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A hypertension emergency department intervention aimed at decreasing disparities: Design of a randomized clinical trial

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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 mm Hg), 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.

1. 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 among 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

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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.

2. Design & methods

2.1. 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 mm Hg) 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 h.

2.2. 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.

2.3. 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.

2.4. 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.

3. Procedure

3.1. Study team organizational structure

The PI chaired the project team and advisory committee. The PI is a board-certified emergency medicine physician (Fig. 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.

3.2. 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 4 h a week over a 3-month period.

3.2.1. 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 (Fig. 2).

3.2.2. 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 h 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