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Development and Preliminary Feasibility of an Automated Hypertension Self-Management System

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Abstract

Background: Uncontrolled hypertension constitutes a significant challenge throughout the world. Blood pressure measurement by patients is informative for both patients and providers, but is rarely performed systematically, thereby reducing its utility. Mobile phones can be used to efficiently prompt individuals to measure blood pressure and automate data management while avoiding technology barriers to widespread adoption. Presented is the design and pilot test results of *MyBP*, an automated texting intervention to support blood pressure self-monitoring and patient self-management.

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Author participation: authors Irizarry, Allen, Einhorn, and Muldoon were involved in the direct data analysis. All authors were involved in conceptualization of the *MyBP* program and directly contributed to writing and iteratively revising the manuscript.

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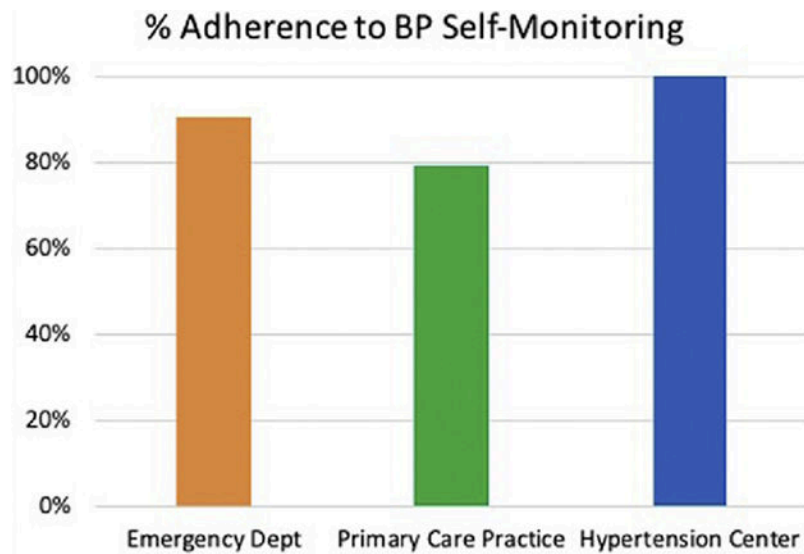
Conflicts of Interest: None

Methods: Three sequential phases are described: 1) stakeholders' needs assessment, 2) preliminary design pilot (n=10), and 3) a six-week pilot of the re-designed comprehensive program with hypertensive patients (n=43) recruited from three clinical sites (Emergency Department, Primary Care, Hypertension Center). Outcomes of interest included, participant adherence, perceived importance of blood pressure monitoring and healthy behavior change.

Results: Median adherence to MyBP prompts over six weeks was 79% (72% Emergency Department, 84% Primary Care and 96% Hypertension Center, $H(2)=5.56$, $p=0.06$). Adherence did not vary by age, gender, education or baseline use of texting, but was lowest among patients recruited from the Emergency Department ($\chi(2)^2=6.66$, $p=0.04$). In the exit survey, MyBP was associated with increased importance of blood pressure self-monitoring and particularly motivated primary care and emergency department groups to improve dietary habits, increase daily physical activity and focus on stress reduction. The majority of participants (88%) indicated interest in using the program for 6 months.

Conclusions: Automated mobile-phone based blood pressure self-monitoring using *MyBP* is feasible, acceptable and scalable, and may improve self-management and support clinical care.

Graphical Abstract:



Keywords

hypertension; home blood pressure measurement; self-management; text messaging; eHealth

Hypertension affects an estimated 30% of the world's adult population¹ and is a primary source of all-cause death as well as stroke, heart disease and kidney failure. Despite significant improvements in hypertension diagnosis and treatment, over half of US adults with hypertension have uncontrolled blood pressure². Due to the recent changes to the ACC/AHA hypertension guidelines, specifically redefining stage 1 hypertension from 140–159/90–99 to 130–139/80–89 mm Hg and setting a goal of <130/80 mm Hg for all patients³, healthcare systems face an even bigger challenge with hypertension management.

