

A Randomized Trial to Improve Patient-Centered Care and Hypertension Control in Underserved Primary Care Patients

Lisa A. Cooper, MD, MPH^{1,2,3,4,5}, Debra L. Roter, DrPH⁵, Kathryn A. Carson, ScM^{1,3}, Lee R. Bone, MPH^{2,5}, Susan M. Larson, MS⁵, Edgar R. Miller III MD, PhD^{1,2,3}, Michael S. Barr, MD, MBA⁶, and David M. Levine, MD, MPH, ScD^{2,5}

¹Welch Center for Prevention, Epidemiology, and Clinical Research, Johns Hopkins University, Baltimore, MD, USA; ²Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, USA; ³Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA; ⁴Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA; ⁵Department of Health, Behavior, and Society, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA; ⁶American College of Physicians, Division of Medical Practice, Professionalism, & Quality, Washington, DC, USA.

BACKGROUND: African Americans and persons with low socioeconomic status (SES) are disproportionately affected by hypertension and receive less patient-centered care than less vulnerable patient populations. Moreover, continuing medical education (CME) and patient-activation interventions have infrequently been directed to improve the processes of care for these populations.

OBJECTIVE: To compare the effectiveness of patient-centered interventions targeting patients and physicians with the effectiveness of minimal interventions for underserved groups.

DESIGN: Randomized controlled trial conducted from January 2002 through August 2005, with patient follow-up at 3 and 12 months, in 14 urban, community-based practices in Baltimore, Maryland.

PARTICIPANTS: Forty-one primary care physicians and 279 hypertension patients.

INTERVENTIONS: Physician communication skills training and patient coaching by community health workers.

MAIN MEASURES: Physician communication behaviors; patient ratings of physicians' participatory decision-making (PDM), patient involvement in care (PIC), reported adherence to medications; systolic and diastolic blood pressure (BP) and BP control.

KEY RESULTS: Visits of trained versus control group physicians demonstrated more positive communication change scores from baseline (−0.52 vs. −0.82, $p=0.04$). At 12 months, the patient+physician intensive group compared to the minimal intervention group showed significantly greater improvements in patient report of physicians' PDM ($\beta=+6.20$ vs. -5.24 , $p=0.03$) and PIC dimensions related to doctor facilitation ($\beta=+0.22$ vs. -0.17 , $p=0.03$) and information exchange ($\beta=+0.32$ vs.

-0.22 , $p=0.005$). Improvements in patient adherence and BP control did not differ across groups for the overall patient sample. However, among patients with uncontrolled hypertension at baseline, non-significant reductions in systolic BP were observed among patients in all intervention groups—the patient+physician intensive (−13.2 mmHg), physician intensive/patient minimal (−10.6 mmHg), and the patient intensive/physician minimal (−16.8 mmHg), compared to the patient+physician minimal group (−2.0 mmHg).

CONCLUSION: Interventions that enhance physicians' communication skills and activate patients to participate in their care positively affect patient-centered communication, patient perceptions of engagement in care, and may improve systolic BP among urban African-American and low SES patients with uncontrolled hypertension.

KEY WORDS: patient-centered care; patient-physician communication; hypertension.

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INTRODUCTION

African Americans and persons of lower socioeconomic status suffer a disproportionate burden of morbidity and mortality from cardiovascular disease.^{1–4} Although environment, economic and social factors,^{5–7} behavioral risk factors^{8,9}, and access to care¹⁰ partially explain these differences in health status, disparities in healthcare quality for cardiovascular disease may also contribute to poorer outcomes among ethnic minorities and the poor.^{11,12} Patient, clinician, and health system factors contribute to disparities in care. Patients' health beliefs and behavior,^{13–16} low health literacy,^{17,18} and involvement in medical decision-making¹⁹ play a role in healthcare disparities and may influence adherence to recommended therapies. Clinician factors such as clinical inertia^{20,21} end-digit preference,²² lack of cultural competence,²³ communication styles,²⁴ and biases in medical decision-making²⁵ also contribute to disparities in treatment and outcomes. Financing, organization and delivery of services such as the degree of organizational focus on

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quality,²⁶ patient-centeredness and cultural competence²⁷ may also play a role.

