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Design of a randomized controlled trial comparing a mobile phone-based hypertension health coaching application to home blood pressure monitoring alone: The Smart Hypertension Control Study

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ABSTRACT

Background: Hypertension is a major cause of morbidity and mortality but frequently remains uncontrolled. A smartphone application that provides coaching regarding home blood pressure monitoring and other aspects of hypertension self-care and related behavior change may be a scalable way to help manage hypertension.
Methods/design: The Smart Hypertension Control Study is a prospective, randomized controlled trial to assess the effects of a hypertension personal control program (HPCP), which consists of an automated artificial intelligence smartphone application that provides individualized support and coaching to promote home monitoring and healthy behavior changes related to hypertension self-management. Enrolled adults with uncontrolled hypertension will be randomized in a 1:1 fashion to the HPCP with home blood pressure monitoring or to home monitoring alone. We plan to enroll 350 participants, with a target of 300 participants with complete six-month follow-up data. The primary study outcome will be systolic blood pressure at six months. Additional outcomes include measures of antihypertensive medication adherence, home blood pressure monitoring practices, self-management practices, weight, and self-reported health behaviors.
Conclusion: The Smart Hypertension Control Study will evaluate blood pressure and hypertension self-management behavior outcomes in participants with uncontrolled hypertension exposed to a smartphone-based hypertension health coaching application in addition to home blood pressure monitoring compared to those exposed to home blood pressure monitoring alone.

1. Introduction

Hypertension is a major contributor to death and disability from heart and vascular diseases [1]. Despite the impressive efficacy of antihypertensive medications in clinical trials, hypertension treatment and control rates remain far from optimal in the United States. Using the criteria of the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, approximately 32% of the adult U.S. population has hypertension, and 46% of them have uncontrolled hypertension [1,2]. By the criteria in the American College of Cardiology/American Heart Association 2017 hypertension guideline, the prevalence of adults with hypertension rises to 46%, and the number of people recommended for treatment or who are above treatment goals increases [2,3].

In some instances, strategies to promote self-monitoring of hypertension have been shown to reduce blood pressure and improve hypertension control rates, particularly when coupled with interventions that lead to treatment intensification [4–7]. However, interventions that require clinicians to monitor and respond to home blood pressure measurements are resource-intensive, and may not be widely used in settings where insurance does not cover these services. Furthermore, outcomes may improve with lifestyle interventions, but again, resources for providing live coaching on diet, physical activity, and other healthy behavior changes are limited.

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Mobile health technologies such as smartphone applications (apps) or interventions using text messages may provide lower-cost ways to support hypertension self-management behaviors, and they have potential for wide scalability [8]. Apps can be designed to promote desirable health behaviors, including blood pressure self-monitoring, medication adherence, dietary changes, and exercise. Furthermore, mobile health apps can be designed to interpret information derived from home monitoring and prompt individuals to take appropriate actions based on home measurements [9–11]. Despite this potential, published studies of mobile health applications for hypertension have not provided strong evidence that use of an app or receipt of text messages improves blood pressure [8,12–14], and the optimal design features of such approaches remain unknown. In one example, an app that promoted medication adherence improved medication adherence slightly, but did not change systolic blood pressure compared to the control group [14]. Limitations of the app were that it did not sync with the home monitor, provide individualized guidance based on measured values, or address non-pharmacologic hypertension-related behaviors, such as weight loss, diet, or physical activity.

We hypothesize that home monitoring along with a hypertension-control app directed at multiple facets of hypertension care will improve hypertension self-management and reduce blood pressure more than home blood pressure monitoring alone, even though the app is not directly tied to clinicians titrating antihypertensive therapy. The goal of this study is to investigate the effects of providing a smartphone-based hypertension health coaching app along with a home blood pressure monitor compared to provision of a home blood pressure monitor alone. We refer to this application as the hypertension personal control program (HPCP).