Hypertension diagnosis and medical management are traditionally based on office blood measurements. However, office measurements are highly variable, potentially unreliable and influenced by the “white coat” effect (the increase of blood pressure that occurs in the medical care environment)⁴. Often, clinicians find these isolated readings insufficient to guide hypertension care including initiating or intensifying therapy^{5,6}. Sparse, periodic BP readings can also leave patients feeling confused, making it difficult for them to understand if and when they need to alter blood pressure-related health behaviors (e.g. medication adherence, DASH diet, daily exercise, and stress reduction)⁷.

Evidence indicates measuring blood pressure outside the traditional clinical setting (i.e., blood pressure self-monitoring) is feasible and informative for both patients and providers^{8–11}. However, patients lack guidance in performing reliable and systematic measurement and documentation. A range of communication technologies to better leverage blood pressure self-monitoring for hypertension management have been tested¹². Despite promising results, broad implementation has not occurred. Limitations of existing programs include: 1) use of blood pressure self-monitoring solely for clinical decision-making (i.e., “telemonitoring”), which neglects patient engagement and inadvertently perpetuates provider-centered care^{8,13,14}); 2) utilization of clinical personnel (e.g. pharmacists, nurses, etc.) for recurring communication via secure websites, email, text or telephone^{9,15}, resources that most general practices cannot provide; and 3) deployment of specialized equipment (e.g. Bluetooth enabled blood pressure devices), assumption of facile use of a smartphone with Wi-Fi service 24/7, or both^{16,17}, thereby creating financial and/or technology literacy access barriers. Therefore, we sought to design a mobile phone-based intervention that assists blood pressure self-monitoring and self-care while minimizing cost and technology barriers.

METHODS

The study had three phases: 1) needs assessment and conceptual modeling, 2) preliminary design and alpha testing, and 3) program redesign and pilot testing in patients with hypertension in varied clinical settings: primary care, emergency medicine, and specialty care. Methods and results of each phase are presented sequentially. The following procedures were approved by the University of Pittsburgh’s Institutional Review Board. For more methodological detail of each phase refer to the online supplement.

Phase 1: Needs Assessment and Conceptual Modeling Methods

A team of representative clinical investigators ascertained the needs of stakeholders (patients with hypertension, primary care providers and health system administrators) through a series of meetings and focus groups.

Results—Input from investigators and stakeholders led to assembly of core constructs (online supplement Table I) and generated a general strategy and conceptual model to support hypertension self-management. Because hypertension is largely asymptomatic, individuals living with elevated blood pressure are often unaware of their condition and whether or not their blood pressure is controlled. Therefore, we identified hypertension health-literacy and blood pressure self-monitoring with timely feedback as key intervention elements. Frequently, patients are unsuccessful in self-management due to inadequate or

inaccurate understanding of hypertension, its health risks and proper measurement, and the various health behaviors that raise or lower blood pressure. Also, patients struggle to understand quantification of blood pressure and its inherent variability. While knowledge of one's blood pressure is considered to be crucial information, patients find it difficult to measure their blood pressure systematically and calculate averages, which would determine hypertension control. This constrains patients from developing accurate health beliefs and adequate self-efficacy related to hypertension self-management.

The conceptual model (Figure I) for *MyBP* illustrates how hypertension education coupled with assistance in systematic blood pressure self-monitoring and feedback may improve relevant health behaviors. We concluded this conceptualization phase with primary objectives and design components including: 1) education delivered at patients' convenience using high-quality, web-accessed videos supplemented by periodic health tip messages, 2) proactive and personalized messaging to aid patients in systematic blood pressure self-monitoring, 3) automated, bidirectional messaging to efficiently provide timely reinforcement and feedback, 4) blood pressure data management with automated summaries, and 5) time delimited averaging to generate reliable estimates and permit detection of change in blood pressure over time. The system requests a blood pressure reading on two mornings and two evenings each week. This provides a sufficient number of readings to calculate an updated blood pressure average every 2 weeks¹⁸ without over-burdening patients during long-term self-monitoring.

Phase 2: Preliminary Design and Feasibility Testing

Methods—Phase 2 aims were to: a) program the alpha version of an automated SMS system to guide blood pressure self-monitoring with feedback, and b) conduct a 4-week feasibility study to assess response rates to prompted blood pressure self-measurement and collect qualitative feedback in a semi-structured phone interview.

