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Counseling African Americans to Control Hypertension (CAATCH): Cluster Randomized Clinical Trial Main Effects

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Abstract

Background—Data is limited on implementation of evidence-based multilevel interventions targeted at BP control in hypertensive African Americans who receive care in low-resource primary care practices.

Methods and Results—Counseling African Americans to Control Hypertension (CAATCH) is a cluster-randomized clinical trial in which 30 Community Health Centers (CHCs) 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, while 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 BP at 12 months, assessed with an automated BP device. 1059 patients (mean age 56 years; 28% men, 59% obese and 36% with diabetes) were enrolled. The BP control rate was similar in both groups (IC= 49.3% vs. UC=44.5%, OR=1.21; 95% CI, 0.90–1.63; p=0.21). In pre-specified subgroup analyses, the intervention was associated with greater BP control in patients without diabetes (IC=54.0% vs. UC=44.7%, OR=1.45; CI, 1.02–2.06); and small-sized CHCs (IC=51.1% vs. UC=39.6%, OR=1.45; CI, 1.04–2.45).

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Conflict of Interest Disclosures: None.

Conclusions—A practice-based multicomponent intervention was no better than usual care in improving BP control among hypertensive African Americans. Future research on 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 Information—<http://clinicaltrials.gov>. Identifier: NCT00233220.

Keywords

hypertension; high blood pressure; behavior modification; high-risk populations; health disparities; and clinical trial

Introduction

African Americans have the highest prevalence of hypertension (HTN),¹ and poor hypertension-related outcomes explain most of the racial gap in mortality between African Americans and whites.² Although barriers to optimal HTN control exist at multiple levels of care,³ interventions targeted at BP control have not targeted these barriers simultaneously.^{4–6} Furthermore, the representation of African Americans in previous practice-based trials is low.⁵ Data is limited on the implementation and evaluation of the effectiveness of evidence-based multilevel interventions in African Americans who receive care in low-resource Community Health Centers (CHCs).

Using the Chronic Care Model as an implementation framework⁷, 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 two-arm cluster-randomized controlled trial implemented in CHCs that are members of Clinical Directors Network (CDN), a practice-based research network in New York City. The study protocol is described elsewhere⁸; eligibility criteria included patients who self-identified as black or African-American; received care at the CHC for ≥ 6 months; had uncontrolled hypertension; and were fluent in English. The Institutional Review Boards of Columbia University, New York University, and CDN approved the study.

Randomization of sites and patient recruitment

Thirty CHCs were pair-wise 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.⁹ Patients who agreed to participate [via letters from their primary care clinicians (PCCs)] were invited to the CHC to meet with a trained research assistant (RA) who obtained informed consent and conducted the baseline visit to assess their BP with BpTRU (VSM Medtech, Model BPM-300 – a validated automated oscillometric BP monitor,¹⁰

Intervention

Patients at the IC sites received: (1) four modules of interactive computerized patient education focused on the causes, complications and treatment of HTN, expected medication side effects, and methods for adoption of healthy lifestyle behaviors; (2) six behavioral lifestyle telephone/group counseling sessions; and (3) free validated automated home BP monitors (Dunedin, FL: Microlife USA, Inc., Model BP 3AC1-1 PC); and encouraged to record their weekly BP readings (twice daily, three days a week) in a diary and bring it to each study visit. The PCCs received monthly onsite CME based on the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7),¹¹ hypertension case rounds, and quarterly chart audits of their patients' office BP readings. They were also provided quarterly feedback on the values of their patients' home BP readings, which were obtained from the patients' diaries. Patients at the enhanced UC sites received a single hypertension patient education session plus printed versions of the NHLBI patient education material "*Your Guide to Lowering Blood Pressure*" and "*Facts about the DASH Eating Plan*", while the PCCs received print versions of JNC-7 guidelines. The PCCs and study investigators were blinded to the study outcomes.

