HHS Public Access

Author manuscript

*Contemp Clin Trials*. Author manuscript; available in PMC 2019 January 01.

Published in final edited form as:

*Contemp Clin Trials*. 2018 January ; 64: 1–7. doi:10.1016/j.cct.2017.11.009.

# A Hypertension Emergency Department Intervention Aimed at Decreasing Disparities: Design of a Randomized Clinical Trial

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Conflicts of Interest: None

Reprints available upon request

Author Contributions Statement:
HP, MDR, RPG, SH, MB, MF and MD conceived the study, designed the trial, and obtained research funding. HP, SH, SES, PKS, JC and MDR supervised the conduct of the trial and data collection. HP, SA, DG, and JCh undertook recruitment of patients and managed the data, including quality control. RDA, JCh, and DG provided statistical advice on study design and analyzed the data; 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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## Abstract

Effective interventions to identify and treat uncontrolled hypertension (HTN), particularly in underrepresented populations that use the emergency department (ED) for primary care, are critically needed. Uncontrolled HTN contributes significantly to cardiovascular morbidity and mortality and is more frequently encountered among patients presenting to the ED as compared to the primary care setting. EDs serve as the point of entry into the health care system for high-risk patient populations, including minority and low-income patients. Previous studies have demonstrated that the prevalence of uncontrolled/undiagnosed HTN in patients presenting to the ED is alarmingly high. Thus ED engagement and early risk assessment/stratification is a feasible innovation to help close health disparity gaps in HTN. A Hypertension Emergency Department Intervention Aimed at Decreasing Disparities (AHEAD2) trial, funded by the National Heart, Lung, and Blood Institute (NHLBI) is a three-arm single site randomized clinical pilot trial of adults presenting to the ED with Stage 2 hypertension (blood pressure [BP] >160/100) comparing (1) an ED-initiated Screening, Brief Intervention, and Referral for Treatment (SBIRT) focused on HTN, (2) the same ED-initiated SBIRT coupled with a Post-Acute Care Hypertension Transition Consultation by ED Clinical Pharmacists, and (3) usual care. The primary outcome is mean BP differences between study arms. Secondary outcomes are proportion of participants with BP control (BP<140/90 mmHg), and improvements in HTN knowledge and medication adherence scores between study arms. The objective of this report is to describe the development of the AHEAD2 trial, including the methods, research infrastructure, and other features of the randomized clinical trial design.

### Keywords

randomized control trial; health disparities; uncontrolled hypertension; emergency department; minorities

## INTRODUCTION

Uncontrolled hypertension (HTN) is the primary risk factor for the development of cardiovascular complications.[1] While poor blood pressure (BP) control can be seen as a global problem in the hypertensive population, significant racial/ethnic disparities exist, with disparities well-documented in the United States. [2–5] The prevalence of HTN is highest among non-Hispanic black (41.2%), as compared to non-Hispanic white (28.0%), non-Hispanic Asian (24.9%), and Hispanic (25.9%) adults. Moreover, the prevalence of uncontrolled/undertreated HTN is highest amongst Hispanics (52.6%) and non-Hispanic Blacks (51.5%) as compared to non-Hispanic whites (44.3%). [2–5].

Emergency departments (EDs) serve a high-risk population not readily captured in other clinical settings.[6–8] The prevalence of uncontrolled/undiagnosed HTN in the ED is as high as 45%.[9] EDs are well situated at the interface between inpatient and outpatient care and can serve as a portal for identifying high-risk individuals and initiating validated screening methods.

In 2015, A Hypertension Emergency Department Intervention Aimed at Decreasing Disparities (AHEAD2) received funding under the R56 mechanism through the National Heart, Lung, and Blood Institute (NHLBI) to determine the acceptability and feasibility of an ED-based screening, brief intervention, and referral for treatment program for uncontrolled HTN (SBIRT-HTN). The study proposed using existing ED resources coupled with an ED pharmacist-led Post-Acute Care Hypertension Transition Clinic (PACHT-c) in a predominately minority patient population with elevated BPs.

