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The Design and Rationale of a Pilot Study: A COmmunity and Tech-Based ApproaCh for Hypertension Self-MANagement (COACHMAN)

Carolyn H. Still, PhD, RN, MSM, AGPCNP-BC [Assistant Professor], **Phuong B. Dang, M.S. [Project Manage]**

Frances Payne Bolton School of Nursing, Case Western Reserve University, Cleveland, OH.

Dolon Malaker, BS [Research Assistant],

Department of Physiology and Biophysics, Case Western Reserve University, Cleveland, OH.

Tangela D. Peavy, RN, BSN [MS Student]

School of Nursing, Cleveland State University, Cleveland, OH.

Abstract

African-Americans with hypertension continue to demonstrate poor blood pressure (BP) control and have markedly lower rates of hypertension self-management compared to non-African-Americans. Innovative and practical solutions such as mHealth technology are promising and can be leveraged to promote self-management of hypertension. Substantial evidence has demonstrated the importance of community support in improving patients' management of chronic illnesses. Unfortunately, such programs do not offer technology-based interventions (TBI) as a delivery method. Thus, this paper describes the design and rationale of an ongoing pilot study that incorporates TBI using a community-based participatory approach.

Keywords

African Americans; community-based research; health disparities; hypertension; self-management

Introduction

As hypertension continues to be a chronic health problem in the United States, African-Americans are disproportionately affected more than any other racial group (Benjamin et al., 2018; Lackland, 2014; Nwankwo et al., 2013). The high incidence of uncontrolled blood pressure among African-Americans puts them at a greater risk for developing adverse cardiovascular diseases (CVD), morbidity, and mortality (Centers for Disease Control & Prevention [CDC], 2017). Overcoming these risks becomes challenging when faced with daily struggles and societal barriers that lead to poor outlook and self-management practices in blood pressure control (Lackland, 2014; Ogedegbe, 2008). Additionally, evidence

Address Requests for Reprints and Correspondence to: Carolyn H. Still, PhD, MSM, AGPCNP-BC, Assistant Professor, Frances Payne Bolton, Case Western Reserve University, 10900 Euclid Ave., Cleveland, OH 44106. cwh11@case.edu.

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suggests that the inability to achieve blood pressure control may arise from a complex interaction of patient, provider, and system-level barriers (CDC, 2013; Ogedegbe et al., 2004). By recognizing the unique barriers that African-Americans face and how they might impact hypertension self-management (Flynn et al., 2013), we can integrate different approaches to address these challenges and further facilitate confidence and motivation to not only improve blood pressure control, but also sustain improved blood pressure control over time (Whelton et al., 2016).

Barriers to blood pressure control and hypertension self-management in African-Americans are multifactorial (Flynn et al., 2013; Lackland, 2014; LaVeist, 2005). A large part of hypertension self-management is the ability to adhere to prescribed anti-hypertensive therapy (AHT). Adherence to anti-hypertensive medications is defined by the extent to which an individual's behavior complies with professional healthcare advice about prescribed medications with respect to timing, dosage, and frequency of consuming anti-hypertensive therapy for long-term management of hypertension (Krousel-Wood et al., 2005; Ogedegbe et al., 2004). However, poor adherence to anti-hypertensive therapy is estimated to occur in 43% to 78% of patients prescribed medications to treat hypertension (Nwankwo et al., 2013). Half of the individuals taking anti-hypertensive therapy will stop taking their medication within the first year of starting therapy and these estimates are notably worse and occur sooner in African-Americans (Nwankwo et al., 2013). The impact of non-adherence to anti-hypertensive therapy has financial ramifications, costing the healthcare industry roughly $300 million in health care costs per year (Luga & McGuire, 2014; National Center for Chronic Disease Prevention and Health Promotion, 2013).

