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CLINICAL TRIAL REPORT

A Community and Technology-Based Approach for Hypertension Self-Management (COACHMAN) to Improve Blood Pressure Control in African Americans: Results from a Pilot Study

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Purpose: Adoption of technology has increased to support self-managing chronic diseases. However, behavioral interventions evaluating such technology have been understudied in African Americans with hypertension. The aim of this study was to explore a community and technology-based intervention for hypertension self-management (COACHMAN) intervention on blood pressure (BP) control and health-related quality of life (HRQoL) in African Americans with hypertension.

Methods: Sixty African Americans (mean age 60; 75% females) who were prescribed anti-hypertensive medications and owning a smartphone were randomized to the COACHMAN (n = 30) or enhanced usual care (n = 30) group for 12 weeks. COACHMAN is comprised of four components: web-based education, home BP monitoring, medication management application, and nurse counseling. Hypertension knowledge, self-efficacy, technology adoption/use, medication adherence, BP, and HRQoL scores were assessed.

Results: Mean systolic and diastolic BP at baseline was 150.49 (SD = 13.89) and 86.80 (SD = 13.39), respectively. After completing the 3-month intervention to improve hypertension self-management, the groups did not significantly differ in BP control and HRQoL. Clinically relevant BP reduction was observed in the intervention group. Paired *t*-test showed that mean medication-taking adherence scores significantly improved in the intervention group ($P = 0.023$) compared to the control group ($P = 0.075$).

Conclusion: Using technology may have a positive impact on supporting hypertension self-management, particularly in medication-taking adherence. Further research is warranted in a larger sample and should include standardization of medication management to isolate the effects of behavioral interventions on changes in BP.

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Keywords: African Americans, hypertension, minority health, technology, self-management

Introduction

Hypertension is the most common, modifiable risk factor for cardiovascular disease, with nearly one in two US adults aged 20 years and older (108 million) estimated to suffer from this condition.[1,2] As the current US hypertension guideline now recommends a blood pressure (BP) target of less than 130/80 mmHg,[1,3] more adults are faced with the challenge of managing this chronic disease. Rates of hypertension are disproportionately observed in non-Hispanic African Americans

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(54%) when compared to non-Hispanic Whites (46%), Asian adults (39%), or Hispanic adults (36%).[1,2] More alarming is that less than half of US adults have their hypertension under control (48.3%), and these rates are lower among African Americans. Research has well-documented the negative effects of poorly controlled BP on well-being and health outcomes.[4–6] In addition, uncontrolled BP is a primary and contributing cause of concomitant morbidity and increase mortality rates,[4,5] and has been estimated to cost the healthcare system $131 billion each year.[2,4]

Self-managing hypertension requires individuals to engage in lifestyle behavioral changes including eating a balanced diet, performing regular physical activity, self-monitoring BP, and most important, adhering to antihypertensive medication.[1] However, effectively controlling BP remains a challenge and growing concern, despite advances in pharmacotherapy for hypertension.[6] Suboptimal adherence to medication-taking occurs in 43–78% of patients prescribed antihypertensive therapy,[7] with 50% discontinuing their medications after 1 year,[8] and notably, a trend more prevalent in African Americans.[9] Strong evidence suggests that suboptimal/poor adherence to antihypertensive therapy is multifactorial and associated with socioeconomic factors, the healthcare system/team (provider–patient interaction), prescribed treatment regimen (dose, frequency, drug efficacy, side effects), and patient factors (low self-efficacy, social support).[3,6,7,10] Furthermore, uncontrolled hypertension is associated with the disproportionately high burden and progressively worse health outcomes of stroke, heart disease, end-stage renal disease, and quality of life in African Americans with hypertension.[4,11]

Hypertension Self-Management with Technology

Previous behavioral interventions have attempted to improve hypertension outcomes by implementing educational interventions targeted at increasing ones' knowledge about hypertension to influence positive health behavioral change.[12] Owing to the fact that educational interventions do not translate to large BP reductions, greater efforts are needed to support self-managing hypertension, including medication-taking adherence, especially in African Americans.[13] Over the last decade, the rapid development and adoption of technology such as mHealth tools (e.g. smartphones, mobile applications

