African American male customers will be eligible to participate in this continuous on-site BP monitoring and medical referral program. Barbers will be taught to offer a BP check with each haircut, to measure and interpret BP, to complete written encounter forms, and to discuss *role model stories*—real stories of other male customers modeling the desired changes in health behavior.[10,23]

Statistical Considerations

Sample Size and Power

The primary observation in each barbershop is the difference between pre-test and post-test HTN control rates. This quantity will be comprised of a fixed intervention effect and a random effect. Estimates of the detectable intervention effect follow from assigning variance values to the random effect.

The random effect has two components, 1) the joint effect of barbershop and time, and, 2) the average effect of customers within a barbershop. The variance of the joint effect of barbershop and time is $2\sigma_b^2(1-\rho_b)$, where σ_b^2=0.003 is the barbershop component of variance estimated from a pilot study[10], and ρ_b is the repeat-measure correlation of barbershops. The variance of the average effect of customers within a barbershop is $2\mu(1-\mu)/m$, where μ and m are the HTN control rate and number of hypertensive customers of the barbershop, respectively. Based on data from a large epidemiological study in Dallas (Dallas Heart Study) [22], the HTN control rate at baseline is expected in the range 15–20%. The intervention is expected to raise this 10–15%. A conservative value of μ, for the purpose of estimating detectable differences, is therefore 35%.

Table I shows the intervention effect detectable with 80% power and two-tailed 5% significance level for a range of barbershop repeat-measure correlations from 0 to 0.5. The study was designed for 8 shops per arm with the aim of enrolling additional shops permitted by the availability of funding to account for attrition of study sites.

10. Data

Barbers take BP, fill out forms. Data is picked up by employees of Temple University.

11. **Analysis Plan**

Primary Analysis

The primary hypothesis is that HTN control rates will increase more in the intervention barbershops than in the control barbershops. The pretest-posttest control group design will allow us to calculate the change in HTN control rate for each barbershop in the study. We will compare intervention barbershops to control barbershops on changes in HTN control rates using a *t* test at a 2-sided, 5% significance level. Specifically, we will test the effect of study-arm × time in a general linear model of HTN control rate. At the barbershop level, the HTN control rate, being a mean value, will be approximately normally distributed and will be treated as a continuous outcome.

The primary analysis will include all customers who participate in either the pre-test or post-test data collections. In the primary intention-to-treat analysis, customers will be assigned to the barbershop in which they complete the pre-test data collection.

Some subjects may patronize barbershops in both study arms but we anticipate that the number of such subjects will be negligible. Our feasibility studies predict that < 10% of the customers will patronize more than one barbershop. The number of study sites in either arm will be small (< 5%) compared to the total number of African American-owned barbershops in Dallas County, thus reducing the probability that a customer of a control barbershop also will be a customer of an active barbershop. The few subjects who patronize more than one study barbershop will not be excluded from the primary analysis in accordance with intention-to-treat. However, such subjects will be removed from secondary cohort-level analyses described below.

Table 1. Characteristics of Black Barbershops and Black Male Patrons With HTN[a]

Characteristic	Baseline		Follow-up	
	Intervention (n=9 shops)	Comparison (n=8 shops)	Intervention (n=8 shops)	Comparison (n=7 shops)
Barbershops				
Barbers per shop, mean (range), No.	5 (3-7)	4 (3-6)	4 (2-5)	3 (2-5)
Patrons with HTN per shop, mean (range), No.	77 (37-163)	75 (30-165)	67 (30-123)	69 (23-149)
Patrons With HTN				
Total No.	695	602	539	483
Age, mean (SEM), y	49.5 (2.4)	51.2 (2.6)	51.8 (2.0)	54.0 (2.3)
Married or living with partner	388 (56.7)[b]	431 (67.3)[b]	344 (65.1)	349 (69.1)
Level of education				
≤High school	342 (46.9)	241 (38.9)	266 (49.7)	169 (32.4)
College	293 (43.4)	279 (48.0)	216 (40.5)	232 (51.6)
Postgraduate	59 (9.7)	82 (13.1)	57 (9.8)	81 (16.0)
Full-time employment	403 (61.6)	354 (64.5)	322 (64.1)	292 (68.8)
Income, % of the poverty level[c]				
≤100	110 (15.8)	76 (12.0)	69 (12.9)	45 (9.2)
101-300	209 (29.8)	145 (26.3)	144 (27.5)	107 (21.2)
301-500	237 (36.0)	202 (33.4)	202 (39.2)	177 (37.9)
>500	116 (18.4)	170 (38.4)	111 (20.4)	148 (31.7)
Primary medical care provider	558 (80.5)	[illegible]	463 (84.5)	448 (91.3)
Health insurance status[d]		524 ([illegible]	[illegible]	
Any policy	587 (85.3)	421 (70.7)	352 (67.0)	443 (89.6)
HMO or private	458 (68.6)	84 (12.1)	76 (12.5)	349 (73.5)
Veterans Affairs	80 (10.2)	88 (10.3)	104 (15.6)	77 (12.8)
Medicare	94 (11.4)	45 (6.7)	47 (9.8)	98 (14.7)
Medicaid	47 (6.4)	23 (2.9)	28 (4.2)	39 (6.2)
Safety net	31 (3.9)			20 (4.4)
Barbershop patronage		9.7 (1.7)	7.9 (1.0)	
Duration of patronage, mean (SEM), y	7.4 (1.3)	3.2 (0.3)	2.9 (0.2)	9.7 (1.8)
Time between haircuts, mean (SEM), wk	3.8 (0.4)			2.8 (0.2)
Cardiac risk factors and history[e]		505 (84.0)	443 (84.2)	
Family history of HTN	576 (83.3)	104 (17.5)	128 (25.1)	423 (88.5)
Current smoker	159 (22.1)	30.7 (0.4)	31.8 (0.7)	88 (19.1)
BMI, mean (SE)	31.4 (0.5)	136 (19.1)	123 (22.8)	30.6 (0.4)
Diabetes	144 (19.2)	297 (44.8)	281 (52.6)	134 (25.1)
High cholesterol level	311 (44.2)	86 (12.9)	100 (15.1)	278 (56.8)
Prior stroke, MI, and/or heart failure	103 (13.0)	14 (1.8)	7 (1.3)	72 (12.8)
Chronic renal failure	11 (1.4)			14 (2.1)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divi[illegible]d by height in meters squared); HMO, health maintenance organization; HTN, hypertension; MI, myocardial infarction.

[a] Unless otherwise indicated, data are reported as number (percentage) of ba[illegible]ershop patrons. Percentages are reported as means of barbershop means.

[b] Significant group difference at baseline (P=.01).

[c] The 2007 United States poverty level was $10 210 for a single person and $[illegible]0 650 for a 4-person household; "middle-income" was defined as 300% of the poverty level.[26]

[d] Some patrons held multiple insurance policies.