Results—Ten patients with hypertension submitted blood pressure readings in response to 84% of prompts after a mean delay of 18 minutes. In an exit phone interview, most participants stated that using *MyBP* was a positive experience, found the program easy to use, and felt it was akin to using a journal to keep themselves accountable.

Phase 3: Program Re-Design and Pilot Testing in Varied Clinical Settings

Methods—Phase 3 aims were to revise and expand the features of *MyBP*, and conduct more in-depth pilot testing in several clinical settings. The pilot study aims were to: 1) examine operational fidelity, 2) quantify participant utilization, 3) assess any impact on patients' beliefs and behaviors related to hypertension and hypertension self-management, and 4) determine whether usage and responses varied as a function of clinical setting, age, gender, race, education or baseline use of texting.

Blood pressure self-monitoring was scheduled for self-selected times on two mornings and two evenings each week and demarcated into two-week recording periods. Receipt of an automated text message prompted participants to take a blood pressure reading with their own blood pressure cuff and text back reading. Every two weeks, participants received a text

report containing adherence to blood pressure self-monitoring and, if at least four readings were submitted, the average blood pressure in comparison with their previous two-week average.

Participant samples: Patients diagnosed with hypertension and able to text were recruited by a research staff member at an urban emergency room, a general internal medicine clinic, and a hypertension referral center. Participants who did not own an automated blood pressure cuff were given a validated device (A&D Medical UA--767FAC), and participants received \$30 at study completion.

Measures

Sample characteristics.: Medical information (current BP, prescription medications, body mass index and medical history) was abstracted from the medical record and patient sociodemographic characteristics were self-reported. At baseline, current blood pressure self-monitoring and use of texting was provided by self-report.

The messaging system database contained all outgoing (computer generated) and incoming messages (participant generated), and was used to examine operational fidelity, participant adherence and reported BP values. Adherence was calculated as the proportion of blood pressure prompts to which patients replied with blood pressure readings divided by the total of prompts in each two-week monitoring period and across all monitoring periods. At study completion, a survey about MyBP acceptance and impact on health behaviors was administered (online supplement Table II).

Statistical Analysis: Descriptive statistical analyses of variables of interest (demographics, health characteristics, participant engagement, texting experience, and adherence) were organized by site. Group differences were determined using chi-square or Fisher's exact for nominal and ordinal variables, and analysis of variance (ANOVA) for continuous variables. Median adherence for each group was calculated and compared across groups using the Kruskal-Wallis H test. Quartile rank of adherence to blood pressure prompts was calculated, with the low adherence quartile contrasted with the upper 3 quartiles using analyses analogous to those described above, with the addition of Spearman's correlation with ordinal variables and point-biserial correlation with continuous variables. A repeated-measures ANOVA was conducted to determine whether there was a statistically significant difference in mean blood pressure over the course of the three two-week periods. Post hoc testing with Bonferroni corrections were performed using standardized adjusted Pearson residuals to determine the source of any significant chi-square or Fisher's exact result with a threshold of $\pm 2^{19}$ and Tukey post hoc comparisons with significant ANOVA results. SPSS version 24.0 software (SPSS Inc.) was used for all analyses.

Results

A six-week pilot test of the re-designed *MyBP* program was conducted with 43 patients enrolled from three clinical settings. Table I provides participant characteristics by recruitment site. Fourteen additional patients signed consent forms but did not enroll. Compared to those enrolled, these 14 individuals were somewhat younger and less educated

but similar in race, gender, average BMI and average blood pressure (online supplement Table III).

There were no statistically significant differences among participants across the three recruitment sites in terms of age, sex, and BMI. Compared to the other two groups, the Hypertension Center group had more white participants, lower blood pressure, had received a greater number of prescribed antihypertensive medications, and more often owned a blood pressure cuff and performed blood pressure self-monitoring at baseline. Emergency Department participants tended to have the lowest level of completed education.

Program fidelity

During the first two months of enrollment at the Hypertension Center and Emergency Department, through participant feedback and manual inventory of the SMS database we found that: 1) the program was failing to send about 25% of blood pressure reminders, 2) the two-week reports occasionally omitted the two-week blood pressure average, and 3) and the two-week reports sometimes miscalculated adherence with blood pressure self-monitoring. These issues were addressed by our programmer within two weeks and before enrollment of Primary Care patients. Subsequent manual auditing of the messaging database revealed high operational fidelity.