[apps]), patient monitoring devices, and other wireless devices have increased to support self-managing chronic disease,[14–17] including cardiovascular disease (CVD).[18–21] Data has also shown there has been an uptake in technology use among African Americans in terms of technology ownership (smartphones, tablets, laptops), as well as their increased access to the internet.[22,23] However, comprehensive reviews have demonstrated that African Americans are underrepresented in technology research to improve health.[14,24,25] Among those studies that have investigated technology and mHealth for improving hypertension self-management, the results are inconsistent, primarily conducted outside of the US, often lacking a theoretical framework, and limited in their generalizability to diverse populations.[14,26] Given that the current evidence is sparse for the efficacy of mHealth and technology-supported behavioral health interventions in African American adults with hypertension,[24] efforts are needed to develop behavioral interventions that incorporate technology to support and sustain self-managing hypertension.[6,22,23]

Based on the identified gaps in the literature, our study is guided by the Ryan and Swain's Individual and Family Self-Management Theory (IFSMT)[27] to offer a systematic approach and scientific basis for studying the factors and relationships that contribute to self-managing a chronic disease such as hypertension in African Americans using technology. The IFSMT suggests that self-management takes place through a process, where patient-centered interventions are directed at increasing knowledge and skills, as well as self-regulation skills and abilities, while taking into account the presence of contextual factors specific to the individual, their health condition, and their physical and social environment. It is through the self-management process that individuals improve their health behaviors and, in turn, achieved positive health outcomes and quality of life.[27] The IFSMT has been tested for effectiveness and applied to a variety of chronic health conditions across diverse populations.[28,29] Therefore, we use the IFSMT as a framework to engage African Americans with hypertension in health-promoting behaviors using a technology-based intervention to support self-managing hypertension to improve BP and health-related quality of life (HRQoL).[25]

Furthermore, we used the principles of community-based participatory research (CBPR) to design and conduct this study in two phases (the design and planning phase and the implementation phase) with community–

provider partnerships that included the local Center for Reducing Health Disparities, the American Heart Association, and the Cleveland Council of Black Nurses (CCBN). Herein, we report the findings of the implementation phase. Therefore, the purpose of this study was to test the effectiveness of a technology-based intervention in improving BP control and HRQoL in African Americans with hypertension. Our primary hypothesis for this study was that individuals assigned to the intervention group would have better BP control and improved HRQoL, a subsequent result from improving their adherence to antihypertensive medication-taking compared to those individuals assigned to the EUC control group.

Materials and Methods
Study Design
The COACHMAN Study (A COmmunity and Tech-Based ApproaCh for Hypertension Self-MANagement) is a CBPR study utilizing a pilot randomized controlled trial design.[25] This research protocol was approved by the University Hospitals Cleveland Medical Center's (UHCMC) Institutional Review Board. All study participants provided written informed consent prior to study enrollment.

Study Setting and Participants
Participants were recruited from the hospital and affiliated community clinics at UHCMC, as well as from community outreach and engagements using various recruitment methods.[30–32] Participants were eligible for this study if they (1) self-identified as African American, (2) were 30 years of age or older, (3) had been diagnosed with hypertension (BP >140/90 mmHg) and prescribed an antihypertensive drug, (4) were able to read/understand English, and (5) owned a smartphone. Individuals were excluded if they had a history of cognitive impairment or recent hospitalization or emergency department visit related to hypertension. We screen 109 potential participants via phone to determine initial eligibility. Sixty participants meeting the inclusion criteria completed the screening visit and were enrolled. Given that this is a preliminary pilot trial, the sample size was conservatively selected to establish an appropriate sample size for a planned larger clinical trial.[33]

Procedures
Participants who met study requirements were invited to schedule a screening visit to further determine their eligibility, provide informed consent, and obtain an initial BP. Eligible participants were scheduled within 7 days for baseline visits with a trained research assistant (RA). At the baseline visit, data were collected on anthropometric measurements (height, weight, body mass index [BMI]), BP, and blood chemistries. After participants completed a series of study questionnaires, they were randomly assigned using a computer-number generator for a 1:1 allocation to the intervention or control group. Participants randomized to the intervention receive one-on-one training on how to use the technology-based components of the intervention. Details about the study conditions are described below. Data were collected at baseline, 8 weeks, and 12 weeks and each visit took approximately 1.5 hours to complete. The COACHMAN study rationale and design has been previously reported.[25]

Intervention Group
The COACHMAN intervention is a 12-week intervention that consisted of three technology components and nurse counseling (Table 1) to support self-managing hypertension in African Americans.[25] The first component, web-based education modules, focused on improving one's knowledge, skills, and attitudes about hypertension management based on the literature and recommendations and resources from the local American Heart Association, the Centers for Disease Control and Prevention, and community partners.[25] Each education module was approximately 7–10 minutes in duration and was delivered weekly for 6 weeks, accessible on a standard web browser compatible with an average household or library computer or mobile device.

