



## **DOCTOR OF NURSING PRACTICE (DNP) PROGRAM**

### **A DNP PROJECT**

# **Improving Blood Pressure Control and Hypertension Management With A Self- Measured Blood Pressure Monitoring Intervention**

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### **Abstract**

Hypertension (HTN) affects about one in every three adults in the United States, yet the rate of blood pressure (BP) control is suboptimal. Poorly controlled HTN contributes to significant target organ damage and increases mortality. Self- measurement of blood pressure (SMBP) is an effective strategy for empowering hypertensive adults to become active participants in the management of their chronic condition and promoting adherence to medications. Practice guidelines strongly recommend SMBP, however, it continues to be underutilized and not routinely encouraged in clinical practice. A pilot program utilizing a quasi- experimental one-group pre-test post-test design was implemented in a community health fitness facility. A convenience sample of thirteen adults who self-reported to have HTN and were currently prescribed antihypertensive medications were included. Three in-person sessions were conducted over the course of four weeks. BPs were measured for participants at the initiation and conclusion of the program. Participants were educated about the benefits of SMBP, its proper technique, and asked to perform it at home for two nonconsecutive weeks. The average differences in systolic/ diastolic BPs and medication adherence scores were calculated using the Wilcoxon signed- ranks test. The SMBP intervention led to a statistically significant reduction in systolic BPs ( $p= 0.041$ , CI: 95%,  $Z= -2.047$ ) and to an improvement in medication adherence ( $p= 0.002$ , CI: 95%,  $Z= 3.068$ ). The post- intervention mean diastolic BP was numerically lower than the pre-intervention mean diastolic BP, however, the change was not statistically significant ( $p= 0.126$ , CI: 95%,  $Z= -1.531$ ). SMBP offers a new approach for managing HTN outside of the clinical setting and healthcare providers should encourage all of their patients who are diagnosed with HTN to utilize it routinely.

*Keywords:* self- measurement, hypertension, blood pressure, medication adherence

### **Introduction**

High blood pressure (BP) or hypertension (HTN) is the most common chronic condition that affects individuals across all of the United States and is a major public health challenge (Whelton et al., 2018). During the years 2003 to 2010, HTN affected approximately 67 million adults nationwide (Centers for Disease Control and Prevention [CDC], 2012). The American Heart Association (AHA; 2016) recognized chronically elevated BP to be the initial cause of the “domino effect” that contributes to a series of health conditions and also poses an associated challenge of increased spending within the healthcare system. Results obtained from various research studies and evidence-based guidelines indicate a current gap in clinical practice related to the management of HTN. There is a need for establishing a program that would encourage hypertensive patients to self- measure and monitor their BPs outside of the clinical setting (Whelton et al., 2018). The implementation of such a program would engage patients to play an active role in the treatment of their HTN, help improve patient health outcomes by lowering BP and improving adherence to treatment, and concurrently reduce the national burden of the disease (Target: BP, 2016).

### **Background and Significance**

HTN in the United States continues to be a highly prevalent disease process and it is a substantial risk factor for cardiovascular causes of morbidity and mortality (Whelton et al., 2018). The 2015- 2017 National Health and Nutrition Examination Surveys (NHANES) found that the prevalence of chronic HTN increased with age, from 7.5% among adults between the ages of 18 to 39, to 33.2% among those aged 40 to 59, and 63.1% among those aged 60 and over (Fryar, Ostchega, Hales, Zhang, & Kruszon-Moran, 2017). This chronic condition has also demonstrated to affect individuals of all races and ethnic backgrounds. Data collected by the

National Heart, Lung, and Blood Institute (NHLBI) from the years 2011 to 2014 revealed that the nationwide prevalence of HTN among black males was 45%, 46.3% among black females, 34.5% among white males, 32.3% among white females, 28.9% among Hispanic males, 30.7% among Hispanic females, 28.8% among Asian males, and 25.7% among Asian females (Benjamin et al., 2018).

### **Poor BP Control**

The Seventh Report from the Joint National Committee noted that although considerable improvements have been made over the preceding years related to HTN awareness and treatment initiation, the rate of BP control among hypertensive American adults remains suboptimal (Chobanian et al., 2003). The most recent guidelines released in 2017 by the American College of Cardiology (ACC) and the AHA, recommended that an optimal BP goal for the general adult hypertensive population is less than 130/80 mmHg (Whelton et al., 2018). Based on the Healthy People Heart Disease and Stroke goal number twelve, the established target for HTN control in all adults by 2020 was 61.2%, but in the years 2015 to 2016 the control of HTN was only at 32.5% in adults ages 18 to 39, at 50.8% in those aged 40 to 59, and at 49.4% in those aged 60 and over (Fryar et al., 2017; Office of Disease Prevention and Health Promotion [ODPHP], 2013). The risk for developing HTN increases with age and studies have shown that the lifetime risk of HTN is approximately 90% for individuals who had normal BPs at ages 55 and 65 and lived to the ages of 80 and 85, respectively (Institute of Medicine [IOM], 2010).

### **Complications of HTN**

Insufficiently controlled HTN has been linked to significant target organ damage and vascular complications (James et al., 2014). Chronically elevated BP causes progressive abnormalities within the heart including left ventricular heart failure and systolic/ diastolic

dysfunction, which leads to hypertensive heart disease and results in symptomatic heart failure (Drazner, 2011). HTN is also a major cause of cerebrovascular (stroke, intracranial bleeding), renovascular (hypertensive nephropathy) and retinal diseases (Whelton et al., 2018). The risk of developing cardiovascular disease is directly related to the level of BP control, and “for every 20 mmHg systolic or 10 mmHg diastolic increase in BP, there is a doubling of mortality from both ischemic heart disease and stroke” (Chobanian et al., 2003, p. 1210). Statistics that were collected from all of the filed death certificates in the United States in 2016 showed that the national leading cause of mortality that accounted for 23.1% of all deaths was heart disease and the fifth ranked national cause that accounted for 5.2% of total deaths were cerebrovascular accidents (Heron, 2018). Between the years of 2000 to 2011, life- threatening manifestations of poorly controlled HTN such as malignant HTN and hypertensive encephalopathy have also increased the burden of HTN-related emergency department visits by more than 27% (Polgreen, A., Suneja, Tang, Carter, & Polgreen, M., 2015).

### **Financial Burden**

Expenditures related to HTN pose a huge economic challenge for the United States (Zhang, D., Wang, Zhang, P., Fang, & Ayala, 2017). In 2013, the estimated annual cost of direct and indirect expenses related to HTN was \$53.2 billion (Benjamin et al., 2018). By the year 2035, the total direct costs of HTN are projected to increase to \$220.9 billion (Khavjou, Phelps, & Leib, 2016). In addition to the hefty financial costs, inadequate control of this silent killer has also been linked to an increased absenteeism of workers and the potential of lost productivity in the workplace (Asay, Roy, Lang, Payne, & Howard, 2016).



### **Strategies for Better BP Control**

Better control of high BP in the adult population is shown to decrease the incidence of cardiovascular complications, improve health outcomes, and reduce the associated economic burden (Go et al., 2014; Lionakis, Mendrinos, Sanidas, Favatas, & Georgopoulou, 2012). Over an average follow-up of two to three years, data from clinical trials have demonstrated that optimal control of BP can reduce the risk of stroke by 18% to 40%, the risk of myocardial infarction by 15%, and all-cause mortality up to 60% (Ettehad et al., 2016). Strategies to improve HTN treatment and achieve optimal control are dependent on pharmacological interventions such as strict adherence to anti-hypertensive therapy and non-pharmacological interventions such as the accurate and routine self-monitoring of BP (Whelton et al., 2018).

### **Medication Adherence**

Correctly taking anti-hypertensive medication as prescribed by the clinician is key for achieving HTN control, yet medication non-adherence is common (Chang, Ritchey, Ayala, Durthaler, & Loustalot, 2018). It is estimated that on any given day about 10% of hypertensive patients miss a dose of their anti-hypertensive medication and a year after initiation of the medication therapy about 50% of patients completely stop taking them (Conn, Ruppar, Chase, Enriquez, & Cooper, 2015). Patients who are non-adherent to their anti-hypertensive medications do not achieve optimal BP control and are at a much higher risk of adverse outcomes including all-cause hospitalization, cardiovascular hospitalization, cardiovascular revascularization, all-cause mortality, and cardiovascular mortality than patients with optimal medication adherence (Perreault, 2018). In 2010, a national estimate found that poor adherence to anti-hypertensive medications also had a profound impact on the United States economy, costing a total of \$105.8

billion or an average of \$453 per adult for the year (Nasseh, Glave Frazee, Visaria, Vlahiotis, & Tian, 2012).

### **Self- measured BP monitoring**

Self- measured BP monitoring (SMBP) is a practice where individuals utilize inexpensive (\$30-\$40) semiautomatic devices to routinely check and track their own BPs in the home environment or other nonclinical settings (Target: BP, 2016). A scientific statement released by the AHA, American Society of Hypertension (ASH), and Preventive Cardiovascular Nurses Association (PCNA) recommended the routine use of SMBP with a supportive co-intervention for the management of patients with HTN (Pickering et al., 2008). A recently conducted systematic review and individual patient data meta- analysis revealed that SMBP accompanied by an educational co-intervention about BP and HTN has been associated with reduced BP levels (Tucker et al., 2017). SMBP can be easily incorporated into a patient's day-to-day activities and it effectively increases the knowledge of their chronic disease, encourages them to become active participants in their own care, empowers them to make lifestyle changes, increases self- efficacy, and promotes autonomy (Fletcher et al., 2016). SMBP is accurate and provides reproducible readings that are more predictive of target organ damage and adverse cardiovascular events than the occasional BP measurements taken in the clinician's office (Drawz, Abdalla, & Rahman, 2012; George & MacDonald, 2015). Casual BP measurements that are self-recorded by patients are more closely correlated to the mean "true BP levels" than BPs that are taken in the clinician's office (Pickering et al., 2008). Sporadic office BP values may not reflect how effectively a patient's HTN is being managed and can result in treatment plan errors (Williams et al., 2018). An additional advantage of SMBP that is supported by a strong base of evidence is that it has a positive economic impact and it is cost-effective (Jacob et al., 2017). A systematic review of the

literature showed that the use of SMBP with additional support reduced healthcare costs per person annually and based on two translation methods the median costs per quality-adjusted life year savings were \$2800 and \$4000 (Jacob et al., 2017). This intervention has also shown to have a beneficial contribution to improving adherence to anti-hypertensive medications (Fletcher, Hartmann-Boyce, Hinton, & McManus, 2015). Individuals who demonstrated an active role in the management of their HTN by routinely measuring and self- recording their BPs were more likely to have better compliance with their anti-hypertensive medications (Fletcher et al., 2015).

