A Pilot Study Evaluating a Community-based Intervention Focused on the ISHIB IMPACT Cardiovascular Risk Reduction Toolkit in African American Patients with Uncontrolled Hypertension

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Objective: To evaluate blood pressure (BP) control utilizing the International Society on Hypertension in Blacks (ISHIB) cardiovascular risk reduction toolkit in an African American community with uncontrolled hypertension.

Methods: This is a randomized controlled pilot study conducted in two Baltimore community-based physicians' offices assigned adults (18–64 years) with uncontrolled hypertension (systolic blood pressure [SBP] ≤169 mm Hg; diastolic blood pressure [DBP] ≤109 mm Hg). The study compares usual care to a community-based intervention. In the usual care group, the patients' BP was managed by the treating physician based on their normal office patient care protocol. In the intervention group, usual care was provided but, a community health worker also gave comprehensive education and assessment to the patients based on the ISHIB IMPACT cardiovascular toolkit during study initiation and follow-up visits. The main outcome of study was change in BP from baseline to six months. A secondary outcome was the proportion of patients achieving BP <135/<85 mm Hg at six months.

Results: Fifty-four African American patients were enrolled; 37 completed six months of follow-up (usual care, $n=25$; intervention, $n=12$). At six months the mean (95% CI) change from baseline in SBP was significantly greater in the intervention group vs the usual care group: −34.75 (−46.55 to −22.95) mm Hg vs −5.65 (−12.84 to 1.54) mm Hg ($P<.001$). Mean (95% CI) change in DBP from baseline to six months was significantly greater for the intervention group vs the usual care group: −16.19 (−24.00 to −8.39) mm Hg vs −4.36 (−8.26 to −0.46) mm Hg ($P=.009$). Median change in BP was significantly greater for SBP in the intervention group compared with the usual care group ($P=.007$), but not for DBP ($P=.197$). The proportion of patients achieving BP <135/<85 at six months was 83% (10/12) in the intervention group vs 60% (15/25) in the usual care group ($P=.263$).

Conclusions: This pilot study on the ISHIB IMPACT toolkit in managing uncontrolled hypertension in the African American community suggests better control of systolic BP and a tendency to better hypertension control with the community-based intervention. The findings support further studies in clinical settings serving African American hypertensive patients to assess effectiveness of approaches for improving BP control and related outcomes. *Ethn Dis*. 2015;25[2]:162–167.

Key Words: Hypertension, Blood Pressure, African American

Introduction

Hypertension is a major driver of health disparities, with a substantially elevated prevalence among African Americans despite advances in hypertension awareness and treatment.[1,2] Although hypertension is a potent modifiable risk factor for cardiovascular heart disease (CHD), formidable barriers to medication adherence and therapeutic lifestyle changes exist at multiple levels, including patients (eg, socioeconomic, cultural, and psychological factors), health care providers (eg, therapeutic inertia), issues with therapy (eg, adverse events, cost, regimen complexity, and environmental issues (eg, access to care, limitations of the practice setting).[3] Such barriers may contribute to the excessive prevalence of uncontrolled hypertension, particularly in ethnic minorities.[4]

Various community interventions for hypertension have reported mixed results, which may not be sustained.[5–10] Possible problems may be the ad hoc or seemingly random nature and fidelity of certain interventions. As part of a comprehensive strategy to improve the health of African Americans with hypertension and related disorders, the International Society on Hypertension in Blacks (ISHIB) developed a cardiovascular risk reduction toolkit study (IMPACT) to translate recommendations for hypertension management to community practices (Figures 1, 2). In addition, the ISHIB 2010 consensus statement recommends effective strategies to manage hypertension in African American patients, with a strong emphasis on the need for comprehensive therapeutic lifestyle changes in all patients.

