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STUDY PROTOCOL

Optimizing Technology to Improve Medication Adherence and BP Control (OPTIMA-BP) Intervention Versus Waitlisted Group in African American Adults with Hypertension: A Randomized Control Trial Protocol

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Background: Consistent adherence to prescribed hypertension treatment regimens is an important goal for persons living with hypertension, yet it remains a challenge for minority and underserved populations. Employing technology-based intervention (TBI) to support self-managing hypertension presents an opportunity to effectively control blood pressure (BP), and potentially have long-term effects on health outcomes.

Objective: The objective of this study is to test the efficacy of a TBI, OPtimizing Technology to Improve Medication Adherence and BP Control (OPTIMA-BP), as an approach to support hypertension self-management to improve BP, health-related quality of life (HRQOL), and long-term compliance in African Americans with hypertension.

Methods: This prospective, 2-arm randomized trial conducted in the Midwest will enroll African American older adults with hypertension, 50 years of age and older, recruited from primary clinics and community settings. Participants are allocated in a 1:1 ratio using computer-generated randomization to OPTIMA-BP intervention (n = 104) or Waitlist control group (n = 104). Participants are asked to participate in the study over a 12-month period and complete 5 study visits. Individuals in the OPTIMA-BP intervention group will receive three technology components (web-based education, medication adherence mHealth app, study provided home BP monitor), coupled with nurse counselling and communication to providers for guideline-directed treatment regimen. We will also collect data on knowledge-attitude mechanisms of self-management (hypertension knowledge, self-efficacy, perceived social support) and proximal behavioral mechanisms (antihypertension medication-taking, diet, exercise). Qualitative analyses will explore participants' experiences with self-managing hypertension using technology.

Results: Participant recruitment began in March 2022, and is currently ongoing. It is anticipated that preliminary findings appropriate for analysis will be disseminated in Summer 2025. The primary endpoint is a change in BP (<130/80 mmHg) and improved HRQOL.

Conclusion: Using TBI along with standard preventive measures provides a unique opportunity to improve BP control and enhance secondary cardiovascular disease prevention in this high-risk group.

Trial Registration: ClinicalTrials.gov NCT05564728; https://clinicaltrials.gov/study/NCT05564728.

Keywords: tech-based intervention, hypertension, self-management, African Americans, older adults, self-efficacy

Introduction

There is an estimated 120 million people in the United States with hypertension and only 22% have their blood pressure (BP) under control.[1] For many adults living with hypertension, uncontrolled BP leads to many adverse cardiovascular disease (CVD) events such as stroke, ischemic heart disease, chronic kidney failure, and other vascular diseases.[2]

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Although hypertension is a modifiable risk factor, prevalence rates have modestly increased over the past several years due to a broader definition of hypertension, updated diagnostic criteria and guidelines, early detection, and increased awareness. Overall, rates of hypertension increased by 5–10% and racial and ethnic minorities have higher rates, with non-Hispanic Blacks (57.3%) and Hispanics (44.7%) having higher rates of hypertension compared with non-Hispanic Whites (43.8%).[2,3] Controlling BP can significantly reduce CVD morbidity and mortality, as well as healthcare burden and cost. Employing technology interventions to support self-managing hypertension, especially in African Americans who are disproportionally burdened, presents an opportunity to identify interventions, including technology, to effectively control BP, and potentially have long-term effects on health outcomes.[4,5]

It has been well documented that self-management of hypertension plays a crucial role in controlling BP and reducing poor health outcomes.[6–8] Self-management of hypertension requires a person to actively engage in day-to-day treatment decisions to manage their health and symptoms, adhere to prescribed treatment regimen and antihypertensive medications, and implement healthy behaviors (diet, exercise, stress reduction).[3,9] Available evidence has demonstrated that effective self-management of hypertension can not only improve BP control, but can reduce stroke incidents and other hypertension associated adverse events by 30%.[10,11] However, many individuals (43−78%) struggle with self-managing their hypertension for several reasons, including barriers at the patient, provider, and system levels.[12,13] Other factors that appear to exist as barriers to BP control included lower socioeconomic status, limited access to healthcare services and resources, lack of knowledge related to hypertension disease and management, poor compliance to treatment regimen and antihypertensive medication-taking, suboptimal provider–patient interaction and communication, and inadequate treatment or clinical inertia by the provider.[6,8,12,14] In addition, lifestyle and unhealthy behaviors contribute to suboptimal BP control.[14–17]