Measurements and Outcomes

This has been described in detail elsewhere⁸. Trained RAs collected data (demographics, self-reported medication adherence, health literacy, and depression) at baseline and every three months for 12 months.⁸ The Charlson comorbidity score 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 mmHg (or mean BP<130/80 mmHg for those with diabetes or kidney disease). The secondary outcomes were mean BP at 12 months and within-patient changes in systolic and diastolic BP from baseline to 12 months. At baseline, three readings were taken by trained RAs using an automated BP monitor (BPTru) with the patient seated comfortably for 5 minutes prior to each measurement, following AHA guidelines. The same procedure was repeated at each study visit. Average of the three readings was used as the outcome measure for each visit.⁸

In order 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 patients' medical records. Specifically, data on drug class, doses and medication adjustment were extracted from patients' medical records 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 addition of a new antihypertensive medication during office visit in which the patient's BP was greater than 140/90 mm Hg.⁴ At each study visit, we reviewed the patient's medical records 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 addition of another antihypertensive medication. Similarly, we collected data on patient's self-reported medication adherence to prescribed medications using the well-validated 4-item scale developed by Morisky that specifically addresses adherence to prescribed antihypertensive medication regimen.⁹ Finally, as part of the requirement of the institutional IRB regulatory requirement at NYU,

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 at least 4 mmHg for systolic BP and 3 mmHg for diastolic BP. 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 1,059 patients for a final sample of 900 patients who would complete the study.

Handling of Missing Data

After computing the Charlson comorbidity index (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 $R^2 = 0.92$]. We used multiple imputations of baseline covariates and visit-specific BP averages. Five datasets with complete data for all covariates and outcome measures were constructed using the multiple imputation (MI) procedure in SAS v9.3, analyzed separately, and their results pooled using the SAS MIANALYZE procedure.

Data Analytic Plan

For the primary hypothesis, we performed a multi-level 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 systolic (SBP) and diastolic (DBP) BP, presence of diabetes, CCI (≥ 3 vs. <3), and resistant hypertension 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, 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 pre-specified subgroup analyses of the primary and secondary outcomes based on site characteristics (small vs. large CHCs), diabetes status (yes/no), depression status (yes/no), medication adherence (yes/no), and CCI (≥ 3 vs. <3).

Unless otherwise specified, all reported primary and secondary analyses for BP control were adjusted statistically for baseline SBP and DBP, presence of diabetes, CCI, and resistant hypertension status at baseline.

For the treatment modification analyses, and as stated earlier, at each study visit, we determined whether patient's antihypertensive regimen had been intensified since the previous visit, by either any increase in the dosage of current medication or by addition of

another antihypertensive medication. Missing data for an interval were imputed using MI 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 (V1 to V2; V2–V3; V3–V4 and V4–V5) between both groups. We also examined whether patients whose treatment regimen was 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 due to randomization at the clinic level), we compared the mean rates of self-reported medication adherence between the IC and the UC group 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, eight had BP controlled at baseline and twelve did not have baseline BpTRU data, and were excluded (Figure 1). For the remaining 1039 patients, baseline characteristics are shown in Table 1. Ninety-six physicians participated in the study, with a mean attendance rate of 66% for the CME sessions; 53% of patients completed all patient education modules; 38% returned home BP diaries for all four visits; and 45% received four to six lifestyle counseling sessions.

Effect of the intervention versus usual care 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 and resistant hypertension status, the BP control rate at the IC sites was 49.3% vs. 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 ($-16.1/-9.3$ mmHg, both $p < 0.0001$), there was no significant intervention effect (SBP: IC -16.1 mmHg versus UC -16.0 mmHg, $p = 0.96$ [Figure 3A]; and DBP: IC -9.6 mmHg versus UC -8.9 mmHg, $p = 0.46$ [Figure 3B]). These differences were non-significant after adjusting for diabetes, comorbidity, and resistant hypertension 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 (54.0% in the IC group vs. 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 vs. 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 vs. 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 patients' medical records] and self-reported medication adherence

As shown in Table 2A, 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 usual care sites. Thus, none of these analyses provide any indication that treatment intensification was different between both groups 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 usual care and intervention groups, respectively). Similarly, we compared the mean rates of self-reported medication adherence between both groups at 12 months. As shown in Table 2B, although the rate of self-reported non-adherence 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 (V3) nor from baseline to 12-month visit (V5) was significant ($p=0.87$ and $p=0.71$, respectively). These findings suggest that the intervention was not associated with a higher rate of medication adjustment than the usual care group.