The second component consisted of self-monitoring BP with a study provided, automatic home BP device (Omron Series 10). Participants received instructions and training on how to self-monitor their BP, and were asked to monitor their BP twice a day (morning and evening), on two nonconsecutive days each week over a 3-month period, and then record their BP measurements on the study's tracking log. The tracking logs were verified by the research assistant at each visit with data stored on the study provided home BP monitor.

The third component consisted of using a commercially free medication management app, Medisafe (www.Medisafe.com). This app operates on Android and iOS phone systems, and provides personalized medication adherence support. For example, key features of Medisafe include its ability to provide SMS

Table 1 COACHMAN Intervention Components

Intervention Component	Duration	Content	
1. Web-based hypertension education	Six weekly module, <10 minutes in duration	Delivers knowledge about hypertension, including managing the disease, monitoring blood pressure, medication adherence via a web-based module	
		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
2. Self-monitoring blood pressure (BP)	12 weeks	Participants instructed to monitor and record blood pressure two non-consecutive days/week, twice a day, for a total of 12 weeks with an Omron 10 Series home BP monitor, provided by study.	
3. Medication management support	12 weeks	1. Participants were instructed and trained to use the Medisafe medication management application on their smartphone to support medication adherence. 2. Participants were provided daily medication reminders and updates about their antihypertensive medication over the 12-week study period.	
4. Nurse counseling sessions	30 minutes phone sessions	Participants received up to four counseling sessions with a research nurse to support self-managing hypertension over 12 weeks.	

reminder messages/alerts of when to take medication, generate weekly adherence reports, input and monitor biometric data (e.g. BP and glucose), and provide updates on selected health information, medications, and lifestyle tips. During the baseline visit, study participants received support from the research assistant with downloading the Medisafe app, followed by a 20-minute training session on how to use the app, including adding information on each prescribed antihypertensive medication to the app. Study participants were asked to use the app for 12 weeks for medication-taking adherence support.

The fourth component consisted of nurse counseling sessions with registered nurses from the CCBN (community partner and local chapter of the National Black Nurses Association). Similar to community health workers, CCBN nurses serve as a bridge between underserved communities and their healthcare needs, and engaged the study participants by delivering heart health education and skill-building strategies to improve their HRQoL.[34–,37] Guided by culturally appropriate educational materials in "On the Move to Better Heart Health for African Americans" (developed by the National Institutes of Health, National Heart, Lung, and Blood Institute), the nurses provided 3–4 sessions of informal counseling focused on discussing medication adherence and BP monitoring BP, and other topics guided by the participant.

Control Group

In addition to standard care, the EUC control group received printed educational materials on managing hypertension and access to one web-based education session on self-monitoring BP. Study participants were also given a home BP monitor (Omron 10 Series) and trained by the research assistant to properly use the device. However, participants in the control group were not required to monitor their BP.

Measures
Demographic and Hypertension Characteristics

Data on demographic and hypertension characteristics were assessed at baseline. Demographics included age, gender, income, education, and marital status, while hypertension-related characteristics included years diagnosed

with hypertension, history of smoking, comorbidities, and number and type of antihypertensive medications. In addition, we collected clinical data pertinent to CVD risk and relevant to hypertension management, such body mass index (BMI), and high-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol at baseline and 12 weeks.

Blood Pressure Change

At each clinic visit (baseline, 8 weeks, and 12 weeks), BP was measured by trained staff at the UHCMC Dahms Clinical Research Unit with an automated device (Omron HEM-907XL, Omron Healthcare, Inc., Bannockburn, IL) that was calibrated according to manufacturer's specifications. Using standardized procedures,[38] including the appropriately sized cuff and technique, BP readings were taken after a 5-minute rest,[1] and the average of three BP readings was recorded at each visit. As noted, our primary outcome was change in BP from baseline to 12 weeks, in which the 12 weeks mean systolic/diastolic BP minus the baseline mean systolic/diastolic BP was calculated for a mean change score. A secondary goal of this study was to achieve lower BP targets (BP < 130/80 mmHg) as recommended by the American College of Cardiology/ American Heart Association (ACC/AHA) 2017 hypertension guideline in at least 65% of those individuals assigned to the intervention group.[1]