Consistent adherence to prescribed hypertension treatment regimen (eg, healthy lifestyle, medication adherence) is an important goal for persons living with hypertension,[4,18] yet it remains a challenge for minority and underserved populations. Behavioral technology-based interventions (TBI), including those that integrate mHealth can offer a solution to support behavioral change and improve and control BP. [19,20] Despite showing great promise for improving chronic disease management, there is a paucity of evidence focused on African American older adults with hypertension using technology to self-manage chronic diseases.[4] In addition, it has been suggested from previous work that technology engagement is hindered by access and perceived usability, low technology health literacy, and cost. [4,15] Likewise, other identified limitations of technology-based intervention studies were limited by their: 1) exploratory nature and heterogeneity, 2) the lack of diverse populations, 3) conducted internationally, 4) methodological shortcomings such as not guided by theoretical underpinnings, 5) the lack of long-term follow-up, and 6) evidence to support long-term effects on health outcomes.[21–23] Lowering BP to prevent and treat hypertension to target goals of <130/80 mmHg (millimeters of mercury) is a public health priority. Such actions are key to prevent CVD consequences and hypertension-related adverse outcomes (eg, coronary artery disease, stroke, chronic kidney disease). There is, therefore, an urgent need for research to understand how technology can improve BP control and medication adherence, especially in African American older adults, who have higher than expected uncontrolled hypertension rates.[5]

This study is guided by the Individual and Family Self-Management Theory (IFSMT)[24] and integrates concepts from the Mobile Health Technology Acceptance Model (Mo-HTAM).[25] The IFSMT is a widely used self-management theory to assess the effectiveness of a variety of behavioral and self-management interventions across diverse populations of adults, and posits that self-management consists of three dimensions: context, process, and outcomes.[24] The underpinnings of Mo-HTAM suggest that the technology, in the presence of high perception of ease of use and usefulness, will influence an individual to accept, adopt, and use technology for self-managing health.[26] Therefore, we describe a protocol, OPtimizing Technology to Improve Medication Adherence and BP Control (OPTIMA-BP), a person-centered, technology-based, multicomponent intervention directed at increasing knowledge, self-regulation skills, and abilities to facilitate hypertension self-management to influence healthy behaviors. Figure 1 presents the conceptual framework.

Aims

The overarching goal of this study is to use OPTIMA-BP, as an approach to support hypertension self-management to improve BP control, quality of life, and long-term compliance. OPTIMA-BP includes evidence-based strategies, hypertension web-based education, and behavioral skills training to use a theoretically driven mHealth medication management app, nurse

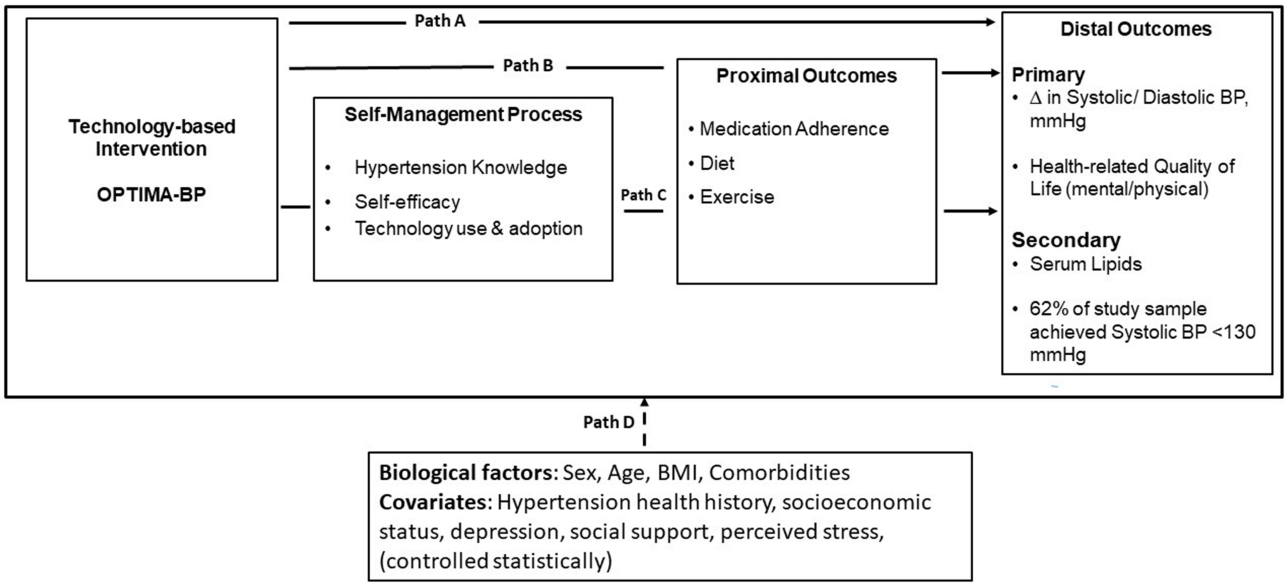

Figure 1 Conceptual Framework.