The AHEAD2 trial is a three-arm randomized controlled pilot trial that compares: (1) usual care (current practice of passive outpatient referral for HTN follow up after discharge), 2) an ED-based SBIRT-HTN program (patient empowerment tool) using existing ED resources followed by assisted referral for primary care follow up, and 3) the ED-based SBIRT-HTN + a standardized brief PACHT-consultation with an ED pharmacist, followed by assisted referral for primary care follow up. The randomization scheme was designed to accommodate a larger number of participants than the pilot study so that the trial could be extended into a multi-year project if additional resources became available during the pilot phase.

The AHEAD2 Trial was the first NIH funded project prioritizing an underrepresented minority ED population with uncontrolled hypertension. The objective of this report is to describe the development of the AHEAD2 trial, including the methods and rationale for engaging stakeholders, the study population, the intervention, primary and secondary outcomes, organization of the study team, and other features of the ongoing study.

## DESIGN & METHODS

### Stakeholder engagement

A significant component of this trial was the desire to link uninsured or underinsured participants with ongoing primary care and preventive care. Prior to the start of the trial, we requested consultation with the University of Illinois at Chicago’s Community Engagement Advisory Board (CEAB) for insight on recruitment and retention strategies in minority and low income populations. We also sought to identify and establish a firm relationship with a primary care location open to receiving patients with limited financial resources. Such a relationship was agreed upon prior to the start of the trial (May, 2013) when a novel collaborative clinical program was implemented at the University of Illinois Hospital and Health Sciences System (UI Health) involving the Department of Emergency Medicine and Mile Square Health System, a federally qualified health center (FQHC) associated with UI Health. Our collaborative specifically prioritized hypertensive patients (BP >140/90 mmHg) without a primary care provider (PCP) to improve medication compliance and decrease the incidence of long term complications from uncontrolled/untreated HTN. Hypertensive

patient referrals were immediately provided with convenient real-time appointments for follow-up and additional HTN management within 48–72 hours.

## Population

The University of Illinois Hospital and Health Sciences System emergency department (ED) is a Level II trauma center and a regional tertiary care center. The geographic location of the ED is within a predominately African-American and Latino neighborhood. The annual census is 46,000 patients. Adult patients represent 80% of all ED visits. The demographics of the patient population reflect those of the primary service area: 35% African-American, 35% Hispanic/Latino, 20% Caucasian, and an increasing number of Asians and Native Americans. All patient recruitment was completed in the University of Illinois Department of Emergency Medicine.

## Recruitment

All participants received emergency department care for their presenting medical complaints per ED clinicians. The tracking board in the ED displays updated BPs (and other vital signs in addition to the patients' chief complaints) during their ED visit. Once a patient is identified for discharge, a discharge icon is displayed on the tracking board. Eligibility criteria were designed to be clinically relevant and feasible to implement in an ED setting. Patients meeting inclusion criteria were approached by trained ED research assistants (RAs) for study participation.

Inclusion criteria: 1) BP ≥ 160/100 (stage 2 HTN) at the time of discharge from ED, 2) no established primary care provider (PCP), 3) verbal fluency in English or Spanish, and 4) age 30–64 years.

Exclusion criteria: 1) Unable to verbalize comprehension of study or impaired decision making (e.g. dementia), 2) history of heart failure, myocardial infarction, or cerebral vascular accident, end-stage renal disease or on dialysis 3) plans to move from Chicago area within the next year, and 4) pregnant or trying to become pregnant.

## Informed consent

The AHEAD2 study was reviewed and approved by the Institutional Review Board (IRB) at the University of Illinois at Chicago. Individuals who expressed interest in the study viewed a brief 3-minute video describing the study objectives, protocol, and the informed consent document. Videos were shown to participants by the RAs and were provided in both English and Spanish. Following the viewing of the video, participants were asked to review and sign the informed consent document. All research staff members were trained in informed consent procedures and were available to read the consent forms to individuals with low literacy levels using IRB-approved procedures.