Blood Pressure Readings

Thirty-three participants submitted blood pressure readings sufficient to calculate an average blood pressure over each of the three successive two-week blood pressure monitoring periods. The average blood pressure for periods 1, 2 and 3 were 144/89, 140/87, and 142/88 mmHg, respectively. There was not a statistically significant change in mean systolic or diastolic blood pressure over the three two-week periods (systolic ($F(1.6, 49.7) = .88, p = .39$), diastolic ($F(2,64) = 1.37, p = .26$)).

Adherence

Of the 43 participants, all but two (both from the Emergency Department) began sending blood pressure readings in response to message prompts. Three other patients (all from the Emergency Department) opted out of blood pressure monitoring for the third two-week monitoring period. Figure II displays the average adherence across the 6 weeks according to recruitment site. Overall, the median blood pressure self-monitoring adherence across the 6 weeks was 79% (72% Emergency Department, 84% Primary Care and 96% Hypertension Center, $H(2) = 5.56, p = 0.06$). The frequency distribution is available in online supplement Figure I.

Characteristics associated with adherence

In the low quartile, the median adherence to blood pressure prompts was 48%, as compared to 92% among remaining patients. Table II compares characteristics of low and high adhering patients. Of the low adherers, 41% were Emergency Department participants ($\chi^2(2) = 6.66, p = 0.04$) and black race trended toward significance ($p = 0.09$). Otherwise, adherence to blood pressure self-monitoring with MyBP did not vary notably by age, gender, education or baseline use of texting.

Effects on patients' beliefs and behaviors related to hypertension and hypertension self-management

An exit survey was completed by telephone in 40 of the 43 participants. The three not completing the survey (all from the Emergency Department group) had withdrawn from the program and multiple attempts to reach them by phone were unsuccessful.

Most respondents indicated that use of *MyBP* increased their sense of the importance of blood pressure self-monitoring. In addition, over 75% of patients indicated an interest in using the program for substantially longer (i.e., 6 months). Overall, participants reported that the *MyBP* program increased the sense of the importance of medication adherence, a healthy diet, regular exercise and stress management (Figure III). In addition, most patients reported changing one or more health behaviors in response to use of the *MyBP* program. Behavioral changes were largest in the Primary Care and Emergency Department groups.

DISCUSSION

This multi-phase study aimed to develop and pilot test *MyBP*, an automated, bidirectional, text-based monitoring system to support patients in hypertension self-management. Findings from the first two phases assisted in the development of a set of key design constructs and a theoretically supported conceptual model and confirmed that SMS was a viable digital communication platform. Feasibility testing of the re-designed *MyBP* program in patients from three distinct clinical sites again revealed high rates of blood pressure reporting overall (79%), but a somewhat lower rate in participants from the urban ED. Using a minimum of four readings (50% adherence) every two weeks in order to provide a reliable average, the large majority of our participants submitted a sufficient number of readings to reasonably estimate and track readings over successive two-week monitoring periods.

Exit survey results showed the majority of participants liked using the *MyBP* program, were willing to use it for an extended period of time and reported changing at least one health-related behavior in response to *MyBP*. Primary Care and Emergency Department patients were especially motivated to increase medication adherence, improve their diet, increase physical activity or engage in stress reduction. This may be attributable to the effects of the program's video education and regular BP self-monitoring on the salience and importance of blood pressure control and behaviors affecting blood pressure.

Meta-analyses of randomized clinical trials indicate that having patients conduct blood pressure self-monitoring leads to a fall in blood pressure^{20,21}. Blood pressure self-monitoring may increase patient's daily awareness of his or her BP and provide feedback that improves adherence to BP-lowering health behaviors and overall hypertension management^{9,22,23}. Current trials using web/mobile technologies to support blood pressure self-monitoring are identifying design features that may increase blood pressure reduction achieved by blood pressure self-monitoring²⁴.