counseling sessions, and patient-provider communication. Specific aims of this study are to: 1) examine the effects of OPTIMA-BP vs Waitlist control group on systolic BP and serum high-density lipoprotein cholesterol (HDL) in African American older adults with hypertension in a prospective, RCT format; and 2) test the knowledge-attitude mechanisms of self-management (hypertension knowledge, self-efficacy, technology use and adoption) and proximal behavioral mechanisms (antihypertension medication-taking, diet, exercise) that mediate OPTIMA-BP vs Waitlist control group's impact on the primary and secondary outcomes.

We hypothesize that OPTIMA-BP, compared with a waitlist control group, will improve hypertension self-management, as well as BP control and medication adherence to antihypertensives in African American older adults with hypertension. Furthermore, OPTIMA-BP may provide an efficient and scalable solution to hypertension self-management and adherence to antihypertensive medication-taking, ultimately improving BP in African American older adults.

Methods

Study Design

This study is a 6-month prospective RCT evaluating the effects of OPTIMA-BP intervention (n = 104) vs Waitlist control group (n = 104) in African American older adults with hypertension. To optimize enrollment and retention as well as collect information on longer-term trajectories of outcomes, individuals randomized to OPTIMA-BP will be followed for a total of 12 months: baseline to 6 months for the initial evaluation and 6–12 months to evaluate sustainability of the OPTIMA-BP intervention. Individuals in the Waitlist control group will receive routine standard of care for the first 6 months, then receive the OPTIMA-BP intervention from Month 6 to Month 12 during their participation in the study.

The primary health outcome will be change in systolic and diastolic BP and health-related quality of life (HRQOL), while secondary health outcomes include change in other biologic parameters of CVD risk (lipid profile) as well as achieved lower BP targets of <130/80 mmHg in at least 62% of the sample.[3] Exploratory analyses will evaluate how contextual factors (age, sex, socioeconomic status, hypertension health history, depression, social support, and perceived stress), process factors (hypertension knowledge, self-efficacy, and technology use and adoption), and proximal health behaviors (medication-taking adherence, diet, and exercise) may influence the primary and secondary distal health outcomes (Figure 1). Qualitative assessment will evaluate the perspectives of African American older adults in both OPTIMA-BP and Waitlisted control group.

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Ethical Considerations

The study protocol was reviewed and approved by University Hospitals Cleveland Medical Center's institutional review board (IRB #20201174). This study complies with the Declaration of Helsinki and has been registered at ClinicalTrials.gov (NCT05293756). To address potential biases associated with the reporting of results using RCT design, we will adhere to the CONSORT (Consolidated Standards of Reporting Trials).[26]

Informed Consent

Prior to any study procedures being conducted, informed consent is obtained from all interested and eligible participants. Further, the consent forms detail study procedures, benefits and risks, as well as efforts to maintain privacy and confidentiality of protected health information (PHI). Research records will be kept in a locked file and an electronic data capture system (REDCap) and access is limited to the researchers, the IRB responsible for protecting human participants, and regulatory agencies (special circumstances—abuse, self-harm). In additional, this research is also covered by a Certificate of Confidentiality from the National Institutes of Health, which protects research participants' privacy and disclosure of identifiable research information to anyone not associated with the research study. Participants will also provide consent to disclose study results (ie, BP, cholesterol) to their primary care provider. Importantly, participants are informed that their participation is voluntary and can withdraw from the study at any time.

Target Population and Eligibility

Participants are included if they self-identify as African Americans, 50 years of age or older, diagnosed with hypertension with a systolic BP ≥130 mmHg but <170 mmHg, currently prescribed at least two antihypertensive drugs that include a diuretic or calcium channel blocker, and able to read/understand English. Participants are excluded if they were unable to give informed consent or judged to have impaired cognitive ability or severe memory deficits, experienced a major CVD event or procedure (eg, myocardial infarction, stroke, heart surgery) within the past year, or have a diagnosis of chronic kidney disease (defined as eGFR < 60 mL/min/1.73m^2) and/or receiving dialysis.