[e] Data are self-reported.

Results

- Statistical Analysis

STATISTICAL ANALYSIS

Because of the cluster design, summary statistics are presented as the means (standard errors of barbershop means [SEMs]). A difference between study arms at baseline was tested with a mixed effects regression model with study arm as a fixed effect and barbershop within the arm as a random effect. A difference between study arms over time was tested with a mixed-effects regression model with arm, time, and arm × time as fixed effects and barbershop, barbershop × time, and patron within barbershop as random effects. The random effects of barbershop and barbershop × time account for the clustering of outcome levels and changes within barbershops, while the random effect of patron within barbershop accounts for repeated measures of clients present at both baseline and final assessment periods. These models simultaneously estimate the outcome measure in both study arms at both time points; the arm × time effect tests the intervention effect, thereby adjusting for baseline values.[19,20] Generalized linear mixed models with logit link functions were used for binary outcome variables, and linear mixed models were used for continuous outcome variables. Adjusted models were fit with centered, individual-level covariates included as additional fixed effects.[20] Model-based significance levels and 95% confidence intervals (CIs) were obtained. $P < .05$ was considered statistically significant. Analyses were conducted using SAS/STAT software, version 9.1.3 (SAS Institute Inc, Cary, North Carolina).

Table 2. Mean Change in HTN Control Rate and Its Components in Barbershops Randomized to Intervention and Comparison Conditions[a]

Characteristic	Intervention Group			Comparison Group			Intervention Effect		
	Baseline	Follow-up	Absolute Change, % (95% CI)	Baseline	Follow-up	Absolute Change, % (95% CI)	Absolute Group Difference, % (95% CI)	*P* Value[b]	Adjusted *P* Value[c]
Control rate[d] among all patrons with HTN	33.8	53.7	19.9 (14.4 to 25.4)	40.0	51.0	11.1 (5.2 to 16.9)	8.8 (0.8 to 16.9)	.04	.03
Control rate[d] among treated patrons with HTN[e]	49.1	65.9	16.8 (10.0 to 23.5)	57.1	64.3	7.1 (−0.1 to 14.4)	9.6 (−0.3 to 19.5)	.06	.05
HTN treatment rate	67.9	79.0	11.2 (7.3 to 15.0)	69.9	76.1	6.2 (2.1 to 10.3)	5.0 (−0.6 to 10.6)	.10	.33
HTN awareness rate	79.5	86.3	6.8 (3.3 to 10.3)	79.1	85.4	6.4 (2.5 to 10.2)	0.4 (−4.8 to 5.7)	.72	.57
Systolic BP, mm Hg	137.6	129.8	−7.8 (−9.7 to −5.9)	136.4	131.1	−5.3 (−7.4 to −3.2)	−2.5 (−5.3 to 0.3)	.08	.09
Diastolic BP, mm Hg	81.5	78.7	−2.8 (−4.0 to −1.6)	80.0	78.1	−1.9 (−3.2 to −0.6)	−0.9 (−2.6 to 0.8)	.28	.18
BP medications per patron with HTN	1.4	1.8	0.5 (0.3 to 0.6)	1.4	1.7	0.3 (0.1 to 0.4)	0.2 (0.0 to 0.4)	.07	.09

Abbreviations: BP, blood pressure; CI, confidence interval; HTN, hypertension.

[a] Unless otherwise indicated, data are reported as percentage of barbershop patrons with HTN.

[b] *P* values were determined by mixed logistic regression for dichotomous study outcomes and by mixed linear regression for continuous outcomes in analyses that used all available data (17 barbershops at baseline and 15 barbershops at follow-up).

[c] Adjusted for effects of age, education, marital status, smoking status, and participation in both baseline and follow-up cohorts.

[d] The HTN control rate is the percentage of hypertensive patrons with BP below recommended out-of-office values (135/85 mm Hg for patrons without diabetes and 130/80 mm Hg for those with diabetes).

[e] Patrons with HTN receiving prescription BP medication.

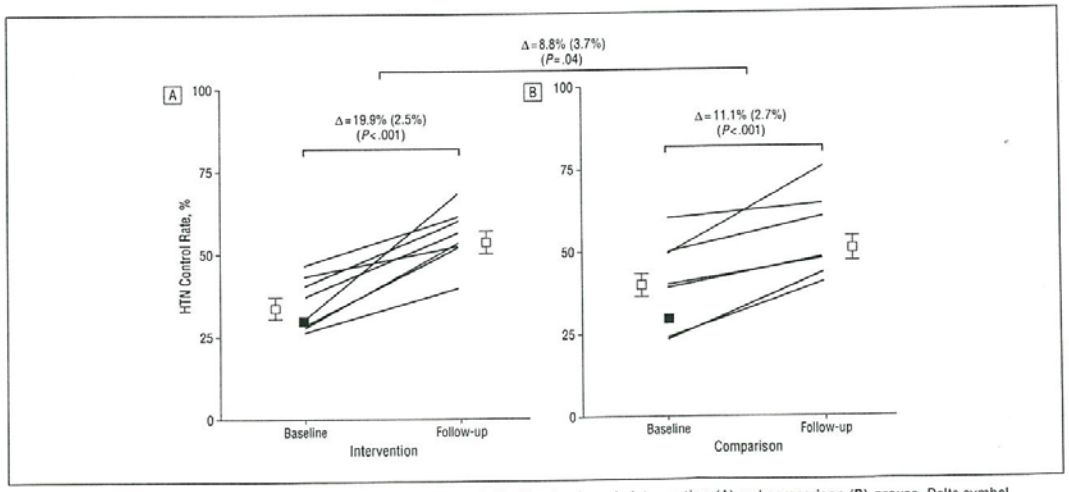

Figure 3. Baseline and follow-up hypertension (HTN) control rates for individual barbershops in intervention (A) and comparison (B) groups. Delta symbol indicates change in HTN control rate, reported as mean (SEM). Paired data are shown for each barbershop except for 1 barbershop in each group lacking follow-up data (black squares). Boxes with error bars indicate group means (SEMs). The significance of the intervention effect on HTN control was not affected by adjustment for baseline blood pressure, age, marital status, college education, smoking status, and participation at both baseline and follow-up (*P*=.03).

8.8% (95% CI, 0.8%-16.9%) (*P*=.04); the intervention effect persisted after adjustment for covariates (*P*=.03). In addition, in a conservative intention-to-treat analysis, which assumed that the 2 barbershops lost to follow-up (1 per arm) both followed the lesser trajectory of the comparison barbershops, the resultant intervention effect was 7.8% (95% CI, 0.4%-15.3%) (*P*=.04).

SECONDARY OUTCOMES

reduction: absolute group difference, −2.5 mm Hg (95% CI, −5.3 to 0.3 mm Hg) (*P*=.08). However, there was no evidence for an intervention effect on HTN awareness.