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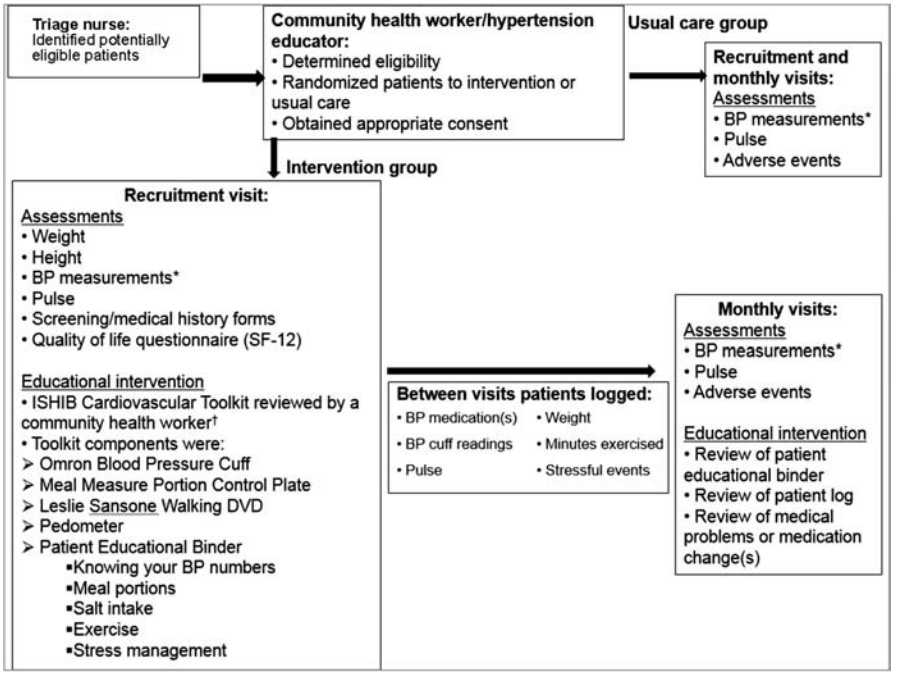

Fig 1. Study procedure: implementation of the ISHIB cardiovascular tool kit. At each visit, the patient's arm was measured; BP was taken with study BP machine: 3 BP measurements during recruitment, 3- and 6-month visits; 5 measurements during 1-, 2-, 4-, and 5-month visits (in some patients monthly follow-up visits were conducted); this was done in an effort to ensure that patients who had difficulty with travel or availability could have more opportunities to come in for their intervention).

METHODS

Study Design

This was a six-month, randomized, controlled pilot study conducted in two Baltimore community-based physicians' offices (1 cardiology, 1 primary care) in a medically underrepresented population. Patients were recruited during routine clinic visits. Potentially eligible patients were identified by a triage nurse who referred the patient to an experienced community health worker (non-physician) responsible for study coordination, recruitment, randomization, and administration of the educational intervention (Figure 1). The study was approved by the Institutional Review Board (IRB) of the University of Maryland School of Medicine.

Fig 2. ISHIB IMPACT cardiovascular tool kit

Study Population

Patients were eligible for participation in this pilot study if they met the inclusion and exclusion criteria listed in Table 1. Once a patient was deemed eligible, the community care worker provided a detailed explanation of the study purpose and expectations. Patients were randomized by a 50/50 randomization scheme and all participating patients signed an IRB-approved informed consent form. In addition, the community worker reviewed the Health Insurance Portability and Accountability Act (HIPAA) with each patient and obtained approval for use of personal health information for study purposes only.

Table 1. Inclusion and exclusion criteria

Inclusion Criteria
- Adults, aged 18–64 years
- Uncontrolled hypertension at screening >135/85 mm Hg
  - Systolic blood pressure (SBP) ≤169 mm Hg
  - Diastolic BP (DBP) DBP ≤109 mm Hg)
- BMI ≤37 kg/m^2
- Hemoglobin A1c (HbA1c) <6.5%
- Estimated GFR greater than calculated 55 mL/min/1.73 m^2

Exclusion Criteria
- BP ≥170/110 mm Hg (including stage 2 hypertension on ≥3 antihypertensive medications, one being a diuretic, and not at goal)
- Previous hospitalization or active treatment for heart failure
- Consumption of ≥3 alcoholic drinks daily (men) and ≥2 alcoholic drinks daily (women) as reported upon enrollment
- Cocaine abuse (within past 6 months)
- History of cancer within the past 5 years
- Chronic diseases that were unstable and likely to require therapeutic adjustments during the study interval
- Life-threatening illnesses with life expectancy <1 year
- Psychiatric disorders likely to interfere with protocol adherence
- For female patients: pregnancy, active nursing, and/or being of childbearing potential but not using appropriate contraception