Despite the abundance of available evidence that supports the advantages of managing HTN with self-monitoring, it is not routinely encouraged in clinical practice and continues to be an underutilized resource (Ayala et al., 2017). The results from the 2009- 2010 NHANES noted that SMBP is rarely performed and only about 20.6% of hypertensive adults in the United States participated in weekly or more frequent home BP monitoring (Ostchega, Berman, Hughes, Chen, & Chiappa, 2013). The use of SMBP is a valuable addition to the routine management of hypertensive adults and according to the 2017 clinical practice guidelines established by the AHA and the ACC, it is a class I (strong) recommendation that can be helpful in obtaining optimal BP control and decreasing the associated target organ damage complications (Whelton et al., 2018).

### **Needs Assessment**

Chronically elevated BP is an alarming global health problem that affects approximately one billion individuals worldwide and is directly linked to around nine million deaths, annually (Forouzanfar et al., 2017; World Health Organization [WHO], 2013). The burden of HTN is significantly evident in the United States and according to the IOM (2010) population- based

changes are needed in order to improve the control of elevated BP. The region of focus for this particular project was in the state of New Jersey (NJ), which had been ranked the nineteenth highest state in HTN prevalence and had an estimated total of 33% of adults who were affected by chronically elevated BP (CDC, 2017). The control of HTN amongst NJ residents aged 18-85 was suboptimal, averaging at only 51% (State of New Jersey Department of Banking and Insurance [DOBI], 2016). Reports from two NJ Health Insurance plans, Oxford- HMO/POS and United PPO/ EPO, showed that the percentage of their hypertensive members who had adequate control of their BPs was even lower than the state average, with rates at 42% and 44%, respectively (DOBI, 2016). Data obtained from a 2016 NJ mortality analysis revealed that heart disease was the leading cause of mortality that accounted for 25.4% of all deaths in the state, and the fourth leading cause was stroke that accounted for 4.6% of all state deaths (CDC, 2016).

Given the alarming level of poorly controlled HTN, the Community Preventive Service Task Force (2015) had recommended the implementation of SMBP in community settings to help reduce BPs in patients with HTN. The United States Department of Health and Human Services (DHHS) had launched the “Million Hearts” program that advocated for the routine utilization of SMBP to increase BP control and reduce the risk of HTN related disability and mortality (Frieden & Berwick, 2011). Another evidence- based quality improvement program called Target: BP (2016) that was established by the American Medical Association (AMA) and the AHA, also focused on the widespread dissemination of SMBP to engage patients as active participants in the management of their HTN as well as to increase adherence to their prescribed medication regimens.

There was an explicit need for implementing SMBP programs within NJ communities to improve the control of BP and reduce the statewide cardiovascular morbidity and mortality

(Ettehad et al., 2016; Tucker et al., 2017). The project was conducted at a community health fitness organization located in East Rutherford, which is a part of Bergen County in NJ. Bergen County has an aging population that is comprised of 70.1% of adults greater than 40 years old (Professional Research Consultants [PRC], 2016). In addition to an aging population, Bergen County had also been noted to have a marked upward trend in the prevalence of adults with HTN, increasing from 28% in 2012 to 36.9% in 2016 (PRC, 2016). This increased proportion of adults with HTN throughout Bergen County was slightly higher than the national average and markedly above the Healthy People 2020 goal of 26.9% (ODPHP, 2013). Considering the high prevalence of HTN in Bergen County and its rising incidence due to population aging, there was a definitive need for establishing a chronic disease program for the management of HTN. This need was confirmed with the organization's wellness director (M. Moore, personal communication, 2019). The East Rutherford facility is actively involved in promoting healthy living for its local residents and hosts an abundance of outreach programs helping to build a healthier community (M. Moore, personal communication, 2019). Furthermore, various similar organizations located across the United States have chosen to collaborate with the AHA and have already begun to take action by offering BP self- monitoring programs in their facilities. This specific site in East Rutherford currently offers only one chronic disease prevention program on diabetes and it is essentially looking to also establish its own SMBP program to help its hypertensive members achieve better BP control and minimize their risk for stroke and heart disease (M. Moore, personal communication, 2019).

### **Problem Statement**

HTN in the United States is one of the most common medical conditions managed in the primary care setting and it is directly associated with the leading nationwide cause of

mortality (Caboral-Stevens, & Rosario-Sim, 2014). Remarkable improvements in the management of HTN have been made since the late 1970s, yet the IOM (2010) referred to HTN as a “neglected disease,” that continues to pose a challenging public health problem. About one in every three American adults over the age of eighteen years has an established diagnosis of HTN (Fryar et al., 2017). Despite the advances in medicine and available treatment modalities approximately 51% of hypertensive adults do not have adequate control of their chronic condition (Merai et al., 2016). Studies have shown an associated increased risk for developing acute cardiovascular events or death when HTN was poorly controlled (systolic BP greater than 150 mmHg) for even a short time period of approximately 1.4 months (Xu, Goldberg, Shubina, & Turchin, 2015). Chronically elevated BP is widely known to be a major modifiable risk factor for myocardial infarctions and strokes, however, more than 800,000 Americans still continue to die annually from those cardiovascular events (Frieden & Berwick, 2011).

The problem of insufficient control of this chronic nationwide condition emphasized the need for more coordinated efforts and enhanced approaches to improve health outcomes in hypertensive adults (Merai et al., 2016). Research studies have shown that hypertensive adults who received educational support regarding the importance of better BP control and were trained on proper techniques for BP self- measurement and monitoring, eventually became active participants in the management of their chronic disease and had a subsequent increase in adherence to their medication therapies and a decrease in BP levels (Stergiou & Bliziotis, 2011). The purpose of this pilot project was to bridge the gap between established research based guidelines which recommended the routine use of SMBP and the lack of its utilization in clinical practice (Ayala et al., 2017). The ultimate goal of disseminating and incorporating SMBP into the routine management of HTN was to decrease the incidence of uncontrolled HTN and

subsequently reduce the associated mortality, morbidity, and financial burden. The clinical question that was the focus of this project was the following: In community dwelling adults with a previously established diagnosis of HTN, will SMBP combined with educational support help to improve BP control and promote adherence to anti- hypertensive medications?

### **Aims and Objectives**

The overall aim of this pilot project was to improve BP control in hypertensive adults and ultimately reduce HTN-related complications. In order to achieve this aim, the following three objectives were developed:

- 1) Designed and implemented an evidence-based educational intervention that focused on the importance of the utilization of SMBP, established correct techniques for SMBP, encouraged documentation of BP in designated logs and incorporated SMBP into the participant's daily routines. This intervention also focused on measures that improved adherence to BP medications among hypertensive adults.
- 2) Evaluated the effect of the educational intervention on BP control by measuring BPs before and after implementing the intervention.
- 3) Evaluated the effect of the educational intervention on anti-hypertensive medication adherence by conducting a medication adherence survey before and after implementing the intervention.

### **Review of Literature**

A comprehensive review of available published literature was conducted. The purpose was to obtain and critically analyze evidence that supported the benefits of SMBP and justified its routine use in the management of adult patients with HTN. When conducting the search for literature, the following databases were searched: Cumulative Index of Nursing and Allied

Health Literature (CINAHL), PubMed/ MEDLINE, and the Cochrane Library. The key terms that were applied in the search query, included, *self monitoring of blood pressure, adults with hypertension, blood pressure monitoring in hypertension, management of high blood pressure, hypertension control, hypertension and medication adherence, anti-hypertensives and blood pressure measurement, home blood pressure monitoring*. Search filters were set up to only identify relevant articles that were full text, scholarly/ peer reviewed, and published in 2009 or later. The preliminary search yielded 205 hits. The result list was then narrowed down to twenty-six potentially eligible articles based on their applicability to SMBP monitoring. After further scrutiny and elimination of non-primary research papers, eleven articles were selected to be included in the synthesis of the literature.

The Table of Evidence (Appendix A) that was developed after the search was completed depicts the studies that were included in the final review, six of which were randomized controlled trials (RCT), two were quasi- experimental trials, and three were systematic reviews with meta- analyses. All of the studies were assessed for methodological quality and level of evidence using the Johns Hopkins nursing evidence- based practice research evidence appraisal tool. Eight out of the eleven articles had a level I evidence strength and three were assigned to a level II (Newhouse, Dearholt, Poe, Pugh, & White, 2007). The systematic reviews done by Tucker et al. (2017) and Fletcher et al. (2015) included only RCTs in their analyses. The third systematic review by Uhlig, Patel, Ip, Kitsios, and Balk (2013) included forty-nine RCTs but also incorporated three non- randomized studies. The AFenPA quasi- experimental studies had control groups that were not completely randomized (Fikri-Benbrahim, Faus, Martínez-Martínez, Alsina, & Sabater-Hernández, 2012; Fikri-Benbrahim, Faus, Martínez-Martínez, & Sabater-Hernández, 2013).



The demographic characteristics of participants in the reviewed studies included both sexes of adults above eighteen years of age residing in different regions of the world, of different racial and ethnic backgrounds, and diverse socio- economic statuses. Most of the studies recruited their participants from outpatient primary care clinics. All of the participants who were included in the studies had a current diagnosis of HTN and reported to be taking at least one anti-hypertensive medication. The selected literature evaluated the effects of the SMBP monitoring intervention when it was implemented alone or when it was accompanied by various additional supportive co-interventions. The synthesis of the eleven research articles validated the efficacy of SMBP in hypertensive adults and revealed the following two major themes: (1) SMBP resulted in improved BP values, (2) SMBP increased adherence to anti-hypertensive medications.

### **SMBP Without Additional Support**

The value and significance of SMBP monitoring in decreasing BP and improving the control of HTN was supported by evidence from the chosen literature. Uhlig et al. (2013) conducted a systematic review that analyzed BP outcomes in participants who utilized the SMBP intervention alone or with additional support. One portion of their review exclusively compared the net changes in BP among hypertensive adults who self- measured their BP without any additional supportive co -interventions to those who received the usual care and just had sporadic measurements of their BP in the clinician's office. Evidence from twenty-six eligible studies was analyzed at various time intervals. At the six-month mark, SMBP monitoring was associated with a statistically significant weighted mean difference of -3.9 mmHg ( $p<0.001$ ) in systolic BP and of -2.4 mmHg ( $p<0.001$ ) in diastolic BP, when compared to usual care. The weighted net changes in systolic and diastolic BP at the twelve-month follow-up were -1.5 mmHg and -0.8

mmHg, respectively. Although the results at the twelve-month follow up were smaller in magnitude and not considered to be statistically significant, the SMBP intervention was still favored by the majority of the studies because it demonstrated overall consistent decreases in BP. Based on the positive findings from this systematic review, the U.S. DHHS established its “Million Hearts” initiative, which provided action steps for clinicians for the implementation of SMBP monitoring into routine practice (CDC, 2014).

