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ORIGINAL RESEARCH

Cardiology

Effect of an emergency department education and empowerment intervention on uncontrolled hypertension in a predominately minority population: The AHEAD2 randomized clinical pilot trial

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Abstract

OBJECTIVE: To determine whether an emergency department (ED) education and empowerment intervention coupled with early risk assessment can help improve blood pressure (BP) in a high-risk population.

METHODS: A hypertension emergency department intervention aimed at decreasing disparities (AHEAD2) is a 3-arm, single-site randomized pilot trial for feasibility in an urban academic ED. A total of 150 predominantly ethnic minorities with no primary care provider and severely elevated blood pressure (BP) (≥160/100 mm Hg) were enrolled over 10 months. Participants were randomized into 1 of 3 study arms: (1) enhanced usual care (EUC), (2) ED-initiated screening, brief intervention, and referral for treatment (ED-SBIRT), or (3) ED- SBIRT plus a 48–72 hours post-acute care hypertension transition clinic (ED-SBIRT+PACHT-c). Primary outcomes were change in systolic and diastolic BP (SBP and DBP) from baseline to 9 months. Secondary outcomes were BP control (BP <140/90 mm Hg), changes in hypertension knowledge, medication adherence, and limited bedside echocardiogram (LBE) findings.

RESULTS: SBP reduction from baseline to month 9 was −26.8 (95% confidence interval [CI]: −32.8, −20.7) mm Hg for ED-SBIRT, −23.4 (95% CI: −29.5, −17.3) mm Hg for ED-SBIRT+PACHT-c, and −18.9 (95% CI: −24.9, −12.9) mm Hg for EUC. DBP decreased by −12.5 (95% CI: −16.1, −9.0) mm Hg for ED-SBIRT, −11.3 (95% CI: −14.8, −7.7) mm Hg for ED-SBIRT+PACHT-c, and −8.4 (95% CI: −11.9, −4.9) mm Hg for EUC. A multicomponent intervention compared with EUC resulted in SBP decrease of −7.9 mm Hg (95% CI: −16.4, 0.6). At 9 months, hypertension was controlled for 29.3% (95% CI: 20.3,

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38.3) of intervention and 23.5% (95% CI: 11.9, 35.2) of EUC participants. All groups saw improvements in hypertension knowledge, medication adherence, and LBEs, with greater improvements in intervention groups.

CONCLUSIONS: The study findings suggest that a multicomponent intervention comprising of ED education and empowerment coupled with early risk assessment may help improve BP in a high-risk population.

KEYWORDS
emergency department, minority, pilot study, uncontrolled hypertension

1 | INTRODUCTION

1.1 | Background

Hypertension, which affects >76 million individuals in the United States, is a primary modifiable risk factor for the development of secondary cardiovascular complications and premature death.[1] Patients with severely elevated hypertension defined as blood pressure (BP) ≥160/100 mm Hg are at the highest risk for developing secondary cardiovascular complications as a result of their uncontrolled hypertension.[2] Although inadequate BP control can be seen as a global problem, significant racial/ethnic disparities exist, with disparities in hypertension treatment and outcomes well-documented both globally and in the United States.[3] Given that efficacious treatments for hypertension have been available for decades, and previous literature supports specific agents to optimize the treatment of minority patients or those with specific disease states,[4,5] the persistent racial/ethnic differences in treatment and control of hypertension remains 1 of the biggest challenges for the medical and public health communities.

1.2 | Importance

Uncontrolled hypertension is more frequently encountered among patients presenting to the emergency department (ED) compared to those presenting to a doctor's office, with a prevalence as high as 45% with >50% having severely elevated BPs.[6,7] Risk assessment based on BP is not currently standard for hypertensive patients before discharge from the ED.[6] The growing volume of ED visits represents a timely opportunity to test implementation of an ED-based education and empowerment intervention.

The importance of a multidisciplinary team for effective hypertension management has been demonstrated in the literature, particularly in the outpatient settings, where this approach has been associated with greater reductions in BP.[8,9] Absent from the literature are examples of effective multidisciplinary hypertension teams in time-constrained settings, such as the ED.

1.3 | Goals of this investigation

A hypertension emergency department intervention aimed at decreasing disparities (AHEAD2) trial is a 3-arm single site randomized clinical pilot trial of 150 adults presenting to the ED with severely elevated BP (>160/100) and no identifiable primary care provider. The pilot was designed to determine whether an ED education and empowerment intervention coupled with early risk assessment can help improve BP in a high-risk population.