# PROCEDURE

## Study team organizational structure

The PI chaired the project team and advisory committee. The PI is a board-certified emergency medicine physician. (FIGURE 1)The project team consisted of a designated full-time project coordinator, a biostatistician, a clinical pharmacist, three ER-physicians with experience in ultrasonography, and 10 research assistants.

The advisory committee was comprised of the senior research investigators and study consultants.

## Research Assistant Training Protocols

Student volunteers, health care pre-professional college students, and medical students were recruited and trained as RAs for this study. In addition, we hired three extra-help employees to help with evening and overnight patient recruitment. All RAs were asked to work a minimum of four hours a week over a 3- month period.

**Enrollment—**RAs were trained by the project coordinator over a 2- week period on data entry, study design, patient eligibility criteria, screening and recruitment procedures, and protocols to follow based on study arm assignment. A study protocol manual was written and distributed to all RAs during training. Once familiar with the protocols, additional training was given on how to use the hospital EMR and intranet systems to identify potential study subjects and provide referrals for patient follow-ups.

**Ultrasonography Training—**RAs interested in learning how to perform cardiac ultrasounds (for arms 2 and 3 of the study) completed additional training. RAs were instructed to watch a series of podcast videos before beginning hands-on training. The podcasts totaled approximately 1.15 hours in length and focused on the basics of ultrasonography, technical terminology, and anatomy. RAs were also required to attend two four-hour training sessions led by an attending ED physician. During these trainings, RAs practiced using the ultrasound machine and obtaining different views of the heart. After completing the training sessions, students were required to perform complete study cardiac scans on ten individuals with the supervision of an attending ER physician. Students were expected to pass an hour-long assessment/examination before being allowed to perform study cardiac scans independently.

**Blood Pressure Reassessments—**Guidelines from the American Heart Association (AHA)[10] were used to develop training protocols for structured repeat blood pressure assessments during the 6-month study follow-ups to maintain the precision and accuracy of the primary and secondary outcome measurements. RAs were trained during a two-hour session on proper technique for measuring blood pressure.

*AHA BP Measurement Guidelines:* Participants were instructed to sit quietly for 5-minutes, with feet flat on the floor before the first BP reading was measured. The first reading was taken after the 5-minute wait period but this value was not used due to the alerting response. Two additional BP values were measured each

separated by at least one minute. These two values were averaged to generate the research measurement. However, if the 2 BP values differed by more than 4 mm Hg (the error of the test), then a fourth BP was measured and the two closest values from the 2nd, 3rd and 4th BP measurements were averaged to generate the research measurement.

## Interventions

Once patients were identified for discharge, the wait time before physically leaving the ED was variable depending upon the return of laboratory and diagnostic tests and finalization of consultant recommendations. This provided ample time to consent and complete the initial assessments based upon participant randomization at the bedside without added delays.

**All study arms—**All participants completed knowledge and health surveys, received an automatic blood pressure cuff and log book for home blood pressure monitoring, and were advised about the importance of prompt follow up with a primary care physician:

**a.** *Hypertension Knowledge Survey:* The survey selected for the AHEAD2 trial is a 10-item, validated tool developed to assess hypertension knowledge in low literacy patient populations. The scale assesses respondents' knowledge in defining hypertension, lifestyle, and behaviors that may affect BP, and the long-term consequences of HTN. The survey has been validated in an urban population that included a high proportion of black and Latino patients. Scores are categorized into tertiles that indicate low (≤7), medium (8), or high (9–10) levels of HTN knowledge.[11]

**b.** *Modified Morisky Scale Health Survey:* The modified Morisky scale is a validated 4-item instrument to assess self-reported patient adherence related to antihypertensive medication. The modified Morisky scale provides a total score with a range of 0 to 4, with higher scores indicating lower medication adherence. The scores of the modified Morisky scale can be classified as low compliers (3–4), medium compliers (1–2), and high compliers (0) based on its criterion validity with BP control. [12]

**c.** *Home BP Monitoring Kits (HBPM):* The patient-centered benefit of home BP monitoring has been repeatedly demonstrated and is recommended as an important component of HTN management. All participants received a home BP monitoring kit containing an automatic BP monitor and self-reporting logbook. Participants were shown how to use the BP monitors by the RA's and watched a standardized 2-minute instructional video prior to leaving the emergency department. The videos were provided by the BP monitor company.