Several effective quality improvement interventions for hypertension have been identified; the most effective target patients, while interventions targeting only clinicians have been found to improve healthcare processes but not patient adherence or outcomes.²⁸⁻³¹ Few of these studies, however, have included adequate samples of African Americans.³²⁻³⁶ Additionally, some patient-activation interventions designed to improve patient-physician communication have been tested in patients with chronic diseases, but relatively few have used culturally and linguistically targeted strategies and focused on ethnic minorities and socioeconomically disadvantaged patients who typically have lower levels of engagement and poorer communication with physicians. Furthermore, few of these studies have simultaneously intervened with patients and their physicians in a comprehensive way—for example, by reinforcing activation and empowerment skills and providing emotional support for patients over time, and by providing individualized feedback to clinicians regarding their communication skills—and few objectively measure intervention effects on health outcomes.³⁷

Interventions to increase patient-physician communication are important strategies to improve hypertension care and outcomes in underserved populations. The objective of the Patient-Physician Partnership Study was to compare the effectiveness of patient and physician interventions, separately, and in combination with one another, with the effectiveness of minimal interventions, by evaluating intervention impact on: 1) patient-physician communication behaviors; 2) patient ratings of the interpersonal process of care; 3) patient adherence to medications; and 4) blood pressure (BP) levels and control over 12 months.

METHODS

Study Design and Setting

The Patient-Physician Partnership Study was a randomized controlled trial, with a two-by-two factorial design. Physicians and patients were randomized with equal probability to minimal or intensive interventions described below. The study occurred in 14 urban community-based primary care sites chosen because they serve primarily low income and/or ethnic minority patient populations. Approximately 60 to 100% of the patients in participating sites were African-American, and 35% to 55% earned below 200% of the federally defined poverty guidelines. The trial received approval from the Johns Hopkins Institutional Review Board. Informed written consent was obtained from all participating physicians and patients.

Inclusion Criteria

Physicians recruited for the Patient-Physician Partnership Study were general internists and family physicians who saw patients at least 20 hours per week at one of the participating study sites. Physicians were excluded if they intended to leave the practice within 12 months. Fifty physicians were randomly assigned to study intervention groups; however, after randomization, nine physicians were excluded from the analyses of study outcomes—

six physicians left their clinical sites prior to patient enrollment, and three physicians became ill, withdrew from the study, or were lost to follow-up, resulting in 41 participating physicians.

Patients recruited for the study were adults aged 18 years and older, had a diagnosis of hypertension (at least one claim with the ICD-9 code 401 in the preceding year), and were able to provide contact information for themselves and at least one other person. Patients who were too acutely ill, disoriented, or unresponsive to complete the baseline assessment and those with medical conditions that might limit their participation in the study (*e.g.*, AIDS/HIV, schizophrenia, cancer (except skin), Alzheimer's or other form of dementia; end-stage renal disease, congestive heart failure, or active tuberculosis) were excluded. Eligibility was assessed for 980 patients; 701 patients were excluded (375 did not meet inclusion criteria, 43 refused to participate, 283 were excluded for other reasons, *e.g.*, they indicated willingness to participate but did not show up for the enrollment visit). Two hundred seventy-nine patients were randomized to study interventions. Details regarding physician and patient recruitment for this study have been described elsewhere.³⁸

Interventions

The physician communication skills program was designed to provide physicians with personalized feedback based on their videotaped performance with a simulated patient scheduled for an office appointment. The feedback focused on communication skills relevant to increasing patient engagement, activation, and empowerment organized within the context of the four functions of the medical interview (data-gathering, patient education and counseling, rapport-building, and facilitation and patient activation).³⁹ In addition, five specific behaviors linked with successful hypertension management were targeted: 1) elicit the full spectrum of patients' concerns; 2) probe patients' hypertension knowledge and beliefs; 3) monitor adherence and identify barriers; 4) assess adherence related lifestyle and psychosocial issues; 5) elicit commitment to therapeutic plan. Intervention group physicians reviewed the videotape of their personal interviews with the simulated patient and completed exercises on the CD-ROM or in the workbook. Control group physicians participated in the simulated visit but did not receive any feedback until the end of the study. All physicians received a copy of the JNC-VII treatment guidelines at the beginning of the study and a monthly newsletter with study updates and summaries of recent journal articles.