2 | METHODS

2.1 | Study design and oversight

This was a 3-arm randomized pilot trial involving a single site urban academic ED located within a predominately African American and Latino neighborhood. Details of the AHEAD2 pilot trial design and analysis plan have recently been published.[10] The institutional review board approved this study. Informed consent was obtained from all participants before randomization.

2.2 | Study participants

Patients identified for discharge from the ED were approached for study participation if the following eligibility criteria were present: (1) elevated BP ≥160/100 at time of identification for discharge from the ED, (2) verbal fluency in English or Spanish, and (3) 30–64 years of age. Patients were excluded if any of the following exclusion criteria were present: (1) pre-existing cardiovascular disease; (2) history of heart failure, myocardial infarction, cerebral vascular accident (CVA), or end-stage renal disease requiring dialysis; (3) plans to move from the Chicago area within 1 year; (4) pregnant or trying to become pregnant; and (5) inability to verbalize comprehension of the study or impaired decision-making (ie, documented history of dementia in the electronic health record). All patient recruitment was completed within the hospital ED. All participants were enrolled and randomized by dedicated research personnel. Randomization schedules were generated by the

study's lead biostatistician using PROC PLAN in SAS Software (SAS Institute) and preloaded into the REDCap data management system.[11] Randomization had 2 strata, with 2 and 3 levels respectively: sex (M, F) and race/ethnicity (Black, Hispanic, Whites + Other). Participants without an identifiable primary care provider were provided with either a self-referral (Enhanced Usual Care) or 48–72 hour facilitated referral (arm 2 or 3) via a secure intranet portal to a UI Health Affiliated Federally Qualified Health Center.

2.3 | All groups

All study participants completed the Hypertension Knowledge Survey and Morisky surveys, and received a home BP monitoring kit due to the enhanced risk of secondary cardiovascular complications associated with severely elevated BP. The BP monitoring kits contained an automatic BP monitor and self-reporting logbook. Participants were shown how to use the BP monitors by research assistants and viewed a standardized 2-minute instructional video provided by the BP monitor company. Home blood pressure monitoring (HBPM) is currently recommended as part of the treatment regimen for especially with severely elevated BPs.[30]

All participants had scheduled phone calls at 3, 5, and 8 months to verify contact information as well as two in-person BP assessments at 6 and 9 months. In-person visits occurred within the PACTH-c designated area located adjacent to the ED or an unoccupied ED examination room and participants received a gift card incentive for their time.

2.4 | Enhanced usual care (control)

Participants randomized to enhanced usual care (EUC) (arm 1) were provided pre-printed discharge educational materials about high BP and given a 72-hour self-directed referral to the UI Health Affiliated Federally Qualified Health Center to schedule a follow-up appointment.

2.5 | Interventions

Participants randomized to the arms 2 and 3 received the ED-initiated screening, brief intervention, and referral for treatment (ED-SBIRT) intervention as a baseline.

2.6 | Echocardiograms

The echocardiograms were performed by dedicated study staff trained on limited bedside echocardiograms. All images were reviewed by an emergency medicine physician fellowship trained in echocardiography. Participants randomized to the intervention arms had limited bedside echocardiograms (LBEs) to identify the presence or absence of subclinical findings left ventricular hypertrophy (LVH), and/or diastolic dysfunction (DD). Findings were recorded as binary (normal vs abnormal).

The Bottom Line

This study enrolled 150 predominantly African-American and Latinx participants with no primary care provider and elevated blood pressure (≥160/100 mm Hg) in a three-arm randomized trial looking at enhanced usual care, care with an ED-based screening and intervention, and multicomponent arm (screening plus rapid outpatient clinic). While all groups saw improvements in hypertension knowledge and medication adherence, the multicomponent intervention compared with enhanced usual care resulted in systolic blood pressure decrease of −7.9 mm Hg (95% CI: −16.4, 0.6) with greater improvements in intervention groups. Multicomponent interventions may be a potential beneficial approach for blood pressure management, particularly for historic vulnerable populations.

2.7 | Post-acute care hypertension transition consultation

Those randomized to Arm 3 additionally received the 48–72 hours post-acute care hypertension transition consultation (PACHT-c) with an ED clinical pharmacist. The PACHT-c included intensification of antihypertensive medication and review of survey assessments and modifiable cardiovascular risk factors. Intensification of antihypertensive medication involved adjustments to current antihypertensive regimen or addition of a new medication, because having a previous diagnosis was not an exclusion factor.