Comparison of adverse effects between both groups

Characteristics of the reported adverse effects are shown in Table 3. Among the 1039 participants, there were 11 deaths, 8 in the intervention group and 3 in the usual care group ($p=0.22$ By 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 intervention group (9.6 per 100 participants) and 66 in the usual care group (12.5 per 100 participants); the difference was not statistically significant ($p=0.16$, by Poisson regression). Almost all of them (214) were unrelated to the study. Outcomes of the adverse effects (Chi-square=1.51, $df=3$, $p=0.68$) as well as the action taken to resolve them (Chi-square=1.77, $df=3$, $p=0.78$) were also similar for both groups.

Discussion

In this study, a multi-level intervention with multiple components was no better than enhanced usual care, in improving BP control among hypertensive African Americans who receive care in low-resource CHCs. In pre-specified subgroup analysis, the intervention was associated with significantly higher BP control rate in patients without diabetes and those who receive care in small-sized practices.

The null effect of the between-group difference in the primary outcome could be attributed to two possible reasons. First is the sub-additivity of the intervention effects on BP reduction – a phenomenon whereby the combined effect of a multicomponent intervention [with two 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 DASH diet on BP reduction, and found a non-significant SBP difference between both groups.¹⁵ The authors concluded that the net BP reduction of the DASH diet component in PREMIER might have underestimated its BP effect if it were implemented alone.^{13,14} 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 intervention is similar to the BP reduction noted from the patient education session in the usual care arm, which in turn may have underestimated the effects of the home BP monitoring plus lifestyle counseling in the intervention arm. The noted sub-additivity effect may be due to poor patient compliance given the complexity of adhering to multiple intervention components and adopting more than one lifestyle change.¹⁶ In the case of CAATCH, the suboptimal adherence to components of the intervention might be due to the complexity of adhering to more than one lifestyle recommendation in addition to regular home BP monitoring. Indeed, only 53% of patients completed all patient education modules; 38% returned home BP diaries for all four visits; and 45% received four to six lifestyle counseling sessions. Second, is the national trend in improvement in BP control;^{1,17} time-trend analysis of nationally representative data showed significant improvements in age- and sex-adjusted BP control rates between 1999 and 2006.¹⁷ A recent analysis of the 2007–2008 National Health and Nutrition Examination Survey showed 50% BP control rate.¹ Widespread adoption of quality improvement programs in primary care practices^{4,18–20} similar to the components of the CAATCH intervention may explain this national trend. We however 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 intervention sites were no more aggressive in titrating their patients' antihypertensive medications than those at the usual care 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 to 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 African Americans in CHCs. Second, although the individual components of CAATCH (patient education, home BP monitoring, CME, physician chart audit and feedback) have proven efficacious and effective for improving BP control,⁵ the effectiveness of a combined approach in CHCs has not been rigorously evaluated. Only four other practice-based trials have targeted both patients and

physicians in practice-based settings;^{21–24} of these, the recent study by Johnson et al – the Baltimore Partnership To Educate and Achieve Control of Hypertension (BPTEACH) trial is the only study that exclusively targeted hypertensive African Americans.²² Third, previous practice-based trials targeted hypertensive patients with high rates of baseline BP control and without comorbidity.^{21,23,24} The demographics of CAATCH reflect high levels of poverty, obesity, resistant hypertension and significant comorbidity, thus enhancing the potential to generalize these findings to a broader population who receive care in low-resource settings.⁹

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 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 under-estimates of true multi-component treatment effectiveness, given the attenuated dose of the intervention received by some study participants. Finally, we should note that pre-specification 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 hypertension-related outcomes, and increase health equity.