Health-Related Quality of Life

HRQoL, another primary outcome for this study, was measured using the Patient-Reported Outcomes Measurement Information System (PROMIS) Global-10 at baseline and 12 weeks.[39] The PROMIS Global-10 is a 10-item questionnaire that assesses the general quality of life (QOL) divided into two domains—physical and mental health. Each domain's scores are derived using T-score normal population distribution mean ± standard deviation (SD) of 50 ± 10, where higher scores indicate better health.[40] The PROMIS Global-10 has been tested in diverse populations with various chronic diseases and is a valid and reliable measure (α = 0.82).[40]

Medication Adherence

The performance and self-report of adherence to hypertension treatment was measured with the Hill-Bone Compliance to High Blood Pressure Therapy Scale.[41] The Hill-Bone Scale consists of 14 items on a 4-point Likert-type scale that assesses three domains of hypertension management (mediation-taking, diet, appointment keeping). In this study, we examined the medication-taking subscale scores, which consisted of nine items on a 4-point Likert-type scale (responses range 1 to 4) with lower scores indicating better medication-taking adherence behaviors (α = 0.71 and 0.75).[41,42] Additionally, we examined adherence to medication-taking of individuals assigned to the intervention group with the Medisafe app, where individuals responded (skipped, snoozed, or taken) to medication reminders for prescribed antihypertensives. We further classified responses based on adherence reports provided by Medisafe as non-responders (<80% use) or responders (>80% use).

Self-Management Process

To examine the self-management process, we assessed hypertension knowledge and awareness using the Hypertension Knowledge-Level Scale (HK-LS).[43] The HK-LS is a 22-item interval scale that measures six domains (medical treatment, drug compliance, lifestyle, diet, and complications) of hypertension, and has good reliability (α = 0.82).[43] Total possible points on the HK-LS is 22, with higher scores indicating higher levels of hypertension knowledge. Another component of the self-management process assessed in this study was self-efficacy, measured on the Self-Efficacy for Managing Chronic Disease Scale.[44] This is a 6-item rating scale used to assess one's confidence in performing activities to self-manage a chronic condition and has been validated in various chronic diseases, including hypertensive patients (α = 0.91).[44] Scores ranged from 1 to 10, with higher scores indicating greater self-efficacy to manage a chronic disease.[44] Lastly, we assessed the process of engaging with and the adoption of technology using two valid and reliable measures, the System Usability Scale (SUS; α = 0.91), a 10-item questionnaire used to measure a global view of mHealth app usability,[45,46] and the Mobile App Rating Scale (MARS; α = 0.91).[47]

Contextual Factors

Known to contribute to hypertension self-management and health outcomes, contextual factors were assessed and included social support, spirituality, and depression. Perceived social support was measured on the 7-item Duke Subjective Social Support Index (DSSI; α = 0.71), for a total score of 14, with higher scores indicating greater perceived social support.[48] Spiritualty was measured on the 16-item Daily Spiritual Experience Scale

(DSES) to assess an individual's perception of the transcendent in daily life.[49] The DSES has demonstrated good reliability (α = 0.90) in various patient populations, with lower scores representing a higher daily spiritual experience.[49] Depression was measured with the 8-item PROMIS Emotional Distress Short Form, which has demonstrated adequate reliability.[40] Scores on this scale range from 8 to 40, with higher scores indicating higher levels of depression.[40]

Analysis Plan

Descriptive statistics were used to examine the distribution of study variables by group. Categorical variables were summarized using frequencies and percentages, while continuous variables were summarized by means and standard deviations. Groups were compared for equivalence in baseline characteristics after normality was verified using Chi-square for categorical data and independent two-sample t-test or the Wilcoxon rank-sum test for continuous data. A paired t-test was used to examine group differences between study measures at baseline and 12 weeks.

To compare changes in systolic and diastolic BP, HRQoL, and scores on other study measures between the intervention and the control groups, a repeated measures linear model with first-order autoregressive covariance structure with SAS Proc Mixed was used to assess mean differences across three points over a 3-month period. Time (baseline, 8 weeks, and 12-week follow-up) served as the level of responses for the within-subjects factor, while the study group (intervention vs control) served as the between-subjects factor to examine the interaction of time x group.[50] All statistical analysis was performed using SAS 14.1 software (Cary, NC), and p-values <0.05 were considered statistically significant.