Process Data on Intervention Implementation, Penetration, Incentive Payments, and Acceptability

In the intervention group, follow-up data

Differential Treatment of Hypertension by Primary Care Providers and Hypertension Specialists in a Barber-Based Intervention Trial to Control Hypertension in Black Men

Florian Rader, MD, MSc[a], Robert M. Elashoff, PhD[b,c], Sara Niknezhad, PharmD[a], and Ronald G. Victor, MD[a,*]

Black men have less physician contact than other groups and thus lower rates of hypertension treatment and control. In the Barber-Assisted Reduction in Blood Pressure among Ethnic Residents trial, hypertension control in 8 active-intervention barbershops where barbers offered blood pressure (BP) checks with haircuts and motivated black male patrons with high BP to seek provider follow-up showed a small improvement over that in 7 comparison shops where patrons received hypertension pamphlets but not barber-BP checks. Undertreatment of hypertension, which is common in primary care, may have impacted the outcomes. Thus, in patrons with a baseline systolic BP of ≥140 mm Hg and 10-month follow-up including BP and medication data, we performed post hoc comparison of systolic BP reduction between comparison-arm patrons (n = 68) treated by primary care providers (PCPs) with (1) intervention-arm patrons (n = 37) treated by PCPs or (2) intervention-arm patrons (n = 33) who lacked access to PCPs and were treated by hypertension specialist physicians serving as safety net providers. The latter group had higher baseline systolic BP than the others (162 ± 3 vs 155 ± 2 and 154 ± 2 mm Hg, respectively, p <0.01). After adjustment for baseline systolic BP and other covariates, systolic BP reduction was 21 ± 4 mm Hg greater than in the comparison group (p <0.0001), when barbers referred patrons to hypertension specialists but was no different when they referred to PCPs (4 ± 4 mm Hg, p = 0.31). Specialist-treated patrons received more BP medication and different classes of medication than PCP-treated patrons. In conclusion, the barber-based intervention—if connected directly to specialty-level medical care—could have a large public health impact on hypertensive disease in black men. © 2013 Elsevier Inc. All rights reserved. (Am J Cardiol 2013;112:1421–1426)

Hypertension is particularly devastating to non-Hispanic black men, who have a greater prevalence of hypertension than most other groups but less physician contact, leading to low rates of hypertension awareness, treatment, and control.[1–6] As a result, black men have the highest hypertension death rate of any United States race, ethnic, or gender group.[4,7] We conducted a cluster-randomized trial of a hypertension control program implemented through black-owned barbershops, enlisting barbers to monitor blood pressure (BP) and promote provider follow-up for uncontrolled hypertension. In this trial (Barber-Assisted Reduction in Blood Pressure among Ethnic Residents [BARBER-1]),[8] we observed a small intervention effect on systolic BP, indicating that further research is needed to develop a more potent intervention model.[8,9] We previously reported a high level of adherence to the study protocol by the barbers and their patrons[8] but had not examined the quality of medical care delivered by the patrons' health-care providers.

Undertreatment of hypertension by office-based primary care providers (PCPs) is increasingly recognized as a key barrier to hypertension control,[10–12] both in provider networks and national databases[13] and thus constitutes 1 hypothesis to explain the smaller than desired effect size in the BARBER-1 trial. To test this hypothesis, we conducted a post hoc subgroup analysis of BARBER-1 participants with unequivocally elevated baseline systolic BP and a completed exit interview. We compared systolic BP reductions and antihypertensive treatment regimens prescribed for hypertensive barbershop patrons in the comparison group—who received hypertension pamphlets and usual medical care by PCPs—with hypertensive patrons in the intervention group who followed their barbers' advice to seek medical follow-up for high BP and had documented office visits with either PCPs

[a]Heart Institute, Hypertension Center of Excellence, Cedars-Sinai Medical Center, Los Angeles, California; [b]Department of Biomathematics, University of California Los Angeles Medical Center, Los Angeles, California; and [c]Department of Biostatistics, School of Public Health, University of California Los Angeles, Los Angeles, California.

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Trial registration: *clinicaltrials.gov* identifier: NCT00325533.

See page 1425 for disclosure information.

*Corresponding author: Tel: (310) 248-7641; fax: (310) 248-8050.
E-mail address: victorr@cshs.org (R.G. Victor).

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Table 1
Baseline characteristics

Group Assignment	Barber-Based Intervention		Comparison
Treating Physicians	Hypertension Specialists	PCPs	PCPs
Variable	n = 33 Patrons, Mean ± SE	n = 37 Patrons, Mean ± SE	n = 68 Patrons, Mean ± SE
Age (yrs)	52 ± 2*	57 ± 2	60 ± 2
Body mass index (kg m^{-2})	33 ± 1	31 ± 1	32 ± 1
Married or living with partner	21 (64)	26 (70)	54 (80)
Level of education, n (%)			
≤High school	15 (46)	20 (54)	23 (34)
College	16 (49)	16 (43)	31 (46)
Postgraduate	2 (6)	1 (3)*	13 (19)
Full-time employment, n (%)	26 (79)*	18 (49)	33 (49)
Any health insurance, n (%)	19 (58)*	34 (92)	64 (94)
Established PCP, n (%)	17 (51)*	33 (90)	63 (93)
Income (% of poverty level)†	330 ± 37	330 ± 31	380 ± 22
Barbershop patronage			
Duration (yrs)	8 ± 1*	7 ± 1*	13 ± 9
Time between haircuts (weeks)	3 ± 0.5	3 ± 0.5	3 ± 2
Baseline systolic BP (mm Hg)	162 ± 3*	154 ± 2	155 ± 2
Baseline diastolic BP (mm Hg)	96 ± 2*	88 ± 2	86 ± 1
Current smoker, n (%)	8 (24)	8 (22)	15 (22)
Diabetes mellitus, n (%)	7 (21)	13 (35)	21 (37)
Hyperlipidemia, n (%)	18 (56)*	20 (54)	33 (49)
History of stroke, myocardial infarction, or heart failure, n (%)	4 (12)	13 (35)*	7 (10)

HTN = hypertension; SE = standard error.

* Likelihood ratio test p value ≤0.05 versus comparison group.

† Calculated as income/2007 United States poverty level: $10,210 for a single person and $20,650 for a 4-person household ×100.

