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A **CO**mmunity and Tech-Based **A**pproa**C**h for **H**ypertension Self-**MAN**agement (COACHMAN)

Protocol 1.0

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Introduction

Given the recently published criteria for hypertension (HTN), a blood pressure (BP) >130/80 mmHg, more Americans are likely to face the challenge of managing this chronic condition.[1] It is projected that HTN prevalence among U.S. adults will increase from 32% to 46%.[2] African Americans (AAs) are disproportionately affected by HTN when compared to all other racial-ethnic groups,[3] and they experience greater disease severity (heart attack, stroke) compared to other racial-ethnic groups.[3,4] Factors associated with nonadherence to HTN self-management include low income, limited access to health care, and or the lack of HTN knowledge,.[4-7] Substantial evidence has demonstrated the important role of community support in improving patients' management of chronic illnesses.[8-11] However, such community support programs rarely offer technology-based intervention (TBI) as a delivery method to improve HTN self-management.[10]

Therefore, this proposal constructs community partnerships with civic, health, and social organizations (Cleveland Council of Black Nurses and American Heart Association) to modify and evaluate TBI to promote medication adherence to antihypertensive therapy and improve BP control among AAs with HTN. *We propose to* adapt and evaluate the efficacy of a multicomponent program for HTN self-management referred to as COACHMAN. The proposed project has two phases: (1) a community engagement phase, and (2) a pilot evaluation phase. Consistent with the principles of community participatory action research,[9,12] the project design will include having stakeholders provide feedback on the key feature of COACHMAN to enhance its feasibility and acceptability. In addition, we will generate data on the efficacy of the intervention that will inform stakeholders. We will gain information on how to allocate community resources to promote HTN self-management using technology, as well as provide data needed for future federal grant proposals. A series of informal sessions and qualitative interviews will be conducted with stakeholders and participants in phase one of the proposed project, and a pilot trial of COACHMAN will be conducted thereafter on AAs with HTN.

COACHMAN innovatively integrates TBI with community resources and enables participants to monitor their blood pressure, access web-based education, mobile application medication management, and receive exposure to behavioral counseling from community health worker to support self-managing their HTN.[12,13] *Our central hypothesis* is that COACHMAN (evidenced-based strategies of HTN education, behavioral skills training, and social support) would be more effective than usual care at motivating AAs with HTN to improve BP control. A *secondary hypothesis* is that the COACHMAN intervention will result in improved BP control. Thus, the aims of this study are:

Aim 1. Identify key content, design, and resources from a community of stakeholders, including determining facilitators and barriers of HTN management among AAs that will inform the development of COACHMAN using qualitative research methods.
Aim 2. Evaluate the feasibility and acceptability of COACHMAN to improve BP control.
Aim 3. Compare the difference in BP control between COACHMAN and EUC.

Impact: The long-term goal of this project is to generate evidence that will inform interventional research that reduces the cardiovascular disease risks and suboptimal or poor HTN self-management in this vulnerable AA population. Cleveland is ideal to conduct this research, as Ohio is ranked 15th nationally for prevalence of HTN, with even higher rates observed in AAs.[14]

A. RESEARCH STRATEGY

Significance. African Americans (AAs) have higher rates of hypertension (HTN) incidence, as well as cardiovascular disease (CVD) morbidity and mortality compared to all other racial-ethnic cohorts.[1-4] HTN is the most influential contributor to incidence of adverse CVD events.[15,16] COACHMAN targets barriers to hypertension (HTN) knowledge, medication adherence, problem-solving skills, patient-provider communication, and social support in an effort to improve blood pressure (BP) control. If demonstrated to be effective, COACHMAN will be practical, scalable, and highly generalizable to a wide variety of individuals and serve as a linkage from community to clinic in the Cleveland area.

Barriers to BP control and HTN self-management are multifactorial. Poor adherence to anti-hypertensive therapy (AHT) is estimated to occur in 43-78% of patients prescribed AHT, with 50% discontinuation after a year, and notably worse and sooner in AAs.[3] Recent research now recommends lower BP goals.[17,18] Evidence suggests that inability to achieve BP control likely arises from a complex interaction of patient, provider, and system-level barriers.[6,19] For this patient-focused project, the key barriers for BP control and HTN self-management are competing health priorities, lack of awareness of HTN knowledge, lack of confidence to self-manage HTN, depression, and lack of social support.[20]