2.8 | Blinding

Study investigators, program coordinators, research assistants, and participants were not blinded to the intervention assignment at the time of randomization. However, research assistants were blinded to intervention assignment of participants during assessment of study outcomes at follow-up visits. All BP measurements were conducted as per American Heart Association (AHA) guidelines.[12]

2.9 | Outcomes

The primary outcome was the individual differences in mean systolic and diastolic BP (SBP and DBP) from baseline to study completion 9 months later between the intervention and control groups. Secondary outcomes were the proportion of participants with controlled

hypertension at 9-months, and change in hypertension knowledge score, change in medication adherence, and LBE results. Controlled BP was defined as improvement in BP <140/90 mm Hg.

Participant's hypertension knowledge was assessed at baseline and at 9 months using a validated hypertension knowledge survey[13] and patient adherence to antihypertensive medication was quantified using the 4-item Morisky Medications Adherence Scale.[14]

Study investigators trained and demonstrating competency in LBEs performed all initial and 9-month follow-up echocardiograms.

2.10 | Sample size

As a pilot, the sample size calculations were underpowered to detect change in BP. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Medication Adherence and Persistence Special Interest Group Systematic Review of the impact of interventions on medication adherence and BP control reported that successful outpatient education programs achieved reductions of 2%–17% in changes in systolic and diastolic BP (SBP/DBP) with a range of 44%–67% achieving optimal BP control (BP <140/90). Based on our previous study, we estimated a mean SBP of 173.1 with standard deviation (SD) of 26.1 and a DBP of 101.9 with a SD of 14.2. We assessed specific pre-specified outcomes to determine if the SBIRT-HTN plus PACHT-c intervention is superior. We calculated sample size for a range of possible SBP changes in each arm with the usual care arm as the reference at a 10% change. Our sample size of 150 after potential dropout of 20% per arm was deemed adequate for these contrasts.

2.11 | Statistical analysis

Descriptive statistical measures were calculated for continuous (mean ± SD) and categorical (%) variables along with 95% confidence intervals (CI). Analysis of variance (ANOVA) was applied to assess mean differences at baseline for all continuous variables (eg, age, weight, height, BMI, SBP, and DBP) and Fisher's exact test for categorical variables (eg, race, sex, and hypertension treatment). BP levels were imputed by the last value carried forward. The change in BP (SBP/DBP) from baseline was calculated at 6 and 9 months and mean change comparisons across groups performed via regression analysis. CI was computed for the change in BP to further illustrate the effect of the interventions over time. Changes in other continuous variables (eg, hypertension knowledge) were tested using multivariable regression, whereas the Fisher's test was applied for dichotomous measures (eg, hypertension control). For the analysis of dichotomous secondary outcome representing proportion with controlled hypertension, the intervention groups were pooled as the observed effect of the 2 interventions on BP control was similar. An intention-to-treat approach was implemented for all analyses. Post-hoc analyses were carried out to adjust for unbalanced variables (ie, hypertension medication use and race/ethnicity) across groups via multivariable regression analysis. Group differences were further investigated by weighting the regression models by the inverse of the probability of missing BP.[15] Furthermore, mixed-effects regression models were implemented to estimate and test rates of change from baseline to 9 months across treatment groups.

Many researchers have argued that "significance testing" of hypotheses alone does not fully address the scientific questions and have advocated the use of CI.[16–19] Therefore, we have presented both CIs and *P*-values. Statistical analyses were carried out in SAS 9.4 and STATA 15.1 (College Station, TX).