Conclusion

Findings from the CAATCH trial suggest that a practice-based multicomponent intervention was no better than usual care, in improving BP control among hypertensive African Americans who receive care in low-resource community-based primary care practices. Possible reasons for the negative trial include the multi-component 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 hypertension 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 multi-component interventions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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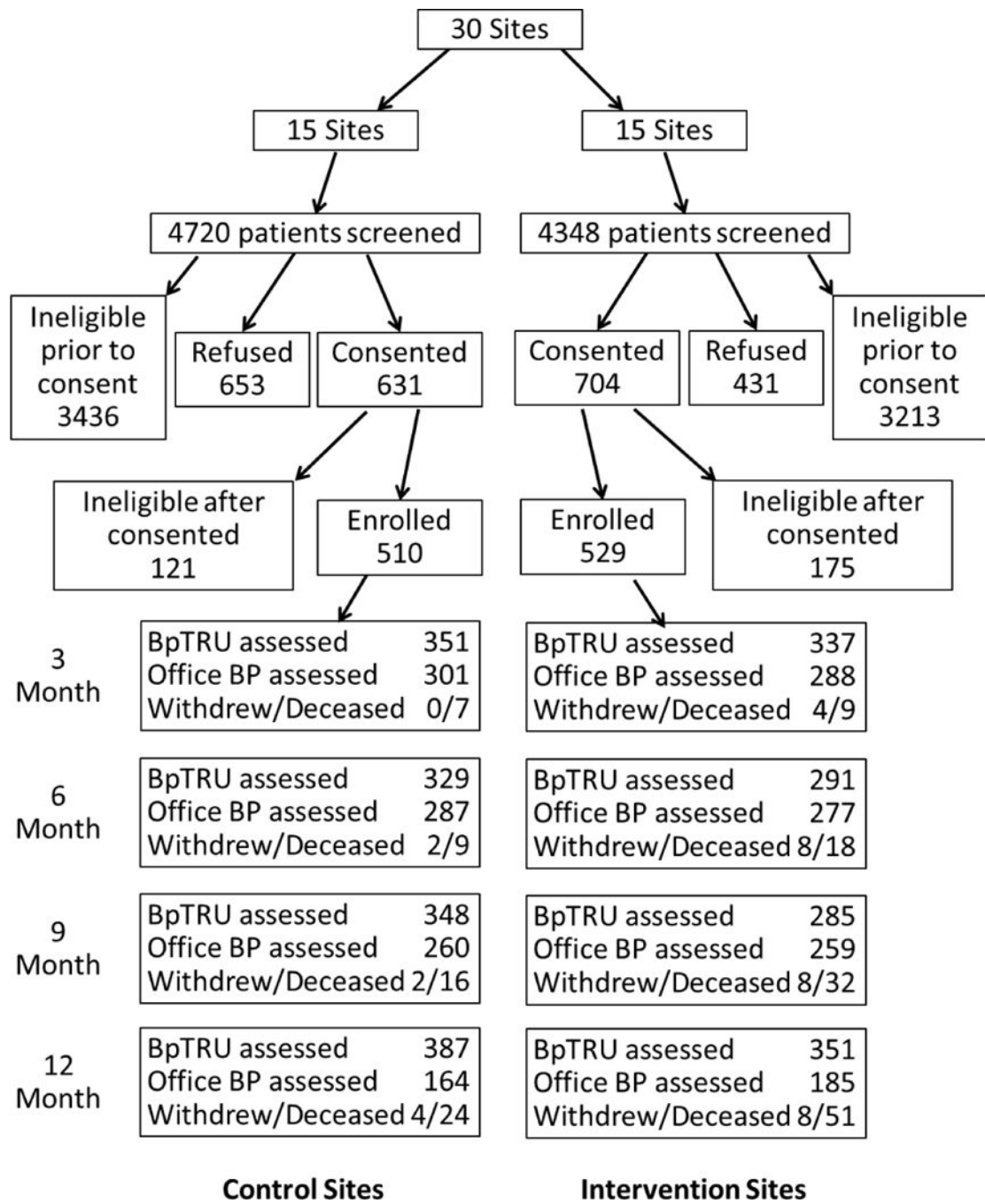


Figure 1.
Consort Diagram for CAATCH Trial.

