



Efficacy of enhanced emergency department discharge for chronic hypertension management – Results of a randomized controlled trial

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ABSTRACT

Introduction: AchieveBP is a randomized controlled trial (RCT) of an education intervention for patients with chronic hypertension who have uncontrolled blood pressure (BP) at discharge from an urban emergency department (ED). The study examined efficacy and moderators of an educational intervention in an RCT on BP control at 180-day post-intervention.

Methods: Participants were recruited from a single, urban ED and randomized to receive or not to receive hypertension education. To minimize potential bias, participants were all started on an evidence-based anti-hypertensive regimen and medications were dispensed directly to participants by the study team. Bivariate analysis was performed to examine differences in sociodemographic characteristics between patients achieving BP control and those who did not. Paired *t*-test was used to compare the difference of systolic and diastolic BP between baseline and 180 days post-discharge. Multiple logistic regression analysis examined interaction of covariates and intervention on achieving BP control.

Results: One hundred and thirty-nine participants were randomized into the study. All were African-American with a mean age of 47.6 (SD = 10.8) years; 51% were male, 63% had smoked cigarettes and 15% had diabetes. A total of 66 patients completed the study (47.4%), 44 of whom (67%) achieved BP control. However, there was no difference in BP reduction or control between the two groups. Age and smoking status showed moderation effects on intervention efficacy.

Conclusion: Despite a neutral effect of our intervention, a high level of BP control was achieved overall, suggesting that the ED may be a viable location for efforts aimed at reducing the impact of chronic hypertension in predominantly African American communities.

1. Introduction

As a leading risk factor for cardiovascular disease, high blood pressure (BP) costs an estimated \$109.1 billion annually in health-care

expenditures [1]. An estimated 75 million adults lived with hypertension nationally in 2011–2014 [2]. Prevalence of hypertension among U. S. adults in 2017 was 45.6%, with evidence suggesting many patients with hypertension had missed opportunities for improving BP control

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[3]. African-American adults have the highest prevalence of hypertension in the United States as well as consistently lower BP control than Whites and Hispanics [4,5]. While physicians prescribe antihypertensive medications, a critical component of effective BP control rests with the individual. In one study, awareness, knowledge, and attitudes were more important than medication costs in achieving BP control [6]. Other individual factors such as chronic stress may be related to hypertension prevalence and BP control, especially for African-Americans [7].

Approximately 25% of emergency department (ED) patients nationally have hypertension and 46% of them are unaware of being hypertensive [8,9]. Studies by members of our research team indicate that subclinical hypertensive heart disease is highly prevalent (90.6%) among African-American ED patients, suggesting the ED is an appropriate and efficient entry point to identify and engage at-risk patients with uncontrolled BP [10,11].

The utilization of electronic and technology-based resources as a part of an intervention strategy has been investigated in multiple randomized controlled trials (RCTs). Members of our research team previously conducted a RCT of heart health education feasibility in a primary care clinic with 51 patients, the majority of whom were African-American. Results indicated that the multiple brief health education sessions delivered by a touch screen kiosk with an attached BP monitor resulted in statistically significant decreases in change in both systolic and diastolic BP for participants at three months [12].

2. Method

2.1. Intervention

The **AchieveBP** study was a pilot RCT for a kiosk-based education intervention for African American patients with a history of hypertension who have uncontrolled BP at ED discharge. The specific protocol for **AchieveBP** is described elsewhere [13]. The study was conducted by a multi-disciplinary team of trained emergency medicine and public health researchers in an urban health environment: an ED and a university based clinical research center (CRC). Under the supervision of a research physician, patient screening, enrollment, baseline assessment, health literacy appraisal and the first education intervention were conducted by research assistants at the ED. The research physician reviewed medication orders and provided instructions for the participant at enrollment [14]. Subsequent study visits occurred at 7-, 30-, 90-, and 180-day in the CRC located about one mile away from the recruitment site. At the beginning of each follow-up visit, the clinical research team reviewed medication side effects, conducted pill counts and provided medication refills. Graduate public health students assisted in conducting post and follow-up interviews and facilitating patient education for the intervention group. To promote retention, reminder calls and/or emails were done several days in advance and contact information was updated at each visit. Both groups were encouraged to monitor their BP on their own and follow-up with a primary care physician. Participants missing visits and not responding to up to three-reminder communications were considered lost to follow-up.

