Counseling African Americans to Control Hypertension
Cluster-Randomized Clinical Trial Main Effects

Gbenga Ogedegbe, MD, MPH; Jonathan N. Tobin, PhD; Senaida Fernandez, PhD; Andrea Cassells, MPH; Marleny Diaz-Gloser, MPH; Chamanara Khalida, MD, MPH; Thomas Pickering, MD, DPhil; Joseph E. Schwartz, PhD

Background—Data are limited on the implementation of evidence-based multilevel interventions targeted at blood pressure (BP) control in hypertensive blacks who receive care in low-resource primary care practices.

Methods and Results—Counseling African Americans to Control Hypertension is a cluster-randomized clinical trial in which 30 community health centers were randomly assigned to the intervention condition (IC) or usual care (UC). Patients at the IC sites received patient education, home BP monitoring, and monthly lifestyle counseling, whereas physicians attended monthly hypertension case rounds and received feedback on their patients’ home BP readings and chart audits. Patients and physicians at the UC sites received printed patient education material and hypertension treatment guidelines, respectively. The primary outcome was BP control, and secondary outcomes were mean changes in systolic and diastolic BPs at 12 months, assessed with an automated BP device. A total of 1059 patients (mean age, 56 years; 28% men, 59% obese, and 36% with diabetes mellitus) were enrolled. The BP control rate was similar in both groups (IC = 49.3% versus UC = 44.5%; odds ratio, 1.21 [95% confidence interval, 0.90–1.63]; \( P = 0.21 \)). In prespecified subgroup analyses, the intervention was associated with greater BP control in patients without diabetes mellitus (IC = 54.0% versus UC = 44.7%; odds ratio, 1.45 [confidence interval, 1.02–2.06]); and small-sized community health centers (IC = 51.1% versus UC = 39.6%; odds ratio, 1.45 [confidence interval, 1.04–2.45]).

Conclusions—A practice-based, multicomponent intervention was no better than UC in improving BP control among hypertensive blacks. Future research on the implementation of behavioral modification strategies for hypertension control in low-resource settings should focus on the development of more efficient and tailored interventions in this high-risk population.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00233220.

Key Words: blacks ■ clinical trial ■ health behavior ■ healthcare disparities ■ hypertension

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lacks have the highest prevalence of hypertension (HTN),\(^1\) and poor HTN-related outcomes explain most of the racial gap in mortality between blacks and whites.\(^2\) Although barriers to optimal HTN control exist at multiple levels of care,\(^3\) interventions targeted at blood pressure (BP) control have not targeted these barriers simultaneously.\(^4,6\) Furthermore, the representation of blacks in previous practice-based trials is low.\(^5\) Data are limited on the implementation and evaluation of the effectiveness of evidence-based multilevel interventions in blacks who receive care in low-resource community health centers (CHCs).

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Using the chronic care model as an implementation framework,\(^7\) the Counseling African Americans to Control Hypertension (CAATCH) trial used a cluster-randomized design to evaluate the effectiveness of a practice-based, multilevel intervention for improving BP control among hypertensive patients. The intervention targeted both physicians and patients in CHCs.

Methods

Setting and Study Population

CAATCH was a 2-arm, cluster-randomized, controlled trial implemented in CHCs that are members of Clinical Directors Network, a practice-based research network in New York City. The study protocol is described elsewhere; eligibility criteria included patients who self-identified as black or African American, received care at the CHC for ≥6 months, had uncontrolled HTN, and were fluent in English. The institutional review boards of Columbia University, New York University, and Clinical Directors Network approved the study.

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From the Division of Health and Behavior and Center for Healthful Behavior Change, Department of Population Health, New York University Langone Medical Center, New York, NY (G.O., S.F.); Clinical Directors Network, New York, NY (J.N.T., A.C., M.D.-G., C.K.); Department of Epidemiology and Population Health, Albert Einstein College of Medicine of Yeshiva University, Bronx, NY (J.N.T.); Center for Clinical and Translational Science, Rockefeller University, New York, NY (J.N.T.); Department of Medicine, Columbia University College of Physicians and Surgeons, New York, NY (T.P., J.E.S.); Department of Psychiatry and Behavioral Science, Stony Brook University, Stony Brook, NY (J.E.S.).