The patient intervention was based on a pre-visit coaching model shown to improve patients' communication with clinicians and health outcomes.^{40,41} The model focused on patient communication skills related to engagement, activation, and empowerment parallel to skills targeted in the physician intervention.³⁹ Trained community health workers (CHWs) administered the intervention to enhance its cultural appropriateness, relevance, and effectiveness. CHWs asked patients to think about any changes they wanted to make regarding interactions with their physicians; allowed patients to practice disclosing concerns, asking questions, and stating preferences; provided pocket-sized diaries for patients to record their appointments, medications, and questions; and helped patients identify sources of support for their new behaviors and strategies to overcome anticipated problems. Telephone

follow-ups reinforced the importance of preparing for clinic visits with a listing of concerns. Intensive intervention patients received bimonthly photonovels that reinforced the coaching messages. All patients received a monthly health education newsletter designed to meet the needs of low literate adult readers. Due to the nature of the interventions, complete masking of participants, investigators, and CHWs was not possible. However, all interviewers and CHWs were masked to physician intervention assignment. Research interviewers at enrollment were masked to patient intervention assignment until after baseline data collection was complete, and interviewers at follow-up were masked to patient intervention assignment until the end of the interview. Physicians were not informed of the intervention assignment of their patients; however, patients may have revealed this information to their physicians either directly in conversation or indirectly by using intervention materials during their visits.

Measurements

Physician Communication Behaviors. Physician communication behaviors were obtained from videotapes of the simulated visit and audiotapes of the first patient study visit. All visits were analyzed using the Roter Interaction Analysis System (RIAS), a widely used coding system with demonstrated reliability and predictive validity.⁴²⁻⁴⁴ Physician verbal dominance, the ratio of clinician to patient statements, is an indicator of the level of participation of the clinician relative to the patient in the dialogue, with scores >1 meaning the clinician verbally dominated the visit dialogue. Patient-centeredness is the ratio of the sum of psychosocial, rapport-building, and facilitative behaviors by clinicians and patients to the sum of biomedical questions, information giving and closed-ended questions. A score >1 indicates that the visit tends to further the patient's agenda while a score <1 means the visit tends to further the clinician's agenda.⁴⁵⁻⁴⁷ Patient-centered interviewing has demonstrated concurrent and predictive validity and has been linked to patient satisfaction and reported rapport with clinicians.^{44,45,48}

Patient Ratings of Physicians' Participatory Decision-Making (PDM) Style. Physicians' PDM style was measured by patient report as the aggregate of three items, each rated on a five-point scale from 0=never, to 4=very often: 1) If there were a choice between treatments, how often would this doctor ask you to help make the decision? 2) How often does this doctor give you some control over your treatment? and 3) How often does this doctor ask you to take some of the responsibility for your treatment?⁴⁹ The raw score is converted to a percent. A higher score means the visit was more participatory. PDM style is an important measure of patient-centered care; it distinguishes race-concordant from discordant visits and has been linked to satisfaction and continuity of care over time.^{46,49}

Patient Involvement in Care. Patient involvement in care was assessed using the Patients' Perceived Involvement in Care Scale (PICS), a patient self-report measure reflecting level of agreement with: doctor facilitation of patient involvement during the visit; information exchange between patient and physicians; and patient participation in medical decision-making.⁵⁰ Scores on each subscale range from 1 to 5, and higher scores reflect more involvement in care. The PICS has

been validated in previous studies; the internal consistency of the scale and subscales has ranged from 0.73-0.89.^{50,51}

Patient Adherence. Patient adherence was measured by self-report at baseline and follow-up using a modified version of the 4-item Morisky medication adherence scale examined as a dichotomous variable of adherent (answered "no" to each of the items) or non-adherent (answered yes to at least one of the items).⁵²

Blood Pressure. BP was measured before the baseline visit and at follow-up visits by trained and certified observers using an automatic oscillometric monitor (Omron HEM 907). This device programs a five-minute delay before activation and has a 30-second delay between the triplicate measurements. The average of the three measurements was used. BP control was dichotomized as uncontrolled (SBP \geq 140 mmHg or DBP \geq 90 mmHg, or SBP \geq 130 mmHg or DBP \geq 80 mmHg if diabetic or chronic kidney disease) or controlled.