2.2. Study population

All potential enrolled patients had uncontrolled BP at discharge according to the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7) guidelines of 140/90 mmHg or greater or 130/80 mmHg or greater for diabetic patients [14]. The study was approved by the Wayne State University Medical Institutional Review Board (IRB) and is registered at <https://clinicaltrials.gov> as Registration Number NCT02069015, Registered February 19, 2014 (Retrospectively registered). The design and conduct of the study adhered to the Consolidated Standards of Reporting (CONSORT) guidelines [15].

2.3. Sample size

Based on our previous study among patients in an urban ED, the mean systolic BP was 184 ± 25 mm Hg [11]. We assumed that the mean of systolic BP would have a greater reduction for the experiment group compared to the control group. Targeting a medium effect size (i.e., $d = .5$) and a clinically significant difference in systolic BP reduction between the two groups of 6 mm Hg with a two-sided type I error of 5%, 50 participants in each arm (100 total) would provide a power ($1-\beta$) of 80%. Based on prior experience, we anticipated that 15% of those recruited in the ED would not show up at the initial 7-day follow-up visit, and that 15% of those who did show up would ultimately be lost to follow-up by 180 days. Accounting for this, we sought to recruit a total of 140 participants from the ED.

2.4. Study flow and participants

Participants' recruitment and enrollment are provided in the CONSORT diagram (Fig. 1). Using an electronic ED patient tracking board, 2822 patients were screened according to inclusion and exclusion criteria based on the protocol. One hundred and forty-one patients were enrolled and randomly allocated into intervention and control groups. Two patients did not complete the full enrollment process, thus a total of 139 patients were included in the analysis. As illustrated in the CONSORT Study Flow Chart, the total number of patients who returned for 7-, 30-, and 90-day sessions and 180-day follow-up were 89, 81, 67, and 66 respectively.

Depending on randomization, patients received either an attention-control or kiosk-based interactive patient education intervention. To control for potential medication effects, all participants were prescribed similar, evidenced-based anti-hypertensive regimens and had their prescriptions filled onsite in the ED and during visits to the CRC.

The primary target outcome for this study was BP reduction both as a continuous measure and a categorical outcome with success in achieving BP control defined as $< 140/90$ mmHg (or $< 130/80$ mmHg if diabetic), assessed at 180-day follow-up post-ED discharge. This analysis also focuses on correlates related to the primary aim of achievement of BP control.

2.5. Statistical analysis

Frequency distributions for variables of interest were calculated. A new variable of achieving BP control was coded as "Yes = 1" if the patient's BP $< 140/90$ mmHg (or $< 130/80$ mmHg if the patient was diagnosed with diabetes), otherwise it was coded as "No = 0" [16]. The proportion of patients who achieved BP control at each time point after ED discharge was calculated. Descriptive analysis for sociodemographic characteristics, risk behaviors and health conditions between control and intervention group was conducted. Age group (i.e., < 48 years old vs. ≥ 48 years old) was divided into two groups by the mean of age as the cut-off. Bivariate analysis was performed to examine the differences in sociodemographic characteristics, risk behaviors and health conditions between the group of patients with achieving BP control and the group of patients who did not achieve BP control. The differences were tested using independent samples *t*-test for continuous variables (e.g., age) and Chi-square test for categorical variables (e.g. gender). In addition, a paired *t*-test was used to compare the difference of systolic BP and diastolic BP between baseline and 180 days post-discharge. To assess whether the effect of the intervention differed across the levels of the covariates, hierarchical multiple logistic regression analyses were performed. Separate analyses were performed for each covariate. In step one of each model, the covariate and intervention were entered. In the second step, the covariate by intervention interaction was entered. The significance of the interaction term was used to determine if the effect of the intervention on BP control achievement differed across the levels of the covariate. The Hosmer-Lemeshow Goodness-of-fit statistic was used