Setting and Recruitment

African Americans constitute about 15% of the Northeast Ohio population, with higher proportions in Cleveland, the largest metropolitan city in the region and the county seat of Cuyahoga County. Thus, recruitment will be conducted at primary care clinical sites associated with a large medical academic institution in Northeast Ohio. The study recruitment efforts will use several organized approaches that include planning, developing, and implementing multiple strategies simultaneously. We will use community outreach and networks to maximize enrollment of African American older adults with hypertension. These outreach efforts will include educational research presentations to organizations who serve diverse racial and ethnic groups (eg, churches, community centers, health fairs, and public housing), as well as recreation and community shared space. In addition, our recruitment efforts will also include local advertising (print, radio, bus advertisements) to diverse audiences/markets with IRB-approved advertisements.

To enhance and promote study enrollment and retention, we will employ several methods known to maximize retention of research participants. We will reimburse patients for transportation, parking, and other logistical barriers, if the expense is an obstacle to coming in for study visits. Email, text, phone calls, or mail letters to remind subjects of study appointments. Lastly, all participants will receive a small stipend (up to $180 total over the course of the study), for their time and travel to offset any hardships participation in study visits may create.

Sample Size and Power Calculation

In designing this study, we are interested in examining the efficacy of OPTIMA-BP on primary outcomes—systolic/diastolic BP and HRQOL. We hypothesize that after the OPTIMA-BP intervention, BP will be reduced to the target goal <130/80 mmHg by a mean of −7.4/-3.45 mmHg. Using Frison's,[27] change method for repeated measures design, we estimated the sample size based on the difference in the two groups of the mean change of the post-OPTIMA-BP measurements at 6 months, assuming that correlation between repeated measurements is 0.50. Conservatively, we

estimate a mean difference of 3.45 mmHg in diastolic BP change between groups (a clinically important relative risk reduction for hypertension-related adverse events). Thus, 90 participants per arm, in a longitudinal measures design with four measurements can be detected with 80% power and a significance level of 0.05. However, the sample size was adjusted to 208 participants (104 per arm) to account for a 15% potential attrition rate. The sample size estimation was performed using PASS 11.0 software.[28]

Allocation

Participants who meet eligibility criteria will be enrolled on 1:1 allocation to OPTIMA-BP or Waitlist control group using a computer-generated randomization list capture in the REDCap.

Intervention

The study intervention targets barriers to hypertension management such as limited knowledge, medication adherence support, problem-solving skills, patient-provider communication, and social support to improve medication adherence and BP control. A trained research assistant will administer the TBI components. The elements of OPTIMA-BP include three technology components (web-based education, medication adherence mHealth app, and study provided home BP monitor) coupled with nurse counseling and communication to providers for guideline-directed treatment regimen.

Web-Based Modules

The web-based modules are delivered weekly over the first six weeks of the intervention period and are focused on improving knowledge and skills about hypertension management (eg, home BP monitoring, medication adherence, modifying health behaviors). The web-based education modules are less than 10 minutes in duration and use established web-based technology that is accessible on a standard web browser compatible with an average household or library computer or mobile device.

Medisafe

The software application (app), Medisafe is a free medication adherence support app that operates on Android and iOS phone systems to provide alerts to take medication (www.Medisafe.com). Personalized medication adherence support includes SMS reminder messages, adherence feedback, health and lifestyle tips. Other features of Medisafe include the ability to generate weekly adherence reports and designate a "Medfriend" (an individual who is granted access to ones' medication-taking history.[29] Participants will be trained to use Medisafe on their smartphone then ask to use the app for 6 months for medication-taking adherence support.

Home Blood Pressure Monitoring

Each participant will be given an Omron series 10 home BP monitor and provided with instructions and training on self-monitoring BP. Participants are asked to monitor their BPs twice a week and record BPs on a tracking log.

Nurse Counseling Sessions

Another component of the intervention includes nurse counseling sessions (4–5 sessions over 6 months), which will provide social support and adjunct education on self-managing hypertension. Counseling sessions will serve as booster sessions to web-based education modules. The nurse educator schedules a 30-minute counseling session by phone at the convenience of the participant. Guided by evidence and culturally appropriate educational materials "On the Move to Better Heart Health for African Americans" (developed by the National Heart, Lung, and Blood Institute), each session is individually tailored based on the participants' concerns and support needed to self-manage their hypertension. Sessions are to be completed by the 6-month visit.