3 | RESULTS

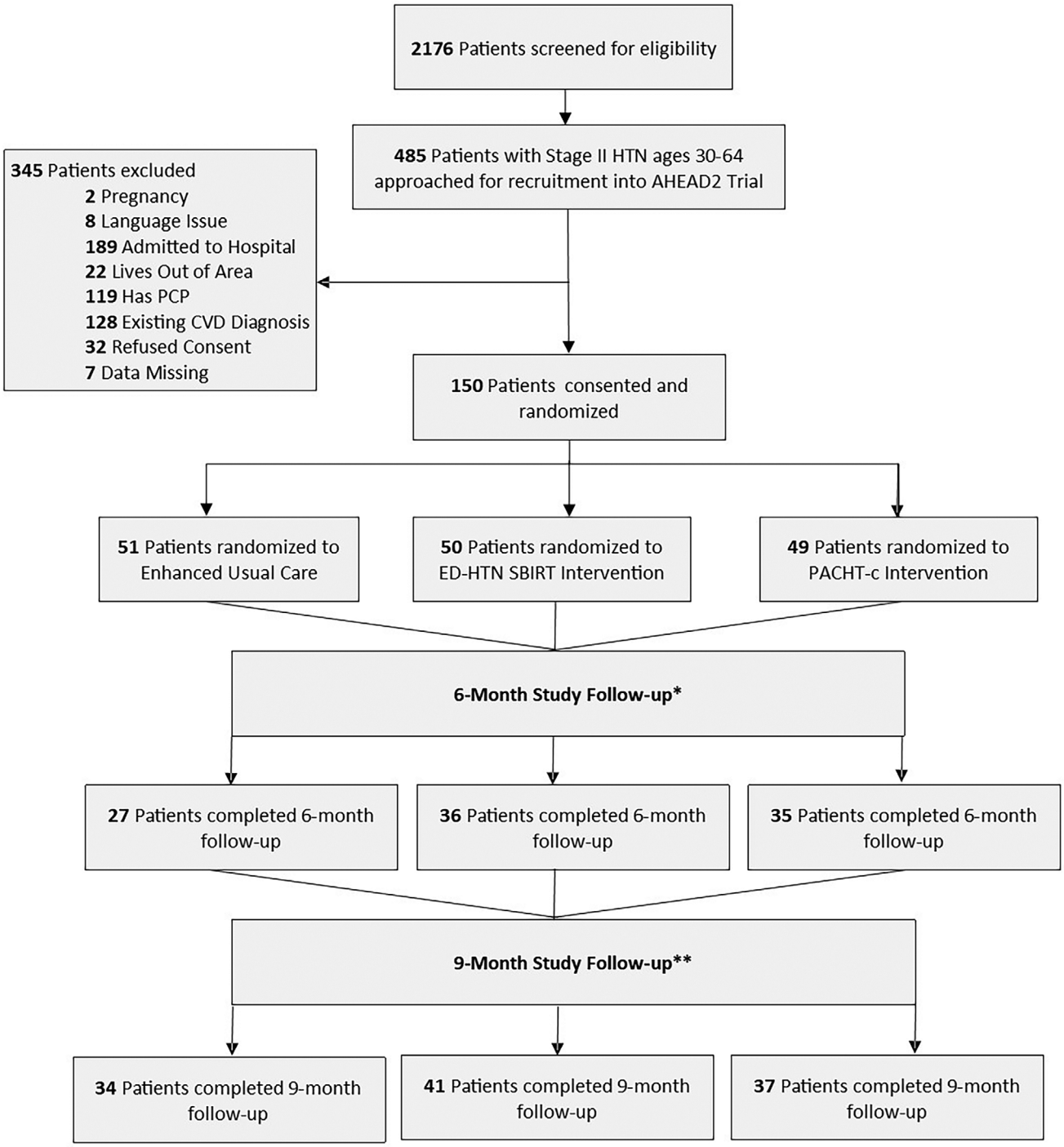
There were 150 patients randomized to the 3 arms of the study (51 EUC, 50 SBIRT, and 49 SBIRT+PACHT-c), of whom 112 (75%) had complete information at 9 months. Recruitment took place from December 2015 to June 2016, and the last follow-up was in April 2017. Recruitment ended when 150 participants were enrolled, and the pilot trial ended after the last 9-month follow-up appointment.

Figure 1 depicts the process of patient enrollment, randomization, and follow up by study arm. Baseline patients' characteristics are presented in Table 1. The hypertension treatment at baseline differs by treatment arm (*P*-value = 0.02), as well as the race distribution (*P*-value = 0.02).

Table 2 illustrates how the observed (before imputation by last value carried forward) change in BP at 9 months is distributed for each of the 3 treatment arms. The top panel shows changes in SBP, whereas the bottom panel shows the corresponding changes in DBP. Mean change in SBP between randomization and 9 months across treatment groups was not statistically significant (*P*-value = 0.19). The estimated change in SBP was −18.9 mm Hg (95% CI: −24.9, −12.9) for EUC (Arm 1), −26.8 (95% CI: −32.8, −20.7) for ED-SBIRT (Arm 2), and −23.4 mmHg (95% CI: −29.5, −17.3) for ED-SBIRT+PACHT-c (Arm 3).