Correspondence to Gbenga Ogedegbe, MD, MPH, Center for Healthful Behavior Change, Division of Health and Behavior, Department of Population Health, New York University Langone School of Medicine, 227 E 30th St, Room 633, New York, NY 10016. E-mail: olugbenga.ogedegbe@nyumc.org

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Randomization of Sites and Patient Recruitment
Thirty CHCs were pairwise matched with respect to size, and within each matched pair one was randomly assigned to the intervention condition (IC) and the other to usual care (UC). Details of patient recruitment are reported elsewhere. Patients who agreed to participate (via letters from their primary care clinicians) were invited to the CHC to meet with a trained research assistant who obtained informed consent and conducted the baseline visit to assess their BP with BpTRU (model BPM-300; MEG International Services Ltd, Coquitlam, British Columbia, Canada), a validated, automated oscillometric BP monitor.

Intervention
Patients at the IC sites received the following: (1) 4 modules of interactive, computerized patient education focused on the causes, complications, and treatment of HTN; expected medication adverse effects; and methods for adoption of healthy lifestyle behaviors; (2) 6 behavioral lifestyle telephone/ group counseling sessions; and (3) free validated automated home BP monitors (model BP 3AC1-1 PC; MicroLife USA, Inc, Dunedin, FL). They were encouraged to record their weekly BP readings (twice daily, 3 days per week) in a diary and bring it to each study visit. The primary care clinicians received monthly onsite continuing medical education based on the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure;11 HTN case rounds, and computerized patient education focused on the causes, complications, and treatment of HTN; expected medication adverse effects; and methods for taking advantage of new antihypertensive medications during the duration of the trial. Using standard definitions, treatment intensification was reported elsewhere. Patients who agreed to participate (via letters from their primary care clinicians) were invited to the CHC to meet with a trained research assistant who obtained informed consent and conducted the baseline visit to assess their BP with BpTRU (model BPM-300; MEG International Services Ltd, Coquitlam, British Columbia, Canada), a validated, automated oscillometric BP monitor.

Measurements and Outcomes
This has been described in detail elsewhere.4 Trained research assistants collected data (demographics, self-reported medication adherence, health literacy, and depression) at baseline and every 3 months for 12 months. The Charlson comorbidity index (CCI) was computed from chart abstraction of medical diagnoses.12 The primary outcome was the rate of BP control at 12 months, defined as mean BP <140/90 mm Hg (or mean BP <130/80 mm Hg for those with diabetes mellitus or kidney disease). The secondary outcomes were mean BP at 12 months and within-patient changes in systolic BP (SBP) and diastolic BP (DBP) from baseline to 12 months. At baseline, 3 readings were taken by trained research assistants using an automated BP monitor (BpTRU) with the patient seated comfortably for 5 minutes before each measurement, following American Heart Association guidelines. The same procedure was repeated at each study visit. The average of the 3 readings was used as the outcome measure for each visit.

To address the mechanisms of intervention effects and provide context for study findings, we extracted medication intensification data (during the 12-month study period) from patient medical charts. Specifically, data on drug class, doses, and medication adjustment were extracted from patient medical charts at each clinic visit throughout the duration of the trial. Using standard definitions, treatment intensification was defined as an increase in the dose of antihypertensive medication or the addition of a new antihypertensive medication during an office visit in which the patient’s BP was ≥140/90 mm Hg. At each study visit, we reviewed the patient’s medical charts and determined whether his/her antihypertensive regimen had been intensified since the previous visit by either any increase in the dosage of current medication or by the addition of another antihypertensive medication. Similarly, we collected data on patient self-reported medication adherence to prescribed medications using the well-validated 4-item scale developed by Morisky that specifically addresses adherence to a prescribed antihypertensive medication regimen. Finally, as part of the requirement of the institutional review board regulatory requirement at New York University and as part of the biannual report provided to the data and safety monitoring board of the CAATCH trial, we tracked the tolerability and safety outcomes/adverse events for each patient enrolled in the trial and compared the rates of adverse events for each arm of the trial.

Statistical Analysis

Power Analysis
We anticipated 12-month treatment effects of ≥4 mm Hg for SBP and ≥3 mm Hg for DBP. With 30 sites, and 30 patients per site, we estimated a power of 91% and 96%, respectively, to detect treatment effects of these magnitudes (using a 2-tailed, 0.05-level test). Allowing for a 15% attrition rate, the enrollment target was set at 1059 patients, for a final sample of 900 patients who would complete the study.