Results

We enrolled 60 individuals; half were randomized to the intervention group (COACHMAN), and half were randomized to the EUC control group. The mean age of all participants was 59.48 ± 8.89 (range, 37–79 years). The majority of the sample were women (75%, n = 45) and had approximately 14.61 (± 3.34) years of education. About 68.3% of the participants were single and 48.3% reported being employed. Most of the sample had been diagnosed with hypertension for 17.35 ± 9.73 years, prescribed 1.90 (± 0.95) antihypertensive medications, and reported living with three or more chronic conditions. Table 2 summarizes the demographic characteristics of the sample stratified by

study conditions. There were no significant differences in demographic characteristics between the control and intervention groups. The groups did not differ in terms of their clinical factors and hypertension-related characteristics (Table 3). No significant differences were found between the contextual factors—social support, spirituality, and depression between the intervention group and control group.

Table 4 shows the self-management process, health behaviors, and study outcomes for both study groups. After completing a 3-month technology-based intervention to improve hypertension self-management, the study participants in the intervention group did not show a statistically significant reduction in systolic and diastolic BP from baseline to 12 weeks when compared to the control group. However, the control group had a nonsignificant 2.17 mmHg decrease in systolic BP. In terms of HRQoL, the groups did not differ in their mental and physical health at the end of 12 weeks. The intervention group showed a greater reduction in LDL cholesterol when compared to the control; however, this difference was not statistically significant ($P = 0.065$).

Table 4 shows a paired t-test analysis for study variables, outcomes, and clinical characteristics stratified by study groups. The mean medication-taking adherence score significantly improved in the intervention group between baseline and 3 months, $t(28) = 2.41$ (95% confidence interval [CI]: 0.09, 2.36), $P = 0.023$ compared to those in the control group, $t(28) = 1.85$ (95% CI: −0.158, 3.05), $P = 0.075$. Sixty-two percent (n = 18) of the intervention group participants demonstrated >80% use of the Medisafe app, responding to taking medication dose as prescribed.

Table 5 presents the unadjusted and adjusted repeated measures analyses of the intervention effects on systolic and diastolic BP, HRQoL, and medication adherence. Results showed that there were no statistically significant between-groups or within-groups effects for study outcomes—systolic and diastolic BP and HRQoL. However, there was a statistically significant within-groups effect for antihypertension medication adherence ($P = 0.006$), indicating the intervention had a moderate effect on increasing antihypertension medication-taking adherence.

Discussion

The purpose of this study was to examine the effectiveness of a community and technology-based approach to support self-management of hypertension and improve BP control in African Americans with hypertension. Study

Table 2 Baseline Sociodemographic Variables of the Sample Stratified by Study Conditions

Characteristics	Control Group (n = 30)	Intervention Group (n = 30)	χ^2/t	p
Age in years, mean ± SD)	58.97 ± 8.37	60.0 ± 9.49	−0.45	0.656
Young (<49), n (%)	4 (13.3)	4 (13.3)	0.746	0.770
Middle (50–64), n (%)	18 (60.0)	15 (50.0)		
Older (65 or above), n (%)	8 (26.7)	11 (36.7)		
Gender n (%)			2.22	0.136
Males	5 (16.67)	10 (33.33)		
Females	25 (83.3)	20 (66.7)		
Education in years, mean ± SD	14.70 ± 3.36	14.52 ± 3.38	0.211	0.834
Marital Status, n (%)			6.653	0.248
Single	22 (73.33)	19 (63.33)		
Married	8 (26.7)	11 (36.7)		
Employment			−0.766	0.45
Unemployed	14 (46.7)	17 (56.7)		
Employed	16 (53.3)	13 (43.3)		
Income			−0.562	0.576
<$20,000	8 (26.7)	8 (26.7)		
$20,000–$59,999	11 (36.7)	9 (30.0)		
>$60,000	11 (36.7)	13 (43.3)		

Notes: Values are expressed as either n (%) or mean ± SD. The P-value are for χ^2 and independent two-sample t-test.