Effects of the SMBP intervention alone versus usual care was also later studied in an individual clinical research trial by Aekplakorn, Suriyawongpaisal, Tansirisithikul, Sakulpipat, and Charoensuk (2015). The investigators conducted a twelve-month trial in a semi-urban community in Thailand. A total of 224 eligible hypertensive adults with uncontrolled BP (systolic BP  $\geq 140$  mmHg or diastolic BP  $\geq 90$  mmHg) were enrolled and assigned via concealed block randomization to either an intervention or control group. Participants in the intervention group (n=111) were provided with a validated oscillometric Omron BP monitoring machine and received individual training on how to use the monitor, record results, and interpret their BP measurements. The study group participants were instructed to measure their BP twice a day, taking three readings during each occurrence. The control group (n=113) received the usual care from their physicians and was not provided with BP machines. A linear mixed model was used to examine the differences in systolic BP between the two groups and a mixed effects logistic regression analyzed the variations in the percentage of uncontrolled BP. At the conclusion of the trial, the comparison of the mean BP measurements revealed that the SMBP group had systolic and diastolic BPs less than the control group by 2.5 mmHg and 1.2 mmHg, respectively. Additionally, a statistically significant benefit of the intervention was found at twelve months in the population subgroup aged  $\geq 60$  years, with an 8.9 mmHg decrease in their systolic BP (95%

CI: -15.1, -2.7), and a decrease in uncontrolled BP from 90% (n= 50) at the baseline to 38.2% (n= 21) at the endpoint (p= 0.02). The authors of the trial noted that the study group participants were not fully adherent to the instructions that they were provided with on BP self- measurement (84.1% reported that they regularly recorded their BP for an average of 123.9 days and only 54.7% reported that they regularly recorded their BP for >135 days), which could have possibly reduced the effectiveness of the intervention. The results of this particular study were complementary to the findings in the systematic review by Uhlig et al. (2013), demonstrating the positive benefit that SMBP had on BP control and highlighted the importance of routinely utilizing it in the management of hypertensive adults.

### **SMBP With Additional Support**

SMBP monitoring on its own has marked benefits, but even better outcomes with more significant reductions in BP were identified when it was used in conjunction with other supportive interventions (Whelton et al., 2018). Bosworth et al. (2009) conducted an RCT with a two- year follow up in Durham, North Carolina. They enrolled 636 study participants from two primary care clinics that were affiliated with the [REDACTED]. All of the participants had an established diagnosis of HTN and were being treated with anti-hypertensive medications. The primary investigators randomly assigned the participants to one of four groups: control/ usual care (n=159), tailored behavioral self- management intervention (n= 160), home BP monitoring intervention (n=158), and a combined home BP monitoring and tailored behavioral self- management intervention (n=159). At the one-year follow up, the home BP monitoring group had a decrease in their mean systolic and diastolic BPs by 3.7 mmHg (95% CI: -6.1, -1.2; p= 0.004) and 3.1 mmHg (95% CI: -4.4, -1.8; p<0.001), respectively, and the combined intervention group had a decrease in their mean systolic and diastolic BPs by 3.3

mmHg (95% CI: -5.7, -0.8;  $p=0.009$ ) and 2.2 mmHg (95% CI: -3.5, -0.8;  $p=0.001$ ), respectively. Conversely, by the two-year follow up, comparisons to the usual care group revealed clinically meaningful decreases in BPs only in the combined intervention group of 3.9 mmHg systolic (95% CI: -6.9, -0.9;  $p=0.010$ ) and 2.2 mmHg diastolic (95% CI: -3.82, -0.6;  $p=0.009$ ). At the completion of the study, participants in the combined intervention group had the greatest improvement in BP control of 11% (95% CI: 1.9%, 19.8%;  $p=0.012$ ) followed by the home BP monitoring group of 7.6% (95% CI: -1.9%, 17%;  $p=0.096$ ). The study results suggested that over time the combination of SMBP with a behavioral co-intervention produced a synergistic effect and thus led to better improvements in BP. The benefits of SMBP were speculated to be related to positive feedback. When patients self monitored their BPs and saw their values decrease, they were further encouraged to continue following their suggested treatment plan. On the contrary when patients visualized that their BP readings were repeatedly high, they may have been more willing to make alterations to their lifestyles and had a better understanding of why certain changes were instituted in their treatment plans.

Another RCT trial was also conducted in Durham, North Carolina by Bosworth et al. (2011) that evaluated the effect of a telemedicine intervention on BP control over a time period of eighteen months. The study included 591 eligible participants that were recruited from general internal medicine clinics and were randomly assigned to the control and intervention groups. The baseline characteristics of the study sample revealed that 48% were African American, 49% were white, 92% were male, 59% had their baseline BP under control, and the average age was 64 years. The participants in the control group did not receive any guidance or home telemonitoring equipment, and were routinely managed according to the decisions of their primary care providers. Participants that were randomized to the behavioral management intervention group,

were provided with a validated wireless home BP monitor and telemedicine device, instructed to measure their BP once every other day, and the measurements were automatically transmitted to a secure server. The behavioral intervention was triggered when the average home BP values recorded over two week intervals exceeded the established thresholds of 135/85 mmHg for people without co- occurring diabetes or 135/80 mmHg for those with diabetes. The supportive behavioral intervention was conducted over the phone, for a duration of about twelve to fourteen minutes, and focused on improving HTN self- management by reinforcing HTN knowledge, offering medication reminders, and addressing the patient-health care provider relationship. Participants who maintained their BPs at threshold were only contacted every six months to reinforce their positive behaviors. Individuals in the intervention group who did not measure their BP at least three times over a two- week period, were contacted by research assistants and reminded to use their equipment as instructed. Results at the twelve- month follow-up that evaluated the outcomes of BP control in the behavioral management group compared to the usual care group found a statistically significant improvement in the intervention group of 12.8% (95% CI: 1.6%, 24.1%;  $p=0.03$ ). Post hoc analyses of the baseline BP control subgroups, found that individuals in the behavioral intervention group with poor BP control at baseline had a decrease in their systolic BP by 8.3 mmHg (95% CI: -15.1, -1.6;  $p=0.02$ ) at the 12 month follow up, and participants who initially had adequate BP control at baseline continued to remain in control throughout the entire eighteen month study period.

Investigating a similar concept of SMBP monitoring with additional support, Fuchs et al. (2012) conducted a sixty-day RCT in Rio Grande do Sul, Brazil. The study included 136 eligible hypertensive adults on anti-hypertensive treatment with uncontrolled office BP ( $\geq 140/90$  mmHg) and uncontrolled 24- hour ambulatory BP ( $\geq 130/80$  mmHg). Participants who were randomized

to the intervention group received an oscillometric BP monitor, were trained on proper standardized BP measurement techniques, were educated about non-pharmacological interventions related to HTN management, and were advised to continue taking their prescribed anti-hypertensive medications throughout the trial. The control group was not provided with the SMBP intervention but received the same educational support. Sixty days post initiation of the study, the decreases in BPs evaluated by ambulatory BP monitoring were significantly higher in the intervention group. The 24-hour ambulatory BP monitoring results of participants in the intervention group were as follows: systolic BP  $\delta$  was 8.8 mmHg ( $\pm 13.1$ ;  $p = 0.02$ ) and diastolic BP  $\delta$  was 5.6 mm Hg ( $\pm 8.4$ ;  $p = 0.002$ ). Furthermore, 32.4% of participants in the intervention group and only 16.2% of participants in the control group had their 24- hour systolic BP less than 130 mmHg ( $p = 0.03$ ). However, similar significant differences in BP values between the control and intervention groups were not appreciated by office BP measurements. At the conclusion of the trial, adherence to SMBP monitoring was high (84.6%), which indicated that it was well received by the participants and it could be a practical intervention to implement in other populations. The authors suggested that the complexity of the intervention could have possibly affected the adherence rate and thus a more simplified SMBP process could be beneficial to promote long- term adherence to the intervention.

Piette et al. (2012) conducted another RCT that evaluated the effects of mobile technology and home BP self-monitoring on HTN management. The six-week study recruited participants from clinics in two low/ middle-income countries, Honduras and Mexico. There were a total of 181 eligible hypertensive adults who were assigned to either an intervention group ( $n=89$ , given a home BP monitor, provided with instructions on how to check their BPs, and received weekly automated calls with information on self- monitoring and self-care) or a

control group (n=92). Results for the overall intervention group sample that were obtained at the six-week follow-up indicated a statistically non-significant reduction in systolic BP (-4.2 mmHg;  $p=0.09$ ). However, compared to the control group, the intervention subgroup (n=117) that included participants with low-literacy and high information needs had a significant decrease in systolic BP of 8.8 mmHg (95% CI: -14.2, -3.4;  $p=0.002$ ). Although the results did not demonstrate statistical significance in the overall sample, the intervention participants on average still had lower systolic and diastolic BPs than the control group, -4.2 mmHg and -3.2 mmHg, respectively. Additionally, based on the BP guidelines established by the Joint National Committee, the percentage of participants who achieved BP control at the six-week mark was greater in the intervention group than in the control group (57% versus 38%;  $p=0.006$ ).

Fikri et al. (2012) conducted a six-month quasi-experimental study, which investigated the effect of a protocol based pharmacist intervention on the control of BP in treated hypertensive patients. The intervention was delivered by local community pharmacists in Spain and consisted of three components: education (HTN, lifestyle habits, and the importance of medication adherence), SMBP, and the referral of participants to a physician if their mean BPs were  $\geq 135/85$  mmHg during five consecutive days. The control group was supplied with their usual medications by the pharmacists but did not receive any additional education and was not given home BP monitors. A total of 176 participants were included in the study, 87 in the intervention group and 89 in the control group. The average age of the participants was 62 years, 37.5% of the total participants were male, and 51.7% of participants had their BP controlled at baseline ( $<140/90$  mmHg). At the conclusion of the study, data analysis showed that the intervention group had significant reductions in both systolic BP (-6.8 mm Hg;  $p<0.001$ ) and diastolic BP (-2.1 mm Hg;  $p=0.032$ ). The calculated adjusted mean difference between the

intervention and control groups was 5.7 mmHg for systolic BP ( $p= 0.001$ ) and 2.6 mmHg for diastolic BP ( $p= 0.013$ ) indicating that the intervention group had much greater decreases in BP. The odds of participants achieving BP control in the intervention group was 2.46 times higher than in the control group (95% CI: 1.15, 5.24;  $p= 0.020$ ), and was substantiated by an increase from 52.9% at baseline to 71.3% at endpoint ( $p= 0.009$ ). On the contrary, no significant changes in BP control were observed from baseline to endpoint in the usual care group, 50.6% to 55.1%, respectively ( $p= 0.481$ ). The outcomes of this study were congruent with the results obtained in the previously mentioned literature, which further supported the benefits of combining SMBP with additional co- interventions and the importance of utilizing it as a daily practice by hypertensive adults.