However, participants randomized to the ED-SBIRT study arm had a decrease in SBP −7.9 mmHg (95% CI: −16.4, 0.6) compared to EUC, whereas the corresponding decrease in the ED-SBIRT+PACHTc was −4.5 mm Hg (95% CI: −13.1, 4.0). Changes from baseline to 6 months exhibit the same pattern. Furthermore, diastolic BP changes at 6 and 9 months behaved in a similar fashion. As seen from Table 1, race and hypertension treatment at baseline differs across treatment arm. Race and hypertension treatment-adjusted BP changes are also shown in Table 2. Applications of mixed-effects models yielded similar results for mean changes in SBP and DBP from baseline to 9 months. Change difference for ED-SBIRT compared to usual care were −7.9 mm Hg (95% CI: −16.3, 0.5), −4.1 mm Hg (95% CI: −8.7, 0.5) for SBP and DBP respectively, whereas for usual care and SBIRT+PACHTc the corresponding differences were −4.5 mm Hg (95% CI: −12.7, 3.6) and −2.8 mm Hg (95% CI: −7.2, 1.5).

Table 3 shows how the percentages of controlled BP at 6 and 9 months are distributed for the combined intervention arms as compared to the EUC arm. The greatest percentages of control were seen in the intervention arms at 9 months (29.5%, CI: 20.5%, 38.4%)



* Loss to follow-up at 6-month — 24 patients in Enhanced Usual Care, 14 patients in ED-HTN SBIRT Intervention, and 14 patients in PACHT-c Intervention

** Loss to follow-up at 9-month — 17 patients in Enhanced Usual Care, 9 patients in ED-HTN SBIRT Intervention, and 12 patients in PACHT-c Intervention

FIGURE 1 Flow diagram of trial participants

TABLE 1 Baseline characteristics and patient demographics of a hypertension emergency department intervention aimed at decreasing disparities (AHEAD2) study participants by arm

Characteristic	Enhanced usual care(n = 51)	ED-SBIRT (n = 50)	ED-SBIRT+PACHTc (n = 49)	*P*
Age, mean (SD) (95% CI)	48.5 (9.2)	46.4 (8.9)	48.6 (9.3)	0.40
	(45.9,51.1)	(44.3,49.3)	(45.9,51.3)	
Women, no. (%) (95% CI)	28 (54.9)	30 (60.0)	29 (59.2)	0.86
	(40.3,68.9)	(45.2,73.6)	(44.2,73.0)	
Race/ethnicity, no. (%) (95% CI)				0.02
Black/African-American	37 (72.6)	37 (74.0)	32 (65.3)	
	(58.3,84.1)	(59.7,85.4)	(50.4,78.3)	
Hispanic/Latino	10 (19.6)	11 (22.0)	5 (10.20)	
	(9.8,33.1)	(11.5,36.0)	(3.4,22.2)	
All other races	4 (7.8)	2 (4.0)	12 (24.5)	
	(2.2,18.9)	(0.5,13.7)	(13.3,38.9)	
Language, no. (%) (95% CI)				0.31
English	49 (96.1)	44 (88.0)	46 (93.9)	
	(86.5,99.5)	(75.7,95.4)	(83.1,98.7)	
BMI, mean (SD) (95% CI)	34.9 (8.5)	35.2 (10.8)	33.8 (12.5)	0.80
	(32.5,37.3)	(32.2,38.3)	(30.3,37.4)	
Blood pressure, mean (SD) mm Hg (95% CI)				
Systolic	175.4 (17.3)	176.0 (13.8)	178.8 (16.9)	0.52
	(170.5,180.2)	(172.1,180.0)	(174.0,183.7)	
Diastolic	102.4 (12.7)	102.9 (12.7)	103.0 (12.8)	0.97
	(98.8,105.9)	(99.3,106.5)	(99.3,106.7)	
Use of antihypertensive medications, No. (%) (95% CI)	24 (47.1)	34 (74.0)	39 (59.2)	0.02
	(32.9,61.5)	(59.7,85.4)	(44.2,73.0)	
HTN knowledge score, mean (SD) (95% CI)	7.8 (1.72)	7.7 (1.73)	7.3 (2.0)	0.32
	(7.3,8.3)	(7.2,8.,2)	(6.7,7.8)	
Modified Morisky score, mean (SD) (95% CI)	2.2 (1.3)	2.3 (1.3)	2.5 (1.2)	0.68
	(1.7,2.8)	(1.9,2.8)	(2.0,3.0)	