Table 3 Hypertension-Related Characteristics

Characteristics	Control Group (n = 30)	Intervention Group (n = 30)	$\chi^2/t/W$	P value
Years diagnosis with hypertension, mean ± SD	15.71 ± 10.34	17.00 ± 9.20	−0.512	0.611
No. of chronic diseases, mean ± SD	3.30 ± 2.15	3.93 ± 2.03	−1.172	0.246
No. of BP medications prescribed, mean ± SD	1.80 ± 1.00	2.00 ± 0.91	−0.812	0.42
Class of BP Medications, n (%)				
Diuretic treatment	13 (43.3)	17 (56.7)	1.067	0.302
ACE inhibitor treatment	7 (23.3)	7 (23.3)	0.00	1.00
Angiotensin receptor blocker treatment	11 (36.7)	7 (23.3)	1.270	0.26
Calcium channel blocker treatment	10 (33.3)	15 (50.0)	1.74	0.19
Beta blocker treatment	7 (23.3)	10 (33.3)	0.739	0.390
Smoker, n (%)	7 (23.3)	13 (43.3)	2.70	0.10
BP at Screening visit, mean ± SD				
Screening Systolic BP	152.20 ± 12.19	156.67 ± 90.53	−1.140	0.259
Screening Diastolic BP	88.07 ± 13.02	90.53 ± 14.66	−0.689	0.494

Notes: Values are expressed as either n (%) or mean ± SD. The P-value are for χ^2 and independent two-sample t-test or Wilcoxon rank-sum test.

participants in the intervention group used three technology-based components—hypertension web-based education, a medication management app (Medisafe), and a home BP monitor, in addition to nurse counseling, to improve BP and medication adherence. Our results demonstrated that among African Americans with hypertension, the intervention did not significantly improve BP and HRQoL. Although our study hypothesis that individuals in the intervention group would have improved BP control and HRQoL compared to those in the control group was not supported, we found that individuals in the intervention group did significantly improve their antihypertensive medication-taking adherence over a 3-month period compared to the control group. Our findings are

Table 4 Study Variables, Outcomes, and Clinical Characteristics Stratified by Study Condition

Variables	Control Group (n = 30)					Intervention Group (n = 30)				
	Baseline		12 Weeks		P value	Baseline		12 Weeks		P value
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Health outcomes										
Systolic BP, mmHg	141.24	16.92	139.07	16.41	0.55	138.51	14.77	139.06	16.54	0.87
Diastolic BP, mmHg	85.28	12.61	84.24	12.06	0.63	81.97	13.45	81.17	11.45	0.67
Physical health, HRQoL	14.28	2.68	14.17	2.59	0.72	14.52	2.85	14.41	3.01	0.76
Mental health, HRQoL	13.38	2.46	13.72	3.39	0.26	13.83	2.83	13.83	3.13	1.00
Clinical characteristics										
Pulse	70.96	11.54	72.71	12.40	0.43	68.13	13.79	73.17	12.39	0.009
Weight, lbs	217.73	47.84	220.21	49.26	0.003	210.15	52.27	211.30	53.12	0.259
Body mass index, kg/m2	35.16	7.60	35.53	7.84	0.005	35.03	8.07	34.73	8.31	0.578
HDL cholesterol, mg/dL	51.75	12.09	52.78	12.53	0.45	53.39	15.09	51.36	15.48	0.060
LDL cholesterol, mg/dL	111.96	32.66	107.54	36.19	0.43	113.08	35.85	105.00	29.35	0.061
Behavioral outcomes										
Medication adherence	13.38	6.09	11.93	4.43	0.075	12.00	3.43	10.72	2.20	0.023
Self-management process										
Hypertension knowledge	17.93	3.05	18.72	2.27	0.14	19.07	1.69	19.38	1.25	0.38
Self-efficacy	41.65	15.24	45.48	13.92	0.09	46.34	11.24	46.62	10.07	0.88
Contextual factors										
Social support	11.90	2.57	11.79	2.47	0.80	12.34	2.00	12.03	2.47	0.37
Spirituality	33.03	10.64	31.21	9.69	0.53	32.00	14.06	33.69	14.52	0.23
Depression	12.45	4.47	12.17	4.61	0.61	13.03	5.78	13.63	5.26	0.17

Note: P-values from paired *t*-test.
Abbreviations: BP, blood pressure; HRQoL, health-related quality of life.