Recent research, namely, the Systolic Blood Pressure Intervention Trial (SPRINT), found that a lower systolic blood pressure (SBP) goal < 120 mmHg among a diverse sample (30% African-Americans and 11% Hispanics) reduces cardiovascular events by ≥ 27% (Wright, et al., 2015). Importantly, all groups, regardless of race or ethnic origin (Still et al., 2017), including individuals 75 years of age and older (Williamson et al., 2016), benefited from intensive treatment toward a lower SBP target. In SPRINT, an average of 3.1 medications were required to reduce blood pressure to the lower targets in African-Americans compared to 2.7 medications in Non-Hispanic Whites and Hispanic patients (Still et al., 2017). To emphasize the importance of early prevention, detection, and treatment of hypertension, and to reduce future cardiovascular risk, recent U.S. guidelines for managing hypertension recommend lower blood pressure targets, < 130/80 mmHg, than the previous recommendation of < 140/90 mmHg (James et al., 2014). This criteria increased the prevalence of hypertension from 32% to 46% and more adults are likely to face the challenge of managing this chronic condition (Whelton et al., 2017). This is expected to compound the adherence problem. Therefore, efforts are needed to develop patient-centered methods to support self-managing hypertension, especially in terms medication adherence. Beyond conventional treatment such as lifestyle modifications, it is also essential to introduce various mediums through which African-Americans can be empowered, educated, and supported to self-manage their hypertension, as well as increase compliance to anti-hypertensive therapy (Nielsen, 2015; Smith, 2014; Whelton et al., 2016).

Purpose of the Study

The objective of this study is to investigate the effectiveness of a community-based approach combined with a technology-based intervention (COACHMAN) to support self-managing hypertension and to improve blood pressure control in African-Americans residing in the Cleveland metropolitan area. Major constructs of this study (Figure 1) are guided by Ryan and Swain's Individual and Family Self-Management Theory (IFSMT) (Ryan & Sawin, 2009). The IFSMT is framed from a self-management process where person-centered interventions are directed at increasing knowledge and skills, self-regulation skills and abilities, as well as technology use and adoption to improve blood pressure (Ryan & Sawin, 2009). Medisafe® is postulated to increase engagement in self-regulation behaviors (e.g., behavioral prompting, monitoring, and feedback for medication-taking of anti-hypertensives) by enhancing self-efficacy and resulting in engagement in self-management behaviors (such as medication adherence, patient activation, and engagement in self-management of hypertension) leading to technology adoption and ultimately improving blood pressure control.

The central hypothesis is that COACHMAN (evidenced-based strategies for hypertension education, behavioral skills training, technology-based interventions, and social support) would be more effective than usual care at motivating African-Americans with hypertension to improve BP control. A secondary hypothesis is that the COACHMAN intervention will result in improved blood pressure control. Specifically, the aims of this study are to

- identify key content, design, and resources from a community of stakeholders, including determining facilitators and barriers of hypertension self-management among African-Americans that will inform the development of COACHMAN using qualitative research methods;
- evaluate the feasibility and acceptability of COACHMAN to improve BP control, and
- compare the difference in blood pressure control between Coachman (intervention group) and the enhanced usual care (control group).

Methodology

Phase I

Phase I of the study will utilize principals of community-based participatory research, a partnership between researchers and the community as full and equal partners in all phases of the research process (Institue of Medicine [IOM], 2003; National Institutes of Nursing Research [NINR], 2003; Wallerstein & Duran, 2003). Study investigators will leverage developed relationships with a local nurse organization, community centers, and leaders at large healthcare institutions to refine the study plan, set research priorities, and implement study the protocol. Informal sessions with all groups will be held prior to inviting individuals to serve on the study's Advisory Committee. Members of the Advisory Committee will include four registered nurses (nurse practitioner, case manager, clinical specialist in ethics, and a staff nurse from the Cleveland Council of Black Nurses), one physician, one

healthcare administrator, two community program directors, and two community members diagnosed with hypertension. Meetings will be scheduled monthly via telephone conference, Zoom, or face-to-face to discuss project progress and other aspects of the study. In addition, the Advisory Committee will identify key content for focus groups and study intervention, enlist community health workers, and provide the study with key resources to conduct the project, including advising and active engagement with recruitment and retention efforts.

Phase II

Phase II of the study is a two-armed, pilot randomized control trial (RCT), comparing the effects of the COACHMAN intervention to the enhanced usual care (EUC) group on blood pressure control in African-Americans with hypertension. COACHMAN is a multicomponent intervention designed to integrate community outreach resources with mHealth technology to support self-managing hypertension. The EUC group will receive one educational session on self-monitoring blood pressure, printed materials about blood pressure, and information about the DASH diet. All participants will receive validated automated home blood pressure monitors (Omron 10 Series).