A systematic review published by Tucker et al. in 2017 provided pooled estimates of the effects of SMBP when it was combined with different levels of co-interventions. After a meticulous selection process, the researchers reviewed twenty- five randomized trials that included a total of 10,487 participants from various regions around the world. All of the studies were required to have at least 100 patients who were followed up for at least twenty- four weeks. Among the selected studies, results at twelve months indicated that compared to usual care, SMBP was associated with a reduced clinic systolic BP by 3.2 mmHg (95% CI: -4.9, -1.6) and a reduced diastolic BP by 1.5 mmHg (95% CI: -2.2, -0.8). The reductions in clinic BP values were strongly correlated to the intensity of the co-intervention that was combined with the self-monitoring. The co- interventions were distributed to four pre-defined levels of support; level one indicated minimal additional contact, level two indicated automated feedback or support but without one on one contact, level three indicated an active intervention that provided support and education in regular classes, and level four indicated significant individually tailored support.



The combination of a level four co-intervention with SMBP resulted in a 6.1 mmHg decrease in systolic BP (95% CI: -9.0, -3.2) and a 2.3 mmHg decrease in diastolic BP (95% CI: -4.0, -0.6), whereas a level one co-intervention resulted in a 1.0 mmHg decrease in systolic BP (95% CI: -3.3, 1.2) and a 1.1 mmHg decrease in diastolic BP (95% CI: -2.4, 0.2). Similarly, the systematic review published by Uhlig et al. (2013) also reinforced the concept of an enhanced BP- lowering effect with the addition of supportive co-interventions to SMBP. The presented evidence- based findings from the literature were relevant and supportive of implementing the SMBP intervention in the proposed pilot project.

### **SMBP and Medication Adherence**

An additional benefit of SMBP that had been acknowledged by the literature was its positive impact on increasing medication adherence in hypertensive adults. A systematic review published by Fletcher et al. (2015) evaluated the effect that SMBP had on adherence to anti-hypertensive medications in twenty- eight eligible RCTs with 7,021 participants. The included studies were conducted in the United States, Australia, Brazil, Germany, Canada, Iran, Spain, United Kingdom, Finland, Nigeria, Netherlands, and Belgium. The investigators used a comprehensive search strategy that captured more than double the amount of studies compared to previously conducted reviews and had sufficient data that allowed for estimation of effect size. The studies assessed adherence to anti-hypertensive medications by electronic monitoring (n=5), pill counts (n=8), self-report (n=9), and pharmacy fill data (n=6). A pooled analysis of all of the measures of adherence indicated that thirteen studies were in favor of SMBP and its positive effect on medication adherence (standard mean deviation 0.21, 95% CI: 0.08, 0.34). A subgroup analysis of the electronic monitoring group detected a significant effect in favor of the SMBP intervention (standard mean deviation 0.45, 95% CI: 0.10, 0.79). This analysis detected

statistically significant improvements in adherence to anti-hypertensive medications as a result of SMBP, which was consistent with the findings in another systematic review that was published by Ogedegbe and Schoenthaler in 2006. Increasing the adherence to anti-hypertensive medications is critical, since about 9% of cardiovascular events in individuals with HTN could be attributed to their poor adherence to pharmacological therapy (Chowdhury et al., 2013).

Souza, Jardim, Brito, Araújo, and Sousa (2012) conducted a 2:1 RCT in Brazil that evaluated whether the use of SMBP for a period of twelve months would promote better BP control, favorable changes in lifestyle and increased adherence to anti-hypertensive treatment. The trial sample consisted of fifty-seven patients, thirty-eight in the study group and nineteen in the control group. Investigators conducted quarterly medical visits as well as other random examinations, collecting data on BP measurements and the number of anti-hypertensive medications ingested daily. The intervention group reached their BP treatment goals faster than the control group, with a marked reduction from baseline in the sixth month for both systolic BP (135.49 mmHg;  $\pm$  12.73;  $p=0.022$ ) and diastolic BP (81.69 mmHg;  $\pm$  10.88;  $p=0.020$ ). Additionally at the twelve-month mark, the adherence to the regular use of anti-hypertensive medications in the study group increased from 76.3% to 100%, whereas adherence in the control group changed minimally from 84.2% to 88.2% ( $p=0.031$ ). There was also a significant decrease in the number of types of anti-hypertensive medications used in the intervention group ( $p=0.043$ ), which could possibly be attributed to the identification of white- coat HTN through SMBP, and the subsequent reduced need for medications.

The AFenPA quasi- experimental study conducted by Fikri et al. (2013) demonstrated a similar impact of SMBP on medication adherence outcomes. The study revealed that 86.3% of participants (151 out of 209) were adherent to their anti-hypertensive medication regimens at

baseline. The intervention group received education on aspects related to HTN and medication adherence. Additionally, patients in the intervention group were provided with BP monitors, and were instructed to measure their BPs on their own. Adherence to medications was assessed via the manual pill counting method. In order minimize threats to internal validity, specifically via the Hawthorne effect, the participants were not aware of when their medications would be counted. Medication adherence in the intervention group increased from 86% at baseline to 96.5% at endpoint ( $p= 0.022$ ). The control group did not demonstrate an improvement in adherence, from 86.5% at baseline to 85.4% at endpoint ( $p= 0.928$ ). The investigators also concluded that the odds of adherence to antihypertensive medications in the intervention group were 4.07 times (95% CI: 1.04, 15.95;  $p= 0.044$ ) higher than in the control group. SMBP was noted to be a key component in the intervention group that contributed positively towards the improvement of participant's adherence to anti-hypertensive medications.

### **Limitations of the Included Studies**

Several limitations should be acknowledged for the studies that were included in the literature review. Three of the trials had short follow up periods; thus, the long-term effects of SMBP on BP control and medication adherence remain unknown (Fikri et al., 2013; Fuchs et al., 2012, Piette et al., 2012). Aekplakorn et al. (2015) and Piette et al. (2012) conducted their studies with a rather ethnically homogenous participant population, which could limit their generalizability to more diverse groups of hypertensive patients. The majority of the participants in the study conducted by Bosworth et al. (2009) were male and the sample population in the study by Fuchs et al. (2012) was predominantly female, which limits their external validity and applicability to patients of both sexes. The systematic review by Uhlig et al. (2013) had noteworthy clinical heterogeneity present among the protocols for the SMBP intervention, which

limited the author's ability to make specific and direct comparisons.

### **Evidence Builds a Case for the Intervention**

The reviewed literature provided sufficient evidence to support the overall aim of the proposed pilot project to improve BP control in adults with HTN by implementing SMBP within community settings. The current studies confirmed that SMBP monitoring improved BP control, decreased systolic and diastolic BPs, and increased adherence to anti-hypertensive medications. Furthermore, the addition of supportive co-interventions to SMBP led to even greater improvements in BP, and should be strongly considered in the management of hypertensive adults. Although the short- term benefits of SMBP were evidenced in the literature, further research is needed to determine its clinical effectiveness over a longer span of time.

### **Theoretical Framework**

Improving BP control by routinely implementing the practice of SMBP requires for affected hypertensive adults to modify their current behaviors. The Transtheoretical Model (TTM) is a well-established theoretical framework, which was used as the conceptual framework to promote behavioral changes in the proposed pilot project (Prochaska & DiClemente, 1982). Originally developed by psychologists James Prochaska and Carlo DiClemente (1982), TTM is an integrative model (Appendix B) of intentional behavior change that focuses on the decision making of individuals. It is a comprehensive framework that describes the process of how individuals either learn to amend a current problematic behavior or adapt a new positive behavior. TTM was initially developed to help individuals quit smoking, but since then numerous studies have successfully applied it to a variety of other health behaviors such as stress management, physical activity to promote weight loss, low fat diets, delinquent adolescent behaviors, safer sex, sunscreen use to prevent skin cancer, radon gas exposure, and

mammography screening (Prochaska et al., 1994). TTM is a gradual cyclical process in which individuals progress through the following five stages of change: precontemplation, contemplation, preparation, action, and maintenance. In order to ensure that individuals experience a smooth transition between each of the stages of change the intervention should be introduced with adequate support.

### **Precontemplation**

Precontemplation is considered to be the initial stage of the process of change at which point the person does not realize that there is a need for change because they are unaware of or fail to recognize that a certain problem exists (Prochaska & DiClemente, 1982). In this particular study, those were the individuals with poorly controlled HTN who did not previously self-monitor their BPs and had not considered any additional methods to help decrease their BPs. The intervention at this stage included a discussion about the risks related to poorly controlled BP and the benefits of adapting SMBP, as well as encouraged the participants to express their opinions and ask questions.

### **Contemplation**

The contemplation stage was when individuals begin to understand the problem and actually considered adapting the intervention by changing their behaviors. At this point it was important to increase the participant's confidence, by providing them with supportive information about simple ways to adapt the SMBP intervention into their lifestyles, and discussing potential barriers that they perceived.

### **Preparation**

During the preparation stage, the individuals intended to adapt the SMBP intervention and had a detailed plan of action. In this step goals were set and each individual was taught the

specific strategies on how to check their own BPs and track the measurements in the provided designated logs.

**Action**

During the action stage, the individuals had finally adjusted their lifestyles and started to engage in the SMBP intervention. Participants in this study attended the pre-designated follow-up sessions where they were provided with ongoing educational support and continued reinforcement on the importance of adherence to the intervention.

**Maintenance**

Maintenance was the ultimate end goal of this study, in which individuals would continue to routinely utilize the SMBP intervention and see sustained improvements in their BP outcomes and adherence to medications. Continued reassurance and positive feedback were necessary to ensure sustainability of the intervention.

**Methodology**

The present pilot project utilized a quasi- experimental one-group pre-test post- test design that assessed anti-hypertensive medication adherence via administered surveys as well as measured BP values with validated monitors before and after the implementation of the SMBP intervention.

**Setting**

The site for this project was a large health fitness community center in East Rutherford, NJ. This recently built facility opened its doors to the general public in 2017 and currently has about 16,000 enrolled members. The site is open seven days a week, and has health programs and services tailored to populations of all ages. The 83,000 square foot facility has a gym, pool, cooking studio, physical therapy, massage therapy, and multiple enclosed rooms that can be used

for conducting various classes and programs. One of those enclosed rooms in the facility was utilized for the project. The room was quiet and free from distractions, easily accessible, and had set up tables with chairs that comfortably accommodated the study participants.