Optimizing Hypertension Treatment

Finally, self-management of hypertension in combination with self-monitoring of BP should include an appropriate drug treatment regimen. Thus, the last component of OPTIMA-BP intervention is communication with providers to achieve target BP goals (BP ≤130/80 mmHg) by recommending an appropriate drug treatment regimen based on guidelines and at the discretion of the provider. Therefore, optimizing BP treatment will address a modifiable barrier to BP control and

focus on communicating with providers and participants to ensure the intensification of antihypertensive regimens that has been proven to be effective in reducing BP in this population. In terms of optimizing antihypertensive agents, nurse coordinators will communicate with the participants' provider using a study form "Provider Plan for Hypertension Management" that will be completed at each visit if the participant is not at target BP goal of < 130/80 mmHg. Appropriate titration of antihypertensive medication is at the discretion of the provider and current US hypertension guideline.[3] Given that we are not testing specific medications, providers are encouraged to use these drugs classes and/or doses of antihypertensive medications as recommended.

Waitlist Control Group

Individuals randomized to Waitlisted control group will participate in their regular medical care for a period of 6 months, after which they will receive the OPTIMA-BP intervention as a supplement to their regular medical care.

Blinding

For this study, implementing blinding for the participants, healthcare providers, and research assistants involved in administering the intervention was not feasible. To reduce bias and promote standard delivery of the intervention, a manual of procedures will be used to train the research assistants. Fidelity of the treatment intervention will be guided by the principles of Bellg et al,[30] which includes provider training, treatment delivery, treatment receipt, and enactment of treatment skills. Frequent quality control checks and refresher training (quarterly) will be conducted to ensure the intervention is implemented appropriately.

Procedures

Table 1 presents the schedule of study procedures and measures. Potential participants are screened for eligibility by phone or during their routine clinic appointments. Individuals meeting inclusion criteria are than scheduled for an in-person screening visit. During the screening visit, participants receive comprehensive information about the study and are permitted time to make an informed decision and/or discuss with family members before enrolling in the study. Once consent is obtained, data is

Table 1 Schedule of Study Procedures and Measures

Variable	Timeline					
	Screen	BL	3 M	6 M	9 M	12 M
Screening, Informed consent	X					
Demographics	X					
Contextual factors: Perceived stress Social Support Comorbidities, CVD risk Patient-Provider Communication		X	X	X	X	X
Randomization		X				
Self-management processes: Hypertension knowledge Self-efficacy Technology use and adoption		X	X	X	X	X
Proximal behavioral outcomes: Medication-taking Diet Exercise		X	X	X	X	X

(*Continued*)

Table 1 (Continued).

Variable	Timeline					
	Screen	BL	3 M	6 M	9 M	12 M
Primary Health Outcome: Systolic BP Diastolic BP Health-related Quality of Life	X	X	X	X	X	X
Secondary Health Outcomes: 62% of study sample with SBP < 130 mmHg Biological risk markers Lipids (HDL, LDL, cholesterol) BMI		X		X		X
OPTIMA-BP implementation in the experimental arm		→				
OPTIMA-BP implementation in the waitlist arm					→	
Participant satisfaction				X		
Qualitative Assessment		X		X		

collected on general demographic information and BP. The BP will be measured using recommended standards: BP obtained with appropriate cuff, feet flat on floor and participant relaxing for 5-minute rest period, followed by three BP measurements (1-minute apart) for an average BP reading at each visit.[3,31] Eligible participants are then scheduled for a baseline visit where they will be randomized and assigned a study ID. At each visit, participants will be asked to complete study measures – laboratories, anthropometric measurements, and self-reported surveys.

Data Collection and Management

Trained research assistants will consent all subjects, conduct study assessments, and enter selected study-related data into a secure web-based data system (ie, the Research Electronic Data Capture Application [REDCap] system). The participant flow through this study is illustrated in Figure 2. Participation in this study will last for about 12 months and involve 6 visits, 1 screening visit and 5 study visits (baseline and follow-up at 3, 6, 9, and 12 months). Of the enrolled participants, 40 participants (20 from each study group) will be randomly selected to participate in two qualitative interviews at baseline and 6 months. In addition, participants will complete their survey responses using REDCap via a study-provided iPad tablet (or with assistance if needed). It is expected that the baseline visit will take approximately 90 minutes, while follow-up visits will take about 60 minutes to complete.

The study data will be routinely checked by research staff and Principal Investigator through the REDCap dashboard for quality, accuracy, and consistency. Fidelity of each component will be monitored. For the first component, the web-based education materials will be embedded in Qualtrics (a cloud-based analytic software), which will allow us to monitor the participants' access to the educational information and completion of each education session. Qualtrics will also allow us to monitor interruptions due to internet connectivity and prolonged states of screen inactivity. Because this educational material is screen-based, the fidelity for this component is relatively high. For the second component, the mHealth app, we will capture and generate weekly medication adherence reports and monitor biometric data (blood pressure [BP] measurements entered into app). These reports will also provide the team with data on the frequency and duration of each participant's session in the mHealth app. Fidelity for the third component – home BP monitoring will be assessed by: (1) monitoring the participants' BP monitoring techniques at each visit, and (2) assessing the frequency/percent of BP readings entered into the app (BP log) that are compliant with the protocol and are successfully reported at the follow-up visit.