Table 5 Unadjusted and Adjusted Model of Repeated Measures for Within- and Between-Group Effects of Study Outcomes

Variables		Unadjusted Model			Adjusted Model[a]		
		df	F	P	df	F	P
Systolic BP	Time	2	0.03	0.9659	2	0.04	0.9639
	Study group	1	0.15	0.7036	1	0.03	0.8661
	Interaction[b]	2	0.12	0.8911	2	0.12	0.8903
Diastolic BP	Time	2	0.19	0.8305	2	0.19	0.8260
	Study group	1	1.84	0.1800	1	1.10	0.2979
	Interaction[b]	2	0.41	0.6650	2	0.40	0.6708
Physical health, HRQoL	Time	1	0.22	0.6392	1	0.21	0.6475
	Study group	1	0.09	0.7643	1	0.09	0.7606
	Interaction[b]	1	0.00	0.9860	1	0.00	0.9867
Mental health, HRQoL	Time	1	0.76	0.3862	1	0.78	0.3807
	Study group	1	0.10	0.7542	1	0.04	0.8513
	Interaction[b]	1	0.65	0.4227	1	0.66	0.4214
Medication adherence	Time	2	4.52	0.0130*	2	4.51	0.0131*
	Study group	1	1.80	0.1848	1	1.37	0.2461
	Interaction[b]	2	0.04	0.9564	2	0.05	0.9557

Notes: *P value < 0.05. [a]Adjusted for age, gender and years of hypertension. [b]Study group x time interaction.
Abbreviations: BP, blood pressure; HRQoL, health-related quality of life.

similar to studies aiming to improve BP control and medication adherence using mHealth and/or related technology.[51,52]

In terms of achieving lower BP targets (BP <130/80 mmHg) in at least 65% of those individuals assigned to the intervention group, only 22% of that group had their systolic BP controlled (<130 mmHg) compared to 21% of the control group, while diastolic BP was slightly above the recommended <80 mmHg in both groups. However, it is important to point out that 60% of the intervention group exhibited average systolic/diastolic BP reductions of 11.2 mmHg and 8.5 mmHg, respectively, over a 3-month period, indicating a clinically meaningful decrease in BP. Similarly, 52% of the control group exhibited an average systolic/diastolic BP reduction of 14.79 mmHg and 9.33 mmHg, respectively, over 12 weeks. One plausible explanation for the lack of significant differences between groups in terms of BP reduction could be partly explained by all study participants receiving a study provided home BP monitoring device that possibly increased their self-monitoring of BP. From a clinical perspective, research suggests that a ≥ 10 mmHg reduction in systolic BP is likely to reduce the incidents of stroke by 37%, coronary heart disease by 21%, and mortality from CVD by 25%.[2,53] Study findings also suggested that using technology to support self-managing hypertension is acceptable by African Americans with hypertension as two-thirds of the intervention group had 80% or greater response rate to all components, with a 90% retention rate.

Regarding clinical characteristics, paired t-tests showed a slight reduction in LDL cholesterol in both groups, with the intervention group demonstrating a nonsignificant 8.08 mg/dL point reduction compared to 4.41 mg/dL reduction in the control group. Epidemiological studies suggest that elevated LDL cholesterol (>100 mg/dL) is a major risk factor for atherosclerotic cardiovascular disease, and a small reduction in LDL cholesterol would reduce that risk.[54] For instance, for every 1 mg/dL (0.03 mmol/L) reduction in LDL cholesterol levels, total mortality is reduced by approximately 12%, and major vascular events are reduced by 21%.[54,55]

Furthermore, considering the underpinnings of the theoretical framework guiding this study,[27] the IFSMT model postulates that individuals who engage in self-management behaviors improve their health outcomes through the self-management process. The self-management mechanisms by which behavioral change is influenced have been extensively explored,[27] and it is through this process that knowledge and self-regulation enhance health behavior change and improves HRQoL. In this study, we explored hypertension knowledge and self-efficacy for managing a chronic condition. At baseline, we observed that both groups had moderately high levels of hypertension knowledge at baseline and 12 weeks. One explanation could be related to the fact that the participants in this study, on average, had been diagnosed and living with hypertension for approximately 16 years.