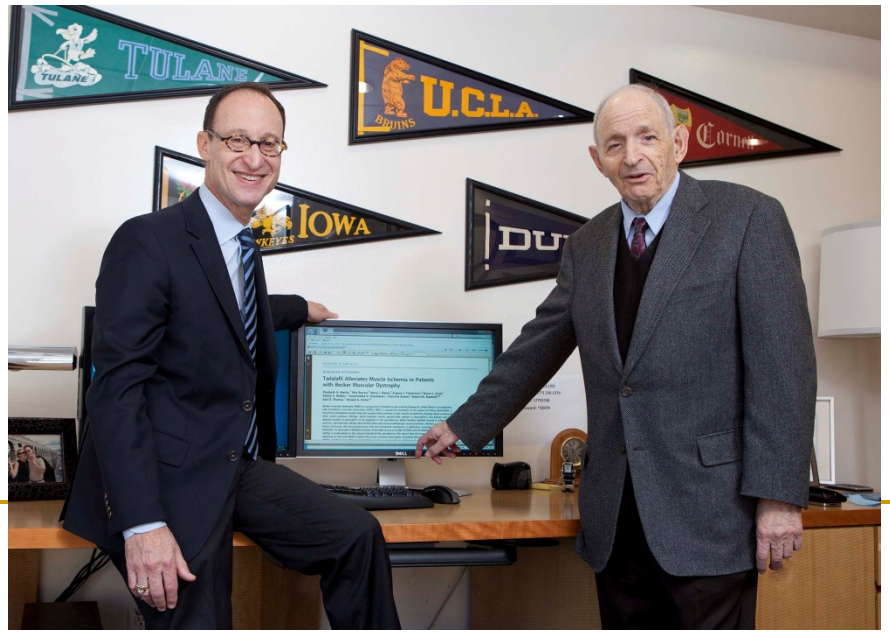
Table 2
Outcomes

Group Assignment	Barber-Based Intervention		Comparison
Treating Physicians	Hypertension Specialists	PCPs	PCPs
Variable	n = 33 patrons, Mean ± SE	n = 37 Patrons, Mean ± SE	n = 68 Patrons, Mean ± SE
Final blood pressure			
Systolic BP (mm Hg)	122 ± 2*	138 ± 3	139 ± 2
Diastolic BP (mm Hg)	75 ± 1*	81 ± 2	80 ± 1
Change of systolic BP (final − initial; mm Hg)	−41 ± 4*	−16 ± 3	−16 ± 3
Change of diastolic BP (final − initial; mm Hg)	−21 ± 3*	−7.4 ± 1	−6.2 ± 1
Hypertension control rate (% with final BP <135/85 mm Hg)†	29 (88)*	18 (49)	29 (43)
Final BP regimen			
Number of medications, n (%)			
None	0*	4 (11)	15 (22)
1	3 (9)	5 (14)	9 (13)
2	6 (18)	12 (32)	19 (28)
≥3	24 (73)*	16 (43)	25 (37)
Mean	3.4 ± 0.3*	2.3 ± 0.2	2.1 ± 0.2
Medications, n (%)			
ACE inhibitor or ARBs	31 (94)*	17 (51)	24 (45)
Calcium channel blocker	30 (91)*	24 (65)	24 (45)
Diuretic	22 (67)	25 (76)	25 (47)
α/β Blocker	11 (33)*	2 (6)	2 (4)
Aldosterone antagonist	5 (20)*	0	0
Central sympatholytic	4 (15)	0	0
Direct vasodilator	1 (3)	1 (3)	1 (2)
β Blocker	0*	10 (30)	10 (19)
α Blocker	0	3 (9)	3 (6)
Medication adherence‡	3.0 ± 0.2	3.1 ± 0.2	3.4 ± 0.2

ACE = angiotensin-converting enzyme; ARBs = angiotensin receptor blockers; SE = standard error.
* Likelihood ratio test p value <0.05 versus comparison group.
† Cutoff for out-of-office BP.
‡ Morisky scale: scores ranging from 0 to 4, with 4 representing perfect adherence.

Barber-Pharmacist-Physician Coordination to Manage HTN in African American Men:

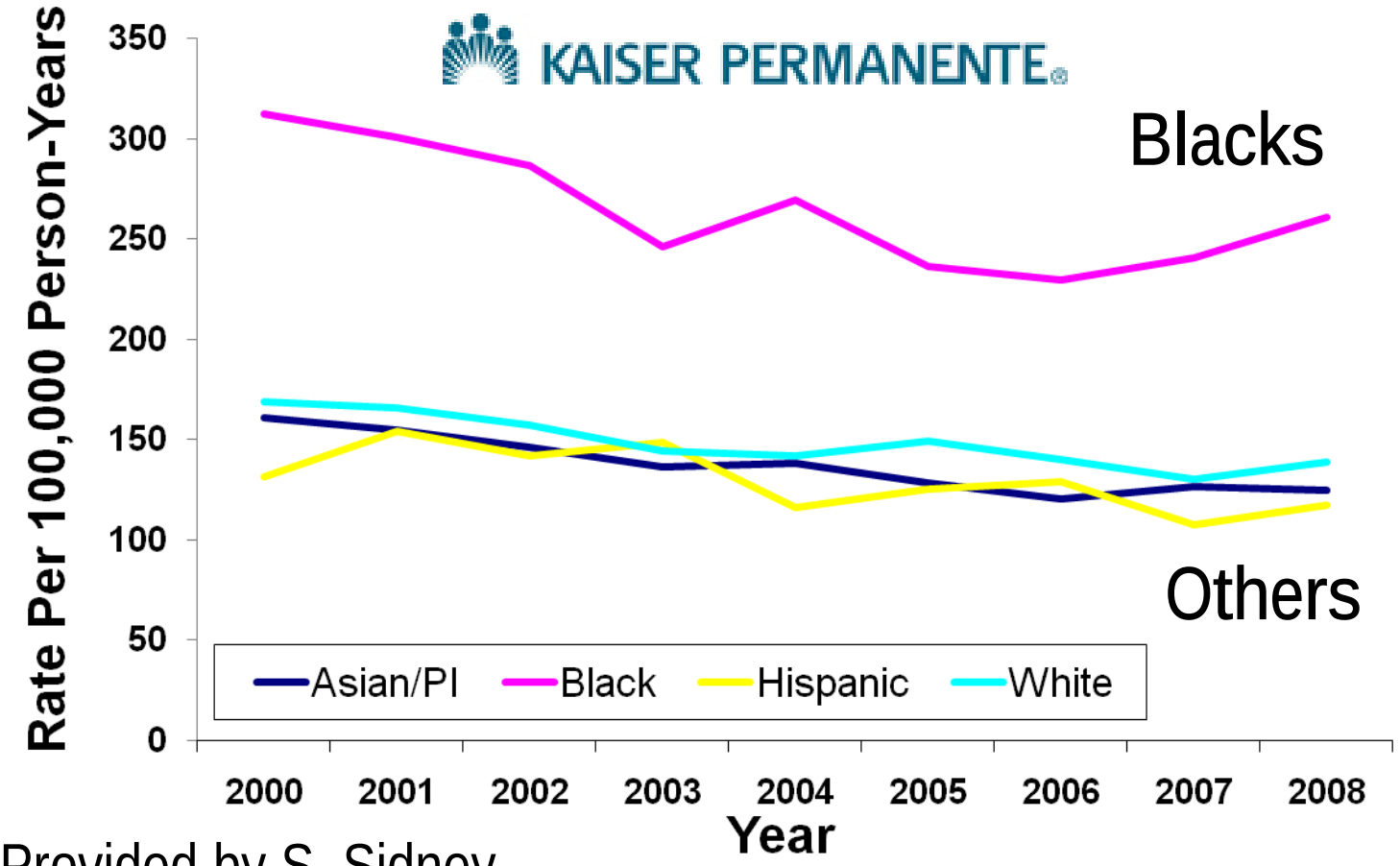
a cluster-randomized trial



Clinical Trial Elements that Are Scored

1. **Significance**
2. **Innovation**
3. **Approach**
4. Investigators
5. Facilities

Ischemic Stroke By Race



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Arch Intern Med. 2011;171(4):342-350.