### **Study Population**

This project included a convenience sample of adults who were members of the fitness facility and self-reported to have a pre-existing diagnosis of HTN. The aforementioned sampling type was chosen in this project because it was a useful technique in acquiring primary data in the pilot study, it was cost- effective, it could be conducted in a short duration of time, and the collection of data was easier due to the convenient availability of the study participants. Due to the pilot nature of the study, the exact amount of participants was not calculated and the goal was to recruit as many participants as possible in order to detect the differences in the pre and post intervention results. Given the limitation of time and resources, the desired sample size was twenty participants. The inclusion criteria for the study were the following: 1) male and female adults over 18 years but less than 90 years with a current diagnosis of HTN, 2) currently taking anti-hypertensive medications, 3) proficient in English, 4) had their own BP monitor or were able to come to the fitness facility and measure their BP with monitors provided by the principal investigator (PI), 5) were physically capable of taking their own BP twice a day. The exclusion criteria for the study were the following: 1) individuals without a current diagnosis of HTN, 2) individuals not under the treatment of any anti-hypertensive medications, 3) pregnant females, 4) individuals with cognitive impairment, 5) individuals with a diagnosis of arrhythmia.

### **Subject Recruitment**

Subjects for the study were initially identified via referral by employees at the health facility as well as subject self-referral in response to the distributed recruitment materials.

Information about the study was delivered to potential research subjects via recruitment posters (Appendix C) that were displayed in the lobby, locker rooms, and gym of the facility. Permission to hang the posters in the facility was obtained from the wellness director. On two separate occasions the PI also attempted to recruit participants by setting up a table in the common area of the facility and handed out flyers to individuals who voluntarily expressed interest. The PI took considerable care when talking to potential research subjects so that they did not feel pressured or coerced to partake in the voluntary study. The recruitment process lasted for two weeks. The posters and flyers provided a general description of the purpose of the research, the eligibility criteria, the required time commitment, the PI's contact information including the email and telephone number, the exact location and the start date/ time of the research study. All of the potential research subjects were informed that participation in the study was voluntary.

### **Consent Procedure**

The individuals who were interested in participating in the study and reported eligibility based on the criteria that they were provided, had an opportunity to speak privately with the PI and ask any questions or express concerns related to the study. The PI allotted two hours prior to the start of the study to explain the purpose of the project and the process, reviewed the accompanying risks and benefits, and discussed how all of the responses would be kept confidential and their anonymity would be protected. Individuals were given sufficient time to consider if they wished to participate. Each prospective research participant was also allowed to decline participating in the study for any reason and could also stop participating during any stage of the process, without any associated penalties. In accordance with [REDACTED] IRB requirements, before any study procedures began, every eligible individual who voluntarily chose to participate was asked to sign an informed consent written in the English language



(Appendix D). The [REDACTED] IRB consent form template was utilized and customized to meet the aims and objectives of the research study. Every participant was also provided with a copy of the consent form, which they could retain for their own reference.

### **Risks/ Harms/ Benefits**

During the process of obtaining consent, potential participants were provided with an accurate and fair description of the anticipated risks, harms, and benefits of participating in the research study. Participation in this research study posed no risk of physical harm or discomfort. There was a very minimal risk related to a possible breach in confidentiality, where the participant's data could have been inadvertently shared. In order to minimize that risk, procedures were incorporated to protect the confidentiality of all of the collected data. To ensure anonymity and privacy, a master code list was generated at the beginning of the study that linked each participant's name to a unique code. The master code list was kept separately from all of the other data in locked cabinets, and was only accessible by the PI. Responses from the pre and post intervention surveys, BP logs, and demographics surveys were linked to the participants based on the unique code. The data was completely de-identified before analysis. Also, a potential inconvenience to the study participants was that they had to dedicate time to participate in the study intervention, specifically, those participants who did not have their own BP monitors and had to come to the facility to measure their BPs. The potential benefits to individuals who participated in this study included having their BPs measured and learning about the SMBP intervention that would help to improve their BP control and lead to better health outcomes.

### **Subject Costs and Compensation**

There were not any costs associated with participating in this research study. Participants did not receive any monetary compensation. Subjects were compensated for the time that they

spent participating in the study with light refreshments, which were provided at all three project sessions.

### **Study Interventions**

The research study was conducted over four weeks and consisted of a total of three in person sessions, each held two weeks apart. All of the sessions were held in the facility at pre-determined dates and times that were agreed upon with the wellness director. The PI obtained guidance from the wellness director on the times and dates that were most convenient for the study participants. All of the sessions were delivered in person, face to face with the study participants. The first session of the project was an hour long, and commenced after written informed consent was obtained from all of the eligible participants. The session began with an explanation of the purpose of the voluntary study, its objectives and the required time commitment. The PI then provided instructions to the participants on how to create their unique identification code. Participants were asked to remember their unique codes for the duration of the study and to only use the codes as identification on all of the surveys and logs. Study participants were then asked to complete a demographic survey (Appendix E) and a nine question Hill-Bone Medication Adherence Scale (HB-MAS; Appendix F). The PI obtained BP measurements for each participant using the appropriate sized BP cuff and a validated Omron M6 comfort oscillometric monitor. Following the collection of the initial BP values, the PI delivered an educational group session that provided an overview on HTN, stressed the importance of adherence to anti-hypertensive medications, as well as explained in detail SMBP and its value. A 3:45 minute SMBP instructional training video that was created by the AHA and AMA was also shown to the participants ([https://targetbp.org/tools\\_downloads/self-measured-blood-pressure-video/](https://targetbp.org/tools_downloads/self-measured-blood-pressure-video/)). Participants were given a BP log and other printed educational

information to take home with them. They were advised to measure and record their BPs using the techniques that were taught to them in the training. Participants were asked to routinely check their BPs for seven days, every morning and evening, recording the average of two measurements taken on the same arm one minute apart. Those individuals that were unable to commit to measuring their BPs for seven consecutive days were encouraged to target as many consecutive days as they could. The PI provided four Omron BP monitors, which were kept in a designated quiet room in the facility with a table and chair. Those BP monitors were available to all of the study participants, specifically those who did not have their own monitors at home or were unsure about the validity of the monitor that they owned. During the facility's operational hours, participants were able to come and measure their BPs with the provided machines.

All study subjects were asked to continue to follow the previously established guidelines from their treatment team, to adhere to all of the lifestyle modifications that were previously advised to them, not to make any alterations to their treatment plans before consulting with their clinicians, and to take their medications as prescribed. Participants were also instructed that the SMBP intervention in this research study was not to be used as a substitute for their regular visits to their physician. At the conclusion of the first session each participant had a chance to ask the PI any questions or request further clarification of any information.

Participants were asked to return in two weeks for the second session, and to bring their completed BP logs for review. The second session was very brief, and lasted only for fifteen minutes. Further educational support about SMBP was provided to participants at the second session. The PI reviewed the individual logs and provided personalized feedback. Participants were encouraged to continue following their lifestyle changes as well as to take their medications as prescribed. Each research subject also had an opportunity to voice any concerns or ask

questions. They were provided with a blank BP log, and asked to record their BPs for another seven consecutive days. The session concluded with a reminder to the participants to return in two weeks for the last session. All of the educational materials (Appendices H-O) that were distributed to the participant's were all developed by the AMA and AHA and obtained from the Target: BP program's website (2016).

The final session was conducted two weeks after the second encounter. The participants were asked to bring back their second BP logs, had their BPs rechecked by the PI, and were given the post- intervention HB-MAS. This session lasted for thirty minutes. All of the data that was collected from the paper surveys, logs, and questionnaires was inputted into the SPSS software for analysis.

### **Outcomes Measured**

Demographic data was obtained from each participant via a seven- question tool. The questionnaire was designed by the PI and collected information about age, race, gender, level of education, duration of HTN diagnosis, number of HTN medications, and the frequency at which BP was measured at home.

The outcomes of this project included mean systolic and diastolic BP (obtained pre and post intervention), and adherence to anti-hypertensive medications.

The Omron M6 comfort oscillometric BP monitor was used to measure BP, before and after the intervention. This device fulfilled the validation criteria determined by the European Society of HTN, and the calculated mean differences between the device and mercury readings were  $-1.8 \pm 5.1$  mmHg for systolic BP and  $-0.4 \pm 2.8$  mmHg for diastolic BP (Topouchian et al., 2014).

Adherence to anti-hypertensive medications was measured before and after the intervention using the HB-MAS tool. The HB-MAS is a well- validated instrument for measuring adherence to medications and it is a sub-scale of the original Hill-Bone Compliance to High Blood Pressure Therapy Scale (Kim, Hill, Bone, & Levine, 2000). The short nine-question HB-MAS was specifically designed to focus on the hypertensive population (Lavsa, Holzworth, & Ansani, 2011). The responses for the tool are organized in a four- point Likert-type format (1 = *none of time*, 2 = *some of the time*, 3 = *most of time*, and 4 = *all of the time*) and the scores can range from nine (indicating very poor adherence to medications) to thirty- six points (indicating perfect adherence to medications).

The internal validity of the HB-MAS was confirmed in several studies. In one study, the nine-item medication taking compliance sub-scale was evaluated in an outpatient setting and it was calculated to have a Cronbach alpha of 0.68 (Krousel-Wood, Jannu, Re, Muntner, & Desalvo, 2005). In another study, the HB-MAS was also found to have good internal consistency, with a Cronbach alpha of 0.76, a mean inter-item correlation of 0.29, and an item-total correlation of 0.46 (Lambert, Steyn, Stender, Everage, & Fourie, 2006). Furthermore, the sub-scale was recently adapted to a Polish population subgroup, and it showed an internal consistency of 0.78 (Uchmanowicz, Jankowska-Polańska, Chudiak, Szymańska-Chabowska, & Mazur, 2016). Written permission was obtained from the Hill- Bone Scales team, which authorized the PI to utilize the scale for this research study (Appendix G).

### **Project Timeline**

In order to ensure timely completion, the project followed a rigorous timeline. From the early stages of this project's development to its final defense and graduation, it was anticipated that it would take the PI seventeen months to complete. The proposal development began in

January 2019 and graduation will occur in May 2020. A detailed visual representation of the timeline can be viewed in Appendix P.

### **Resources Needed/ Economic Considerations**

The PI was responsible for all of the costs that were associated with this research study. The resources that were needed for this project include recruitment materials (flyers/ consent), materials for the educational program (educational handouts, measuring tapes, pens, BP monitors, hand sanitizer, disinfectant wipes) and refreshments for the participants. The BP monitors comprised the bulk of the expenses for this project. A detailed budget of the costs is displayed in Appendix Q.