Statistical Considerations

Randomly assigned treatment group (physician+patient intervention, physician intervention only, patient intervention only, or physician+patient minimal intervention) was the main independent variable for this study. To examine the change in physician communication behaviors, the physician intervention groups were compared. All efficacy analyses were performed using the 'intention-to-treat' principle. Clinic site was a stratification variable for randomization and was expected to be balanced across treatment groups by design. Descriptive statistics were used to summarize patient and physician characteristics at baseline and to assess the comparability of the intervention groups. The primary time point was the 12-month follow-up, and for continuous outcome measures, change from baseline was calculated. Mixed effects regression models were used to assess the intervention effect while accounting for the nesting of patients within physician. Missing data were assumed to be missing at random and the primary analyses used listwise deletion. Sensitivity analysis, hierarchical models including available data from all time points for continuous outcomes and multiple imputation for dichotomous outcomes, was used to check the validity of the results. Analyses were performed using SAS version 9.2 (SAS Institute, Inc., Cary, North Carolina). All reported *P* values are two-sided.

Role of the Funding Source

This study was conducted with grant support from the National Heart, Lung, and Blood Institute (NHLBI). The NHLBI had no role in the design, conduct, or reporting of the study.

RESULTS

Physician Characteristics

Table 1 shows the baseline characteristics of the 41 physicians for whom we have patient outcome data according to their

Table 1. Demographic and Baseline Characteristics of the 41 Physicians who had Patients in the Study by Physician Intervention Status

Characteristic	Intervention Group		P Value ^a
	Intensive (n=22)	Minimal (n=19)	
Age, mean (SD), y	41.8 (6.7)	44.3 (10.3)	0.36
Women, No. (%)	11 (50)	11 (58)	0.76
Ethnicity, No. (%)			
African American	5 (23)	7 (37)	0.75
Asian	6 (27)	4 (21)	
White	10 (45)	8 (42)	
Hispanic/Latino	1 (5)	0 (0)	
Practice experience, mean (SD), y	10.0 (6.2)	12.6 (8.9)	0.27
Internal medicine, No. (%)	17 (77)	16 (84)	0.70
U.S. medical graduate, No. (%)	16 (73)	15 (79)	0.73
Board certified, No. (%)	22 (100)	16 (84)	0.09
CME in communication skills ^b , No. (%)	11 (50)	8 (42)	0.76
CME in hypertension ^b , No. (%)	15 (68)	9 (50)	0.33
Very confident caring for, No. (%)			
Socially disadvantaged	12 (55)	12 (63)	0.75
Minority patients	14 (64)	13 (68)	0.99
Hypertensive patients	18 (82)	14 (74)	0.71
Non-adherent patients	5 (23)	8 (42)	0.31

^aP value from Fisher's exact test or two-sample t-test

^bEver attended continuing medical education (CME) training

intervention assignment. Physicians were mostly general internists (74%) with a mean age of 43.0 years and mean practice experience of 11.9 years. Just over half (52%) were women, and they were ethnically diverse. Most were very confident in their ability to care for socially disadvantaged (60%), ethnic minority (70%), and hypertensive patients (82%); however, only a third (34%) were confident in their ability to care for non-adherent patients. There were no significant differences between physicians in minimal and intensive intervention groups with regard to sociodemographics, training, or self-efficacy. A slightly higher percentage of intensive intervention physicians were board certified (100% vs. 84%, $p=0.09$).

Patient Characteristics

Table 2 shows baseline characteristics of the 279 patients who enrolled in the study according to their own and their physicians' intervention assignments. They were 61.3 years of age on average; 66% were women and 62% were African American. The average years of education was 11.8 years, only 24% were employed, and 70% reported an annual household income of less than \$35,000. Ninety percent had health insurance and 92% had prescription drug coverage. Diabetes was the most common co-morbid medical condition (44%), followed by depression (24%), and cardiovascular disease (17%). The sample had a mean body mass index of 32.9, and 48% had controlled blood pressure using JNC-VII criteria. Patients in the physician+patient intensive group had the lowest percentage of high school graduates and had lower

levels of income. Patients in the physician minimal/patient intensive group had the highest percentage of diabetes and the lowest percentage of self-reported depression.