ARCHIVES OF
INTERNAL MEDICINE

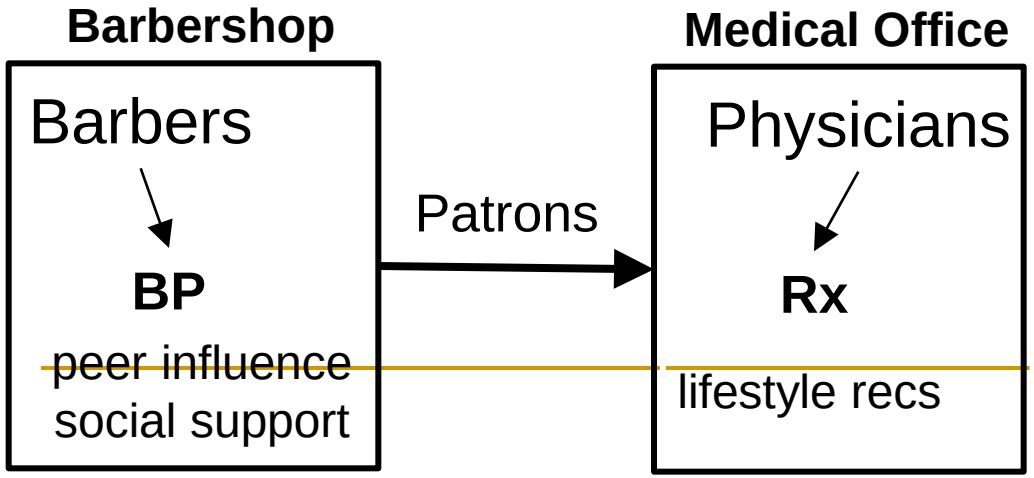
ORIGINAL INVESTIGATION

ONLINE FIRST

Effectiveness of a Barber-Based Intervention for Improving Hypertension Control in Black Men

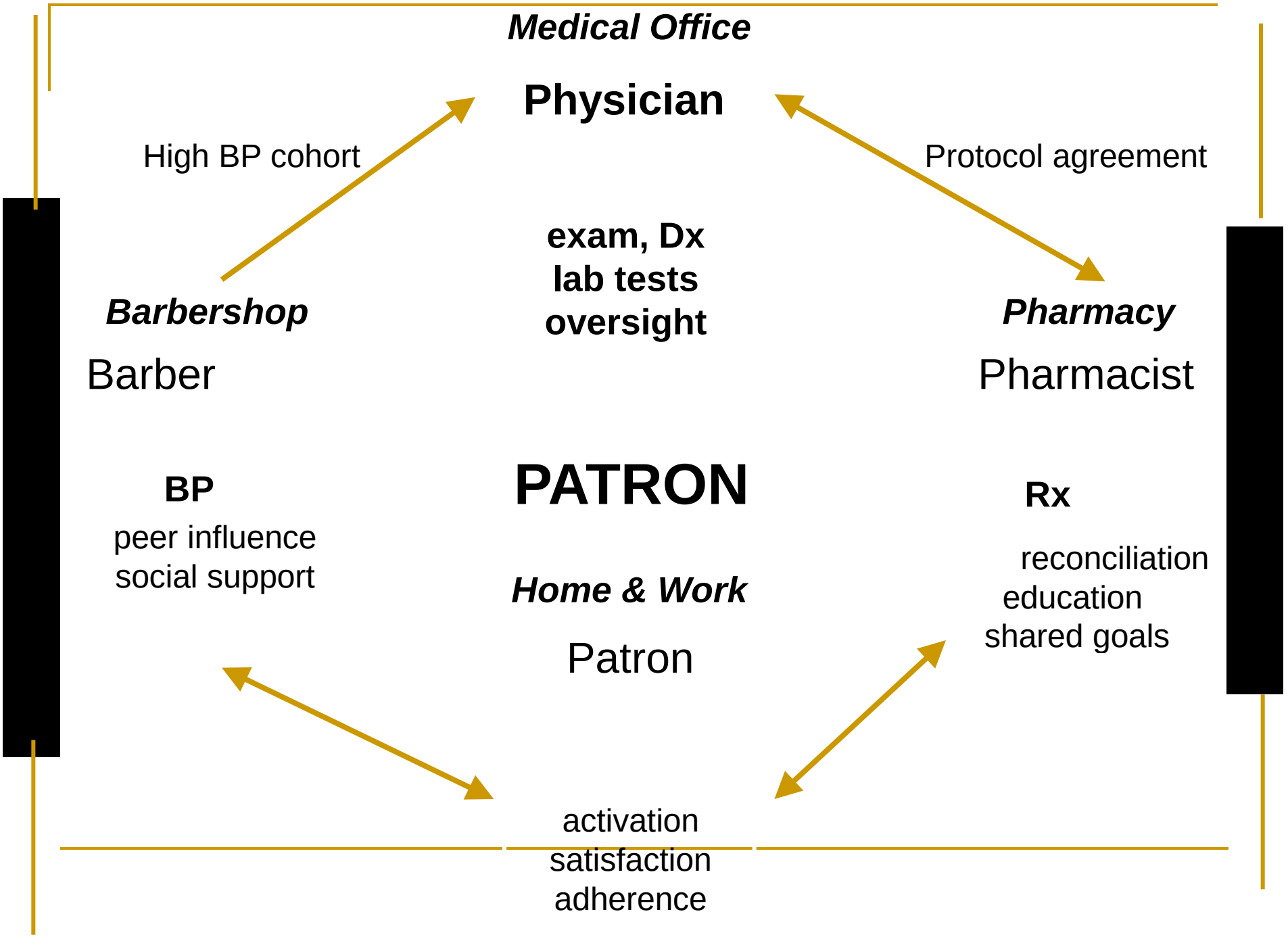
The BARBER-1 Study: A Cluster Randomized Trial