**d.** *Federal Qualified Health Center Referral Process*: All participants were referred for primary care follow up at a FQHC (or community center if pre-assigned though Illinois Medicaid). Participants randomized to usual care received preprinted discharge instructions on HTN and the phone number to the FQHC to schedule a follow-up appointment (current standard of care). Study participants randomized to the intervention arms (arms 2 and 3) received ED-facilitated

primary care referrals. Using the HTN primary care referral collaboration framework established with Mile Square, our FQHC partner, participants without a PCP who were randomized to arms 2 and 3 had their contact information transmitted via a secure intranet tool directly to the appointment facilitator (located at Mile Square Health Center). The appointment facilitator contacted study participants directly to secure appointments within 48–72 hours at the nearest FQHC facility based upon zip codes. The appointment facilitator also had the ability able to check assigned medical home (for Medicaid recipients) and make the appropriate referrals.

**Arms 2 and 3: ED Screening, Brief Intervention Referral and Treatment (ED-SBIRT-HTN)—**Our SBIRT-HTN intervention alerted patients to the existence of early target organ damage to increase their motivation to change their behavior and increase their knowledge to improve BP control. Participants in the ED-SBIRT-HTN group received two screening tests to increase their motivation to improve their BP control; 1) Limited bedside echocardiogram (LBE) and 2) Urine microalbumin test (a validated screening test for early cardiovascular disease). Preliminary results of the LBE were discussed in real time with participants. All LBEs were reviewed by a second emergency physician trained in echocardiography for quality control. Microalbumin testing results were not immediately available as this test was processed by an outside laboratory. Any disagreements with the preliminary interpretation of the LBEs as well as abnormal microalbumin test results were notified to participants within one week of enrollment.

**a.** *Non-Invasive Limited Bedside Echocardiogram (LBE)*: LBEs were performed as a tool to alert, educate and motivate patients to change their behavior to improve their BP. In our preliminary studies, **the real time performance and interpretation of the LBE with brief education of the patients on the effects of elevated blood pressure on their own heart was a significant patient motivator and empowerment tool** as well as a significant factor in the compliance with returns for repeat assessments 1 year later.[13] Echocardiography is the gold standard for detection of subclinical heart disease such as diastolic dysfunction and left ventricular hypertrophy, and it can be used for subsequent monitoring of hypertensive disease progression.[14] LBEs are widely used across most EDs and the literature clearly demonstrates that emergency physicians have the ability to perform these studies with high diagnostic accuracy.[15] Many of the early subclinical changes (diastolic dysfunction and left ventricular hypertrophy) detected on the echocardiograms can be reversible with improved BP control, therefore we believed this screening modality was a critical component of the success of the AHEAD2 trial by increasing patient engagement with their ongoing HTN care.

Echocardiogram protocol:

All LBEs were either performed by ultrasound fellowship trained faculty or by students supervised by this faculty. A GE Vivid Q (GE Healthcare, Milwaukee, WI) cardiac probe (3SC-RS, 1.3 – 4.0 MHz) was used for the cardiac images. Parasternal long axis (PSLA), parasternal short axis (PSS), and apical four

chamber (A4C) views were obtained in all participants. M-mode was performed on the PSLA to allow for linear internal measurements of the left ventricle (interventricular septum diameter, interventricular diameter, and the posterior wall). Pulse wave Doppler was performed on the A4C to assess blood flow velocity through mitral valve and tissue Doppler was used at the mitral valve annulus (septal and lateral) to measure ventricular motion. In addition, 2-chamber and 3-chamber views were obtained when possible to augment analysis for cardiac strain. Collectively, measurements and calculations from all these images were used to evaluate for systolic function, diastolic function, left ventricular hypertrophy, and cardiac strain analysis.