Handling of Missing Data
After completing the CCI for those with no missing items, we used a regression-based procedure to impute values for 60 patients with missing data for 1, 2, or 3 of the 15 items in the CCI; this procedure assigned the expected value for CCI, conditioned on patients’ available items (each imputation equation had R²≥0.92). We used multiple imputations of baseline covariates and visit-specific BP averages. Five data sets with complete data for all of the covariates and outcome measures were constructed using the multiple imputation procedure in SAS version 9.3 (SAS Institute Inc, Cary, NC), analyzed separately, and their results pooled using the SAS MIANALYZE procedure.

Data Analytic Plan
For the primary hypothesis, we performed a multilevel, random effects logistic regression model (using the GLIMMIX procedure in SAS to adjust for clustering) predicting BP control at 12 months from treatment condition with baseline SBP and DBP, presence of diabetes mellitus, CCI (≥3 versus <3), and resistant HTN status at baseline (taking ≥3 antihypertensive medications, including a diuretic) treated as covariates. For the secondary hypothesis, we performed a 3-level repeated-measures analysis using the MIXED procedure in SAS (visit nested within patients nested within CHCs) predicting BP at baseline and 3, 6, 9, and 12 months from enrollment, with similar covariates. Contrast statements were used to test the change in BP from baseline to each follow-up assessment. We also conducted prespecified subgroup analyses of the primary and secondary outcomes on the basis of site characteristics (small versus large CHCs), diabetes mellitus status (yes/no), depression status (yes/no), medication adherence (yes/no), and CCI (≥3 versus <3). Unless otherwise specified, all of the reported primary and secondary analyses for BP control were adjusted simultaneously for baseline SBP and DBP, presence of diabetes mellitus, CCI, and resistant HTN status at baseline.

For the treatment modification analyses, and as stated earlier, at each study visit, we determined whether the patient’s antihypertensive regimen had been intensified since the previous visit by either any increase in the dosage of current medication or by the addition of another antihypertensive medication. Missing data for an interval were imputed using multiple imputation method (50 samples). We then compared the rates of treatment intensification from baseline to 12 months between the IC and the UC groups. In addition, we compared the rates of treatment intensification from visit to visit (visit 1, 2, 3, 4, and 5) between both groups. We also examined whether patients whose treatment regimens were intensified at any point between baseline and the 12-month assessment were more likely to have their BP controlled at the 12-month follow-up. Finally, using multilevel, repeated-measures ANOVA, with tests of group differences at each study visit, and differential change from baseline (adjusted for clustering because of randomization at the clinic level), we compared the mean rates of self-reported medication adherence between the IC and the UC groups at 12 months.

Results
Patient recruitment occurred between October 2004 and February 2009, with study follow-up completed in March 2011. We enrolled 1059 patients across the 30 sites; of these, 8 had BP controlled at baseline, and 12 did not have baseline BpTRU data and were thus excluded (Figure 1). For the remaining 1039 patients, baseline characteristics are shown in Table 1. A
total of 96 physicians participated in the study, with a mean attendance rate of 66% for the continuing medical education sessions; 53% of patients completed all of the patient education modules; 38% returned home BP diaries for all 4 of the visits; and 45% received 4 to 6 lifestyle counseling sessions.

**Effect of the Intervention Versus UC on BP Control Rate at 12 Months by BpTRU (Primary Outcome)**

In an unadjusted intent-to-treat analysis, BP control at 12 months was 50.2% at the IC sites and 45.3% at the UC sites (odds ratio [OR], 1.22; 95% confidence interval [CI], 0.92–1.63; \( P = 0.18 \)), with no significant intervention effect. After adjusting for baseline BP, comorbidity, diabetes mellitus, and resistant HTN status, the BP control rate at the IC sites was 49.3% versus 44.5% at the UC sites (OR, 1.21; 95% CI, 0.90–1.63, \( P = 0.21 \)). The proportion of patients whose BP was controlled at 12 months for each matched pair of CHCs is shown in Figure 2. The between-group difference in BP control favored the intervention for 73% of the CHC pairs (11 of the 15 randomized pairs, \( P = 0.06 \), 1-tailed). Although the unadjusted within-patient reduction in SBP and DBP from baseline to 12 months was statistically significant for both groups (\(-16.1/-9.3\) mm Hg, both \( P < 0.0001 \)), there was no significant intervention effect (SBP: IC –16.1 mm Hg versus UC \(-16.0\) mm Hg, \( P = 0.96 \) [Figure 3A]; and DBP: IC \(-9.6\) mm Hg versus UC \(-8.9\) mm Hg, \( P = 0.46 \) [Figure 3B]). These differences were nonsignificant after adjusting for diabetes mellitus, comorbidity, and resistant HTN status.