Ronald G. Victor, MD; Joseph E. Ravenell, MD, MS; Anne Freeman, MSPH; David Leonard, PhD; Deepa G. Bhat, ME; Moiz Shafiq, MD; Patricia Knowles; Joy S. Storm, BS; Emily Adhikari, BA; Kirsten Bibbins-Domingo, PhD, MD, MAS; Pamela G. Coxson, PhD; Mark J. Pletcher, MD, MPH; Peter Hannan, MStat; Robert W. Haley, MD



Intervention effect was small due to:

- Physician inertia
- Several design issues


Medical Office
Physician
High BP cohort
Protocol agreement
exam, Dx
lab tests
oversight
Barbershop
Barber
Pharmacist
Pharmacist
PATRON
BP
peer influence
social support
Rx
reconciliation
education
shared goals
Home & Work
Patron
activation
satisfaction
adherence

Aims

Aim 1: Effectiveness

△SBP at 6 months

Aim 2: Sustainability

6 month extension study

Aim 3: Scalability

implementation pilot study

cost-effectiveness projections

Cluster RCT
20 barbershops
25 patrons/shop

Phases of the Trial

1. Accrual: 10 weeks
2. Intervention and Evaluation:

   all participants observed for 6 months
3. Sustainability:

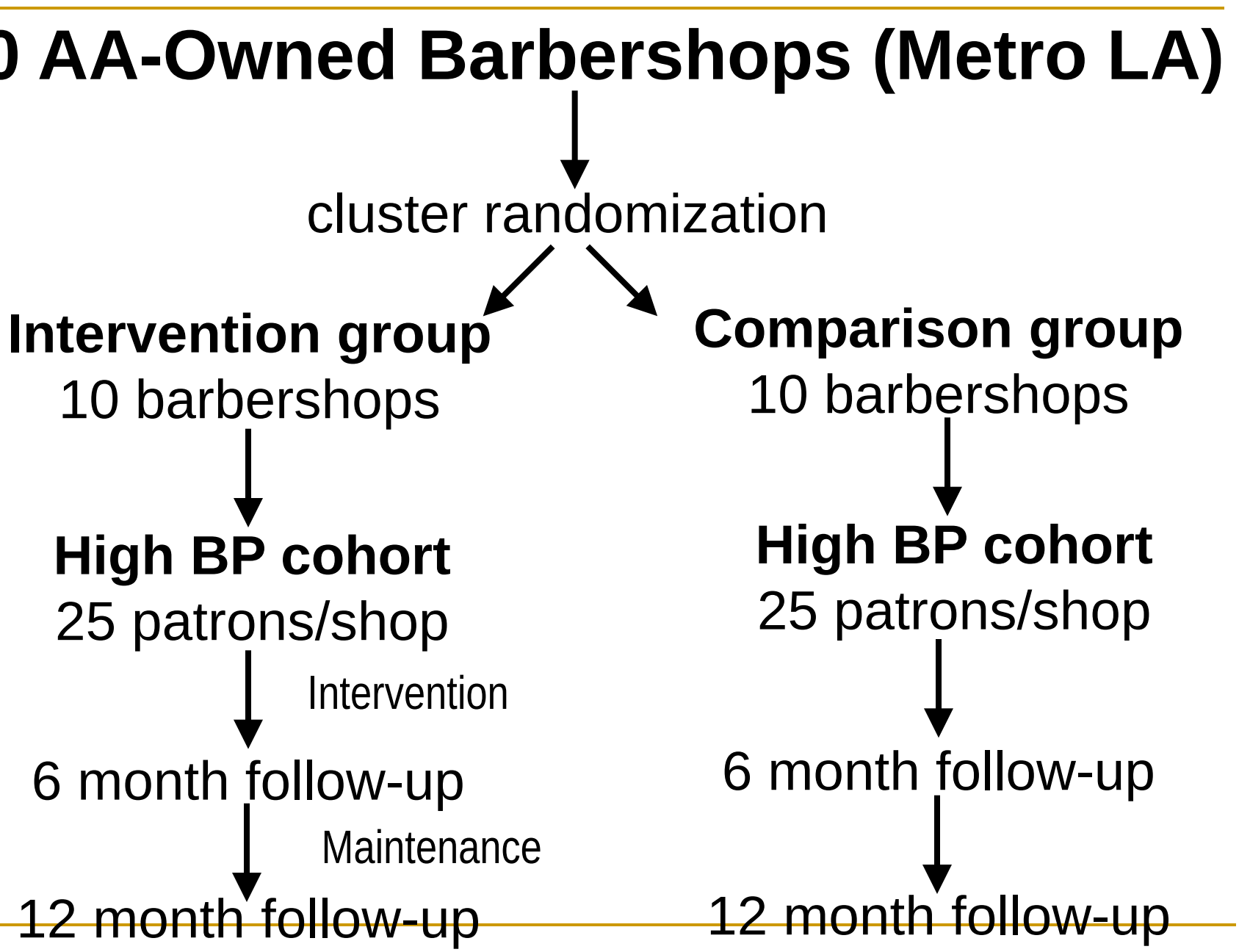
   all observed for an additional 6 months

Type of Trial: cluster randomized

Clusters are barbershops owned by African American proprietors.

Randomization

- Barbershops, not individuals, are randomized.
- Barbershops are randomized to intervention or comparator groups equally.
- Randomization algorithm is reviewed by NIH.


20 AA-Owned Barbershops (Metro LA)
cluster randomization
Intervention group
10 barbershops
High BP cohort
25 patrons/shop
Intervention
6 month follow-up
Maintenance
12 month follow-up
Comparison group
10 barbershops
High BP cohort
25 patrons/shop
6 month follow-up
12 month follow-up

Inclusion and Exclusion Criteria

Inclusion

- AA men
- Age ≥ 18
- SBP ≥ 140 x 2 screenings
- Regular patrons

Exclusion

- Not AA, women
- Minors
- SBP < 140 at either screening
- New/infrequent patrons
- Serious complicating illness (e.g., cognitive impairment, cancer chemotherapy)