suggesting the long-term benefits and the potential for sustainability of the educational and empowerment components following the initial ED intervention. The percentage of controlled hypertension in EUC at 9 months was 23.2% (95% CI: 11.7%, 34.8%). Although the intervention arms had an additional 6% improvement in controlled BP compared to the EUC group, the findings were not statistically significant (*P*-value = 0.45). Race and hypertension treatment-adjusted control rates at 6 and 9 months are also displayed in Table 3.

Table 4 examines the secondary outcomes of changes in hypertension knowledge, medication adherence, and subclinical findings on LBE. Although improvements in hypertension knowledge scores and medication adherence were seen among all participants with greater improvements noted in the intervention groups (with the exception of hypertension knowledge score that decreased in the non-intervention group), the improvements were not statistically significant. Improvement in % of normal LBEs was noted in the intervention groups.

3.1 | Limitations

This study has several limitations. It is single-site randomized pilot trial in a predominately minority setting, and findings may not be generalizable to other EDs with different patient populations. In addition, recruitment was limited to times where there were both a pharmacist and provider to complete the LBE, and thus represented more of a convenience sample. Although selection bias was possible, recruitment times were equally distributed across days, evenings, nights, and weekends to capture a representative sample of patients with severe (stage 2) hypertension. Important covariables also were adjusted to limit potential confounding effects. Another limitation is that

TABLE 2 Mean blood pressure[a] difference (95% confidence interval) in each of the 3 treatment groups. Differences of change in BP in ED-initiated screening, brief intervention, and referral for treatment (ED-SBIRT), ED-SBIRT+PACHTc compared to enhanced usual care (95% confidence interval)

Control			Interventions						
Enhanced usual care			ED-SBIRT			ED-SBIRT+PACHTc			
	N	Mean(95% CI)	N	Mean(95% CI)	Net difference[b] (vs control) (95% CI)	N	Mean(95% CI)	Net difference[b] (vs control)(95% CI)	*P*
Unadjusted estimates*									
Change in systolic blood pressure from baseline, mm Hg									
Month measured									
6	51	−16.0 (−22.4, −9.7)	50	−21.4 (−27.8, −15.0)	−5.4 (−14.4, 3.7)	49	−21.2 (−27.6, −14.7)	−5.1 (−14.2, 3.9)	0.42
9	51	−18.9 (−24.9, −12.9)	50	−26.8 (−32.8, −20.7)	−7.9 (−16.4, 0.6)	49	−23.4 (−29.5, −17.3)	−4.5 (−13.1, 4.0)	0.19
Change in diastolic blood pressure from baseline, mm Hg									
Month measured									
6	51	−7.6 (−10.9, −4.3)	50	−10.7 (−14.1, −7.4)	−3.2 (−7.9, 1.5)	49	−8.7 (−12.1, −5.4)	−1.2 (−5.9,3.6)	0.41
9	51	−8.4 (−11.9, −4.9)	50	−12.5 (−16.1, −9.0)	−4.1 (−9.1, 0.9)	49	−11.3 (−14.8, −7.7)	−2.8 (−7.8, 2.2)	0.25
Race and hypertension treatment-adjusted estimates**									
Change in systolic blood pressure from baseline, mm Hg									
Month measured									
6	51	−17.6 (−23.9, −11.3)	50	−20.3 (−26.7, −13.9)	−2.6 (−11.7, 6.4)	49	−20.6 (−27.1, −14.1)	−3.0 (−12.1, 6.2)	0.04
9	51	−19.9 (−25.9, −13.8)	50	−25.6 (−31.7, −19.4)	−5.7 (−14.4, 3.0)	49	−23.6 (−29.9, −17.4)	−3.7 (−12.5, 5.0)	0.09
Change in diastolic blood pressure from baseline, mm Hg									
Month measured									
6	51	−8.6 (−11.6, −4.9)	50	−10.2 (−13.6, −6.8)	−1.9 (−6.7, 2.9)	49	−8.6 (−12.0, −5.1)	−0.3 (−5.2,4.4)	0.18
9	51	−8.9 (−12.4, −5.4)	50	−11.9 (−15.1, −7.8)	−3.1 (−8.1, 2.0)	49	−11.4 (−15.1, −7.8)	−2.6 (−7.7, 2.5)	0.06

[a] Estimates of mean blood pressure (blood pressure change) values, as well as confidence intervals, are calculated after imputing missing observations using the last value carried forward approach.
[b] Net difference = intervention minus control.
**P*-value reported for the mean change in blood pressure across the 3 treatment arms (ANOVA)
***P*-value reported for the mean change in blood pressure across the 3 treatment arms adjusted for race and hypertension treatment (ANCOVA).