**Prespecified Subgroup Analysis of the BP Control Rates at 12 Months**

As shown in Figure 4, the prespecified subgroup analyses indicated that the intervention was associated with significantly greater BP control at 12 months in patients without diabetes mellitus (54.0% in the IC group versus 44.7% in the UC group; OR, 1.45 [95% CI, 1.02–2.06]) and in those who received care in small-sized CHCs (51.1% in the IC versus 39.6% in the UC group; OR, 1.60 [95% CI, 1.04–2.45]). The multicomponent intervention was associated with marginally significantly greater BP control in patients with moderate-to-good health literacy (50.6% in the IC group versus 40.8% in the UC group; OR, 1.48 [95% CI, 0.99–2.22]). Depressive symptoms, comorbidity, and medication adherence at baseline did not moderate the intervention effects.

**Effect of Intervention on Treatment Intensification (Extracted From Patient Medical Charts) and Self-Reported Medication Adherence**

As shown in Table 2, the rates of treatment intensification between visits did not differ between groups, indicating that patients at the intervention sites were no more likely to have their treatment regimen intensified than those at the UC sites. Thus, none of these analyses provide any indication that treatment intensification was different between either group throughout the 12-month study period or at any given study visit. We also examined whether patients whose treatment regimen was intensified at any point during the study period were more likely to have their BP controlled at the 12-month follow-up. In the sample as a whole, there was a small and not statistically significant (\( P = 0.49 \)) positive association between medication intensification and BP control at 12 months. The same was true when we analyzed the groups separately (\( P = 0.45 \) and \( P = 0.84 \) for the UC and IC groups, respectively). Similarly, we compared the mean rates of self-reported medication adherence between both groups at 12 months. As shown in Table 3, although the rate of self-reported nonadherence was higher in the UC group at each visit, the group difference was not significant at any visit; furthermore, neither the change from baseline to 6-month visit (visit 3) nor from baseline to the 12-month visit (visit 5) was significant (\( P = 0.87 \) and \( P = 0.71 \), respectively). These findings suggest that the IC was not associated with a higher rate of medication adjustment than the UC group.

**Comparison of Adverse Effects Between Both Groups**

Characteristics of the reported adverse effects are shown in Table 4. Among the 1039 participants, there were 11 deaths, 8 in the IC group and 3 in the UC group (\( P = 0.22 \), Fisher’s exact test). There were a total of 217 adverse events reported. Comparison of the rates of adverse events, as well as the type of adverse effects in each group, was similar. Specifically, there were 120 hospitalizations, 54 in the IC group (9.6 per 100 participants) and 66 in the UC group (12.5 per 100 participants); the difference was not statistically significant (\( P = 0.16 \), by Poisson regression). Almost all of them (n=214) were unrelated to the study. Outcomes of the adverse effects (\( \chi^2 = 1.51 \), degrees of freedom=3, \( P = 0.68 \)), as well as the action taken to resolve them (\( \chi^2 = 1.77 \), degrees of freedom=3, \( P = 0.78 \)), were also similar for both groups.

**Discussion**

In this study, a multilevel intervention with multiple components was no better than enhanced UC in improving BP
control among hypertensive blacks who receive care in low-resource CHCs. In prespecified subgroup analysis, the intervention was associated with significantly higher BP control rates in patients without diabetes mellitus and in those who receive care in small-sized practices.