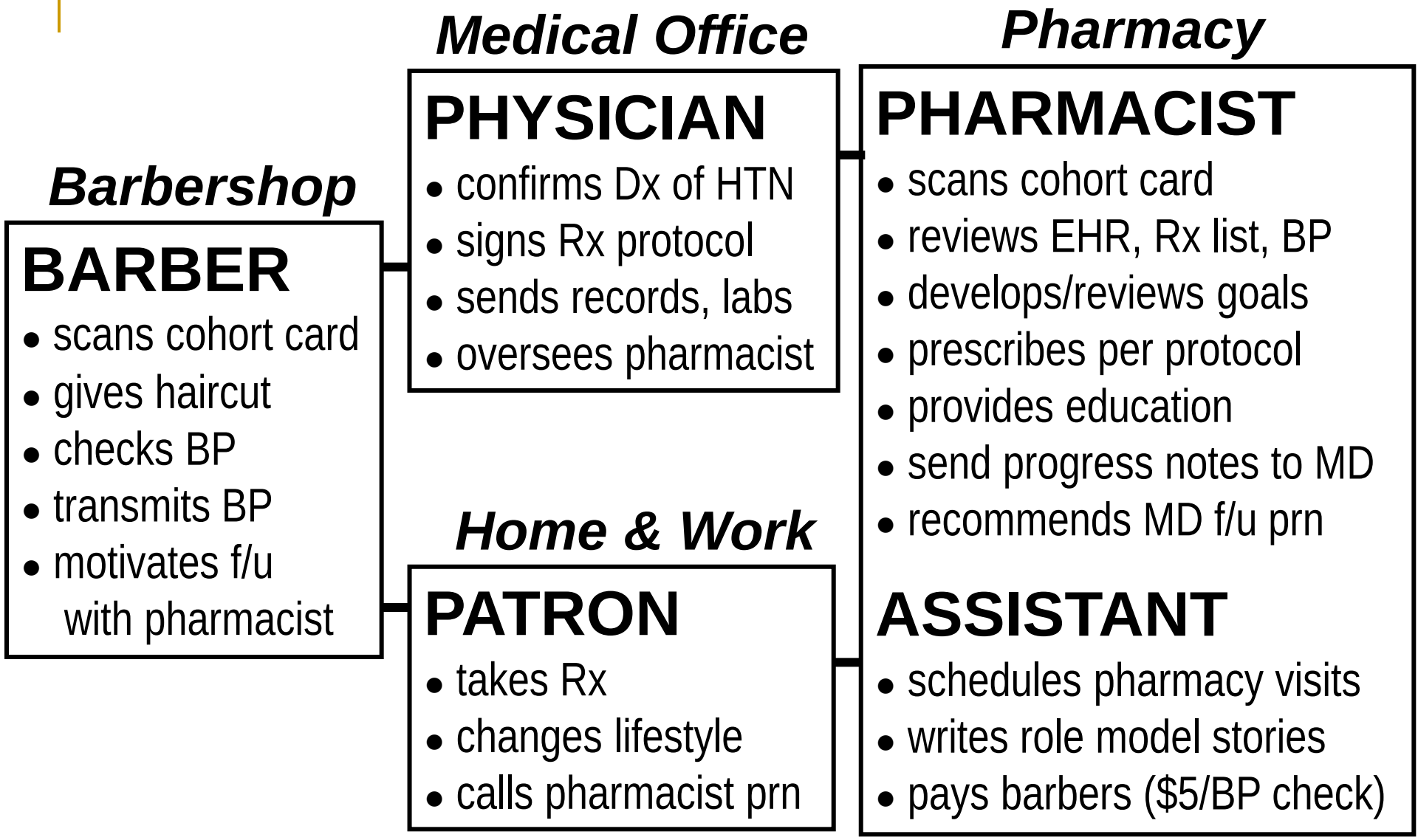
Treatments

- **Comparator Condition**

  standard HTN pamphlets + usual care

- **Active Intervention**

  barber-pharmacist-physician coordination



Barbershop

BARBER

- scans cohort card
- gives haircut
- checks BP
- transmits BP
- motivates f/u with pharmacist

Medical Office

PHYSICIAN

- confirms Dx of HTN
- signs Rx protocol
- sends records, labs
- oversees pharmacist

Home & Work

PATRON

- takes Rx
- changes lifestyle
- calls pharmacist prn

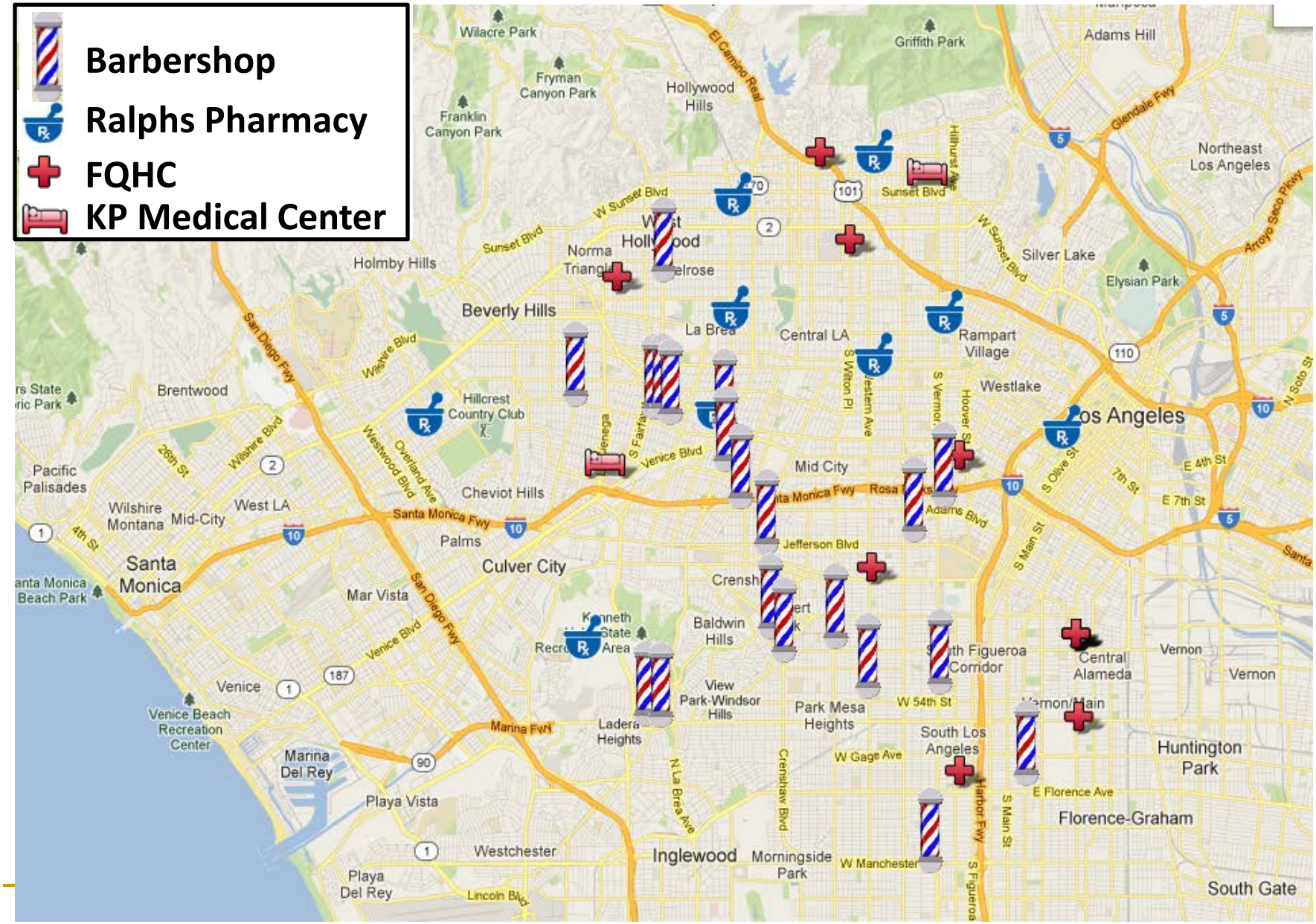
Pharmacy

PHARMACIST

- scans cohort card
- reviews EHR, Rx list, BP
- develops/reviews goals
- prescribes per protocol
- provides education
- send progress notes to MD
- recommends MD f/u prn