However, as mentioned in the introduction many of these innovations constitute barriers to usefulness and feasibility in routine clinical practice. For example, the trials led by Magid and Margolis each achieved BP control 20%–30% more often in intervention patients

compared to control patients, but the programs provided patients with a special BP monitor which they used to periodically download readings to a website monitored by clinical pharmacists who had recurring contact with patients via face-to-face visits, phone appointments or secure email^{15,25}. The CAATCH trial included computerized patient education modules, a series of nurse-administered behavioral/lifestyle telephone group counseling sessions, and monthly onsite continuing education for the primary care physicians. It failed to show effectiveness due to low adherence with the multicomponent intervention²⁶. These considerations, along with development work completed in Phase 1, drove *MyBP* design objectives: simplicity for the user, convenient low-cost patient education, tailoring for patient convenience, and automated, proactive communication with recurring feedback.

Several features of *MyBP* are worth highlighting. First, it uses a ubiquitous, inexpensive and proactive modality (i.e. SMS) to communicate with patients. The utility of SMS is particularly relevant since, due to controversial concerns about data security health systems may feel compelled to invest in alternative, “secure messaging systems”²⁷. Second, the algorithm provides patients with running averages of their BP with a data refresh every two weeks. This served the purpose of emphasizing one’s blood pressure average, thus reducing unnecessary preoccupation with isolated readings. Third, *MyBP* provided summary data on blood pressure trends, empowering patients by delivering valid feedback on the blood pressure effects of their behaviors. Fourth, simple self-management strategy tips were delivered each week; these may prompt specific behaviors within the context of patients’ daily lives, thus increasing the chances of behavioral adoption.

The current feasibility data are small in number but suggest that *MyBP* may be acceptable to and used by the majority of patients across different clinical settings and sociodemographic characteristics. Additionally, the program generates what we believe are reliable blood pressure averages over successive two-week monitoring periods²⁸, and favorably motivates patients as reflected in changes in perceived importance of blood pressure control and self-reported changes in health behaviors. It is unclear whether continued use of *MyBP* will encourage improvement in, and maintenance of healthy behavior changes via the direct feedback of acceptable blood pressure readings. Our work to date is also limited by its short duration and absence of integration with the provider or electronic health record. Our next version of *MyBP* will add automated reports routed to the primary care provider. Providers are often dubious regarding the reliability of patient-generated blood pressure readings^{29–31}. Using *MyBP*, patients take blood pressure measurements after learning proper technique and using a systematic approach to self-monitoring which generates sequential, time-delimited blood pressure averages. These features may raise providers’ confidence in blood pressure self-monitoring data³² and permit more informed and timely medication management^{13,33,34}.

Ultimately, the effectiveness and feasibility of *MyBP* as an adjunct to standard medical care depends on patient engagement but also on providers’ sense of its utility in achieving and maintaining blood pressure control in patients with hypertension. Thus, testing *MyBP* in randomized trials of clinical effectiveness along with implementation research³⁵ are necessary to more fully evaluate its potential role in clinical practice.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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- Emmi Solutions, Inc. created the hypertension education videos which were used through a lease agreement with UPMC Health System.

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Highlights:

- Blood pressure self-monitoring is vital in patients with uncontrolled hypertension.
- *MyBP* uses ubiquitous texting as its platform for automated communication.
- Feedback consisted of blood pressure averages and trend reports every two weeks.
- Initial testing in three diverse clinical settings suggested high engagement.
- Use was associated with patient-initiated improvements in health behaviors.

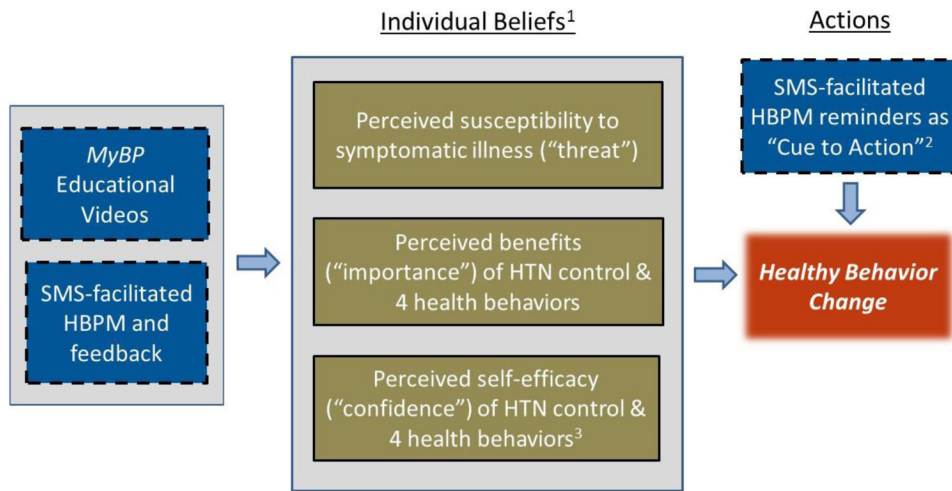


Figure 1: Conceptual Model for the Design of MyBP in Hypertension Self-Management. Adapted from Health Belief and other health behavior models. Intervention components are noted in blue boxes.