Process Measures

Changes in physician verbal dominance and patient-centeredness were calculated by subtracting the physician's simulated visit from the physician's actual patient visits. Verbal dominance diminished (improved) significantly in all patient visits relative to the simulation with little difference by the physician intervention group ($\beta=+0.27$ for the intensive group compared to minimal, $p=0.35$). In both physician intervention groups, the patient centeredness ratio was lower (worse) in the visits of actual patients than with the standardized patient; however, the physician intensive intervention group showed a smaller decline in performance than the physician minimal group ($\beta=+0.30$, $p=0.04$) (Table 3). Patient report of physicians' PDM showed significantly greater improvements among patient+physician intensive group than the patient+physician minimal group ($\beta=+6.2$ vs. -5.2 , $p=0.03$). Similarly, two aspects of the PICS, physician facilitation ($\beta=+0.22$ vs. -0.17 , $p=0.03$) and information exchange ($\beta=+0.32$ vs. -0.22 , $p=0.005$), showed improvements for intensive relative to minimal groups. (Table 4) Changes in patient-reported adherence to medications at 12 months did not differ for any of the intervention groups compared to the patient+physician minimal intervention group. (Table 4)

Outcome Measures

In the overall sample, changes in systolic and diastolic BP at 12 months did not differ for any of the intervention groups when compared to the patient+physician minimal intervention group (Table 5). However, among patients who had uncontrolled BP at baseline, large reductions in systolic BP were observed among patients in the patient+physician intensive (-13.2 mmHg), physician intensive/patient minimal (-10.6 mmHg), and the patient intensive/physician minimal (-16.8 mmHg), compared to the patient+physician minimal group (-2.0 mmHg) [p-values 0.14, 0.27, and 0.07, respectively] (Table 5).

Missing Data

Follow-up rates at 3 months and 12 months for interview data (65% and 71%) and blood pressure (58% and 55%) were lower than expected. Compared to patients with BP data at 3 months, those who were missing BP data at 3 months were younger (59.6 vs. 62.5 years, $p=0.05$), more likely to be white (39% vs. 34%, $p=0.09$) less likely to be insured (86% vs. 93%, $p=0.06$), and had higher diastolic BP at baseline (78 mmHg vs. 74 mmHg, $p=0.02$). Compared to patients with BP data at 12 months, those who were missing BP data at 12 months were more likely to be white (42% vs. 31%, $p=0.03$), married (41% vs. 31%, $p=0.09$), and had fewer co-morbid medical conditions (2.5 vs. 2.9, $p=0.08$). Results from analyses using hierarchal

Table 2. Baseline Demographic and Clinical Characteristics of Patients by Intervention Group