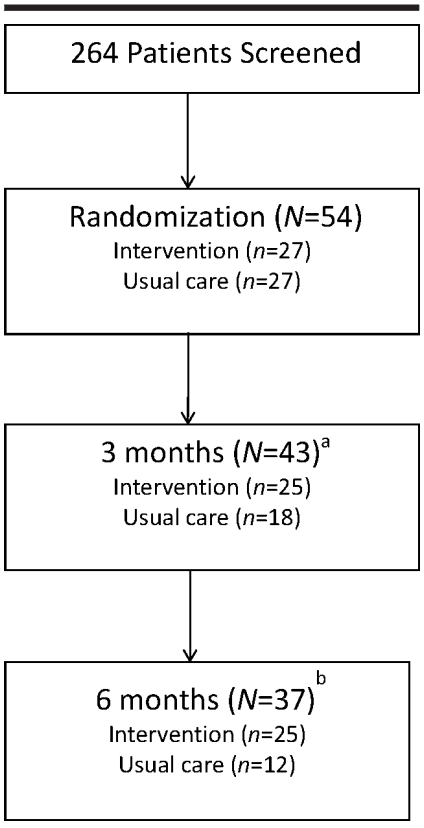

Fig 3. Patient disposition [a]At three months, two patients in the usual care group and seven patients in the intervention group were lost to follow-up. [b]At six months, data were unavailable due to loss to follow-up and halting of study for six additional patients (all in the intervention group)

INTERVENTION

All patients in this study continued to have BP managed by their physician based on the physicians' usual office patient care protocol. While treating physicians at both study sites were aware of the ISHIB risk stratification and treatment algorithm, strict implementation of the algorithm was only required in the protocol for the intervention group.[2]

Patients who were randomized to the intervention group had an initial educational session with the experienced community health worker/hypertension educator to review all components of the ISHIB IMPACT cardiovascular tool kit and met with this community health worker at educational follow-up visits. Patients in the usual care group met with the community health worker for assessment of BP, pulse and adverse events at the same time intervals as the intervention group, but did not receive the educational intervention. Details of the IMPACT toolkit and educational intervention are provided in Figures 1 and 2.

As part of the initial detailed education session, patients in the intervention group were trained on use of the BP cuff and had to successfully demonstrate their ability to self-monitor BP. For each patient, the same BP device with an appropriately sized arm cuff was used for all study BP measurements. Follow-up assessment and education sessions were conducted by the same community health worker throughout the study and included a review of patients' recorded home BP measurements.

In order to compensate patients in both groups for their participation, and in an effort to improve adherence to the study protocol, all patients were given a $20 gift card at each visit and a written reminder of their next follow-up visit date. Patients received a telephone reminder from the community health worker one week prior to each visit to confirm or reschedule their follow-up.

Statistical Analysis

Baseline characteristics between the usual care and intervention groups were compared using non-parametric analysis, as appropriate. Frequencies and proportions of categorical variables were calculated and Fisher's two-sided exact test was used to determine statistical differences. The difference in median ages was tested using Pearson's Chi-squared test of equality of medians.

Mean SBP and DBP (mm Hg) were estimated at baseline, one month, three months, and six months, and the usual care and intervention groups were compared using a two-sided *t*-test for independent groups. The change in SBP and DBP from baseline to the six-month follow-up was analyzed using interquartile range and means with 95% confidence intervals (CI). The two groups were compared using Pearson's Chi-squared test of equality of medians and *t*-tests for means.

In order to control for baseline differences between study groups, a multivariable analysis was performed for the six-month change in both SBP and DBP. None of the measured baseline characteristics were significant ($P>.30$) when included as independent variables alone or in a step-wise fashion (data not shown).

All analyses were conducted using STATA version 13 (STATACorp LP, College Station, Texas).

RESULTS

Patient Disposition and Baseline Characteristics

Patient disposition is shown in Figure 3. A total of 54 patients were enrolled in the study ($n=27$ randomized to each study group) and 37 patients completed six months of follow-up ($n=25$ [92.6%] in the usual care group and $n=12$ [44.4%] in the intervention group). All patients enrolled in this study were African American. Baseline characteristics of all patients who were randomized to the intervention or usual care groups are summarized in Table 2. Generally, no differences were observed between groups for parameters assessed at baseline, with the exception of alcohol consumption (significantly more patients reported alcohol consumption in the intervention group than in the usual care group [$P<.001$]). Baseline parameters were also compared for patients in the intervention and usual care groups who completed 6 months of follow-up (data not shown); alcohol consumption remained significantly greater in the intervention group compared with the usual care group ($P<.001$). For patients completing 6 months of follow-up,