**b.** *Urine Microalbumin Test:* Microalbuminuria has been linked with an increased risk of cardiovascular disease in the hypertensive patient and predicts all-cause and cardiovascular disease mortality in the general population, [16] and it is a useful **marker of early cardiovascular disease**.[17] The urinary excretion of albumin is closely associated with BP and salt intake. Microalbumin is a cost-effective, noninvasive marker of subclinical organ damage in hypertensive patients that is now recommended as part of the screening and treatment for hypertensive patients in outpatient settings. In order to increase the portability of this intervention to other ED settings (community and rural), we believe that it is important to have alternative yet effective risk assessment/stratification tools for those EDs where LBE may not be available.

**c.** *Hypertensive Educational Video:* The purpose of the video was to educate participants about high blood pressure, how it is diagnosed, and the importance of treatment to prevent secondary complications. Based upon the existing literature and our own experience from our pilot studies, overall hypertension knowledge is extremely low among minority populations. Participants viewed a 3-minute animated video on HTN. Videos were available in both English and Spanish and were culturally sensitive. The customized video was pilot tested in our ED and was well received by participants.

**Arm 3: ED Screening, Brief Intervention Referral and Treatment +Post-Acute Care Hypertension Transition Clinic (ED-SBIRT-HTN+PACHT-c)—**Participants in this third study arm received all of the interventions described above plus were provided an appointment for follow up within 72 hours with a Post Acute Care Hypertension Clinic (PACHT-c)

**a.** *Post-Acute Care Hypertension Transition Clinic (Arm 3):* All participants randomized to the ED-SBIRT-HTN + PACHT-c received a 48–72 hour follow-up visit in the Post-Acute Care Hypertension Transition Clinic (PACHT-c). The PACHT-c was located in an office suite adjacent to the ED. The PACHT-c was operational 3 times a week for 4 hours and staffed by a clinical pharmacist paid on an hourly basis. The PACHT-c hours featured early morning and late evening hours (7am–9am and 5pm–7pm on Monday, Tuesday and Thursday) to accommodate participants within 48–72 hours of study enrollment. Participants completed a consultation with the clinical pharmacist during which BP was

measured again; screening assessment results were reviewed; hypertension, medication use, and prevention of complications associated with uncontrolled BP was discussed; and a dedicated follow-up appointment with a PCP at the FQHC was secured. All PACHT-c clinic notes were accessible in the EMR. The same EMR is shared between both the ED and the FQHC.

PACHT-c protocol:

Based on the current literature[18] and in compliance with hospital guidelines, the clinical pharmacist designed an algorithm to determine which patients needed medication therapy and which initial agents to recommend based on patient characteristics (age, race, comorbidity). If patients were currently taking antihypertensives that were not maximized, clinical pharmacists could elect to increase doses of current therapy or add on an additional agent. Clinical pharmacists who became study personnel met for a 60- minute training session with the lead PACHT-c clinical pharmacist. Clinical pharmacists participating in the PACHT-c received initial training to go over the treatment algorithm, clinic visit components (BP reading, medication evaluation and initiation/titration, consultation, handouts, documentation). Each pharmacist received a copy of the checklist (clinic visit components), treatment algorithm, electronic medical record PACHT-c note template and REDCap instructions. The lead clinical pharmacist, reviewed all of the notes entered for PACHT-c visits and provided feedback or recommendations if needed. The lead clinical pharmacist retained all copies of study documentation used in the PACHT-c.

## Participant Retention

Several strategies were implemented to enhance participant retention and limit attrition. These included 1) monetary reimbursement for each in-person data collection ($50 per assessment for in-person data assessment; 2) periodic phone calls to verify address and phone data (at 1 and 3 months post study enrollment); 3) use of secondary alternative contact information (two additional contact numbers); 4) text messages sent 24 hours prior to follow-up appointments and study assessments; 5) mailing birthday/holiday cards; and 6) quarterly newsletters containing recruitment updates.