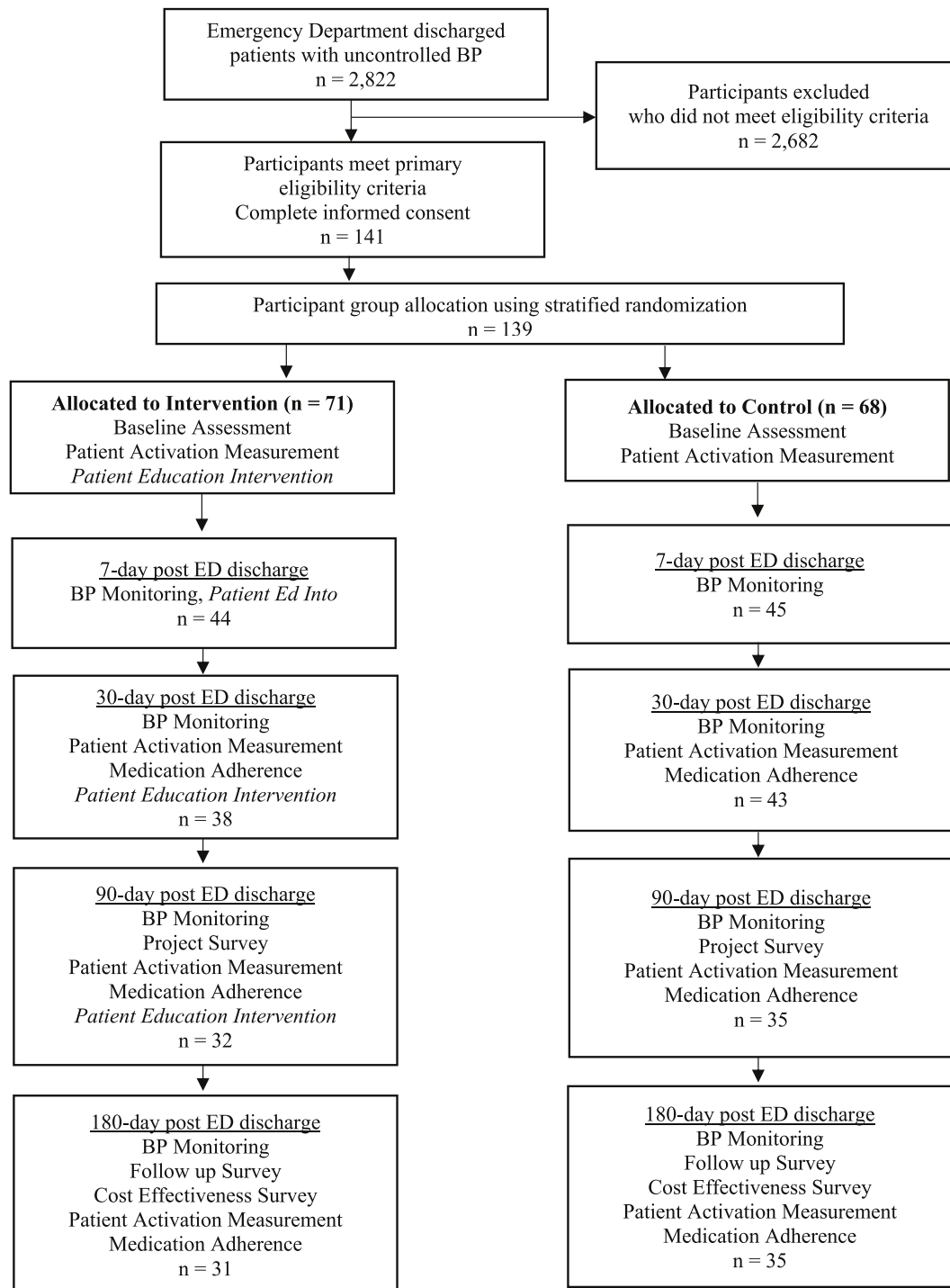


Fig. 1. CONSORT diagram for the AchieveBP study.

to assess model fit. Adjusted odds ratio (aOR) and 95% confidence interval (95% C.I.) were calculated. All statistical analysis was performed using SPSS v.25 [17].

3. Results

3.1. Patient demographics

All of the 139 patients were African American. The mean age was 47.6 years (S.D. = 10.8), 51.1% (n=71) were male and 15.1% (n = 21) reported having diabetes. Almost two-thirds (63.3%, n = 88) had

smoked at some point in their history. Fifty-five (41.4%) participants reported having family history of hypertension. The majority (85.6%, n = 119) had adequate health literacy levels. Almost half of participants were employed (48.2%, n = 67) and almost two-thirds (63.0%, n = 80) had health insurance. There was a higher proportion of patients who did not have an associate degree or higher level of education in the intervention group than in the control group ($p < 0.05$). See Table 1.