2. Methods and design

2.1. Study overview

The Improving Hypertension Using a Smartphone-Enabled Personal Control Program, or "Smart Hypertension Control Study," is a non-blinded randomized controlled trial among hypertensive adults receiving care from a group of outpatient clinics affiliated with a large healthcare system. The institutional review board of Northwestern University reviewed and approved the study procedures. Participants are randomized in a 1:1 fashion to the intervention group, consisting of HPCP plus a home blood pressure monitor (HBPM), or the control group (HBPM alone). Eligibility is assessed by in-person standardized examination. The primary study outcome is systolic blood pressure measured at six months adjusted for baseline systolic blood pressure, sex, and age. The study is registered at ClinicalTrials.gov (Identifier: NCT03288142).

2.2. Setting

Recruitment takes place at outpatient primary care clinics in downtown Chicago that are part of Northwestern Medical Group (NMG). NMG is part of Northwestern Memorial Healthcare, a large academically affiliated health system in the Chicago area.

2.3. Participant eligibility

Table 1 lists inclusion and exclusion criteria. Because we used Bluetooth® technology to connect the HBPMs to smartphones, and there is variation in how this technology is employed among non-iOS systems, participants are required to have a compatible iOS device. Participants are eligible if their baseline blood pressure (see measurements below) is equal or > 135/85 mmHg (either value) and < 180/110 mmHg (both values).

Table 1
Inclusion and Exclusion Criteria.

Inclusion criteria
Adults aged 18 years to < 85 years at the time of screening
Standardized mean blood pressure ≥ 135 mmHg systolic or ≥ 85 mmHg at initial study visit
Have and use an iOS device(s) (iPhone generation 5 s or newer)
Able to provide written informed consent prior to participation in the study
Receive primary care from a Northwestern Medicine clinic site
Exclusion criteria
Current user of a Lark health coaching app
Baseline blood pressure ≥ 180 mmHg (systolic) or ≥ 110 mmHg (diastolic)
Persistent atrial fibrillation
Pregnant or planning to become pregnant during the study period
Severe kidney disease, defined as estimated glomerular filtration rate < 30 per 1.73 m^2 or currently on renal replacement therapy (i.e., hemodialysis or peritoneal dialysis)
Hearing impaired and unable to respond to phone calls
Lack of fluency in English
History of a cardiovascular event (stroke, transient ischemic attack, myocardial infarction, coronary artery bypass grafting) in the past three months
Diagnosis of dementia
Diagnosis of psychosis
Terminal cancer diagnosis
New York Heart Association class III or IV heart failure
Individuals requiring blood pressure monitor cuff size larger than 17 in.

2.4. Recruitment and randomization

We use structured queries of electronic health record (EHR) data to detect potentially-eligible participants with elevated blood pressure who do not have exclusion criteria at participating practices. We use the criteria of most recent in-office blood pressure of at least 145 mmHg systolic or 95 mmHg diastolic to identify individuals who may be likely to meet the eligibility criteria of equal to or > 135/85 mmHg at the initial research study visit. Primary care physicians receive these patient lists and then have two weeks to indicate which patients on the list should not be contacted. We recruit from the remaining population via mail and telephone. In addition, clinicians in NMG primary care practices can directly refer patients to the study, and other individuals can contact study personnel using information from flyers distributed in the practices.

Study staff assess potentially eligible participants for inclusion and exclusion criteria by telephone, and following phone screening, volunteers present onsite for a final eligibility determination and to provide written informed consent. Individuals found ineligible following an in-person screening receive $10. Enrolled participants receive $25 for completing the first study visit and $50 for completing the follow-up visit. Enrolled participants may keep the home blood pressure monitor provided.

After enrollment and consent, participants are randomized to HBPM only or to HPCP and HBPM. Randomization uses a centralized computer-generated assignment sequence uploaded a priori to Northwestern University's REDCap (Research Electronic Data Capture) platform [15]. Randomization is performed in four strata by age (< 65 or ≥ 65 years of age) and baseline systolic blood pressure (< 145 or ≥ 145 mmHg) with the aim of obtaining similar populations in each treatment group.

2.5. Interventions

2.5.1. Home blood pressure monitoring device (HBPM) only (control group)

Control group participants receive a home blood pressure monitoring device (HBPM) (Omron 7 Series Wireless Upper Arm Blood Pressure Monitor Model BP761N HEM-7320 T, Omron Healthcare Co., Ltd., Kyoto, Japan), are instructed on how to perform self-monitoring, and are asked to demonstrate the use of the device at the baseline study