Sample

A convenience sample of 40 African-Americans ($N = 60$) with uncontrolled hypertension will be recruited from the Cleveland, OH metropolitan area. Cleveland is ideal to conduct this research as Ohio is ranked 15th nationally for prevalence of hypertension, with higher rates observed in African-Americans (Hornbeck et al., 2015). Participants who meet the following inclusion criteria will be enrolled: (1) self-identify as African-American; (2) is 30 years of age or older; (3) has a hypertension diagnosis and is on an anti-hypertensive drug therapy; (4) is able to read/understand English; and (5) owns a smartphone with a data plan with and the capability to download a mobile application (app) or view videos. Exclusion criteria include: (1) history of cognitive impairment; (2) recent hospitalization or emergency department visits.

The recruitment efforts began March 2019, using multiple evidence-based recruitment strategies simultaneously that have been observed to be successful in hypertension trials enrolling large number of African-Americans (Ramsey et al., 2017). Participants are being recruited in the greater Cleveland area from clinics affiliated with local hospitals in areas designated as medically underserved areas. In addition, the study team will identify potential subjects from the Electronic Health Records (EHR) using a set of IRB approved procedures. Once potential subjects are identified, and subjects' physicians agree to contact, a letter of recruitment describing the study will be mailed, followed by a follow-up phone call by a trained research assistant. The research assistant will screen subjects for eligibility by phone or in the clinic to determine interest and eligibility. Those individuals meeting inclusion criteria, express interest, and able to provide consent will be scheduled for a baseline visit. Other recruitment strategies include using targeted advertisements (e.g., Facebook) and having a visible presence at community centers and events where African-Americans work, congregate, and worship to recruit eligible participants.

Study Conditions

Intervention Group.—The COACHMAN intervention is comprised of four components: (a) self-monitoring blood pressure, (b) web-based education, (c)) training to use a medication management app, Medisafe (www.Medisafe.com), and (d) nurse counseling. The web-based modules that focus on improving African-Americans' knowledge, skills, and attitudes in hypertension management and are described in Table 1. These modules were developed based on recommendations from evidence in the literature (American Heart Association [AHA] and CDC) and with community partners. The web-based educational content will be accessible at any time and convenient to participants in the intervention group via a secure study website compatible with smartphones, iPads, tablets, or home computers, for the study duration. Of note, the education modules will be delivered weekly over 6 weeks with each session lasting less than 10 minutes.

Personalized medication adherence support (SMS reminder messages, adherence feedback, and health and lifestyle tips) will be through the Medisafe smartphone app (www.Medisafe.com). Medisafe is a free medication management app that operates on both Android and iOS phone systems. Medisafe provides alerts of when it is time to take medication, generates weekly adherence reports, and monitors biometric data (blood pressure once entered into app). It also has the ability to designate a "Medfriend," who will be granted access to medication taking history. After training and support to use Medisafe, subjects will download the application to their smartphones and ask to use the app for 12 weeks for medication taking adherence support (see Figure 2).

Instructions and training to self-monitor blood pressure (SMBP) will be with a study provided Omron 10 Series home blood pressure monitor. Participants will be asked to monitor their blood pressures twice a week and record blood pressures on a tracking log. Individuals in the EUC group will not be given prescriptive instructions to monitor their blood pressures, but will be provided with a home blood pressure monitor.

Registered nurses from a local nurse organization (Cleveland Council of Black Nurses) serve as community health workers and a bridge between the community and health care area in this project. The community health workers will provide informal counseling and social support, as well as follow-up phone sessions on medication adherence and monitoring blood pressure to those participants in the intervention group, COACHMAN.

Control Group.—The EUC (enhanced usual care) group will receive one educational session on self-monitoring blood pressure, printed materials from the AHA "Facts about blood pressure," and information about the DASH diet. All participants will receive validated automated home blood pressure monitors (Omron 10 Series).

Focus Groups.—All enrolled participants will have the opportunity to participate in two 90-mintue focus group sessions to answer the questions according to their assigned study condition (COACHMAN vs EUC). Initially, members of the research team who have expertise in facilitating focus groups will lead focus group interviews in order to gain information on participant's views on motivators and barriers of hypertension self-management as well as using technology to help support self-managing hypertension, again

in approximately 4 weeks after the start of the study, and finally after completion of the last study visit. In addition, we will also conduct separate focus group interviews with the EUC group to explore facilitators and barriers to hypertension management. All sessions will be audio recorded and another member of the research team will record field notes. We will track the number of times each participant speaks to ensure that each participant has equal opportunity to share their perspective.