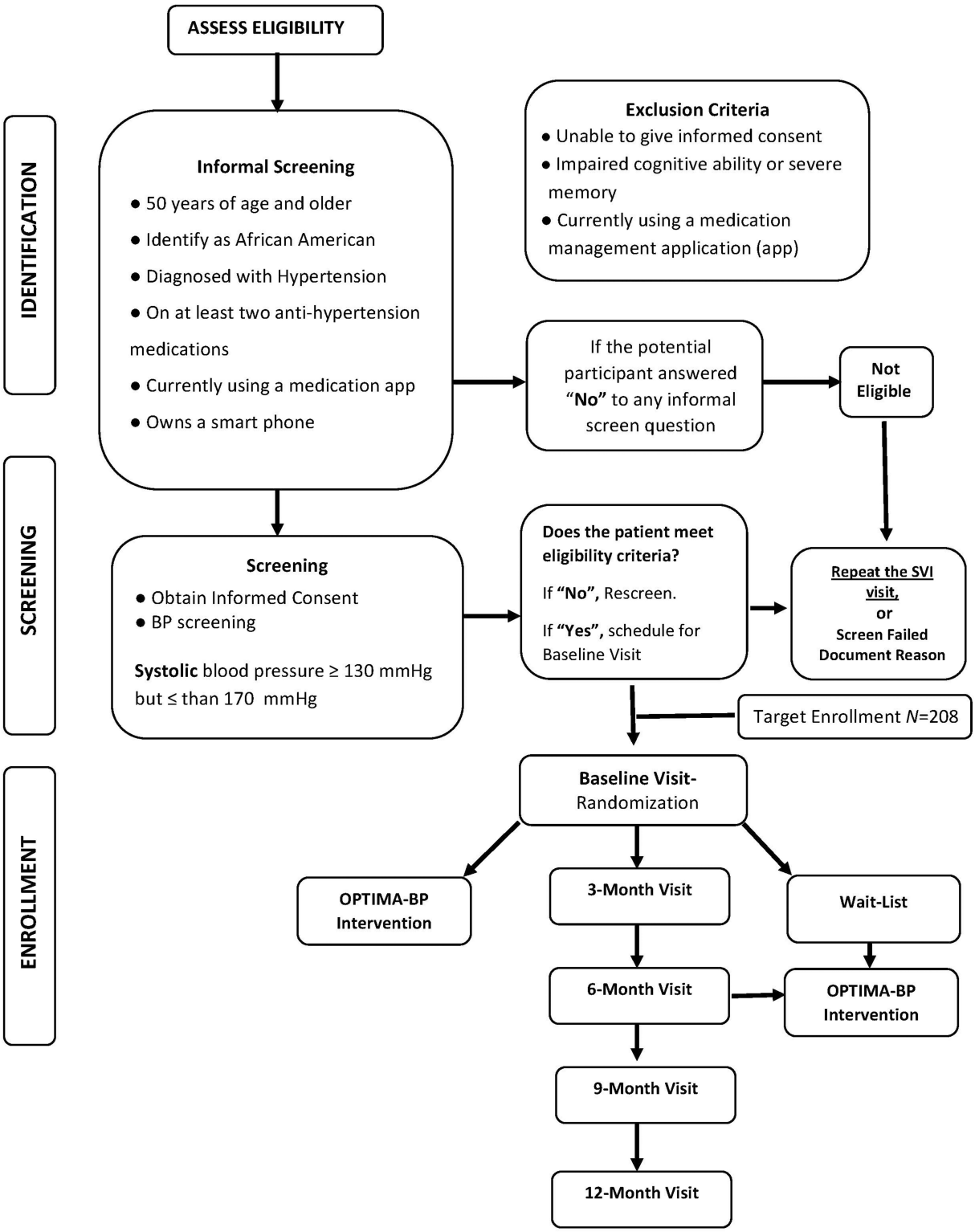

Figure 2 Concert Study Diagram.

Confidentiality of research data will be protected in several ways. All study personnel will be required to be certified in the protection of human subjects throughout the study. Data collected on hard-copy forms will be stored in a locked cabinet with access limited to study staff and PI. Identifiable participant information and de-identified outcome data will be stored separately. Databases with identifiable participant information will be password protected with access limited to

the PI and study staff. The records of this research will be kept confidential. This research is also covered by a Certificate of Confidentiality from the National Institutes of Health. Only aggregate data will be presented or published such that individual participants cannot be identified.