TABLE 3 Proportion with controlled hypertension comparing control and intervention group

	Control	Intervention		
	Enhanced usual care (n = 51)	ED-SBIRT + ED-SBIRT+PACHTc (arms 2+3) (n = 99)		
	Proportion (%)(95% CI)	Proportion (%)(95% CI)	Net difference[a](95% CI)	*P*
Unadjusted*				
Month measured				
6	17.6 (7.2, 28.1)	19.2 (11.4,26.9)	1.6 (−11.8,14.9)	0.82
9	23.5 (11.9, 35.2)	29.3 (20.3,38.3)	5.8 (−9.5,21.0)	0.45
Race and hypertension treatment-adjusted**				
Month measured				
6	18.2 (7.5,28.9)	18.9 (11.2,26.6)	0.7 (−12.5,13.9)	0.61
9	23.2 (11.7,34.8)	29.5 (20.5,38.4)	6.3 (−8.4,21.0)	0.38

[a]Net difference = intervention minus control

**P*-value for comparison of treatment control rates across groups

***P*-value for the comparison of race and hypertension treatment-adjusted control rates across groups.

TABLE 4 Hypertension knowledge, Morisky score, and limited bedside echocardiogram for a hypertension emergency department intervention aimed at decreasing disparities (AHEAD2) participants by study arm

	Enhanced usual care			ED-SBIRT			ED-SBIRT+PACHTc		
	Hypertension knowledge score								
	N	Mean (95% CI)	Difference (95% CI)	N	Mean (95% CI)	Difference (95% CI)	N	Mean (95% CI)	Difference (95% CI)
Pre	40	7.6 (6.9,8.3)	−2.7 (−4.1, −1.3)	39	7.6 (7.1,8.2)	−1.2 (−2.4,1.2)	41	6.5 (5.6,7.4)	−0.9 (−2.4,0.7)
Post	39	4.9 (3.6,6.1)		39	6.5 (5.3,7.7)		37	5.6 (4.3,7.0)	
	Morisky score								
Pre	40	0.7 (0.3,1.1)	−0.3 (−0.7,0.2)	39	1.3 (0.8,1.7)	−0.5 (−1.0,0.1)	41	0.8 (0.4,1.1)	−0.1 (−0.6,0.4)
Post	39	0.4 (0.1,0.7)		39	0.8 (0.5,1.1)		37	0.6 (0.3,1.0)	
	Limited bedside echocardiogram								
Pre	NA			38	89.5 (79.3,99.7)	−12.8 (−30.8,5.1)	33	93.9 (85.3,102.5)	−16.7 (−34.8,1.5)
Post				30	76.7 (60.6,92.7)		22	77.3 (58.3,96.3)	

Abbreviation: NA, Not applicable.

intervention contamination, if any occurred, might have diluted the observed effect.

4 | DISCUSSION

The AHEAD2 is the first randomized controlled trial pilot to test the feasibility and participant acceptability of an ED-initiated intervention targeting patients with uncontrolled hypertension using a multidisciplinary team to improve BPs in a predominately minority population. Advantages of a multidisciplinary team as a successful strategy to address uncontrolled hypertension have been well-established.[9,23] However, randomized controlled trials demonstrating benefit in time-constrained acute care settings where there may be limited physician–patient interactions opportunities to expand on the importance of lifestyle modification interventions (LMI) and medication adherence are lacking. Using members of the ED healthcare team in their current roles in a time-efficient and streamlined manner, the AHEAD2

trial highlights that education and empowerment hypertension-based interventions are viable options in acute care settings with high-risk patient populations. The multidisciplinary team's awareness of previous literature and most current guidelines to optimize medication therapy based on race or comorbidities also helped to optimize treatment.