Instrumentation

The primary outcome for this study is change in blood pressure and health-related quality of life (HRQoL) from baseline to 3 months. Blood pressure control (defined as BP <130/80 mmHg) will be measured by the average of three seated blood pressure readings obtained at the 3-month visit. HRQoL will be measured by the PROMIS Global Health-10 (Hays et al., 2009), a 10-item valid and reliable interval scale ($\alpha = 0.82$), at baseline and at 12 weeks. A secondary outcome will be the proportion of participants achieving BP <130/80 mmHg at 3 months. Major constructs of this study will be guided by IFSMT Theory (Ryan & Sawin, 2009). Study variables, measures, and data collection points are shown in Table 2 and will be collected across three time points: baseline, 8 weeks, and 12 weeks.

Self-management process.—Hypertension knowledge and awareness will be measured using the Hypertension Knowledge-Level Scale (HK-LS), a 22-item interval scale ($\alpha = 0.82$) that measures six domains of hypertension awareness and knowledge about blood pressure (Erkoc et al., 2012). The widely-used and reliable Self-Efficacy for Managing Chronic Disease, a 6-item rating scale (scores range from 1–10), is used to assess ones' confidence to carry out certain behaviors related to self-management for hypertension (Lorig et al., 2001). Higher scores indicate greater self-report of confidence to manage hypertension. To gauge technology use and adoption we will use two valid and reliable Likert scales. The System Usability Scale (SUS; $\alpha = 0.91$), a 10-item questionnaire, is used to measure global subjective view of mHealth app usability (Bangor et al., 2008; Brooke, 1996). Technology adoption will be measured by the Mobile Application Rating Scale (MARS; $\alpha = 0.91$) (Domnich et al., 2016).

Behavioral outcomes.—Medication-taking (adherence) is assessed by self-report on the 14-item, a 4-point Likert-type Hill-Bone Compliance Scale, that focuses on three domains of hypertension management (mediation-taking, diet, appointment keeping) with Cronbach alpha's that range from 0.74 to 0.84 (Culig & Leppee, 2014).

Contextual and covariates variables.—Contextual factors will include variables known to contribute to hypertension health disparities as well as individual covariates that may influence the effects of COACHMAN on African-Americans. At baseline, we will collect self-reported demographic information and medical history (as measured by the Charlson Morbidity Index [CMI]), Cronbach alpha of 0.90 (Charlson et al., 1987). Individual perceived social support will be evaluated with the Duke Subjective and Instrument Support Scale (DSSI), 7 items ($\alpha = 0.71$), on a 3-point Likert scale, with higher scores indicating greater perceived social support (Hughes et al., 1990). Other covariates, spiritualty, will be obtained using the Daily Spiritual Experiences survey (Underwood &

Teresi, 2002), while depressive symptoms will be measured with the 8-item PROMIS Short Form (Cella et al., 2010). Biological and physical measures evaluated in this study include chemistry panels to examine kidney and liver function, and glucose. Urine specimens will be collected to examine proteinuria. Standometer and balance scales will be used to measure height and weight directly, while body mass index (BMI) for each participant will be calculated using the formula: weight in kilograms divided by the square of height in meters.

Institutional Review Board Approval

Institutional Review Board (IRB) approval was obtained prior to beginning research procedures. All research staff were trained regarding research-related procedures, including screening and enrollment of potential subjects, study protocol, and data collection and management prior to implementing the study protocol. In addition, community partners were also required to be a part of the training-related research activities.

Study Procedures

The Project Manager and research team identifies eligible participants using various recruitment methods previously described. Once eligibility is confirmed, the research assistant will schedule an appointment to further determine eligibility at a mutually agreed upon date and time. After consent is obtained, and eligibility is determined, the participant will be assigned to one of two study conditions (COACHMAN or EUC) using a computer-generated randomization program. Both groups will be asked to participate in the study over a 3 month period, which will involve three visits: Baseline (T1), a second visit in 8 weeks (T2), and a final visit approximately 12 weeks from the first visit (T3).

At T1 (Baseline), the participants will meet with a member of the research team who will explain the study procedures, collect data on blood pressure, height, weight, and blood and urine samples. The average of three blood pressure readings will be recorded at each study visit with a standard automated blood pressure device (the OMRON HEM-907 XL Professional Digital Blood Pressure Monitor). The research assistant will collect blood pressures using the following protocol: a) the appropriate cuff, b) after 5 minutes of rest, c) at the beginning of each visit, and d) with proper positioning of the subject in a chair with back support. Next, participants will complete study questionnaires, which should take about 30–45 minutes. Following data collection, the research assistant will provide instructions to the participant according to their assigned group of COACHMAN or EUC. All participants will be informed about participating in two 90-minute focus groups or interviews on motivators as well as barriers of hypertension self-management and the study intervention. At T2 (8 weeks), the research assistant will collect blood pressure and the self-reported questionnaire data. At T3 (12 weeks), participants will return for the administration of select study measures and the collection of blood and urine samples.