4. Outcomes

Almost a third (36%, n = 50) of patients did not return for their seven

day visit and about half did not return for their 90-day visit (52%, n = 72). At 180-day follow-up, 66 (47.5%) patients completed follow-up. Overall, patients who completed the 180-day study protocol achieved a significant reduction in systolic BP from baseline to 180-day follow-up (159 mm Hg vs. 131 mm Hg; $p < 0.001$), although the difference in the reduction between the two groups were not statistically significant (Fig. 2).

Similar findings were noted for diastolic BP (92 mmHg at baseline vs. 84 mmHg at 180-day follow-up; $p < 0.001$) with no statistically significant difference between study groups (Fig. 3).

Overall, about two-thirds (67%) of participants achieved BP control (65% in the intervention and 69% in the control group) with no difference between groups (Table 2). While a greater proportion of patients with an associate degree or higher level of education and a higher percentage of those without diabetes achieved BP control, odds ratios did not reach statistical significance.

Subgroup analyses were performed to assess whether the intervention effects varied across variables. Multiple logistic regression analysis results indicated that age group and smoking status showed moderation effects on intervention efficacy ($p < 0.05$). Please see Table 3.

5. Discussion

The **AchieveBP** study showed that achieving BP control in African American patients with hypertension recruiting from an ED clinical setting is practical and feasible, with a statistically significant reduction

Table 1
Demographics of the sample by assigned group.

Variables	Total, N (%)	Control, N (%)	Intervention, N (%)	OR (95% CI)	p
Race (African American)	139	68 (48.9)	71 (51.1)	-	-
Age, mean (SD)	47.6 (10.8)	48.0 (11.2)	47.2 (10.5)	0.869 (-2.185, 3.905) ^a	.637
Age group					
<48	67 (48.2)	35 (51.5)	32 (45.1)	1.293 (0.664, 2.518)	.499
≥48	72 (51.8)	33 (48.5)	39 (54.9)		
Gender					
Male	71 (51.1)	30 (44.1)	41 (57.7)	0.578 (0.295, 1.131)	.108
Female	68 (48.9)	38 (55.9)	30 (42.3)		
Education					
≤ HS diploma/ GED	109 (78.4)	47 (69.1)	62 (87.3)	0.325 (0.136, 0.774)	.009*
≥ Associate degree	30 (21.6)	21 (30.9)	9 (12.7)		
Smoking behavior					
Never smoke	51 (36.7)	27 (39.7)	24 (33.8)	1.290 (0.646, 2.574)	.470
Have ever smoked	88 (63.3)	41 (60.3)	47 (66.2)		
Diabetic diagnosis					
No diabetes	118 (84.9)	56 (82.4)	62 (87.3)	0.677 (0.265, 1.729)	.413
Have diabetes	21 (15.1)	12 (17.6)	9 (12.7)		

Note: SD = Standard deviation. 95% CI = 95% Confidence interval. * $p < 0.01$. HS²= High school. GED = General education development.

^a difference in means and 95% confidence interval for the difference based on Welch t-test.

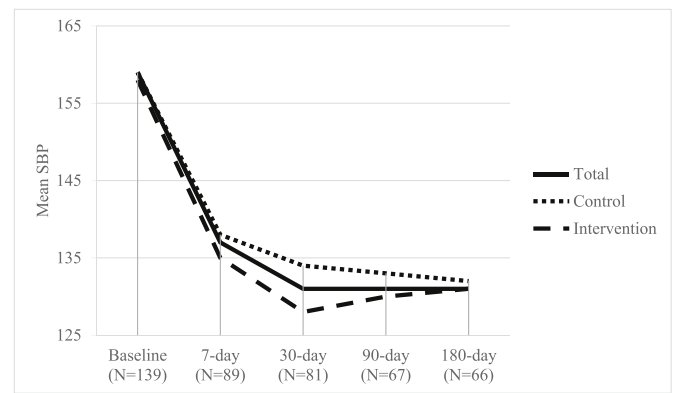


Fig. 2. Mean Systolic BP at baseline, 7, 30, 90 and 180-day post-intervention visit.