In terms of self-efficacy, both groups self-reported fair to good scores on the self-efficacy measure in terms of managing their hypertension. The intervention group reported slightly higher levels of self-efficacy from baseline to 12 weeks when compared to the control. Self-efficacy has been regarded as a significant component in adherence to managing hypertension and is associated with improving self-management activities such as medication-taking, healthy eating, and physical activity.[56] In our study, participants rated their self-efficacy somewhat fair (42 out of 60 total points), which is consistent with other studies.[56,57] Hypertension self-management encompasses a broad array of behaviors,[58] and our findings suggest that African Americans could benefit from interventions that specifically target and strengthen one's self-efficacy beyond adherence to antihypertensive medication-taking.[56,59] Despite fair self-efficacy scores, our findings demonstrated a moderate significant within-group effect for antihypertensive medication-taking adherence over a 3-month period in the intervention group. However, our findings did not reflect significant between- and within-group effects or time-by-group interaction effects for all study outcome variables. Additionally, social support, spirituality, and depression did not differ between the groups.

Control of hypertension in African Americans poses a distinct clinical challenge, as aggressive treatment is required to achieve an optimal and lower BP target.[1,60] Research suggests that treating systolic BP to achieve <130 mmHg in African Americans to improve overall BP and reduce mortality may require up to three antihypertensive medications.[1,60] For example, at study entry, approximately half of the sample was prescribed on average 1.9 antihypertensive medications, with 50% prescribed a thiazide diuretic and/or 42% were prescribed a calcium channel blocker. Compelling evidence in randomized controlled trials has demonstrated that thiazide diuretics and calcium channel blockers are superior to renin-angiotensin

inhibitors, alpha blockers, and beta blockers in lowering BP in the African American population.[1]

Despite the evidence for BP treatment,[1] our study findings of a lack of achieved BP control may be due to clinical inertia (failure to adequately prescribe antihypertensives),[61] blunted by patients achieving a previously recommended BP target of <140/90 mmHg vs the current target of <130/80 mmHg. In fact, at the beginning of this study, as the US hypertension guideline emerged, organizations such as the American College of Physicians and the American Academy of Family Physicians denounced the lower BP thresholds complicating providers' decisions to shift practice to intensify BP treatment to the lower BP threshold.[62,63] Moreover, our study collected information about prescribed antihypertensive medications only at baseline. Given the patient-centered focused of this pilot study, we did not take into account whether or not participants' followed up with their health care provider as recommended during nurse counseling sessions, or if participants' antihypertensive medications were intensified over a 3-month period. Therefore, future research should consider a medication protocol that emphasizes effective multidrug regimens in African Americans consistent with current recommendations prior to determining the effectiveness of a behavioral intervention using a technology-based intervention.

Strengths and Limitations

Research recommends lowering BP targets to <130 mmHg,[1] which requires aggressive treatment strategies that can make controlling BP a challenge. Technology-based interventions, including mHealth technology, have demonstrated improvement in the self-management of chronic conditions,[14,15] but often lack a theoretical framework and diverse participants, especially underserved African Americans with hypertension. A strength of this study is that this is the first theory-based study evaluating the effects of technology-based intervention in African Americans guided by the IFSMT framework, uniquely combined contextual factors and the self-management process to engage individuals in health behaviors to improve BP control. An important finding from this study is that self-report of adherence to antihypertensive medication-taking improved in the intervention group, despite the lack of corresponding reductions in systolic and diastolic BP. Taking these findings into account, self-management interventions that use technology alone will be insufficient to support or sustain self-managing hypertension in

African Americans without an effective treatment regimen prescribed to lower their BP.[1]

This study is not without limitations. First, it is possible that the small convenience sample, a lack of heterogeneity in terms of sociodemographic characteristics (eg gender), and the brevity of the 12-week timeframe, limited our ability to observe the full benefits of the intervention in this pilot study. Second, participants in this study had more than one chronic condition, including living with hypertension for 2–3 decades, which might require a longer intervention period, as well as a planned maintenance phase. Another possible limitation was of this study was that all participants received a study-provided BP monitor, which could have increased self-monitoring of their BP, and/or the Hawthorne effect in the control group that may have contributed to the lack of statistically significant differences in the outcomes between the two study groups.

Conclusion

In summary, technology, including mHealth, is increasingly being used to improve chronic disease management and health outcomes. Our findings suggest that behavioral interventions using technology can improve adherence to medication-taking. However, technology alone may be insufficient to support and sustain self-managing hypertension without the appropriate medication treatment being prescribed. Further research is warranted in a larger sample and should include the standardization of medication management to isolate the effects of technology-based behavioral interventions on changes in BP.

Data Sharing Statement

The Authors agree to make data and materials supporting the results or analyses presented in their paper available from CHS upon reasonable request.

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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.

Disclosure

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