Fidelity of the intervention “dose” (delivered, received, enacted) will be monitored on an ongoing basis by obtaining measures of the use of subject responses to medication reminders, receipt of behavior change, and attendance to follow-up visit. Research data will be collected via iPad-assisted (or other technology devices such as PC tablets, smartphones) questionnaires, demographics, and blood pressure measurements. Study data will be

collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at University Hospitals of Cleveland (Harris et al., 2009). REDCap is a secure, web-based application designed to support data capture for research studies, providing: a) an intuitive interface for validated data entry, b) audit trails for tracking data manipulation and export procedures, c) automated export procedures for seamless data downloads to common statistical packages, and d) procedures for importing data from external sources (Harris et al., 2009).

Data Analysis Plan

Focus group sessions will be transcribed verbatim and analyzed with NVivo 10 or a similar software package using principles of inductive content analysis to assess African-Americans' experiences with technology as well as the barriers and facilitators of hypertension self-management. Preliminary data analysis includes examining the frequencies and descriptive statistics for continuous variables. This involves examining means, standard deviations, and testing for normality using skewness and kurtosis. The primary analysis compares blood pressure levels between the COACHMAN intervention and the EUC group across three time points. Repeated measures analysis of variance (RMANOVA) built around a two group by 3 time points to assess mean differences across time, group differences, and the interaction of time × group will be used to answer Aims 2 and 3 (Field, 2009).

Results

The purpose of this manuscript is to describe the design and rationale of a pilot study using a community-based participatory research approach to delivery TBI intervention (COACHMAN) to African-Americans with hypertension. The Principal Investigator (PI) is actively enrolling participants in this study and will report preliminary results later. Figure 3 illustrates the pilot RCT diagram.

Conclusions

Lower blood pressure targets (< 130/80 mmHg compared to < 140/90 mmHg) highlight the importance of prevention and early treatment to reduce CVD mortality (Whelton et al., 2017). The long-term goal of this project is to generate evidence that will inform interventional research that reduces the CVD risks and suboptimal or poor hypertension self-management in this vulnerable population. COACHMAN targets barriers to hypertension knowledge, medication adherence, problem-solving skills, patient-provider communication, and social support to improve blood pressure control using a community-based participatory research approach.

Substantial evidence has demonstrated the importance of community support in improving patients' management of chronic illnesses (Ferdinand et al., 2012; Hurtado et al., 2014; Kim et al., 2004). Programs that incorporate multiple strategies, such as involving prominent community members as well as trustworthy health educators, and providing convenient, low cost, and culturally tailored interventions, are more likely to attract African-Americans

(Ferdinand et al., 2012). Unfortunately, such programs do not offer technology-based interventions (TBI) as a delivery method to support self-managing hypertension in underserved minority populations. These applications, such as mHealth technologies (mobile phone apps, SMS text, or video messaging), are promising tools to facilitate behavioral change (Buis et al., 2017; Carrera et al., 2016). These readily available technologies offer many features that can be leveraged to improve African-Americans' adherence to anti-hypertensive medications.

To date, more African-Americans have access to smartphones and data packages that support their utilization of mobile phone apps (Smith, 2014). Unfortunately, the acceptance, feasibility, and effectiveness of mHealth apps to improve health outcomes of hypertension have been under studied in underrepresented racial/ethnic populations (Burke et al., 2015). Evidence also suggests that the majority of mHealth apps lack a theoretical framework and have not undergone rigorous evaluation (Davidson et al., 2015). Our ongoing pilot study aims to address these identified gaps in hypertension self-management science through the conceptualization of a pilot randomized controlled trial (RCT) to examine the effects of a theoretically-derived mHealth app among African-Americans with hypertension using a community-based participatory research (CBPR) approach.