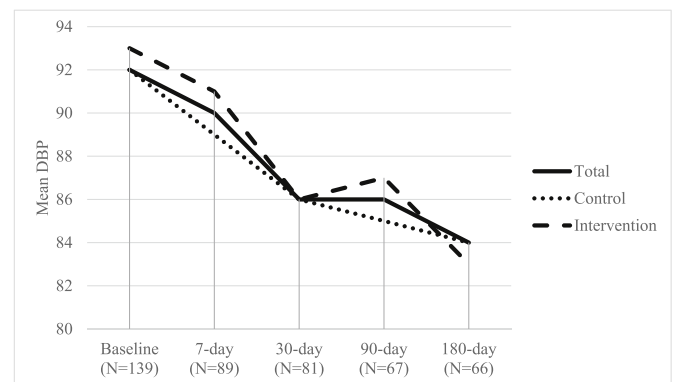


Fig. 3. Mean Diastolic BP at baseline, 7, 30, 90 and 180-day post-intervention visit.

in BP from baseline to 180-day follow-up in the overall cohort. Although results appear to show no benefit from the intervention health education modules, the indirect benefit of usual care and provision of medication may have impacted differential BP outcomes. All patients were given antihypertensive medication at the time of follow-up, were able to talk to a healthcare professional about the health consequences of uncontrolled BP and had consistent appointments, progress monitoring, and BP treatment adjustments. While this was all initiated to help isolate the effect of the kiosk-based intervention, it likely had a broader impact on BP outcomes.

Although IMB has been used in an ED RCT protocol for HIV education and risk reduction [18], **AchieveBP** may be the first to use the IMB model as a conceptual framework for an ED RCT behavioral patient education intervention for blood pressure control.

As evident from our data, post-discharge retention of study participants was a challenge, despite multiple individualized reminder communications from research staff. The largest decrease was for the 7-day follow-up visit, in which patient participation fell by 36%. Of those who did show at 7-days, 74% attended their the final 180-day follow-up. While we did show an overall reduction in BP at 180-days, patients who completed follow-up may have been more likely to achieve control, for whatever reasons, than those who did not. Insufficient research funds were available to conduct follow-up beyond up to three appointment reminders for each patient visit. A potential positive factor for patient dropout could be concern about their hypertension and a subsequent visit to a primary care provider. A potential negative factor regarding patients who dropped out at the seven day visit could be their perception of the short time-frame and logistical (e.g., work schedule or family support) or economic (e.g., transportation) inconvenience. Further study is warranted to assess both potential positive and negative factors

Table 2
Association between factors and achieving SBP/DBP control at 180-day post-discharge.

Variables	Total of Sample (N)	Achieved SBP/DBP goal n (%)	OR (95% CI)	p
Race				
African American	66	44 (66.7)	–	–
Intervention	31	20 (64.5)	0.83(0.30, 2.32)	0.727
Control	35	24 (68.6)		
Age group				
≥48	40	26 (65.0)	0.83(0.29, 2.37)	0.722
<48	26	18 (69.2)		
Gender				
Female	28	18 (64.3)	0.83(0.30, 2.33)	0.725
Male	38	26 (68.4)		
Education				
≥ Associate degree	14	11 (78.6)	2.11(0.50, 9.77)	0.354 ^a
≤ HS diploma/ GED diploma	52	33 (63.5)		
Smoking behavior				
Have ever smoked	41	28 (68.3)	1.21(0.43, 3.46)	0.720
Never smoked	25	16 (64.0)		
Diabetic diagnosis				
Have diabetes	12	6 (50.0)	0.42(0.10, 1.71)	0.193 ^a
No diabetes	54	38 (70.4)		

Note: SD=Standard deviation. CI = Confidence Interval. OR = Odds Ratio. HS = High school. GED = General education development. BP=Blood pressure. SBP=Systolic blood pressure. DBP = Diastolic blood pressure. HTN=Hypertension. Achieving SBP/DBP Control = SBP/DBP <140/90 mm Hg or <130/80 mm Hg if patients are with diabetics.

^a Fisher's Exact Test and exact 95% CI.

for retention of study participants.

Limitations

A major study limitation is that, despite up to three reminder phone calls for each visit, the study had low retention rates. Almost a third of patients did not return for their first visit at seven days, and over half did not return for their 180-day follow-up visit. Because there was a high percentage of missing data (>10%) for variables of interest (e.g., SBP and DBP measures at follow-up), missing data were replaced using the multiple imputation method in SPSS. We assumed our data were missing completely at random. Variables of interest were selected in the imputation model. The differences of SDB/DBP at baseline and SDP/DBP at follow-up between the intervention and control, or between the results data and imputation data, did not show statistical significance ($p < 0.05$).