(1) Individuals beliefs are also influenced by a variety of fixed factors, such as age, gender, culture, and education.

(2) SMS reminders directly cue BP self-measurement and indirectly nudge thinking and action of related health behaviors.

(3) Although not illustrated, feedback loops exist through which behavior change, BP change, or both may increase self-efficacy.

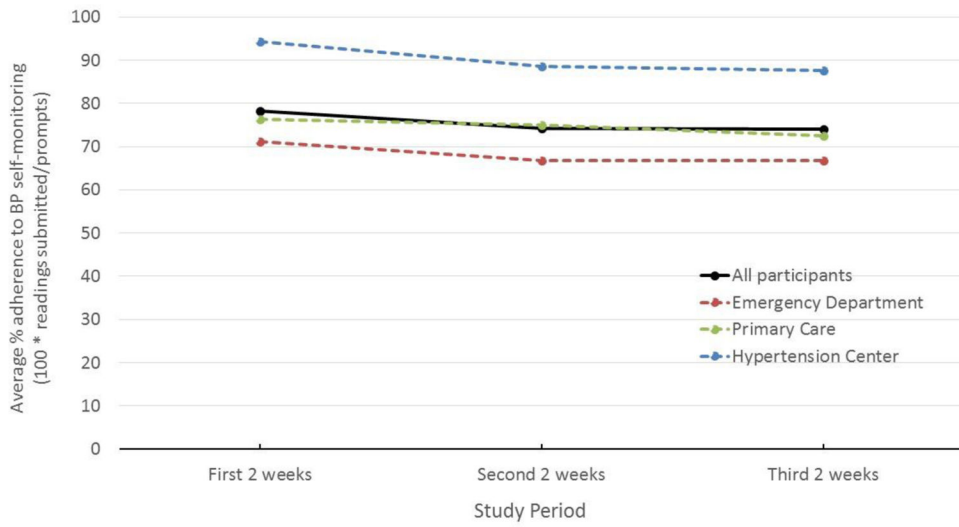


Figure II. Average adherence to home BP monitoring in response to MyBP prompts by recruitment site.

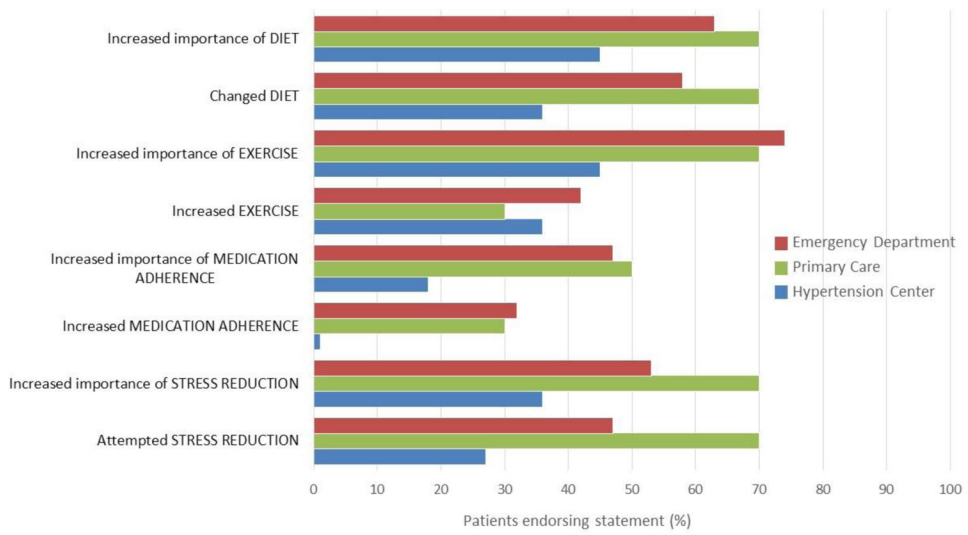


Figure III. Survey results -- Patient-reported changes in cognitions and health behaviors after using MyBP

Table I.