### **Evaluation Plan**

#### **Data Analysis**

Descriptive statistics (mean, frequencies, % and their 95% confidence intervals) were used to describe the sample of participants. Analytical statistics were used to determine the efficacy of the project intervention. The non-parametric Wilcoxon signed- ranks test was used to examine median differences in HB-MAS scores as well as systolic BPs and diastolic BPs, pre and post intervention. A p-value equal to or less than 0.05 was accepted as the significance level. The IBM SPSS Statistics for Windows (Version 25.0) software package was used for the analysis of the data.

#### **Data Maintenance/Security**

The protection of participant information was important during the course of the research study. After each participant consented to participate in the study and prior to the collection of any data, they were asked to create a random four-digit identification code. The four-digit code was not the date of their birthday. The code master list and the name master list were kept

separately. For example, if Jane Lewis was participating in this project, she could select any random number, such as 3876. All of the collected paperwork, including signed informed consents, code lists, surveys, questionnaires, and logs were kept in a locked cabinet in room 1115, at Rutgers University School of Nursing campus located at 65 Bergen Street, Newark, NJ, 07107. All of the electronic data files were password protected, encrypted, and saved both on the computer itself and to the Rutgers cloud based storage, One Drive. Data was de-identified after the completion of the data collection process and only de-identified data was used for analysis. The link between the identification codes and subjects was destroyed once the data was inputted for analysis. The PI was the only one who had access to the collected data. Upon completion of the project, closure of the IRB, and the final writing of the manuscript, all of the data was stored securely for six years. After the six- year mark all of the data will be destroyed in accordance with Rutgers University guidelines.

### **Results**

Thirteen individuals who met the predetermined eligibility criteria participated in this pilot project. The educational intervention and data collection began on September 20, 2019 and continued over a period of four weeks. The third and final implementation session of the project was conducted on October 18, 2019. All thirteen of the participants attended all three of the sessions and completed the pre and post intervention surveys. At the conclusion of the sessions, all of the collected data was de-identified and entered into SPSS (Version 25.0). A double entry verification method was used to ensure that the inputted data precisely matched the original responses and measurements.

### **Characteristics of the Sample Population**

Descriptive statistics were used to evaluate the responses that were obtained from the demographic surveys and the results can be viewed in Table T1 (Appendix T). Out of the total sample population, 53.8% (n=7) identified themselves as male and 46.2% (n=6) identified themselves as female. The ages of the participants ranged from 35 to 74 years, and 61.6% (n=8) of the participants were 55 and older. The baseline characteristics of the study sample also revealed that 61.5% (n=8) were white and 23.1% (n=3) were Hispanic or Latino. Approximately one third of the participants (30.8%, n=4) reported to have completed “some college, no degree,” 38.5% (n=5) had a bachelor’s degree, and 15.4% (n=2) had a master’s degree. The majority of participants had been diagnosed with HTN for at least five years (69.3%, n=9). Almost 70% of the participants (n=9) were currently prescribed two or more anti-hypertensive medications. Prior to the initiation of this project, only three participants (23.1%) reported to monitor their BPs daily, four participants (30.8%) randomly checked their BPs, and three participants (23.1%) did not monitor them at all.

### **Effect of the SMBP Intervention on BP Control**

To analyze the effect of the intervention on BP control, the Wilcoxon signed- ranks test was conducted to compare the mean systolic and diastolic BPs pre and post intervention for the same group of participants. Due to a small sample size and uncertainty regarding data normality assumptions, the Wilcoxon signed- ranks test was chosen as it allowed for the comparison of nonparametric data obtained from two related samples. Appendix U provides the details of the Wilcoxon signed-ranks test for the mean systolic and diastolic BPs.

The calculated mean of systolic BPs prior to the intervention was 131.08 mmHg (SD 14.767) and after the intervention it was 124.62 mmHg (SD 12.494). The reduction in mean



systolic BP was statistically significant ( $p=0.041$ , CI: 95%,  $Z=-2.047$ ). The statistical significance of the result suggests that the reduction in mean systolic BP occurred due to the intervention and not by chance alone.

The calculated mean of diastolic BPs prior to the intervention was 79.54 mmHg (SD 11.377) and after the intervention it was 75.85 mmHg (SD 10.558). The mean diastolic BP post-intervention was numerically lower than the pre-intervention, however, this change was not statistically significant ( $p=0.126$ , CI: 95%,  $Z=-1.531$ ). The lack of statistical significance reflects the uncertainty that the decrease in the mean diastolic BP can be attributed solely to the intervention in this project.

### **Effect of the SMBP Intervention on Medication Adherence Scores**

The pre and post intervention medication adherence score totals were summated prior to the data analysis. Each of the nine items on the HB-MAS tool had a four-point Likert-type response format, with lower scores indicating worse adherence to medications and higher scores indicating increased adherence to medications (minimum score of 4, maximum score of 36). The Wilcoxon signed-ranks test was performed to evaluate if the differences in adherence scores were significantly different before and after the intervention. The pre-intervention mean HB-MAS score was 30.54 (SD 3.152) and the post-intervention mean HB-MAS score was 35.08 (SD 1.320). The mean difference was statistically significant ( $p=0.002$ , CI: 95%,  $Z=3.068$ ), indicating that the improvement in medication adherence occurred due to the intervention and not by chance alone. Appendix V provides the details of the Wilcoxon signed-ranks test for HB-MAS scores.

### Discussion

The present pilot study evaluated the effect of an educational SMBP intervention on improving BP control and increasing adherence to anti-hypertensive medications. The results of this project revealed that education about SMBP and its subsequent utilization led to a statistically significant reduction in systolic BPs. These results were consistent with findings from previously published literature. An RCT trial conducted in Durham, North Carolina found that individuals with poor BP control at baseline who were asked to routinely measure their BPs at home and were provided with information on improving HTN self- management experienced a statistically significant mean decrease in their systolic BPs by 8.3 mmHg (95% CI, -15.1 to -1.6 mm Hg;  $p=0.02$ ) at the twelve month follow- up (Bosworth et al., 2011). Similarly, a systematic review and individual patient data meta- analysis reported that over a twelve-month period, SMBP was associated with a statistically significant 3.2 mmHg decrease in systolic BP (Tucker et al., 2017). Results from the TASMINH4 unmasked RCT found that after twelve months the mean systolic BP was 3.5 mmHg lower (-5.8 to -1.2,  $p=0.0029$ ) in the SMBP intervention group than in the group which had their BPs measured only during routine clinic visits (McManus et al., 2018).

Based on the analysis of the collected data, the current project also demonstrated a statistically significant post- intervention improvement in the overall adherence to anti-hypertensive medications. This increase in medication adherence is congruent with results obtained from prior studies. A 2:1 RCT study conducted by Souza et al. (2012) discovered that individuals in the study group who participated in BP self-monitoring reported a 100% adherence to the regular use of anti-hypertensive medications at the endpoint of the study, whereas the control group reported only 88.2% adherence. Additionally, Fikri et al. (2013) noted

that the odds of adherence to anti-hypertensive medications in their SMBP intervention group were 4.07 times higher than in the control group (95% CI: 1.04, 15.95;  $p=0.044$ ). Fletcher et al. (2015) completed a systematic review and meta-analysis and found thirteen studies that attributed statistically significant improvements in anti-hypertensive medication adherence rates to SMBP (SD 0.21, 95% CI: 0.08, 0.34).

In this study the post-intervention decrease in mean diastolic BP by 3.69 mmHg could not be solely attributed to the effects of the SMBP intervention because the data analysis did not find it to be statistically significant. It is important to note that the pre-intervention mean diastolic BP was 79.54 mmHg, which fell below the recommended optimal diastolic BP goal of 80 mmHg, and may potentially suggest why the changes in diastolic BPs were not statistically significant after the intervention (Whelton et al., 2018). On the contrary, it is also possible to assume that SMBP alone was not sufficient to significantly decrease diastolic BPs. Other previously conducted studies such as the TASMINH4 and the study conducted by Bosworth et al. (2011) could also not find significant evidence to support that their participants' diastolic BPs were reduced by the SMBP intervention (McManus et al., 2018). A meta-analysis that systematically assessed the results of nineteen studies, revealed that SMBP monitoring was associated with a statistically significant net decrease in diastolic BPs at six months (weighted mean difference, -2.4 mmHg), yet those net changes were no longer statistically significant at the twelve month follow-up (weighted mean difference, -0.8 mmHg) (Uhlir et al., 2013).

The three predetermined study objectives that included designing and implementing an evidence-based educational SMBP intervention, and evaluating the effects of the intervention on BP control and anti-hypertensive medication adherence were all met. The SMBP intervention was designed utilizing the recommendations and educational materials that were offered by the

Target: BP program. All of the corresponding educational handouts were printed and distributed to every participant at the first implementation session. A thorough training (including return demonstration) on accurate techniques for BP measurement was individually conducted with the participants. The effect of the SMBP intervention on BP control and on anti-hypertensive medication adherence was measured utilizing the defined tools, surveys, and questionnaires. All of the necessary data, including pre and post intervention measurements, was obtained from all of the thirteen participants.

The key facilitators that allowed for the project objectives to be achieved included the availability of the free and reproducible educational materials on the Target: BP website, an HB-MAS tool that was easily adapted to the specifics of this project, open communication and transparency with the project site's fitness director, and the currently established and functioning SMBP programs in the same chain of fitness facilities located in other areas across the United States. On the contrary, the participants' previous experiences with measuring their own BPs, their lack of knowledge about SMBP, as well as their resistance to change, were all considered to be initial barriers to the project's objectives.

This study did not result in any adverse events or harm to participants, however, it is important to address two unintended consequences that emerged at the conclusion of the project. Several participants who did not have their own automated BP machines and had to come to the fitness facility to measure their BPs, reported that they consequently had an increase in exercise. They explained that because they were already present at the fitness facility measuring their BPs for the study they felt positively influenced to engage in physical activities. A negative unintended consequence of the project was that it increased the workload of the participants' daily lives by requiring them to routinely measure their BPs and log them.

There were several limitations to this study. One limitation of the study was that it was conducted over a short period of time (four weeks). Due to the time constraints, the study did not allow for adequate follow up time, thus, the long- term results and lasting consequences of the intervention are unknown. Also, the study did not permit the participants to fill-out the post-intervention HB-MAS surveys at home, several weeks after the conclusion of the study, which could have positively influenced the medication adherence results. It is also important to note that the average pre-intervention medication adherence score (30.54) was relatively high and therefore populations that score much lower on the HB-MAS pre-test could potentially have different results. Another limitation of this study was the lack of randomization and possible selection bias. The project was implemented at a single health fitness facility, which restricted the amount of prospective participants, and a convenience sample of adult members of the fitness facility was used. The study also had limited generalizability. Based on the responses obtained from the demographic questionnaires, the majority of participants identified as white, greater than 55 years of age, and had some college degree. The outcomes of this study may not translate to individuals of other ethnicities, younger age groups, or to those without any college education.