Table 2. Baseline characteristics

Variable	Usual Care (n=27)[a]	Intervention (n=27)[a]	P[b]
Sex			
Male	11 (40.7)	12 (44.4)	1.00
Female	16 (59.3)	15 (55.6)	
Age, median (25th, 75th) years	59 (55, 66)	58.5 (53, 63)	.90
BMI			
Normal (19≤BMI≤24 kg/m^2)	8 (29.6)	2 (7.4)	.051
Overweight (25≤BMI≤29 kg/m^2)	9 (33.3)	7 (25.9)	
Obese (30≤BMI≤40 kg/m^2)	10 (37.0)	18 (66.7)	
Cigarette smoking			
Yes	11 (40.7)	7 (25.9)	.39
No	16 (59.3)	20 (74.1)	
Alcohol consumption			
None	16 (59.3)	0 (0.0)	<.001
Occasional	2 (7.4)	17 (63.0)	
2–3 drinks/day	9 (33.3)	10 (37.0)	
Illicit drug use			
Yes	9 (33.3)	5 (18.5)	.35
No	18 (66.7)	22 (81.5)	
Diabetes diagnosis			
Yes	6 (22.2)	5 (18.5)	1.00
No	21 (77.8)	22 (81.5)	
Timing of hypertension diagnosis			
≤2 years ago	7 (25.9)	3 (11.1)	.23
3–10 years ago	12 (44.4)	11 (40.7)	
≥11 years ago	8 (29.6)	13 (48.1)	
SBP, mean (SD) mm Hg	136 (19)	143 (18)	.14
DBP, mean (SD) mm Hg	85 (12)	90 (12)	.13

BMI = body mass index; SBP = systolic blood pressure; DBP = diastolic blood pressure.
[a] Values are presented as *n* (%) unless otherwise indicated.
[b] Fisher's two-sided exact test was used to test the difference between the intervention and control groups for all categorical variables. Pearson's Chi-squared test of equality of medians was used to test differences of medians; a *t*-test was used to test the differences for continuous variables.

a significant difference between groups was noted for baseline BP values; compared with the usual care group, the patients in the intervention group had higher baseline mean (SD) SBP (154 [15] mm Hg vs 136 [19] mm Hg, P=.005) and DBP (93 [11] mm Hg vs 85 [12] mm Hg, P=.038). No other significant differences in baseline parameters were observed between the intervention and usual care groups for patients completing 6 months of follow-up.

Blood Pressure Outcomes

Mean BP at 1-, 3-, and 6-months

In both the intervention and usual care groups, the mean BP measurements generally declined over the course of follow-up (Table 3). The mean (SD) SBP was significantly lower in the intervention group compared with the usual care group (120 [14] mm Hg versus 131 [18] mm Hg; P=.035) at the 6-month assessment, but not at the 1- and 3-month assessments. Mean (SD) DBP measurements were not significantly different between groups at 1-, 3-, or 6-month assessments.

Mean Change in BP

BP reductions from baseline were observed in both the usual care and intervention groups at all of the prespecified study time points; these reductions were significant in the intervention group at each of these time points (1 month, P<.05; 3-months, P<.011; 6-months, P<.001), but did not achieve significance in the usual care group. At 6 months, the mean (95% CI) change from baseline in SBP was significantly greater for patients in the intervention group compared with the usual care group: −34.75 (−46.55 to −22.95) mm Hg vs −5.65 (−12.84 to 1.54) mm Hg (P<.001). Mean (95% CI) change in DBP from baseline to six months was also significantly greater for the intervention group vs the usual care group: −16.19 (−24.00 to −8.39) mm Hg vs −4.36 (−8.26, −0.46) mm Hg (P=.009). Box plots of the median (25th and 75th percentiles) change in SBP and DBP from baseline to six months are shown in Figure 4; the median change in BP in the intervention group compared with the usual care group was significantly greater for SBP, but not for DBP.