While we projected a groupwise difference of 6 mmHg, we did not achieve this as both groups reduced BP to significant degrees. As a result, our final sample size was underpowered to detect a statistical difference in BP between groups, and findings are subject to an increased margin of error [19]. In addition, both intervention and control group patients used the interactive touch-screen kiosk to self-administer patient activation and medication adherence surveys. After completing those surveys, the intervention group used the same kiosk to complete their educational modules. The extended length of time on the kiosk, with the education modules as the third activity, could have decreased education intervention impact. Lastly, all of the participants in this study were African-American, precluding subgroup analyses and generalizability of findings to other ethnic or racial groups.

Table 3
Potential intervention moderators for achieving SBP/DBP control at 180-day post-discharge.

Model	B (SE)	aOR (95% CI)	p
Model 1			
Age group (<48 years old as the reference)	0.875 (0.744)	2.400 (0.558,10.324)	0.240
Intervention	1.322 (0.944)	3.750 (0.589,23.867)	0.162
Age group by intervention	-2.380 (1.168)	0.093 (0.009,0.914)	0.042*
Model 2			
Gender (male as the reference)	-0.182 (0.730)	0.833 (0.199,3.487)	0.803
intervention	-0.182 (0.705)	0.833 (0.209,3.321)	0.796
Gender by intervention	-0.105 (1.079)	0.900 (0.109,7.459)	0.922
Model 3			
Education (≤HS diploma/GED diploma as the reference)	0.811 (0.894)	2.250 (0.390,12.968)	0.364
intervention	-0.045 (0.577)	0.956 (0.309,2.960)	0.938
Education by intervention	-0.243 (1.514)	0.784 (0.040,15.234)	0.872
Model 4			
Smoke status (Never smoke as the reference)	1.253 (0.762)	3.500 (0.786,15.578)	0.100
Intervention	1.253 (0.945)	3.500 (0.549,22.304)	0.185
Smoke status by intervention	-2.351 (1.183)	0.095 (0.009,0.968)	0.047*
Model 5			
Diabetes (No diabetes as the reference)	-0.629 (0.871)	0.533 (0.097,2.939)	0.470
Intervention	-0.105 (0.596)	0.900 (0.280,2.896)	0.860
Diabetes by intervention	-0.588 (1.331)	0.556 (0.041,7.549)	0.659

Note: * $p < 0.05$.

Dependent variable is achieving SBP/DBP control. S.E. = Standard error. aOR = Adjusted odds ratio.

95% CI = 95% Confidence interval. B = Regression coefficient.

Achieving SBP/DBP Control = SBP/DBP <140/90 mm Hg or <130/80 mm Hg if patients are with diabetes.

Goodness-of-fit not significant for all of model.

Future direction

The evolution of mHealth technology could potentially replace **AchieveBP** kiosk-based health education modules. Our research group has experience with such an approach and is currently conducting a prospective RCT in the same population using mHealth modules based on hypertension management recommendations for lifestyle modifications from the American Heart Association on smoking cessation, dietary sodium reduction, physical activity, weight reduction and alcohol consumption [20–22] which parallel the **AchieveBP** kiosk modules curriculum. Given our findings, recognition of the kiosk as a potential bias factor in intervention contamination may need more attention in future research, particularly in mHealth if patients in both intervention and control groups use electronic devices for patient self-administration of health-related assessments and education [23]. Research has shown that strategies to support chronic disease management with appropriate therapy for patients with hypertension are critical. Beyond the study design, efforts to improve chronic disease management should facilitate access to a regular source of care [24], which was done in our study. The research short-term outcome of two-thirds of our high-risk patients having their BP under control at six months underscores the importance of primary care linkage to assure long-term hypertension management.

Authors' contributions

JGC, PL, AS and AG conceived the original concept of the study and applied for the grant. AB, AP, LM and RD provided protocol study development and implementation. WC, SP and CW conducted literature review and preliminary statistical analyses. JJ, LZ and RW provided final statistical analyses. All authors contributed to the final article and have read and approved the final manuscript.

Availability of data and materials

Datasets generated from the current study are available in the OnCore Clinical Trial Data Management System through Wayne State University, Detroit Michigan through Dr. Julie Gleason-Comstock, Corresponding Author and the Project Co-PI, Dr. Phillip Levy, on reasonable request.

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