The Transtheoretical model was applied as the conceptual framework to guide this project's proposed change and promote the utilization of the SMBP intervention (Prochaska & Di Clemente, 1982). SMBP was introduced to each participant at the precontemplation stage. After choosing to adapt the intervention and routinely self- measuring their BPs for four weeks, the participants progressed through the other sequential stages of change; contemplation, preparation and action. At the final session of the project, the participants were encouraged to maintain the SMBP intervention long- term in order to continue achieving positive results. To

further promote maintenance and ensure the sustainability of the intervention, participants were also provided with additional SMBP resources.

Overall, the project progressed according to the proposed plan and it achieved statistically significant decreases in two of the three measured outcomes. There was only one minor setback in the process, which was related to the timing of the first implementation session. The initial implementation session was initially scheduled to begin during the first week in September of 2019. However, after discussion with the health facility's fitness director it was decided to delay the start of the project by two weeks, in order to allow for members to return from their Labor Day vacations and to make more prospective participants aware of the upcoming study. Due to the pilot nature of the project, the goal was to recruit as many participants as possible. The initial desired sample size was set at twenty people, and at the conclusion of the study there were thirteen individuals who had participated. From the initial planning phases of the project to the completion of the data analysis, the PI received adequate support and guidance from the project's chair, team member, and the health fitness facility. Since this was a pilot project, the associated financial costs were minimal and were entirely covered by the PI. However, if this project is implemented on a larger- scale in the future, sponsors should be considered to assist with funding. Furthermore, it would also be advisable for future similar studies to simultaneously implement the intervention in multiple primary care settings and to increase the time frame. Both of the aforementioned suggestions would hopefully increase the heterogeneity of the sample population as well as allow for a longer follow-up time and evaluation of the long-term effects of the SMBP intervention. Future research can also focus on measuring the participant's level of adherence to the SMBP intervention and its effect on HTN outcomes.

## **Implications/ Recommendations**

### **Clinical Practice**

The findings of this particular study demonstrated that SMBP led to an improvement in BP control by decreasing mean systolic BP and it also enhanced HTN management by increasing adherence to anti-hypertensive medications. Based on these results, it would be strongly recommended to expand the SMBP intervention to primary care offices and to make it the cornerstone of HTN management. Primary care offices should join the national Target: BP initiative to learn the best strategies on how to incorporate SMBP into their current workflows and to obtain a variety of resources for their patients. Primary care offices should also designate select staff as SMBP champions, who can help lead the intervention in its initial stages and promote full engagement from all other members of their health care teams.

Healthcare providers should introduce SMBP to their hypertensive patients and stress its importance in the management of their chronic condition. Patients should be offered adequate support and assessed for their readiness to incorporate SMBP into the self- management of their HTN. Patients who are agreeable to the intervention should be provided with brief education about SMBP and instructed on accurate BP measurement techniques. Targets for treatment should be explained and patients should be taught to promptly communicate concerning BP results to their healthcare providers. Routine contact should be made with the patients in order to ensure adherence to the intervention as well as to answer any of their questions. Providers should encourage their patients to bring their recorded BP logs to every appointment (Cuenca, 2016). During the encounters, providers can collaboratively review the logs with their patients and offer positive reassurance if the BPs are at the target goal, explore possible reasons for poor BP control such as medication non- adherence, and if necessary decide to make any adjustments to

the treatment. Similar to how the home blood glucose monitoring intervention is performed every day by diabetics, SMBP should also become incorporated into every hypertensive patient's daily care routine. In addition to monitoring their BPs the patients should be continuously reminded to adhere to the suggested lifestyle modifications and to their anti-hypertensive medication regimens.

### **Healthcare Policy**

The outcomes of this pilot project supported the most recent Healthy People Heart Disease and Stroke goal, which targeted to increase the proportion of hypertensive adults with optimally controlled BP to 61.2% by the year 2020 (ODPHP, 2013). The demonstrated significance of SMBP in HTN management also coincided with the clinical practice guideline established by the AHA and ACC in 2017, which listed SMBP as a class I recommendation in clinical practice (Whelton et al., 2018). To continue optimizing SMBP efforts, policies should also be created to support a community wide process of collaboration between various care models. Standardized SMBP toolkits should be developed and offered to a variety of organizations that routinely interact with hypertensive individuals, such as primary care offices, health fitness facilities, and community centers. These toolkits should include SMBP education, training, and bi-directional referral workflows. The established workflows can be utilized by community organizations and clinical sites to collectively recognize patients with HTN and based on their identified needs set them up with the appropriate SMBP resources.

Policies should also focus on developing new methods for easily integrating the BP values obtained with self- measurement into the patients' electronic health records. Furthermore, primary care offices should develop policies for loaner BP programs, which will provide patients with temporary BP machines until they are able to obtain their own. Patients who choose to



participate in these loaner programs should be screened to meet designated selection criteria and be advised that participating in the SMBP intervention program is not merely an opportunity to get a free BP machine. It is anticipated that with the development of the aforementioned policies, the value of SMBP will become more widely recognized and the intervention will become adopted nationwide.

### **Quality and Safety**

HTN is an immensely challenging public health problem, which contributes to more than 800,000 deaths across the United States and also significantly decreases the health related quality of life (Frieden & Berwick, 2011). The overall results of this study support the use of SMBP in managing HTN. To achieve HTN related improvements in quality of care, quality of life, and safety, organizations should be urged to incorporate standardized SMBP programs into their HTN treatment plans.

SMBP encourages hypertensive patients to become actively engaged with their healthcare providers in the management of their condition, as well as increases their motivation and adherence to treatment. These behavioral changes increase individuals' quality of lives by preventing or delaying the development of other serious comorbid illnesses, which subsequently prevents functional decline, loss in productivity, unnecessary hospitalizations and dependence on invasive treatments (Soni, Porter, Lash, & Unruh, 2010). Compared to the occasional BP measurements that are obtained in the provider's office, self- measured BP values are more predictive of target organ damage and adverse cardiovascular outcomes (Drawz et al., 2012). Quicker adjustments to treatment can be made when BPs are self-monitored and shared with healthcare providers, thereby reducing the associated risks of persistently elevated BPs and increasing patient safety (Jacob et al., 2017).

**Education**

Offering education to healthcare providers on SMBP is an essential preliminary step for ensuring the intervention's success and improving HTN control. Pre-existing knowledge and thoughts pertaining to SMBP should be assessed prior to initiating any changes, to determine the potential barriers that may impede SMBP education and implementation efforts. Flexible and succinct education plans should be developed and tailored to overcome the identified barriers. Depending on provider preferences and learning styles, the educational sessions can be offered either in person or via online continuing education modules.

Various types of educational plans about SMBP are already available on the Target: BP website. The website is co-led by the AMA and AHA, and it consists of an extensive amount of information related to the intervention. The website offers free pamphlets, infographics, videos, and webinars that are easily accessible and available to the general public. To target the vast majority of healthcare providers, SMBP education should be offered when providers renew their professional licenses or during new hire orientations.

After the providers and care teams are educated about SMBP, they can begin to properly and effectively communicate that information to their patients. Patients should be informed that the most recent HTN guidelines strongly recommend the use of SMBP. Education on SMBP should be culturally appropriate and personalized to each patient's healthy literacy. The educational materials should be provided in various forms and offered in the patient's native language. SMBP education posters can be displayed in primary care office exam rooms and bulletin boards, videos can be played on the waiting room TV monitors, and portable materials such as brochures and paper handouts can be distributed to each patient at the conclusion of their

appointment with their visit summaries (National Association of Community Health Centers, 2018).

### **Economy**

Expenses related to poorly controlled HTN are very costly and pose a huge financial burden for the United States (Zhang et al., 2017). The total direct costs of HTN are projected to increase to \$220.9 billion by the year 2035 (Khavjou, Phelps, & Leib, 2016). Improving the control of HTN with SMBP can have a positive economic impact as well as generate net savings that are expected to grow with time (Arrieta, Woods, Qiao, & Jay, 2014).

In July of 2019, during the final phases of this project's development, the IRS and the United States Department of Treasury released a notice that expanded the list of covered preventive care benefits for certain chronic conditions. This change emerged because the IRS and the Department of Treasury recognized that due to financial barriers people living with certain chronic conditions failed to receive the necessary preventive care, which consequently exacerbated their conditions. One of the items that were added to the list were BP monitors for individuals diagnosed with HTN. However, this modification only applied to coverage by high-deductible health plans with health savings accounts. In the future, all types of private and public health insurance companies should be required to also cover the costs of automated BP monitors for patients with HTN. A study demonstrated that insurance companies who reimbursed their health plan members for the cost of BP monitors, saw a reduction in both short- and long-term healthcare costs as well as improved healthcare quality. According to Arrieta et al. (2014) the estimated savings associated with SMBP in the first year ranged from \$33 to \$166 per member and in ten years ranged from \$425 to \$1364 per member. A joint statement released by the AHA, ASH, and PCNA also recommended that in addition to covering the cost of home BP monitors

insurances should also cover the time that health care providers devote to train and counsel their patients on SMBP (Pickering et al., 2008). The current procedural terminology (CPT) codes should be revised to allow for providers to get reimbursed for SMBP counseling.

### **Sustainability**

The SMBP intervention that was evaluated in this pilot project proved to be an effective method for improving HTN control. The ultimate end goal is to incorporate SMBP into the standard of care for managing this prevalent chronic condition. The intervention may be implemented in other health facilities and primary care offices across the United States. These offices and facilities routinely interact with a large number of people, and engaging them in this process can be helpful for promoting public awareness and nationwide sustainability of the intervention. The reputable national Target: BP initiative provides direct access to trained field support specialists, a data platform, an SMBP training framework, and an abundance of other evidence-based tools and resources to help organizations successfully launch their own SMBP programs. The materials can be retrieved from the Target: BP website and easily translated into community settings and primary care offices. In order to avoid misinformation there should be consistency in the type of SMBP materials that are distributed.

To help further sustain this intervention it would be helpful to obtain routine reports from organizations on both the SMBP implementation challenges and progresses. Recognition programs can be useful for acknowledging organizations that are successfully utilizing SMBP. Furthermore, promoting their achievements can set precedents. The Target: BP program currently has two recognition levels; the Gold status which recognizes practices that have achieved BP control in 70 percent or more of their adult patient population and the Participant status which recognizes practices that have submitted data and demonstrated commitment to

reducing the number of adult patients with uncontrolled BPs. In addition to the organizational recognition, individual patients who participate in the intervention can also be acknowledged and incentivized to continue utilizing SMBP by receiving free exercise classes or nutrition seminars (National Association of Community Health Centers, 2018). Developing this type of sustainability for SMBP is essential to foster improvements in HTN control and reduce the associated disease burden.