Study Measures

We have carefully chosen measures based on their appropriateness for this population, validity, reliability, and level of burden (Table 1). Majority of the questionnaires use Likert-type scales and questions range from 4 to 36 items. Total time to complete all surveys is approximately 25–35 minutes.

Primary Health Outcomes

Systolic/diastolic BP control (defined as BP<130/80 mmHg) will be measured on the research unit by a research nurse using a standard automatic BP device (Omron HEM-907XL) according to standard procedures,[32,33] at 5 time points. HRQOL will be measured by the 10-item PROMIS Global Health-10, a valid and reliable interval scale ($\alpha = 0.82$).[34] For secondary health outcome, we will assess change in systolic BP and diastolic BP from baseline to 6-month follow-up by statistical analysis.

Self-Management Process

Three measures will be used to capture the self-management process. First, the Hypertension Knowledge-Level Scale, developed by Erkoc et al,[35] measures hypertension knowledge and awareness. This 22-item interval scale measures 6 domains of hypertension knowledge and awareness (medical treatment, complications, attitudes, behaviors, drug compliance, and lifestyle). Scores range from 0–22, with higher scores indicating more hypertension knowledge ($\alpha = 0.82$).[35] Second, the 6-item Self-efficacy for Managing Chronic Disease will be used to assess ones' confidence to self-management their hypertension.[7] Self-efficacy scores range from 0–10 ($\alpha = 0.91$), higher scores indicate higher perceived self-efficacy.[7] Finally, the System Usability Scale ($\alpha = 0.91$), a 10-item questionnaire will be used to measure global subjective view of mHealth app usability and adoption.[36]

Proximal Behavioral Outcomes

We will assess both subjective and objective measures to assess participants' medication-taking adherence.[37] To assess subjective medication adherence, the Hill-Bone Compliance to High Blood Pressure Scale,[38] with 14 items on a six-point Likert type scale that measures self-report of medication adherence in three domains (medication-taking, diet, appointment keeping). Scores range from 14–56 with higher scores reflecting poorer adherence, Cronbach alpha's range from 0.74–0.84.[38] In addition, objective medication-taking adherence will be monitored with the mHealth medication management app, *Medisafe*, where participants will respond to daily medication adherence reminders.[29] Total medication-taking adherence with Medisafe is defined as the ratio of total daily adherence to number of days monitored for a composite adherence score. In addition, pill counts are conducted to corroborate self-reported medication adherence and to address potential bias with self-reported adherence.

Contextual Factors

We will collect demographic information (age, gender, socioeconomic status), hypertension medical history, and comorbidities as measured by Charlson Comorbidity Index ($\alpha = 0.90$),[39] anthropometric measures (weight, height), and serum lipid levels (cholesterol, HDL, LDL) at baseline. Perceived stress will be measured using the Perceived Stress Scale ($\alpha = 0.83$).[40] Social Support will be measured with the Medical Outcomes Study Social Support Survey ($\alpha = 0.91$).[41] To assess affective and cognitive manifestations of depression, the Promis Depression Short Form 8b ($\alpha = 0.97$) will be used.[42,43] The perceptions of provider-patient communication will be measured with the Medical Communication Competence Scale ($\alpha = 0.88$) to further understand information exchange and communication with healthcare provider.[44]

Qualitative Assessment and Analysis

We will conduct in-depth qualitative interviews with a random sample of 40 participants (20 from OPTIMA-BP and 20 from Waitlist control groups). A semi-structured interview guide will be used to elicit information about African

American older adults' experiences with self-managing hypertension. In addition, the interviews will query the participants about barriers and motivators to adherence, problems they experienced, advice from family and friends, perception of one's patient-provider interaction and communication, and their experience with the OPTIMA-BP intervention and using technology to support adherence to antihypertensives medication-taking and BP control. Interviews will be conducted at baseline and 6 months.[45]

Statistical Methods

Descriptive statistics will be used to summarize all measured variables. Continuous outcome variables will be summarized using mean, standard deviation, median, and interquartile range. Continuous and categorical covariates and confounders will be summarized using descriptive statistics, frequency analysis, cross tabulations, sample count and percentage of subjects in each category. The pattern of missing data will be examined to determine whether missing values are random or systematic omissions. The distributions of all outcome variables (primary and secondary) will be examined and necessary transformations (eg, Box-Cox transformation) will be used to achieve normality with results back transformed for ease of interpretation. Pearson's Correlation will be used to examine the relationships among study variables. For this confirmatory study, a significance level of 5% will be used for all hypothesis tests and Bonferroni correction method will be used for multiple hypothesis testing.