Characteristic	Physician+ Patient Intensive (n=83)	Physician Minimal/ Patient Intensive (n=57)	Physician Intensive/ Patient Minimal (n=84)	Physician+Patient Minimal (n=55)	P Value ^a
Age, mean (SD), y	59.7 (11.9)	63.7 (11.1)	60.5 (12.0)	62.4 (12.1)	0.19
Female, No. (%)	54 (65.1)	41 (71.9)	55 (65.5)	34 (61.8)	0.71
Ethnicity, No. (%)					
African American	52 (62.6)	38 (66.7)	51 (60.7)	32 (58.2)	0.76
Asian	2 (2.4)	1 (1.8)	0 (0)	0 (0)	
American Indian	0 (0)	0 (0)	1 (1.2)	1 (1.8)	
White	29 (34.9)	18 (31.6)	32 (38.1)	22 (40.0)	
Married, No. (%)	31 (37.8)	22 (38.6)	26 (31.3)	19 (34.6)	0.78
Education, mean (SD), y	11.3 (2.6)	12.2 (2.1)	11.8 (2.4)	12.2 (2.3)	0.08
REALM, ≥9th grade, No. (%)	49 (59.8)	34 (61.8)	51 (61.4)	39 (70.9)	0.58
Income <\$35,000, No. (%)	64 (84.2)	34 (66.7)	59 (71.1)	33 (63.5)	0.03
Employed, No. (%)					
Full or part time	17 (21.0)	14 (25.9)	23 (27.4)	13 (23.6)	0.94
Not employed	20 (24.7)	9 (16.7)	13 (15.5)	10 (18.2)	
Retired	26 (32.1)	20 (37.0)	29 (34.5)	21 (38.2)	
Disabled	18 (22.2)	11 (20.4)	19 (22.6)	11 (20.0)	
Any health insurance, No. (%)	74 (89.2)	51 (91.1)	73 (86.9)	51 (92.7)	0.74
Medicaid, No. (%)	28 (34.2)	15 (26.8)	23 (27.4)	19 (34.6)	0.88
Medicare, No. (%)	28 (34.6)	25 (44.6)	31 (36.9)	23 (42.6)	0.69
Private insurance, No. (%)	40 (49.4)	30 (53.6)	46 (55.4)	24 (43.6)	0.56
Prescription plan, No. (%)	77 (93.9)	51 (91.1)	75 (89.3)	54 (98.2)	0.21
PCS SF-12, mean (SD)	39.8 (12.5)	40.5 (12.2)	40.4 (12.6)	40.4 (11.4)	0.99
MCS SF-12, mean (SD)	51.6 (10.3)	49.5 (11.9)	50.2 (10.6)	50.0 (11.5)	0.71
Comorbid conditions, No. (%)					
Diabetes mellitus	36 (43.9)	32 (58.2)	28 (33.7)	25 (45.4)	0.04
Cardiovascular disease	11 (13.2)	11 (20.0)	12 (14.5)	14 (25.4)	0.24
Depression	20 (24.4)	7 (13.0)	19 (23.2)	18 (33.3)	0.10
Body mass index, mean (SD)	33.6 (8.9)	33.9 (9.2)	31.8 (6.8)	32.3 (7.3)	0.36

Abbreviations: REALM, Rapid Estimates of Adult Literacy in Medicine; PCS SF-12, physical component scale of Medical Outcomes Study 12-item short form; MCS SF-12, mental component scale of Medical Outcomes Study 12-item short form

^aP value from Fisher's exact test or F test

models and imputed data were consistent with those shown in the tables.

DISCUSSION

In this randomized trial, patient and physician interventions to enhance hypertension management led to several process and

Table 3. Patient-physician communication Measures of Physician with Standardized Patient and Change^a with Actual Patient by Physician Intervention Group

Characteristic	Physician Intervention Group		P Value
	Intensive	Minimal	
Verbal dominance ratio ^b :			
With standardized patient, geometric mean (SD)	3.20 (1.31)	3.45 (1.36)	0.40
Change with actual patients	-1.67 (-2.06, -1.28)	-1.94 (-2.36, -1.53)	0.35
Patient centeredness ratio:			
With standardized patient, mean (SD)	1.10 (0.43)	1.46 (0.52)	0.02
Change with actual patients	-0.52 (-0.71, -0.32)	-0.82 (-1.02, -0.61)	0.04

Abbreviation: SD, standard deviation;

^a Change is reported as the coefficient and 95% confidence interval from mixed effects regression controlling for nesting within physician

^b Verbal dominance minus back channeling ratio

outcome effects favoring intensive relative to minimal intervention groups. While no improvements in patient adherence to medication were reported, positive intervention effects include those related to patient-centered communication behaviors, patient report of physicians' decision-making styles, facilitation, and information exchange, and the suggestion of clinically significant reductions in systolic BP among uncontrolled hypertensive patients. The greatest improvements were seen among patients who received coaching by a CHW and whose physicians also received patient-centered communication skills training. The improvements in blood pressure did not reach statistical significance, but the direction was consistent across groups and suggestive in the intervention group with the largest systolic BP reduction. Reductions in systolic BP—as small as 5 mmHg—have been associated with significant reductions in mortality.⁵³