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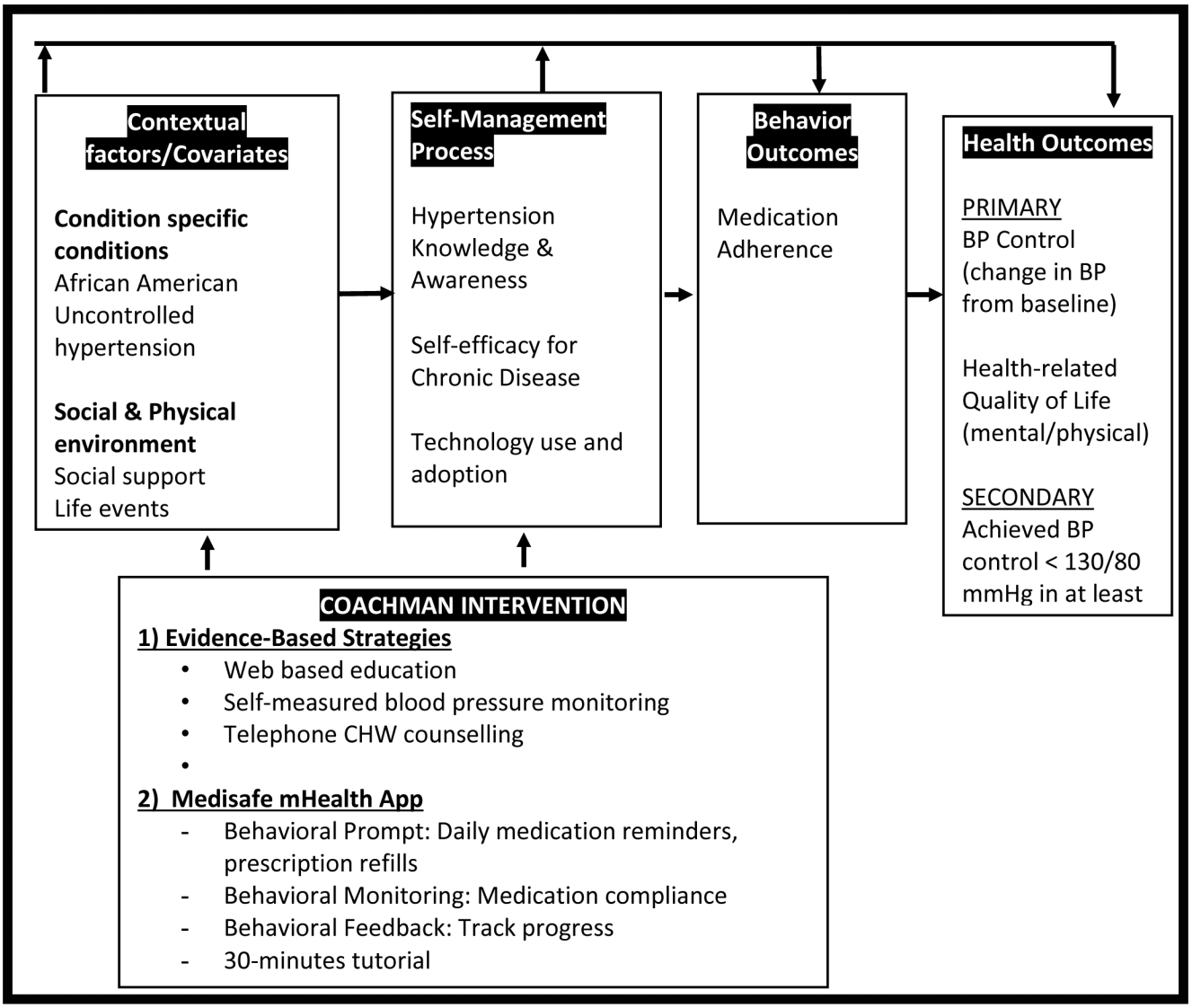

Figure 1:
Conceptual Model Guided by the Ryan and Swain's Individual and Family Self-Management Theory (IFSMT).