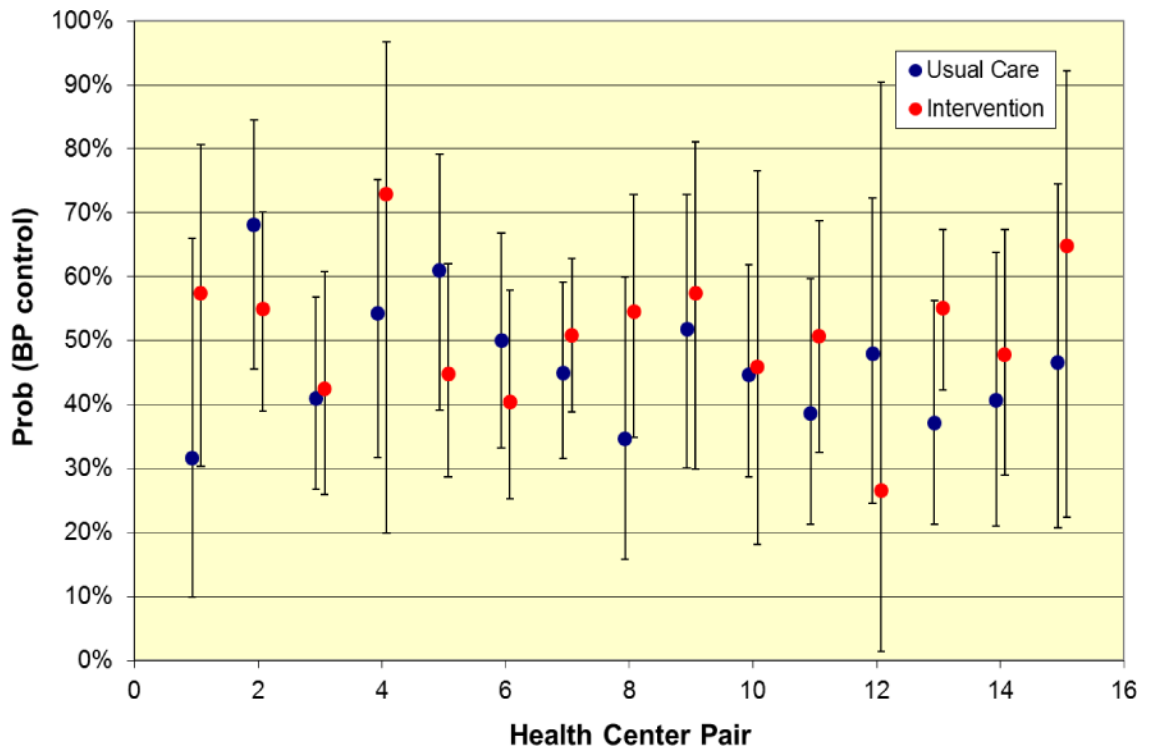


Figure 2.
Blood Pressure Control Rates at 12 Months By CHC (based on BpTRU).