Characteristics of Enrolled Participants by Recruitment Site

	Total n=43	Emergency Department n=22	Primary Care Office n=10	Hypertension Referral Center n=11	Group Differences
Age, mean (range)	54 (34–70)	53 (34–70)	59 (49–67)	54 (38–66)	p= 0.11
Sex, n (% female)	25 (58%)	10 (46%)	8 (80%)	7 (64%)	p= 0.19
Race, n (% black)	26 (61%)	15 (68%)	8 (80%)	3 (27%)	p= 0.03
Education, n (%)					
High school only	17 (40%)	11 (50%)	3 (30%)	3 (27%)	p= 0.06
Some college/tech training	12 (28%) 14 (33%)	8 (36%) 3 (15%)	3 (30%) 4 (40%)	1 (9%) 7 (64%)	
Bachelors or higher					
Body mass index (kg/m ²)	34 (22–47)	33 (22–43)	36 (30–41)	33 (23–47)	p= 0.44
Systolic BP, mean (range)	157 (110–250)	169 (140–250)	156 (129–193)	136 (110–160)	p<0.001
Diastolic BP, mean (range)	94 (70–130)	98 (72–130)	96 (74–124)	83 (70–100)	p= 0.01
Number of Antihypertensive medications, mean (range)	2.1 (0–5)	1.6 (0–5)	2.1 (0–4)	3.1 (1–5)	p= 0.02
Owned a BP cuff, n (%)	12 (28%)^a	2 (9%) ^c	0 (0%)	11 (100%)	p<.001
Checked own BP in past month, n (%)	18 (42%)^b	7 (32%) ^d	0 (0%)	11 (100%)	p<.001
Average number of texts sent per day, n (%)					
0	2 (5%)	1 (5%)	1 (10%)	0 (0%)	p=0.76
1–2	10 (23%)	5 (23%)	3 (30%)	2 (18%)	
3 or more	31 (72%)	16 (72%)	6 (60%)	9 (82%)	

^a
n=40,^b
n=42,^c
n=19,^d
n=21

Table II.

Characteristics of Low and Adequately Adherent Participants

	Low Adherers n=11	Adequate Adherers n=32	Group Differences
Mean percent Adherence to blood pressure self-monitoring (range)	38% (0–68%)	88% (69–100%)	$P < 0.001^c$
Recruitment site			
Emergency Department	9 (82%)	13 (40%)	
Primary Care	2 (18%)	8 (25%)	$p = 0.04^d$
Hypertension Center	0	11 (24%)	
Age, mean (range)	54 (43–67)	55 (34–70)	$p = 0.81$
Sex, n (% female)	6 (54%)	19 (59%)	$p = 0.78$
Race, n (% black)	9 (82%)	17 (53%)	$p = 0.09$
Education, n (%)			
High school only	5 (46%)	12 (38%)	
Some college/tech training	4 (36%)	8 (25%)	$p = 0.38$
Bachelors or higher	2 (18%)	12 (38%)	
Body mass index (kg/m ²)	34 (25–42)	33 (22–47)	$p = 0.74$
Systolic BP, mean (range)	157 (129–187)	157 (110–250)	$p = 0.99$
Diastolic BP, mean (range)	97 (72–130)	93 (70–130)	$p = 0.44$
Number of Antihypertensive medications	2.5 (1–5)	2 (0–5)	$p = 0.26$
mean (range)			
Owned a BP cuff, n (%)	1 (9%) ^a	11 (34%) ^b	$p = 0.36$
Checked own BP in past month, n (%)	3 (27%) ^a	15 (46.9%)	$p = 0.47$
Self-reported text messages sent per day, n (%)			
0	4 (36%)	6 (19%)	
1–2	7 (64%)	24 (75%)	$p = 0.55$
3 or more			

^a n=10,

^b n=30,

^c $r_{pb}(41) = 0.8$,

^d $\chi^2(2) = 6.66$