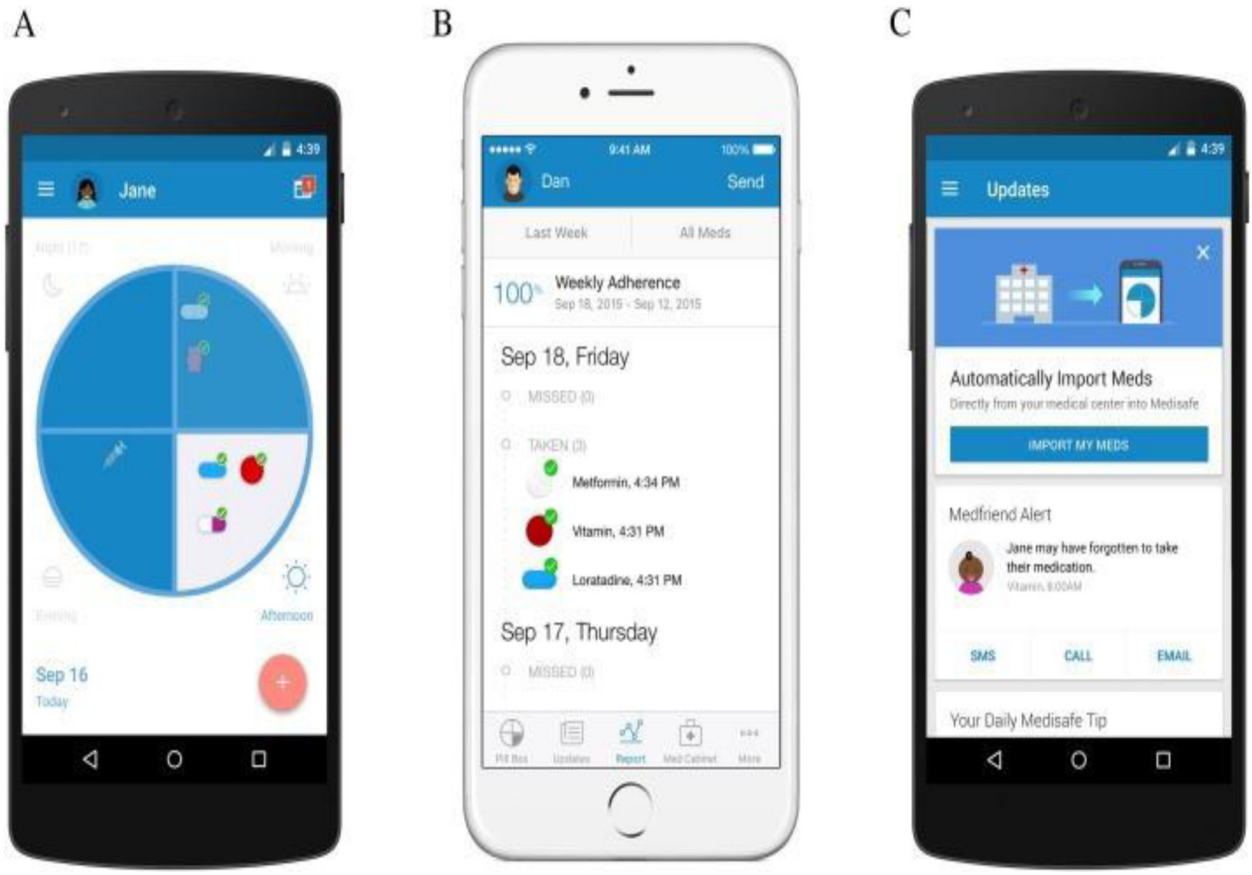

Figure 2:
Medisafe® Medication Application

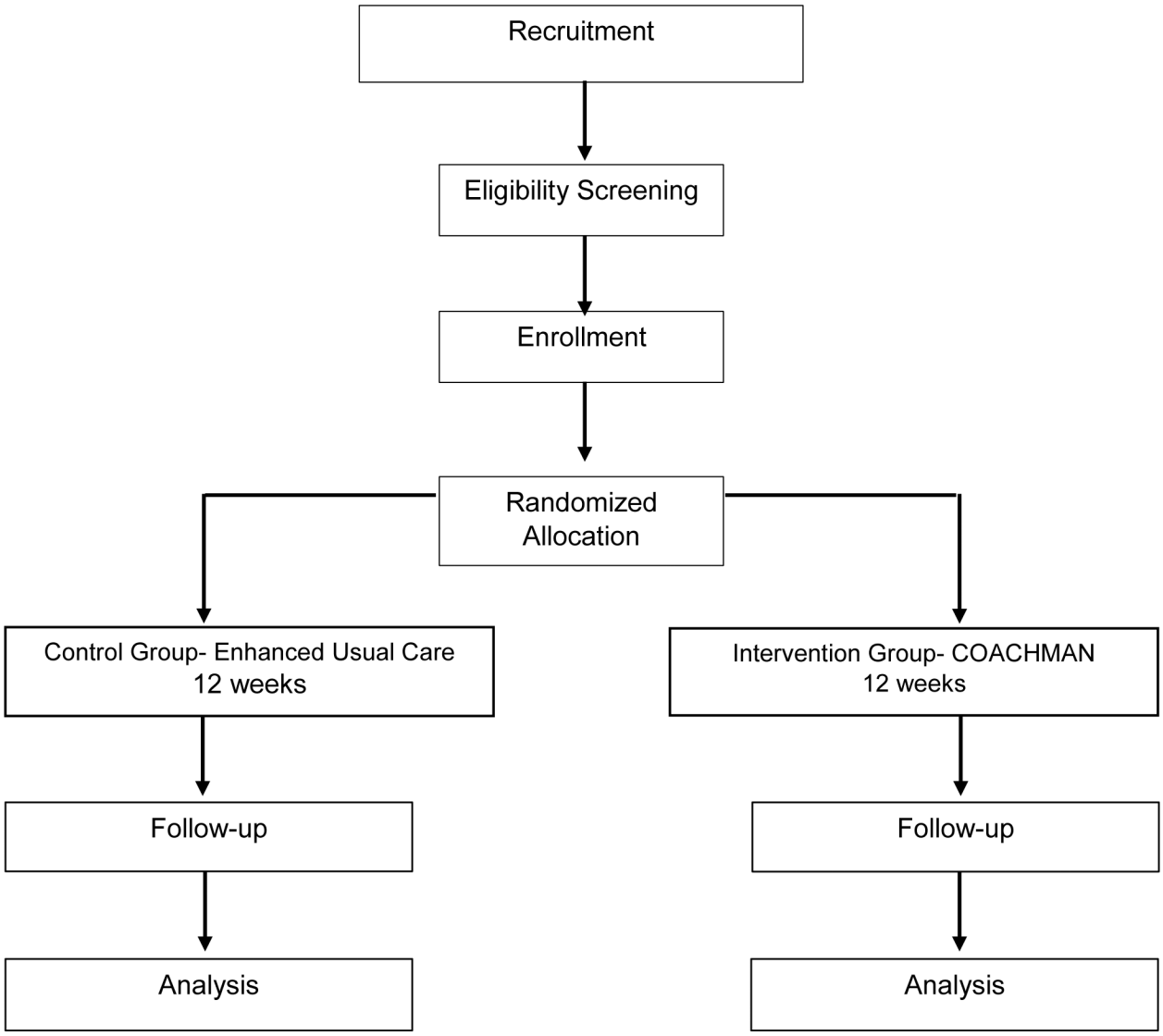

Figure 3:
Pilot Randomization Control Trial Diagram

Table 1.

Hypertension Web-based Education Session

Sessions	Title
Week 1	Overview and understanding hypertension
Week 2	Self-monitoring your blood pressure
Week 3	Importance of adherence to your blood pressure medications
Week 4	Modifying behaviors-Increasing physical activity
Week 5	Modifying behaviors-Healthy Diet
Week 6	Understanding health consequences of hypertension

Table 2.

Study variables, measures, data collection points.

Variable	Measure	Time of Measure		
		Baseline	8 Weeks	12 Weeks
Health Outcomes				
BP Change	BP <130/80 mmHg	X	X	X
Health-related QOL	PROMIS Global Health-10 (Hayes et al., 2009)	X		X
Secondary Health Outcomes				
BP Control	At least 65% of participants with BP control<130/80 mmHg			X
Behavior Outcomes				
Medication Adherence	Hill-Bone Compliance Scale (Culig & Leppee, 2014)	X	X	X
Self-Management Outcomes				
HTN knowledge and Awareness	Hypertension Knowledge-Level Scale-HK-LS (Erokc et al., 2012)	X		X
Self-efficacy	Self-efficacy for Managing Chronic Disease (Lorig et al., 2001)	X		X
Technology Use	System Usability Scale-SUS (Bangor et al., 2008; Brooke, 1996)		X	X
Technology Adoption	Mobile Application Rating Scale-MARS (Domnich et al., 2016)		X	X
Contextual Factors				
Demographics	Demographic Questionnaire	X		
Hypertension History	Charleston Morbidity Index (Charlson et al., 1987)	X		
Biometric Health Screening	Height and Weight, BMI, Comprehensive metabolic panel (for Kidney, liver, function, electrolytes, and protein function.	X		X
Social Support	Duke Subjective and Instrument Support (Hughes et al., 1990)	X	X	X
Spirituality	The Daily Spiritual Experience Scale (Underwood & Teresi, 2002)	X	X	X
Depression	PROMIS Depression Scale-Short Form (Cella et al., 2010)	X	X	X