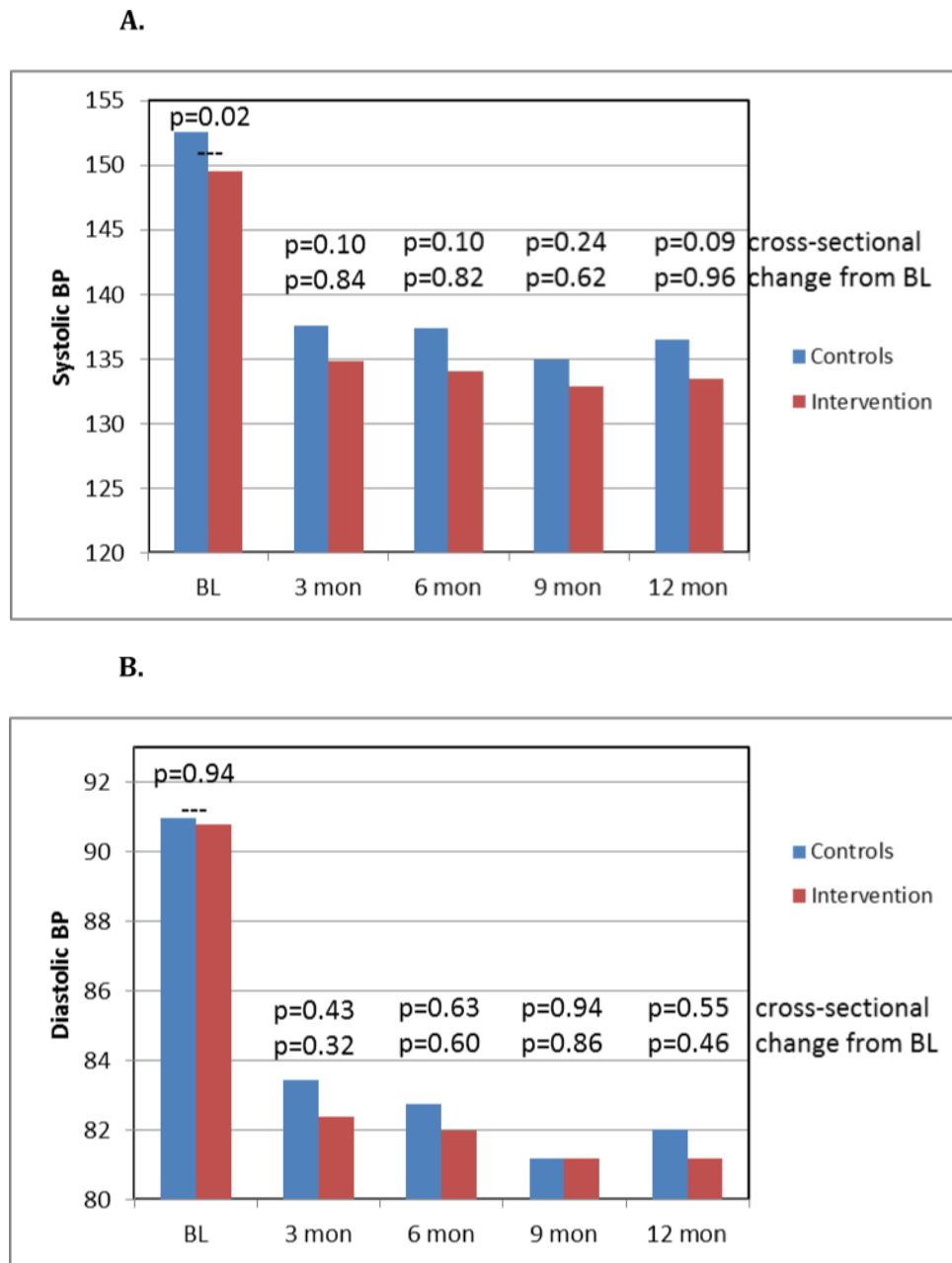


Figure 3. **A.** Within-patient change in BpTRU Systolic BP from Baseline to 12 Months. **B.** Within-patient change in BpTRU Diastolic BP from Baseline to 12 Months.