The use of technology for self-management of chronic disease is evolving.[21] Contrary to the popular belief that AAs use less technology,[22] AA smartphone use is 81% compared to 74% of the total population, and AAs spend close to 56 hours a month using apps or mobile Internet browsers on their smartphones.[22,23] The proposed COACHMAN intervention represents a conceptual progression of the digital age and leverages technology for education and training, including the benefits of convenience, cost, and the ability to remotely deliver a highly focused, short-duration, HTN self-management intervention. Preliminary Work. In one study, our research team conducted a 90-minute focus group session to explore AAs' (N=21) experiences with using technology (mobile devices and apps) for HTN self-management,[24,25] The majority of the participants owned smartphones and used this technology to communicate; seek, acquire, and share information; engage in entertainment; and organize and manage time. Participants expressed concerns about not being informed or trained to integrate technology for HTN self-management.[26]

Community engagement in HTN self-management. Substantial evidence has demonstrated the importance of community support in improving patients' management of chronic illnesses.[11] 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 engage AAs.[11,27] Unfortunately, such programs rarely offer technology-based intervention (TBI) as a delivery method. We propose to evaluate the feasibility and acceptability of a TBI among AAs with HTN. PI Dr. Carolyn Still has already begun informal sessions with community partners (National Black Nurses Association and American Heart Association) as well as hypertension experts to develop this grant proposal and to obtain input to begin the initial design of the TBI for HTN self-management for AAs.

B. INNOVATION. Many communities have begun HTN screening or provider/system initiatives to improve BP control. However, such programs have not focused on effective patient engagement strategies with TBIs for self-managing HTN. This proposal addresses those gaps by leveraging

successful and replicable community programs with the addition of TBIs to advance the science of HTN self-management.

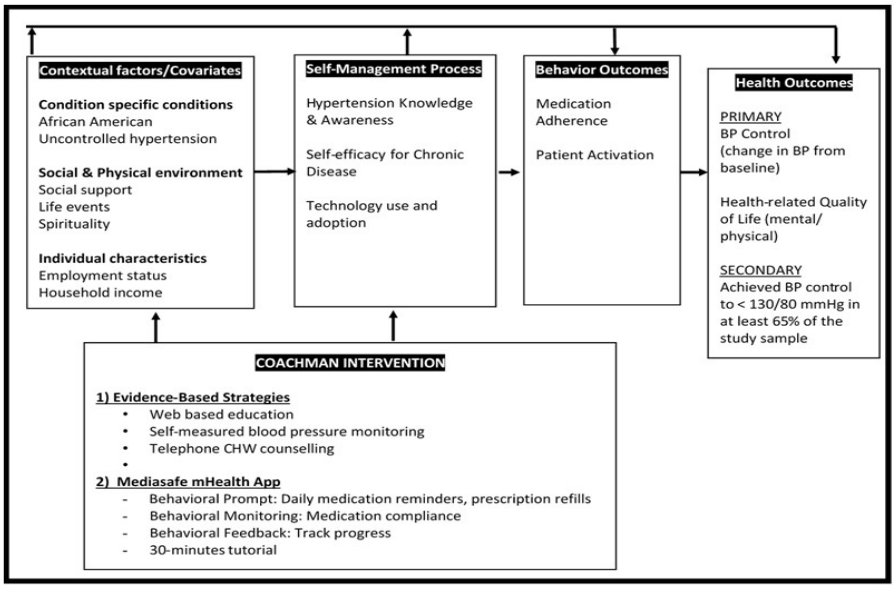

Figure 1: Conceptual Framework

C. APPROACH. A convenience sample of AAs with uncontrolled HTN will be conducted to obtain data on study variables and outcomes at baseline, 8 weeks, and 12 weeks. The primary outcome is change in BP from baseline to three months. A secondary outcome will be the proportion of participants achieving BP < 130/80 mm Hg at three months. Ryan and Swain's Individual and Family Self-Management Theory,[28] (Figure 1) guides the major constructs of this study. Community stakeholders will be engaged throughout the project for continual input to refine and implement study intervention (see Statement of Work). The *initial phase* of this inquiry will begin by conducting informal sessions and focus groups to assess motivators as well as barriers to HTN management (Aim 1) followed by implementation of COACHMAN. Dr. Cheryl Killion (Nursing Professor at Case Western Reserve University) has extensive expertise in community participatory research and will provide qualitative method support.

Study Intervention. The COACHMAN intervention is comprised of ***four components***: 1) self-monitoring blood pressure (SMBP), 2) web-based education (adapted from the American Heart Association's Check, Change, Control),[12] 3) training/support for Medisafe application, and 4) nurse counseling. Study investigators will also use forged and ongoing relationships with the Cleveland Council of Black Nurses (CCBN) and other community partners to engage in all aspects of this study and serve as Community Health Workers (CHWs).[10] The Enhanced Usual Care (EUC) group will receive one education session on SMBP and printed materials from the American Heart Association on "The Facts About High Blood Pressure" and the DASH Diet. All participants will receive study-provided automated home BP monitors (Omron 10 Series).