Unique to this study was the inclusion of individuals at the highest cardiovascular risk, those with severely elevated hypertension (>160/100). Studies have shown that an increase of 20 mm Hg in SBP or 10 mm Hg in DBP above 115/75 mm Hg doubles the risk of death from cardiovascular disease, an increase that is independent of other risk factors for cardiovascular disease. In a predominately minority population with significant rates of uncontrolled hypertension, high rates of tobacco use and obesity, identifying effective opportunities to engage around secondary cardiovascular prevention is of paramount importance.[24,25] Through an intensification of the study interventions, the AHEAD2 trial demonstrated a trend of decreasing BPs at both the 6-month and 9-month follow-up visits across all study arms. Although these pilot results were not statistically significant due to the sample size and being unpowered, there was a noted maximum decrease of 8 mm Hg in the intervention arm as compared to the EUC group (EUC). Studies have confirmed that in high-risk populations small improvements in BP control are associated with large reductions in cardiovascular risk.[23,24] The Atherosclerosis Risk in Communities study involved over 15,000 participants and found that a 1 mm Hg population-wide SBP reduction was associated with a significant decrease in cardiovascular events in African-Americans versus Whites (20.3 vs 13.3 per 100,000 patient years).[23] Another study evaluating short-term outcomes (3-month follow-up period) in a high-risk working patient population identified in the outpatient setting emphasized the association between clinically significant BP reduction and the associated reduced systemic inflammation.[26] Even without statistical significance, the individuals included in the intervention arm received a new or up-titrated antihypertensive medication, that otherwise would not have been addressed in the ED.

A key component of the ED-SBIRT-HTN intervention was the use of LBE as an empowerment educational platform. The AHEAD2 pilot found significant rates of subclinical heart disease particularly DD among study participants. A more detailed analysis of echocardiogram findings will be presented in a separate manuscript. It is well established that DD is common in early hypertension, and improving BP control improves diastolic function.[27] Therefore the AHEAD2 findings of a trend toward controlled BPs (<140/90 mm Hg), although not statistically significant, is likely to be of clinical significance in this high-risk patient population and have long-standing positive cardiovascular implications. Moreover, the net difference in mean BP at 9 months was marginally significant when adjusted for race and hypertension treatment. The distributions of net difference appear to be concentrated toward negative numbers reflecting a decrease in BP in all treatment arms and a tendency toward larger effects of the interventions compared to EUC.

Finally, the AHEAD2 pilot trial also demonstrates the range of ED interventions that can be effective for BP improvement and control in high-risk populations particularly in resource-limited settings where ED clinical pharmacist support or limited bedside echocardiogram capabilities may not be available.

Among a predominately minority patient population with severely uncontrolled hypertension in an urban ED setting, a multicomponent intervention compared with EUC resulted in a decrease in SBP 7.9 mm Hg (95% CI: −0.6, 16.4) compared to EUC. Risk assessment based on BP is not the current standard for asymptomatic hypertensive patients before discharge from the ED. The results of this randomized pilot trial have significant public health implications. The ED visit presents a significant opportunity to implement risk reduction associated with elevated BP in a diverse, high-risk patient population identified for discharge from the ED. Through a streamlined education and empowerment initiative, EDs can play a pivotal role in addressing the health disparity associated with uncontrolled hypertension. In resource-limited settings, a simple intervention, such as providing automated BP monitors to high-risk asymptomatic hypertensive patients being discharged from the ED, can be impactful. Given the continued increase in ED visits nationwide, EDs are evolving into outlets servicing a wider range of health care needs than their current function to largely address acute isolated needs.[28,29] Further research is needed to assess generalizability and cost effectiveness of this intervention and to understand which components may have contributed most to the outcome. We believe this study will be instrumental in establishing future evidence-based guidelines for management and risk assessment that will be portable to other urban EDs with high-risk populations.

CONFLICTS OF INTEREST

None

AUTHOR CONTRIBUTIONS

HP, MDR, RPG, SH, and MD conceived the study, designed the trial, and obtained research funding. HP, SH, SE-S, and MDR supervised the conduct of the trial and data collection. HP, SE-S, MJ, and RD-A undertook recruitment of patients and managed the data, including quality control. RPG implemented the pharmacy component of the intervention. RD-A provided statistical advice on study design and analyzed the data. SK and BL contributed to the revisions and data analysis. HP chaired the data oversight committee. HP drafted the manuscript, and all authors contributed substantially to its revision. HP takes responsibility for the paper as a whole.

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