The null effect of the between-group difference in the primary outcome could be attributed to 2 possible reasons. First is the subadditivity of the intervention effects on BP reduction, a phenomenon whereby the combined effect of a multicomponent intervention (with 2 or more BP-lowering strategies) is less than the sum of BP reductions expected from each component alone.13,14 This phenomenon was reported in PREMIER,15 which compared the effect of established lifestyle recommendations alone versus the established plus Dietary Approaches to Stop Hypertension diet on BP reduction, and found a non-significant SBP difference between both groups.15 The authors

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concluded that the net BP reduction of the Dietary Approaches to Stop Hypertension diet component in PREMIER might have underestimated its BP effect if it were implemented alone. Similarly, CAATCH was a multicomponent intervention with patient education, lifestyle counseling, and home BP monitoring. As such, the combined effect of BP reduction from the multicomponent IC is similar to the BP reduction noted from the patient education session in the UC arm, which in turn may have underestimated the effects of the home BP monitoring plus lifestyle counseling in the intervention arm. The noted subadditivity effect may be because of poor patient compliance given the complexity of adhering to multiple intervention components and adopting more than 1 lifestyle change. In the case of CAATCH, the suboptimal adherence to components of the intervention might be because of the complexity of adhering to more than 1 lifestyle recommendation in addition to regular home BP monitoring. Indeed, only 53% of patients completed all of the patient education modules, 38% returned home BP diaries for all 4 visits, and 45% received 4 to 6 lifestyle counseling sessions. Second is the national trend in improvement in BP control, time-trend analysis of nationally representative data showed significant improvements in age- and sex-adjusted BP control rates between 1999 and 2006. A recent analysis of the 2007-2008 National Health and Nutrition Examination Survey showed 50% BP control rate. Widespread adoption of quality improvement programs in primary care practices similar to the components of the CAATCH intervention may explain this national trend. However, we did not collect information on quality improvement programs at the UC sites to ascertain the magnitude of this effect. Another factor that may explain the null effect may be the lack of intervention effect on the rate of treatment intensification noted during the trial, such that physicians in the IC sites were no more aggressive in titrating their patients’ antihypertensive medications than those at the UC sites. In a subgroup analysis of medication adjustments between both groups, controlling for clinic visits, we found no difference between the levels of treatment intensification, thus indicating that the intervention was not associated with better physician behavior at the IC sites compared with the UC sites. Similarly, although the relationship between treatment intensification and BP control was positive, this association did not reach statistical significance either, and there was no difference in self-reported medication adherence between both groups. The following unique aspects of our study should be noted. First, to our knowledge, CAATCH is the largest practice-based implementation trial of a multilevel, evidence-based intervention targeted at BP control in hypertensive blacks in CHCs. Second, although the individual components of CAATCH (patient education, home BP monitoring, continuing medical education, physician chart audit, and feedback) have proven efficacious and effective for improving BP control, the effectiveness of a combined approach in CHCs has not been rigorously evaluated. Only 4 other practice-based trials have targeted both patients and physicians in practice-based settings; of these, the recent study by Johnson et al, the Baltimore Partnership To Educate and Achieve Control of Hypertension trial, is the only

![Figure 2. Blood pressure (BP) control rates at 12 months by community health centers (CHCs; on the basis of BpTRU).](image)

![Figure 3. A. Within-patient change in BpTRU systolic blood pressure (BP) from baseline to 12 months. B. Within-patient change in BpTRU diastolic BP from baseline to 12 months. BL indicates baseline; and mon, months.](image)
study that exclusively targeted hypertensive blacks. Third, previous practice-based trials targeted hypertensive patients with high rates of baseline BP control and those without comorbidity. The demographics of CAATCH reflect high levels of poverty, obesity, resistant HTN, and significant comorbidity, thus enhancing the potential to generalize these findings to a broader population who receive care in low-resource settings.