## Outcomes measured

The AHEAD2 study was designed to determine the effectiveness of an ED initiated educational intervention on uncontrolled HTN and to identify the role that EDs can play in secondary prevention of cardiovascular complications.

Primary outcomes include mean differences in SBP and DBP from baseline to 6- months post randomization between each study arm. A 6- month timeframe was selected in order to be consistent with other BP educational intervention studies.

The secondary outcomes are proportion of patients with controlled hypertension at 6-months (SBP< 140 mmHg and DBP < 90 mmHg) and improvements in HTN knowledge survey and medication adherence (measured by Morisky Scale) for each of the study arms.

## Data collection schedule

Data were collected at enrollment (baseline) and at follow-up visit at 6 months for BP measurement. Repeat BP assessment occurred in the PACHT-c space (adjacent to the ED). All participants received phone calls to verify contact information at 1 and 3 months. No medical information was sought during these calls. During their final visit (at 6 months), study personnel repeated the Hypertension Knowledge Survey, the Modified Morisky Scale and BP assessments. BP reassessments were performed as per American Heart Association (AHA) guidelines. Study personnel were blinded to initial study group assignments for all study participants.

## Data Management

All data forms were developed and tested on paper; Spanish language versions of participant questionnaires were prepared and back-translated to English prior to obtaining certified translations. After thorough pilot testing, paper forms were converted to equivalent electronic data entry forms with use of REDCap.[19] REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry, 2) audit trails for tracking data manipulation and export procedures, 3) automated export procedures for seamless data downloads to common statistical packages, and 4) procedures for importing data from external sources. Study information within the virtual environment was available for participant tracking activities such as production of result and reminder letters, scheduling of interim telephone contacts, and scheduling and tracking of follow-up visits. Statistical analyses prior to the 6-month outcome evaluations was limited to quality control, enrollment and drop out reporting and participant demographics. No interim looks were performed, but quality control and data entry errors and omissions were continuously monitored and reported to staff for remediation.

## Data Safety and Monitoring

The AHEAD2 study included an independent Data Safety Monitoring Board (DSMB) with four individuals who were not affiliated with the study institution. A senior researcher with experience in hypertension and clinical trials served as the Chair of the DSMB. Other members of the DSMB included senior researchers with expertise in Preventive Medicine, Behavioral and Community Health, and a Biostatistician. The DSMB convened to review and approve the study protocol prior to the start of participant enrollment and convened quarterly to review study performance and safety data and make an affirmative recommendation to the study principal investigator whether to 1) continue without modifications, 2) continue with modifications, or 3) terminate the study early.

## Analyses

General: In anticipation that the pilot trial might be expanded into a multi-year project if additional funding was secured, a stratified block randomization scheme for 360 participants (120/arm) was prepared prior to the start of the trial with the use of a SAS PROC PLAN. Six strata were included in the design (Black men, Black Women, Hispanic men, Hispanic women, All other men, and All other women). Within each strata level, randomization was

allocated in randomly ordered blocks of 9, 12 and 15 participants to ensure the study arms would remain reasonably well balanced if the pilot trial was not extended. The primary analysis was conducted at 6 months (all study participants); durability of effects was examined in a secondary analysis in which further data from 9-month observations were included. The analyses was done in accordance with the intent-to-treat principle (primary analysis).

### Primary outcome

Null hypotheses 1: Mean BP difference at 6-months in arm 3 (ED-SBIRT-HTN +PACHT-c) will not differ from mean BP difference at 6-months in arm 2 (ED-SBIRT-HTN).

Null hypotheses 2: Mean BP difference at 6-months in arm 2 (ED-SBIRT-HTN) will not differ from mean BP difference at 6-months in arm 1 (usual care).