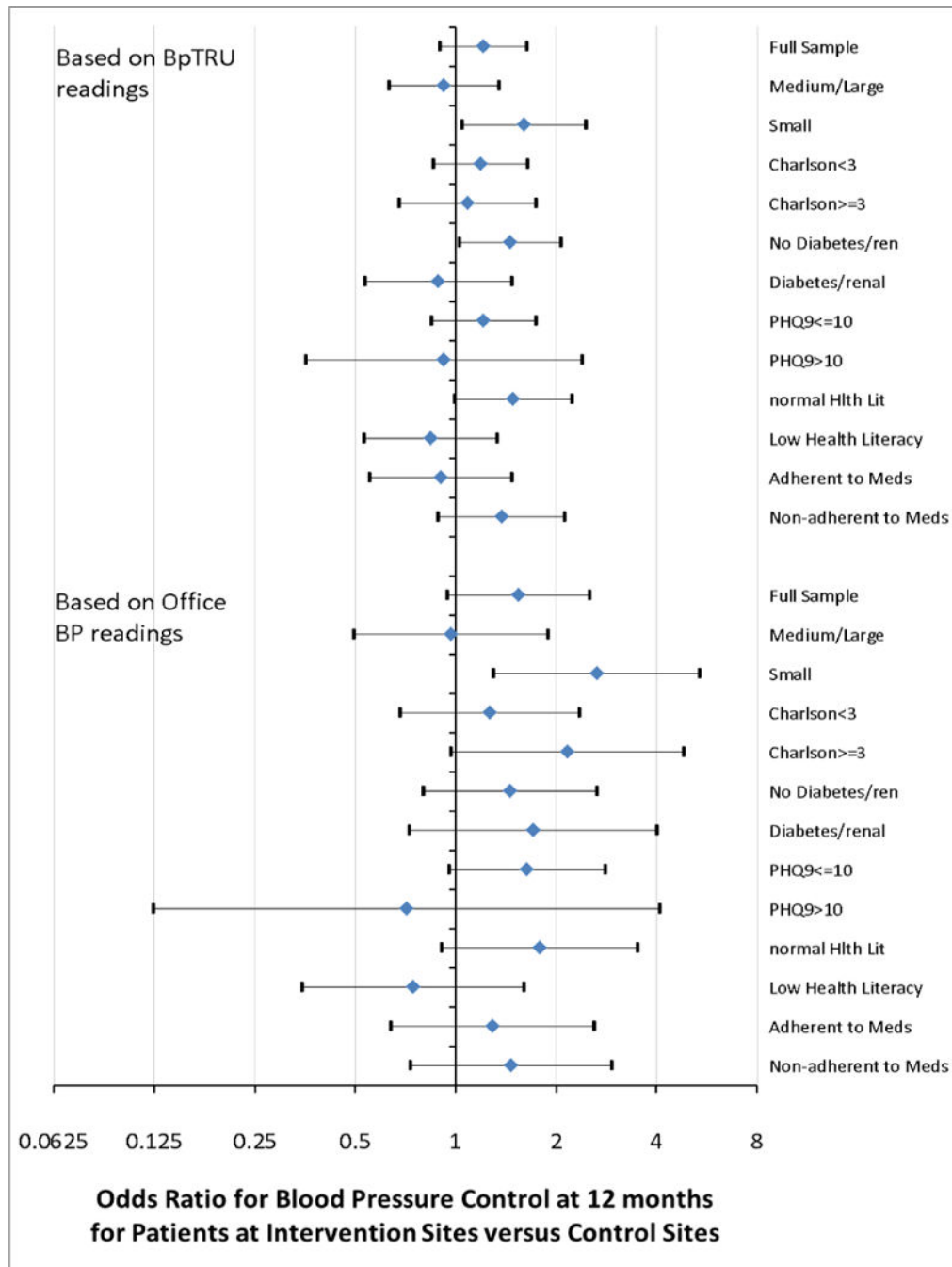


Figure 4. Forrest Plot of Subgroup Analysis: Odds Ratio for BP Control in IC versus UC Sites.

Table 1

Baseline Patient Characteristics (Total and by Treatment Group)

Characteristics	N	Total (N=1039)	Intervention (N=529)	Usual Care (N=510)	p
Age, mean (SD), y	1025	56.5 (12.1)	56.3 (11.5)	56.7 (12.8)	0.42
Age 65	1025	23.7%	23.4%	24.0%	0.83
Male	1014	28.4%	30.7%	26.0%	0.33
Employment Status	953				0.29
Not employed		11.5%	12.9%	10.2%	
Retired/Homemaker		55.2%	57.3%	52.9%	
Employed		33.3%	29.8%	36.9%	
Household income <\$20,000/yr	940	72.4%	78.6%	65.8%	0.04
Education	956				0.07
High school or less		72.0%	76.4%	67.3%	
Some college		25.5%	22.0%	29.2%	
Some graduate school		2.5%	1.6%	3.4%	
Insurance Status	1039				0.30
Self-pay/HMO		13.1%	9.6%	16.7%	
Medicaid/Medicare		63.5%	65.2%	61.8%	
None		11.8%	15.1%	8.4%	
No info		11.5%	10.0%	13.1%	
Current cigarette smokers	945	51.2%	54.7%	47.5%	0.31
Sedentary or insufficiently active (Less than 1000 Kcal/week)					
BMI, mean (SD), kg/m ²	705	32.6 (7.9)	32.6 (7.7)	32.7 (8.3)	0.78
Weight classification	705				0.91
Normal (BMI<25)		13.5%	12.8%	14.5%	
Overweight (BMI, 25–29.9)		27.1%	28.0%	25.8%	
Obese (BMI ≥30)		59.4%	59.2%	59.7%	
Charlson Comorbidity	965				0.54
0–1		42.4%	43.5%	41.2%	
2–3		33.0%	33.0%	32.9%	