Our study has the following limitations. First is the attrition rate of 30%, which is not uncommon for this underserved population. The second is a relatively low patient adherence to the various components on the intervention. Both of these limitations highlight the structural difficulties inherent in implementing a complex, practice-based intervention in a high-risk patient population recruited from low-resourced primary care settings such as CHCs. The lower adherence makes the finding of significant effects even more striking and suggests that these are underestimates of true multicomponent treatment effectiveness, given the attenuated dose of the intervention received by some study participants. Finally, we should note

Table 2. Comparison of Treatment Intensification Between Intervention and Usual Care Sites (Percentage of Patients Whose Hypertensive Treatment Regimen Was Intensified, by Period)

<table>
<thead>
<tr>
<th>Period</th>
<th>Usual Care</th>
<th>Intervention</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1-2</td>
<td>22 (16–29)</td>
<td>24 (18–29)</td>
<td>0.73</td>
</tr>
<tr>
<td>Visit 2-3</td>
<td>16 (9–23)</td>
<td>21 (16–27)</td>
<td>0.26</td>
</tr>
<tr>
<td>Visit 3-4</td>
<td>14 (7–19)</td>
<td>14 (9–19)</td>
<td>0.88</td>
</tr>
<tr>
<td>Visit 4-5</td>
<td>23 (16–31)</td>
<td>18 (13–23)</td>
<td>0.26</td>
</tr>
</tbody>
</table>

Data show the percentage and 95% confidence interval.

*Data show the P value for test of group difference, with adjustment for clustering by clinic.

Table 3. Mean (95% CI) of Morisky Medication Adherence Scale, by Treatment Group and Study Visit

<table>
<thead>
<tr>
<th>Visit</th>
<th>Usual Care</th>
<th>Intervention</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>1.18 (0.98–1.21)</td>
<td>1.01 (0.81–1.21)</td>
<td>0.21</td>
</tr>
<tr>
<td>6 mo</td>
<td>1.05 (0.85–1.25)</td>
<td>0.87 (0.66–1.07)</td>
<td>0.19</td>
</tr>
<tr>
<td>12 mo</td>
<td>0.98 (0.78–1.17)</td>
<td>0.77 (0.57–0.97)</td>
<td>0.15</td>
</tr>
</tbody>
</table>

*Data show the P value for test of group difference, with adjustment for clustering by clinic.
that prespecification of data analysis does not remove the limitation inherent in diminished power for subgroup analysis that we conducted for the secondary outcomes. Specifically, the significance of the subgroup findings in our study is weakened by the fact that the overall number of patients studied is not large and subgroups are rather small. Despite these limitations, we strongly believe that evaluation of practice-based clinical trials in a highly mobile and indigent population, although fraught with challenges, will provide important information for the development of evidence-based strategies to mitigate the racial disparities in HTN-related outcomes and increase health equity.

In conclusion, findings from the CAATCH trial suggest that a practice-based multicomponent IC was no better than UC in improving BP control among hypertensive blacks who receive care in low-resource, community-based primary care practices. Possible reasons for the negative trial include the multicomponent nature of the intervention and resulting poor adherence to intervention components. Adoption of such complex interventions without adequate external practice facilitation may not be practical in CHCs. Future research on implementation of behavioral modification strategies for HTN control in CHCs will benefit from the development of more efficient and tailored interventions including the use of technology and practice facilitation to overcome the barriers to adhering to the complexities of such multicomponent interventions.

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Disclosures
None.

References

CLINICAL PERSPECTIVE
Blacks have the highest prevalence of hypertension in the United States, and they experience disproportionately higher rates of hypertension-related mortality compared with whites. Although poor blood pressure (BP) control has been implicated as a potential mechanism for the racial disparities in cardiovascular outcomes, data are limited on the implementation of evidence-based multilevel interventions targeted at BP control in blacks. Counseling African Americans to Control Hypertension is the largest practice-based trial to evaluate the comparative effectiveness of a multicomponent intervention ( provision of home BP monitoring, patient education, and lifestyle counseling to patients, as well as hypertension case rounds plus chart audits for physicians) versus the provision of print patient education and hypertension treatment guidelines, among 1059 hypertensive blacks (mean age, 56 years; 59% obese and 36% with diabetes mellitus) who receive care in community health centers. Although patients in both groups had significant BP reduction (~16.1/–9.3 mm Hg), the intervention was no better than usual care in improving BP control (intervention group=49.3% versus usual care group=44.5%; odds ratio, 1.21 [95% confidence interval, 0.90–1.63]; P=0.21). Findings from this study suggest that adoption of such complex interventions without adequate practice facilitation may not be practical in low-resourced, community-based primary care practices. Future research on the implementation of evidence-based strategies for hypertension control in blacks should focus on more efficient and tailored interventions, including the use of technology to overcome the barriers to adhering to the complexities of such multicomponent interventions.
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