### Secondary outcome

Null hypotheses 1: BP control at 6-months in arm 3 (ED-SBIRT-HTN+PACHT-c) will not differ from BP control at 6-months in arm 2 (ED-SBIRT-HTN).

Null hypotheses 2: BP control at 6-months in arm 2 (ED-SBIRT-HTN) will not differ from BP control at 6-months in arm 1 (usual care).

Since the treatment intensity increases from arm 1 to arm 2 to arm 3, (arm 1 < arm 2 < arm 3), we hypothesize that the mean BP difference after 6 months will follow a linear trend as well. However, two hypotheses are of interest, namely $\mathbf{H_1}$: treatment 3 (ED-SBIRT-HTN +PACHT-c) better than treatment 2 (ED-SBIRT-HTN ) and $\mathbf{H_2}$: treatment 2 (ED-SBIRT-HTN) better than treatment 1 (usual care).

Comparison of the mean BP difference across treatment arms is accomplished via ANOVA. A linear contrast will be constructed to test for a linear trend of the mean BPs. We will then contrast the two sets of hypotheses using a one-sided, two-independent sample, 5%-significance t-test. The ANOVA (and t-test) implementation will be applied in the context of the general linear model, which will allow us to adjust for potential confounders (unbalanced key variables). Stata 13.1 (StatCorp) will be used to carry out all the statistical analyses.

## Power/sample size calculations

The sample size estimation was based on testing differences in BP. For the pilot phase of the trial, we proposed to enroll and randomize 120 participants over 6- month (40 for each of the 3 treatment groups), representing 6% (120/1922) of the expected pool of potentially eligible adults between the ages of 30–64 discharged from the ED with BP >160/100.

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 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 baseline mean SBP of 173.1 with standard deviation (SD) of 26.1 and a DBP of 101.9 (SD = 14.2). Since patients arrive to the ED with elevated BP, regardless of the treatment group, we anticipate a reduction in the mean BP of about 5 mmHg, a phenomenon known as regression to the mean. Thus, after rounding, we assume that the Usual Care treatment group will experience a reduction in SBP from about 170 mmHg to 165 mmHg due to the regression to the mean effect. Patients in Usual Care (Arm 1) will experience a modest 2.5% decline in their average SBP (From 165 mmHg to 161 mmHg). We anticipate an additional 5% reduction in BP in the ED-SBIRT-HTN (Arm 2) group (161 mmHg → 153 mmHg). Furthermore, Arm 3 of the study (ED-SBIRT-HTN + PACHT-c) will reduce the average SBP by an estimated additional 10% (153 mmHg → 137 mmHg).

## Discussion

The NIH-funded AHEAD2 Study addresses the role that emergency departments can play in secondary cardiovascular prevention in a predominately minority population presenting to the ED with uncontrolled HTN by testing the acceptability and feasibility of an ED initiated SBIRT education/empowerment intervention. The AHEAD2 study builds upon a foundation of efforts in a trajectory of research aimed at the development of cost-effective ED-initiated transitions of care pathways targeting underrepresented populations with uncontrolled HTN with a goal of decreasing the secondary cardiovascular morbidity and mortality.[20] The AHEAD2 study is the only project funded by the NHLBI addressing uncontrolled HTN in the ED.

We employed a three-arm randomized clinical pilot trial to compare an ED initiated SBIRT-HTN to empower and educate predominately minority participants with uncontrolled HTN, and the same ED initiated SBIRT-HTN with a ED-clinical pharmacist led PACTH-c to intensify the empowerment/educational benefits, versus usual care, on a single primary outcome of mean BP differences between arms at 6-months.

Risk assessment or stratification based upon BP assessment is not currently standard for hypertensive patients prior to discharge from the ED. Recent emergency medicine literature suggests that if evidence-based guidelines were available for management of these patients and better follow-up mechanisms were in place, it would result in greater compliance with referral guidelines and heightened awareness of secondary prevention interventions available to ED physicians. This study addresses the evidence gaps in the disposition of patients with asymptomatic HTN from the ED. We believe the intervention could be portable to other ED settings with similar at –risk patient populations.