Characteristics	N	Total (N=1039)	Intervention (N=529)	Usual Care (N=510)	P
>3		24.7%	23.5%	25.9%	
Diabetes Mellitus	965	36.3%	37.4%	35.0%	0.81
Stroke	965	12.5%	11.7%	13.5%	0.44
Congestive heart failure	964	10.4%	7.5%	13.5%	0.02
Chronic kidney disease	958	2.5%	2.4%	2.6%	0.93
Coronary heart disease	965	9.4%	9.1%	9.8%	0.69
Blood pressure, mean (SD)					
Systolic, mm Hg	1039	151 (17)	150 (17)	153 (17)	0.03
Diastolic, mm Hg	1039	91 (11)	91 (10)	91 (11)	0.74
Resistant Hypertension	887	27.6%	29.3%	25.7%	0.39
Mean number of BP medications	887	2.2 (1.0)	2.2 (1.0)	2.2 (1.0)	0.75
Medication Nonadherence	961	55.7%	48.7%	63.1%	0.31
PHQ-9 depressive symptoms, mean (SD)	859	5.0 (4.7)	4.5 (4.6)	5.4 (4.7)	0.17

* P-values are adjusted for clustering due to participants being nested within CHCs.*

Table 2A

Comparison of Treatment Intensification between Intervention and Usual Care Sites (Percentage of patients whose hypertensive treatment regimen was intensified, by period)

Period	Usual care	Intervention	p-value [†]
V1 to V2	22% (16 – 29) [‡]	24% (18 – 29)	0.73
V2 to V3	16% (9 – 23)	21% (16 – 27)	0.26
V3 to V4	14% (7 – 19)	14% (9 – 19)	0.88
V4 to V5	23% (16 – 31)	18% (13 – 23)	0.26

[†] p-value for test of group difference, with adjustment for clustering by clinic

[‡] percentage (95% confidence interval)

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Table 2B

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

Visit	Usual care	Intervention	p-value [†]
Baseline	1.18 (0.98 – 1.21)	1.01 (0.81 – 1.21)	0.21
6-month	1.05 (0.85 – 1.25)	0.87 (0.66 – 1.07)	0.19
12-month	0.98 (0.78 – 1.17)	0.77 (0.57 – 0.97)	0.15

[†] p-value for test of group difference, with adjustment for clustering by clinic

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Table 3

Characteristics of Adverse Events by Group

<i>Type of adverse event</i>			
Mean # per 100 patients	Intervention Group	Usual Care Group	P-value * for Group Difference
Serious	0.115	0.139	0.28
Non-serious	0.074	0.075	0.96
Total	0.189	0.216	0.34
<i>Relation of adverse event to study</i>			
% (N)	Intervention Group	Usual Care Group	Total
None	98 (102)	99 (112)	99 (214)
Possible	1 (1)	0	0.5 (1)
Probable	0	0	0
Definite	1 (1)	1 (1)	1 (2)
Differences too small to merit testing			
<i>Action Taken to Resolve Adverse Events</i>			
% (N)	Intervention Group	Usual Care Group	Total
None	12 (13)	11 (13)	12 (26)
*Hospitalization	52 (54)	58 (66)	55 (120)
Reported to Medical Director	15 (16)	14 (16)	15 (32)
Study termination	0	0	0

* P-value based on Poisson regression model predicting N of events for each patient

* The difference in rates of hospitalization was not statistically significant (p=0.16, by Poisson regression).