The pattern of results suggests a clinical impact comparable to or exceeding other educational interventions that have attempted to improve the management of hypertension among the poor and ethnic minorities. While CME interventions using practice-enabling or reinforcing strategies improve physician performance, among eight studies identified in a review as having achieved a positive change in at least one clinical outcome, none were in the area of hypertension control.⁵⁴ In contrast to the disappointing findings generally reported in the literature, a recent high intensity CME intervention study was successful in reducing the number of patients with uncontrolled BP treated by intervention compared with control group participants.⁵⁵ Notably, the intervention effect was related to a

Table 4. Process Measures at Baseline^a and Change^b at 12-Month Follow-Up by Intervention Group

Characteristic	No. of Patients	Physician+Patient Intensive	Physician Minimal/Patient Intensive	Physician Intensive/Patient Minimal	Physician+Patient Minimal
PDM at baseline	269	68.0 (23.3)	67.3 (26.1)	68.9 (21.4)	75.9 (22.0)
Change at 12 months	192	6.2 (-0.5, 12.9)	3.2 (-4.8, 11.3)	3.1 (-3.9, 10.2)	-5.2 (-13.0, 2.5)
P value compared to ref		0.03	0.13	0.12	Ref
Patient Involvement in Care:					
Doctor facilitation at baseline	273	3.75 (0.62)	3.78 (0.76)	3.67 (0.38)	3.94 (0.66)
Change at 12 months	181	0.22 (0.00, 0.43)	0.12 (-0.15, 0.39)	0.09 (-0.14, 0.33)	-0.17 (-0.43, 0.09)
P value compared to ref		0.03	0.11	0.14	Ref
Information exchange at baseline	273	3.74 (0.68)	3.79 (0.73)	3.60 (0.79)	3.83 (0.76)
Change at 12 months	181	0.32 (0.08, 0.56)	0.16 (-0.14, 0.45)	0.13 (-0.13, 0.38)	-0.22 (-0.51, 0.07)
P value compared to ref		0.005	0.08	0.08	Ref
Patient decision making at baseline	273	2.56 (0.68)	2.68 (0.68)	2.63 (0.66)	2.77 (0.65)
Change at 12 months	181	0.21 (-0.03, 0.44)	0.07 (-0.23, 0.36)	0.16 (-0.10, 0.41)	-0.13 (-0.42, 0.16)
P value compared to ref		0.08	0.35	0.14	Ref
Adherent on Morisky scale:					
Baseline, %	269	58.2	66.1	63.8	68.5
12-month follow-up ^c	199	0.75 (0.62, 0.84)	0.80 (0.65, 0.90)	0.66 (0.53, 0.77)	0.77 (0.63, 0.87)
P value compared to ref		0.75	0.76	0.22	Ref

Abbreviations: PDM, participatory decision making, Ref, reference group

^aBaseline measures are reported as means (standard deviations), unless otherwise stated

^bChange at 12 months is reported as the coefficients and 95% confidence intervals from mixed effects regression controlling for nesting within physician

^cReported as predicted probability and 95% confidence interval from logistic mixed effects regression controlling for nesting within physician

significant reduction in systolic BP among patients with uncontrolled hypertension at baseline.

Several limitations should be discussed. The high level of loss to follow-up among randomized physicians limited the number of patients recruited, and failure to reach our patient recruitment target reduced our statistical power to detect differences in the primary outcomes. The intervention exposure for physicians was limited to a one-time administration, and for patients, to one in-person contact. The quality and accessibility of clinical and administrative data from participating practices varied substantially, making it a challenge to collect data on processes of care. Two occurrences prohibited collection of objective data for the primary outcomes of the study on which the sample size

was calculated—adherence to appointment-keeping and medication possession ratios. These were to be tracked using clinic schedules and pharmacy and claims data. Several sites switched to open access scheduling, thwarting the study's ability to ascertain patient adherence to appointments. Early implementation of the Health Insurance Portability and Accountability Act restricted access to individual patient data from clinics and pharmacies; thus, we were unable to gather data on prescription refill rates. We did not specify patients' presenting complaints. While we did not observe differences in patients' physical and mental health status across intervention groups, competing clinical demands at the enrollment visit may have differed across intervention groups and affected communication

Table 5. Outcome Measures at Baseline^a and Change^b at 12-Month Follow-Up by Intervention Group