## Acknowledgments

This grant was funded by the National Heart, Blood, and Lung Institute (NHLBI)

Grant number: 1R56HL126657-01A1

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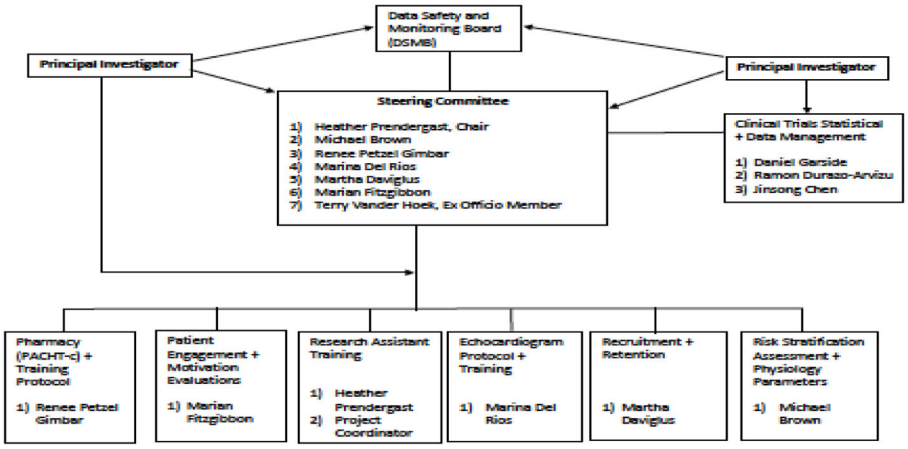


**Figure 1.**
Study Team Organizational Structure

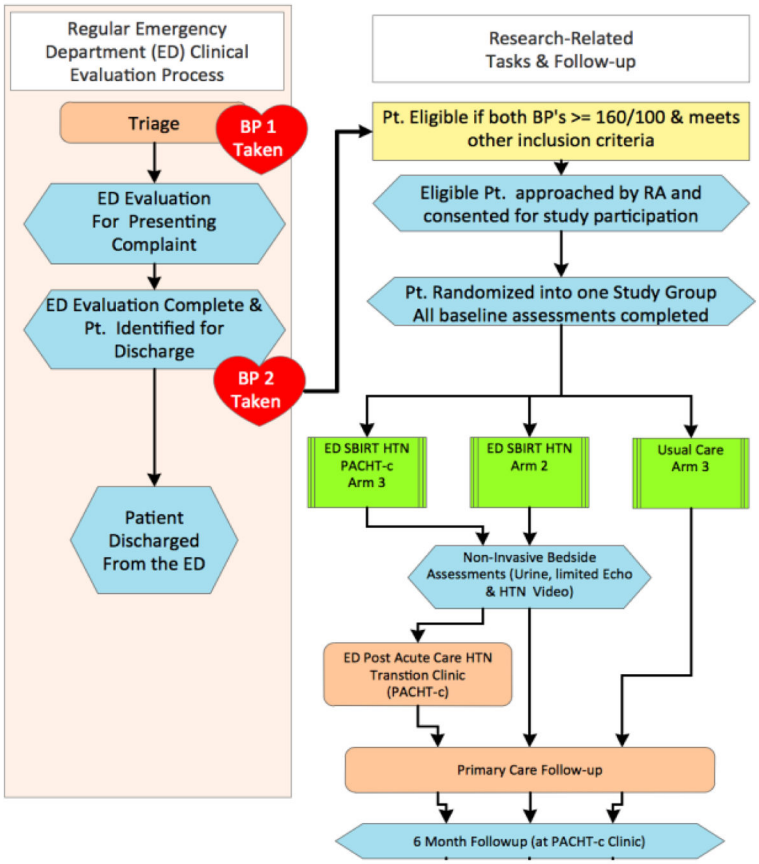


**Figure 2.**
AHEAD2 Program Components