Setting and Sample. Given that this is a pilot study, a sample size of 40 is considered adequate. Participant inclusion criteria are as follows: (1) self-identifying as AA; (2) aged 30 years or older; (3) diagnosed with HTN (BP $\geq$ 140/90 mm Hg) and taking at least one antihypertensive medication; (4) able to read/understand English; and (5) own a smartphone with a data plan, with the capability to download the Medisafe app and view videos. Exclusion criteria are: (1) history of cognitive impairment, and (2) currently using medication management app.

Recruitment and Retention. Various recruitment strategies such as fliers, brochures, and target ads through social media platforms (Facebook, ResearchMatch.org), as well as advertisements at community events and clinics,[29] will be used simultaneously. In addition, our community partners will assist recruitment. Our study population will be recruited from University Hospitals and from community outreach engagement. We anticipate limited difficulty in recruiting participants due to the Dr. Still's experience in clinical research and long-term working relationship with the participants and providers, as well as continued work with other cardiovascular trials. We will recruit three participants per week over a 4-month (December-April) period. While Dr. Still has experience with recruiting and managing clinical trials, she is an Early Stage Investigator (without NIH grant awards) in her second year as an Assistant Professor (tenure track) in the School of Nursing at Case Western Reserve University.

Variable	**Measure**	**Time of Measure**		
		Baseline	**8 Weeks**	**12 Weeks**
Health Outcomes				
BP Change	BP <140/90 mmHg	X	X	X
Health-related QOL	PROMIS Global Health-10,[30]	X		X
Secondary Health Outcomes				
BP Control	At least 65% of participants with BP control<140/90 mmHg			X
Behavior Outcomes				
Medication Adherence	Hill-Bone Compliance Scale,[31]	X	X	X
Patient Activation	Patient Activation Measure Short Form-PAM-13,[32]	X	X	X
Self-Management Outcomes				
HTN knowledge and Awareness	Hypertension Knowledge-Level Scale-HK-LS,[33]	X		X
Self-efficacy	Self-efficacy for Managing Chronic Disease,[34]	X		X
Technology Use	System Usability Scale-SUS,[35]		X	X
Technology Adoption	Mobile Application Rating Scale-MARS,[36]		X	X
Contextual Factors				
Demographics	Demographic Questionnaire	X		
Hypertension History	Charleston Morbidity Index,[37]	X		
Biometric Health Screening	Height and Weight, BMI, Kidney function, proteinuria	X		X
Social Support	Duke Subjective and Instrument Support,[38]	X	X	X
Spirituality	The Daily Spiritual Experience Scale,[39]	X	X	X
Depression	PROMIS Depression Scale-Short Form,[40]	X	X	X

Data Collection and Procedures. Study variables, measures, and data collection points are shown in Table 1 (page 5). After consent is obtained, participants will be randomized to COACHMAN or EUC with a 1:1 ratio. At baseline and 12 week visits, we will conduct biometric health screening test (height, weight, and blood samples). A trained RA will provide subjects assigned to COACHMAN a structured 30-minute training session on how to use study website and Medisafe on smartphone. For those subjects assigned to EUC, the RA will provide education materials. Follow-up phone sessions on medication adherence and additional training will be provided by the CCBN trained as CHWs.

Fidelity of the intervention "dose" (delivered, received, enacted) will be monitored regularly throughout the study by obtaining measures of subject responses to medication reminders, receipt of behavior change, and attendance to follow-up visits.

Statistical Analysis. For Aims 1 and 2, focus group sessions and key informant interviews will be transcribed verbatim and analyzed with NVivo 10 or a similar software package using principles of inductive content analysis. For Aim 3, the primary analysis compares BP levels between the COACHMAN intervention and the EUC group across three time points (baseline, 8, and 12 weeks). We will use a repeated measures analysis of variance (RMANOVA) built around a two group by three time points to assess mean differences across time, group differences, and the interaction of time X group.[42]

Study Timeline. Months 1-2: Project start-up, finalize online web-based system, begin recruitment. Months 2-5: Recruitment, randomization, enrollment; begin intervention delivery; Months 3-9: Continue intervention delivery; data collection and system monitoring and retention; Months 9-12: Data cleaning, analysis, dissemination.

Potential Problems and Alternative Strategies. Due to the pilot nature of this study, each participant will be required to use their own data plan. As noted in preliminary studies, a majority of participants own or have cell phones in our qualitative study. Thus, we expect few exclusions related to cell phone ownership. Participants will receive a total of $215, which is intended to cover any costs incurred from cell phone usage, and overall study participation. This pilot trial is intended to inform the design of a larger clinical trial, including its scalability, especially in terms of costs that are not more than we anticipate, or pose a problem for participant or retention. Future trials will provide study phones with prepaid data plans for those individuals with limited resources.

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