Characteristic	No. of Patients	Physician+Patient Intensive	Physician Minimal/Patient Intensive	Physician Intensive/Patient Minimal	Physician+Patient Minimal
Systolic BP, mmHg:					
Baseline	275	138.3 (22.8)	137.2 (19.1)	131.4 (16.1)	133.8 (18.6)
Change at 12 months	152	-2.8 (-9.5, 3.8)	-6.5 (-14.2, 1.2)	-2.3 (-8.7, 4.0)	-0.1 (-7.5, 7.4)
P value compared to ref		0.58	0.24	0.65	Ref
Change for uncontrolled at baseline	74	-13.2 (-23.1, -3.4)	-16.8 (-28.0, -5.6)	-10.6 (-21.5, 0.3)	-2.0 (-13.2, 9.2)
P value compared to ref		0.14	0.07	0.27	Ref
Diastolic BP, mmHg:					
Baseline	275	76.8 (14.1)	75.6 (13.3)	76.5 (12.0)	73.6 (12.4)
Change at 12 months	152	0.2 (-3.7, 4.1)	-0.9 (-5.4, 3.6)	-1.4 (-5.1, 2.3)	0.2 (-4.1, 4.6)
P value compared to ref		1.0	0.72	0.57	Ref
Change for uncontrolled at baseline	74	-5.2 (-11.1, 0.7)	-5.4 (-12.1, 1.3)	-5.2 (-11.7, 1.3)	0.0 (-6.7, 6.7)
P value compared to ref		0.24	0.26	0.27	Ref
Baseline BP controlled, %	275	40.7	42.9	57.8	50.9
12-month BP controlled	153	0.53 (0.38, 0.68)	0.61 (0.43, 0.77)	0.65 (0.50, 0.78)	0.55 (0.37, 0.71)
P value compared to ref		0.92	0.58	0.35	Ref
12-month BP controlled for uncontrolled at baseline	60	0.44 (0.19, 0.73)	0.63 (0.28, 0.88)	0.39 (0.17, 0.67)	0.31 (0.11, 0.63)
P value compared to ref		0.52	0.15	0.67	Ref

Abbreviations: BP, blood pressure; Ref, reference group

^aBaseline measures are reported as means (standard deviations), unless otherwise stated

^bChange at 12 months is reported as the coefficients or conditional probabilities from mixed effects regression controlling for nesting within physician

behaviors. Finally, the small sample size prevented us from being able to determine whether patients belonging to sub-groups received greater benefit from the interventions.

Despite considerable study limitations, this study has several strengths. The interventions incorporated several successful features of previous interventions in ethnic minority and socio-economically disadvantaged populations as well as some novel elements. Physician and patient interventions were designed in tandem to support the therapeutic partnership from both perspectives, an approach advocated but infrequently implemented.⁴³ Adaptation of the traditional role of CHWs to the role of coach—an approach that the investigators used because of the evidence for cultural relevance and effectiveness of CHWs in health education and promotion among patients from minority and underserved groups—was also novel. Physicians' requests for a self-administered program with individualized feedback were incorporated into the communication skills program.

Recruitment, retention, and execution challenges were significant; therefore, future work should identify factors associated with successful implementation of evidence-based patient-centered strategies for hypertension in real-world settings. Efforts are needed to identify levels of intensity and particular intervention components that contribute to improved outcomes, as well as sub-groups of clinicians and patients most likely to benefit from these approaches. Future interventions might be strengthened by including health system-level strategies³¹ and further emphasis on patients' social and environmental context.⁵⁶ Finally, given the growing influences of national and state health policy on healthcare delivery, multi-level intervention studies are needed to understand how to optimize the interactions among broader policy and community influences, organizational processes, clinician and staff behaviors, and patient barriers to positively affect quality of care and health outcomes for patients belonging to underserved groups.

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Corresponding Author: Lisa A. Cooper, MD, MPH; Welch Center for Prevention, Epidemiology, and Clinical Research, Johns Hopkins University, 2024 E. Monument Street, #2-515, Baltimore, MD 21287, USA (e-mail: lisa.cooper@jhmi.edu).

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