Aim 1

The primary objective of Aim 1 is to determine the extent to which participants in the OPTIMA-BP intervention will have a reduction in blood pressure and improvement in quality of life, compared with those randomized to the control group. For measuring the efficacy of OPTIMA-BP, we will formulate a general semiparametric linear mixed effects model. The model includes splines for capturing nonlinear responses over the study period. The outcome variables will be measured at 5 time points during the 12-month period.

Aim 2

Our goal is to identify indirect effects of the self-management process when we are measuring efficacy of intervention on the primary outcome of interest (Aim 1). Because of the complicated waitlist nature of the design, we will evaluate the influence of the self-management process on the effects of OPTIMA-BP to the health outcomes, cross-sectional (baseline, 3 and 6 months) and longitudinal settings. We will build a multiple linear regression predicting the effect of self-management variables on health outcomes by adding a mediator (self-efficacy) as a covariate while controlling for other important covariates.

Results

In this study, we describe the protocol of an ongoing efficacy study testing technology-based interventions (OPTIMA-BP) compared with a waitlisted control group in a prospective, RCT in African American older adults with hypertension. This study is funded by the National Institutes of Health (NIH), National Institute of Nursing Research (NINR). Enrollment began in March 2022 and some delays have been due to readjusting for COVID-19. Enrollment is planned until May 2026. This study aims to enroll 208 African American older adults with hypertension, randomly assigned to OPTIMA-BP (n = 104) and the Waitlist control group (n = 104). We will report preliminary result in 2025.

Discussion

African American older adults with uncontrolled BP are at high risk for hypertension-related adverse events, in part, due to suboptimal self-management.[2,12] Importantly, older adults account for 15% of the US population, and two-thirds of older adults over age 60 have hypertension with African American older adults having a disproportionate burden.[46] Thus, strategies to support self-management of hypertension and BP control are crucial as the older population is projected to age substantially and become more racially and ethnically diverse.

The novel aspects of this research include: 1) the inclusion of African American older adults; 2) the investigation is informed by Individual and Self-Management Theory (ISMT), a conceptual model that may help explain salient experimental

elements;[25] 3) the integration of a technology-based intervention (TBI) with a medication management app (Medisafe) to support and sustain hypertension self-management in African American older adults; 4) standardization of medication management is required to isolate the effect of behavioral interventions on changes in BP; and 5) an external element of connectivity between the patient and provider to improve communication, adherence to treatment, and self-management.

The implications of digital health interventions, that is, web-based education,[47] home BP monitoring,[48] and personalized mobile short message service (SMS),[49–51] on chronic disease prevention and management has the potential to improve BP control and enhance secondary CVD prevention in this high-risk group. By examining the mechanism by which the OPTIMA-BP intervention exerts its effect on self-managing hypertension, our study will advance both behavioral and self-management science. Specifically, the TBI is postulated to promote engagement in self-regulation behaviors through behavioral prompting, monitoring, and feedback for medication-taking of antihypertensives (thus enhancing self-efficacy and leading to engagement in self-management behaviors). Being able to provide the TBI approach using a waitlist format provides an opportunity for all participants to eventually receive the TBI intervention. By extending the observation period to 12 months, we will see if TBI-OPTIMA BP effects are sustained over time and its impact on health outcomes. In addition, the extended observational period will also facilitate a finer-grained evaluation of contextual, process and outcomes factors over time.

Conclusion

In summary, the impact of this work has the potential to advance behavioral and self-management science by leveraging OPTIMA-BP to facilitate and sustain self-management behaviors, as well as improve patient-provider communication and BP control in African American older adults with hypertension. The potential implication of this intervention is a practical and generalizable approach suitable for implementation in primary care or community settings and has the potential to reverse the unacceptably high morbidity seen in African American older adults due to hypertension-related complications.

Abbreviations

App, application; BP, blood pressure; CVD, cardiovascular disease; HDL, high-density lipoprotein cholesterol (HDL); HRQOL, health-related quality of life; ID, identification; IFSMT, Individual and Family Self-Management Theory; mmHg, millimeters of mercury; Mo-HTAM, Mobile Health Technology Acceptance Model; OPTIMA-BP, OPtimizing Technology to Improve Medication Adherence and BP Control; PI, Principal Investigator; RCT, randomized controlled trial; TBI, technology-based intervention.

Data Sharing Statement

Data sharing is not applicable to this study, as no new data were created or analyzed.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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