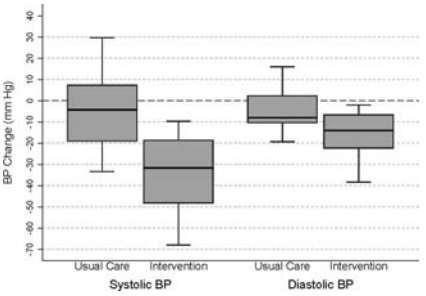

Fig 4. Box plots of change in systolic blood pressure (SBP) and diastolic blood pressure (DBP) after six months of follow-up Using Pearson's Chi-squared test for equality of medians, at six months, the median (25th, 75th) change in SBP was −4.33 (−19.00, 7.33) mm Hg for patients in the usual care group (n=25) compared with −31.67 (−48.17, −18.67) mm Hg for patients in the intervention group (n=25); P=.007. At six months the median (25th, 75th) changes in DBP were −8 (−10.33, 2.33) mm Hg and −14.00 (−22.33, −6.67) mm Hg, for the usual care and intervention groups, respectively; P=.197

Table 3. Mean systolic and diastolic blood pressure over follow-up

BP, mean (SD) mm Hg	Usual Care	Intervention	*P* (Comparison between Groups)
Baseline[a]			
SBP	135 (19)	143 (18)	.14
DBP	85 (12)	90 (12)	.13
One month[b]			
SBP	130 (22)	129 (16)	.90
DBP	80 (11)	82 (8)	.38
Three months[c]			
SBP	129 (15)	129 (18)	.99
DBP	82 (12)	83 (7)	.70
Six months[d]			
SBP	131 (18)	120 (14)	.035
DBP	81 (9)	77 (6)	.092

SBP = systolic blood pressure; DBP = diastolic blood pressure.
[a] 27 usual care and 27 intervention patients.
[b] 25 usual care and 18 intervention patients.
[c] 25 usual care and 18 intervention patients.
[d] 25 usual care and 12 intervention patients.

Proportion of Patients Achieving Goal BP of <135/<85 mm Hg

At the six-month follow-up assessment, 83% (10/12) of patients in the intervention group achieved an ISHIB goal BP of <135/<85 mm Hg compared with 60% (15/25) of patients in the usual care group (P=.263).

DISCUSSION

In this six-month, randomized pilot study of African American patients with uncontrolled hypertension, greater BP reductions were demonstrated among patients who received a community-based educational intervention compared with those who received usual care. These findings support the fact that increased patient knowledge and awareness facilitated by a community health care worker utilizing the ISHIB IMPACT educational intervention can be a practical and effective strategy to reduce racial disparities in hypertension control. The involvement of a trained non-physician community care worker is a relatively low-cost strategy that can help address practice- and resource-related barriers in the management of hypertension.

Preliminary findings on other aspects of BP management reported by patients in the intervention group were changes in diet and salt intake, increased exercise (particularly walking), better stress management, and weight loss. A larger, long-term randomized controlled study is needed to validate these findings.

While many community-based educational interventions lower BP or improve other aspects of hypertension management, results have been variable.[5–10] For example, in a recent randomized controlled study of hypertensive African American patients (N=256) in two primary care practices, patient education enhanced with a behavioral intervention improved adherence to BP medications compared with patient education alone; however, reductions in SBP and DBP from baseline to 12 months did not achieve statistical significance.[9] Thus, given the limited sample size of the current pilot study (25 usual care versus 12 intervention), the BP lowering effects demonstrated need to be validated in a larger scale, long-term randomized controlled trial.

Our pilot study provides a proof of concept/feasibility for the use of ISHIB IMPACT tool kit in the management of uncontrolled hypertension in the African American community.

Our study provides data on BP control in a minority population with socioeconomic challenges. One strength of our study is the randomized, prospective design. In addition, the same community care worker implemented the intervention throughout our study, therefore assuring consistency of patient assessments and delivery of patient education. Limitations of this study are similar to those noted for other community-based interventions.[5,6,10] Blinding was not possible given the educational nature of the intervention and provision of a physical toolkit. An important issue is that more than half of the patients in the intervention group did not have six-month follow-up data. This was due, in part, to loss to follow-up. Prevalence of alcohol use was significantly greater among patients in the intervention group and may be a possible contributing factor to the greater loss to follow-up of this group. In addition, the study was halted for administrative reasons before all patients completed six months of follow-up. However, the study investigators felt the sample size was sufficient to establish proof of concept given the difficult-to-recruit patient demographic.

In conclusion, our pilot study provides a proof of concept/feasibility for the use of ISHIB IMPACT tool kit in the management of uncontrolled hypertension in the African American community. This may prove to be a cost-savings approach to blood pressure management, and the potential benefit

of helping prevent end organ damage through hypertension management should be considered. An important next step will be to determine the effectiveness of the ISHIB toolkit facilitated by a patient educator on a larger scale in additional clinical sites.

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