ASSISTANT

- schedules pharmacy visits
- writes role model stories
- pays barbers ($5/BP check)


Barbershop
Ralphs Pharmacy
FQHC
KP Medical Center
Wilacre Park
Fryman Canyon Park
Franklin Canyon Park
Hollywood Hills
Griffith Park
Adams Hill
Northeast Los Angeles
Silver Lake
Elysian Park
Holmby Hills
Beverly Hills
Norma Triangle
Central LA
Rampart Village
Westlake
Los Angeles
Brentwood
Hillcrest Country Club
Pacific Palisades
Wilshire Montana
Mid-City
West LA
Cheviot Hills
Mid City
Palms
Culver City
Santa Monica
Mar Vista
Baldwin Hills
Venice
Venice Beach Recreation Center
Marina Del Rey
Playa Vista
Ladera Heights
View Park-Windsor Hills
Park Mesa Heights
South Los Angeles
Central Alameda
Vernon
Huntington Park
Florence-Graham
Westchester
Inglewood
Morningside Park
Playa Del Rey
South Gate
El Camino Real
Sunset Blvd
W Sunset Blvd
Wilshire Blvd
Santa Monica Fwy
San Diego Fwy
Venice Blvd
Jefferson Blvd
Adams Blvd
Marina Fwy
W 54th St
W Gage Ave
E Florence Ave
W Manchester
Harbor Fwy
Glendale Fwy
Arroyo Seco Pkwy
Hillhurst Ave
Hoover St
S Vermont
S Wilton Pl
Western Ave
S Fairfax
Westwood Blvd
Overland Ave
26th St
4th St
S Olive St
7th St
E 4th St
E 7th St
S Main St
N La Brea Ave
Crenshaw Blvd
S Figueroa
Lincoln Blvd
Santa Monica Beach Park
Rosa Parks Fwy
Hillcrest Country Club
Venice Beach Recreation Center

Endpoints

Primary: △SBP at 6 months

Secondary:

a. △SBP at 12 months (priority)

b. △DBP at 6 and 12 months

c. # of BP medications per regimen (clinical inertia)

d. Patient reported outcomes (satisfaction, activation, adherence)

Evaluation

- Intensive monitoring plan with scheduled research visits (for protocol compliance)
- Conducted by an independent professional survey research company (Westat)

To reduce observer bias:

- 6 separate Westat teams
  - Different teams for 2 treatment groups
  - New teams for 6- and 12- month evaluations

Research Procedures	Baseline		6 Month Evaluation		12 Month Evaluation	
	Day 1	Day 2	Day 1	Day 2	Day 1	Day 2
Screening	X	X				
Written Informed Consent		X				
BP Measurement	X	X	X	X	X	X
CAPI Health Questionnaire		X	X		X	
Medication List		X		X		X
Qualitative Interview				X		X

Clinical Data Management

- Data on SBP, DBP at each phase of the trial are collected at each barbershop by Westat surveyors, transferred from the shop by a web-based system to Westat HQs in Virginia and sent via the internet to UCLA.

Data Editing

- Data are edited in Dr. David Elashoff's group in the Dept. of Medicine and sent to the Dept. of Biomathematics.
- All data management and editing methods are in place.

Sample Size Estimation

- The sample size is based on:

  A) Number of barbershops

  B) Patrons per shop

  C) Estimated mean △SBP

  D) Retention rate for subjects

  E) Intraclass correlation

The next slide shows the computation…

Sample Size Computation

- Enrollment of 20-30 subjects per shop:

this restriction should enable the sample size computation to be a close approximation of a fully balanced design.

Sample Size Computation

Table 4: Retention Rate: 80%, two-sided alpha level: 0.05, systolic blood pressure included as a covariate, power: 90%						
Subjects per shop at baseline	Intervention Effect Size: mean systolic BP (mm Hg)	% Retention	Subjects per shop at final	ICC	Design Effect	Shops per arm at baseline
25	-5.6	80	20	0.01	1.2	13
25	-5.8	80	20	0.01	1.2	12
25	-6.1	80	20	0.01	1.2	11
25	-6.4	80	20	0.01	1.2	10
25	-6.7	80	20	0.01	1.2	9
25	-7.1	80	20	0.01	1.2	8
25	-7.6	80	20	0.01	1.2	7
25	-8.2	80	20	0.01	1.2	6
25	-9.0	80	20	0.01	1.2	5

Sample size (cont.)

- The computation of the sample size (# of barbershops) is based on a 2004 paper by Tu et al.; essentially a regression model within a linear mixed model.
- A related approach by Donner gives a close approximation to Tu's computation.

Data Analysis

- A simple summary is the linear mixed model with terms for baseline SBP, treatment group, BP medications, and age.
- Expanded models will be used.
- Prediction studies to be implemented

Interim and Futility Analyses

- No such analyses will influence the ea termination of the primary trial.
- Such analyses will be carried out to proce or not with the sustainability phase.

Missing Data (especially on individuals)

- The literature on missing data in cluster-randomized trials is light.
- The team of Profs Ning Li, Gang Li, Chi-Hong Tseng, and R Elashoff will be studying new methodology for this problem (write a stats paper).

Key Problems

- Effectiveness of the patron and barbershop monitoring. Fortunately, considerable funding for monitoring is budgeted – QED.

CTSI Team Science

UCLA-CTSI

Cedars- Victor, Niknezhad

UCLA- R Elashoff et al., Shapiro

CDU- Martin

USC- Chen

UCSF- Pletcher, Bibbins-Domingo, Coxson

UTSW- Haley

Stakeholder partners

KP So. Cal.- Kanter

Ralphs (*Kroger)-FQHC (Healthy Way L.A.)*- Cupp

Barber (Texas Assn. Tonsorial Artists)- Smith

Patron - Bluitt

Assn. Black Cardiologists - Ferdinand (New Orleans)

HAAF- Jones

Stakeholder partners

- **KP So. Cal.**- Kanter
- **Ralphs (Kroger) Pharmacy-** Cupp
- **Walgreens Pharmacy**- Crawford
- **Barber** – Smith (Dallas), Riddle (Altadena)
- **Patron** – Harris (Altadena)
- **Assn. Black Cardiologists**-Ferdinand (New Orleans)
- **HAAF**- Jones
- **County of Los Angeles DHS**- Katz