### **Future Scholarship**

It is important to communicate the results of this pilot project in order to change current practice methods and improve population outcomes. The findings from this study will be reported to the project site's health wellness director, which will hopefully support the integration of the SMBP intervention into the health facility's chronic disease management program. The final project will also be presented in front of an audience of other graduate students and faculty at Rutgers University using PowerPoint slides. Additionally, a concise visual representation of the overall project will be shared via a poster that will be displayed for public viewing at the university's poster day.

After the defense of this project, future scholarship efforts will also include the submission of an abstract to the Preventive Cardiovascular Nurses Association for presentation at the annual Cardiovascular Nursing Symposium. The results of this project will also be modified into manuscripts and submitted to *The Journal for Nurse Practitioners* and to the *Journal of Community Health Nursing* to be considered for publication. Furthermore, the significant positive results of this pilot project will hopefully encourage the development of future larger research studies that will incorporate a much broader sample population and be conducted over longer time periods.

### **Summary**

The purpose of this study was to evaluate the effects of an evidenced based SMBP intervention on BP control and medication adherence. Based on the data analysis, the intervention led to a statistically significant reduction in systolic BPs and to an improvement in the adherence to anti-hypertensive medications. Although there was also a post-intervention decrease in mean diastolic BPs there was insufficient statistical evidence to attribute the results to the effects of SMBP. Based on other prior literature studies, improving BP control has significant implications for preventing the development of HTN related complications and reducing healthcare spending. Implementing SMBP programs in health facilities and primary care offices can serve as a step forward toward achieving optimal control of this nationwide chronic condition.

### References

- Aekplakorn, W., Suriyawongpaisal, P., Tansirisithikul, R., Sakulpipat, T., & Charoensuk, P. (2015). Effectiveness of Self-Monitoring Blood Pressure in Primary Care: A Randomized Controlled Trial. *Journal of primary care & community health*, 7(2), 58-64.
- American Heart Association. (2016). *Health Threats From High Blood Pressure*. Retrieved from <https://www.heart.org/en/health-topics/high-blood-pressure/health-threats-from-high-blood-pressure>
- Arrieta, R., Woods, J., Qiao, J., & Jay, J. (2014). Cost–Benefit Analysis of Home Blood Pressure Monitoring in Hypertension Diagnosis and Treatment: An Insurer Perspective. *Hypertension*, 64(4), 891–896.  
<https://doi.org/10.1161/HYPERTENSIONAHA.114.03780>
- Asay, G., Roy, K., Lang, J., Payne, R., & Howard, D. (2016). Absenteeism and Employer Costs Associated With Chronic Diseases and Health Risk Factors in the US Workforce. *Preventing Chronic Disease*, 13(10), E141–E141. <https://doi.org/10.5888/pcd13.150503>
- Ayala, C., Tong, X., Neeley, E., Lane, R., Robb, K., & Loustalot, F. (2017). Home blood pressure monitoring among adults—American Heart Association Cardiovascular Health Consumer Survey, 2012. *Journal of Clinical Hypertension*, 19(6), 584–591.  
<https://doi.org/10.1111/jch.12983>
- Benjamin, J., Virani, S., Callaway, W., Chamberlain, M., Chang, R., Cheng, E., ... Deo, R. (2018). Heart Disease and Stroke Statistics—2018 Update: A Report From the American Heart Association. *Circulation*, 137(12), e67–e492.  
<https://doi.org/10.1161/CIR.0000000000000558>

Bosworth, H., Olsen, M., Grubber, J., Neary, A., Orr, M., Powers, B., ... Bosworth, H. (2009).

Two self-management interventions to improve hypertension control: a randomized trial. *Annals of Internal Medicine*, 151(10), 687–695. <https://doi.org/10.7326/0003-4819-151-10-200911170-00148>

Bosworth, H., Powers, B., Olsen, M., Mccant, F., Grubber, J., Smith, V., ... Oddone, E. (2011).

Home Blood Pressure Management and Improved Blood Pressure Control: Results From a Randomized Controlled Trial. *Archives of Internal Medicine*, 171(13), 1173–1180. <https://doi.org/10.1001/archinternmed.2011.276>

Caboral-Stevens, M., & Rosario-Sim, M. (2014). Review of the Joint National Committee's

Recommendations in the Management of Hypertension. (Disease/Disorder overview). *Journal for Nurse Practitioners*, 10(5), 325–330. <https://doi.org/10.1016/j.nurpra.2014.02.021>

Centers for Disease Control and Prevention. (2012). *Vital Signs: Awareness and Treatment of Uncontrolled Hypertension Among Adults — United States, 2003–2010*. Morbidity and Mortality Weekly Report, 61(35), 703–709.

Centers for Disease Control and Prevention. (2014). *Self-Measured Blood Pressure Monitoring: Actions Steps for Clinicians*. Atlanta, GA: Centers for Disease Control and Prevention, US Dept of Health and Human Services.

Centers for Disease Control and Prevention. (2016). *Stats of the State of New Jersey*. Retrieved from <https://www.cdc.gov/nchs/pressroom/states/newjersey/newjersey.htm>

Centers for Disease Control and Prevention. (2017). *Behavioral Risk Factor Surveillance System Survey Data*. Atlanta, Georgia.



- Chang, T., Ritchey, M., Ayala, C., Durthaler, J., & Loustalot, F. (2018). Use of strategies to improve antihypertensive medication adherence within United States outpatient health care practices, DocStyles 2015-2016. *Journal of Clinical Hypertension*, 20(2), 225–232. <https://doi.org/10.1111/jch.13188>
- Chobanian, A., Bakris, G., Black, H., Cushman, W., Green, L., Izzo, J., ... the National High Blood Pressure Education Program Coordinating Committee. (2003). The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: The JNC 7 Report. *JAMA*, 289(19), 2560–2571. <https://doi.org/10.1001/jama.289.19.2560>
- Chowdhury, R., Khan, H., Heydon, E., Shroufi, A., Fahimi, S., Moore, C., ... Franco, O. (2013). Adherence to cardiovascular therapy: a meta-analysis of prevalence and clinical consequences. *European Heart Journal*, 34(38), 2940–2948. <https://doi.org/10.1093/eurheartj/eh295>
- Community Preventive Service Task Force. (2015). *Cardiovascular Disease Prevention and Control: Self-Measured Blood Pressure Monitoring Interventions for Improved Blood Pressure Control*. Retrieved from <https://www.thecommunityguide.org/findings/cardiovascular-disease-self-measured-blood-pressure-when-used-alone>
- Conn, V. S., Ruppert, T. M., Chase, J. A., Enriquez, M., & Cooper, P. S. (2015). Interventions to Improve Medication Adherence in Hypertensive Patients: Systematic Review and Meta-analysis. *Current hypertension reports*, 17(12), 94.
- Cuenca, A. (2016). Improving Blood Pressure Control With Strategic Workflows. *Family Practice Management*, 23(3), 23–28.

- Drawz, P. E., Abdalla, M., & Rahman, M. (2012). Blood pressure measurement: clinic, home, ambulatory, and beyond. *American journal of kidney diseases: the official journal of the National Kidney Foundation*, 60(3), 449-62.
- Drazner, M. (2011). The Progression of Hypertensive Heart Disease. *Circulation*, 123(3), 327–334. <https://doi.org/10.1161/CIRCULATIONAHA.108.845792>
- Ettehad, D., Emdin, C., Kiran, A., Anderson, S., Callender, T., Emberson, J., ... Rahimi, K. (2016). Blood pressure lowering for prevention of cardiovascular disease and death: a systematic review and meta-analysis. *The Lancet*, 387(10022), 957–967. [https://doi.org/10.1016/S0140-6736\(15\)01225-8](https://doi.org/10.1016/S0140-6736(15)01225-8)
- Fikri-Benbrahim, N., Faus, M., Martínez-Martínez, F., Alsina, D., & Sabater-Hernández, D. (2012). Effect of a pharmacist intervention in Spanish community pharmacies on blood pressure control in hypertensive patients. *American Journal of Health-System Pharmacy*, 69(15), 1311–1318. <https://doi.org/10.2146/ajhp110616>
- Fikri-Benbrahim, N., Faus, M., Martínez-Martínez, F., & Sabater-Hernández, D. (2013). Impact of a community pharmacists' hypertension-care service on medication adherence. The AFenPA study. *Research in Social and Administrative Pharmacy*, 9(6), 797–805. <https://doi.org/10.1016/j.sapharm.2012.12.006>
- Fletcher, B., Hartmann-Boyce, J., Hinton, L., & McManus, R. (2015). The Effect of Self-Monitoring of Blood Pressure on Medication Adherence and Lifestyle Factors: A Systematic Review and Meta-Analysis. *American Journal of Hypertension*, 28(10), 1209–1221. <https://doi.org/10.1093/ajh/hpv008>
- Fletcher, B., Hinton, L., Hartmann-Boyce, J., Roberts, N., Bobrovitz, N., & Mcmanus, R. (2016). Self-monitoring blood pressure in hypertension, patient and provider perspectives: A

- systematic review and thematic synthesis. *Patient Education and Counseling*, 99(2), 210–219. <https://doi.org/10.1016/j.pec.2015.08.026>
- Forouzanfar, M., Liu, P., Roth, G., Ng, M., Biryukov, S., Marczak, L., ... Akinyemiju, T. (2017). Global Burden of Hypertension and Systolic Blood Pressure of at Least 110 to 115 mm Hg, 1990-2015. *JAMA*, 317(2), 165–182. <https://doi.org/10.1001/jama.2016.19043>
- Frieden, T., & Berwick, D. (2011). The “Million Hearts” Initiative — Preventing Heart Attacks and Strokes. *The New England Journal of Medicine*, 365(13), e27. <https://doi.org/10.1056/NEJMp1110421>
- Fryar, C.D., Ostchega, Y., Hales, C.M., Zhang, G., Kruszon-Moran, D. (2017). *Hypertension prevalence and control among adults : United States, 2015-2016*. Hyattsville, MD. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics.
- Fuchs, S.C., Ferreira-Da-Silva, A.L., Moreira, L.B., Neyeloff, J.L., Fuchs, F.C., Gus, M., ... Fuchs, F.D. (2012). Efficacy of isolated home blood pressure monitoring for blood pressure control: randomized controlled trial with ambulatory blood pressure monitoring – MONITOR study. *Journal of Hypertension*, 30(1), 75–80. <https://doi.org/10.1097/HJH.0b013e32834e5a4f>
- George, J., & MacDonald, T. (2015). Home Blood Pressure Monitoring. *European cardiology*, 10(2), 95-101.
- Go, S., Bauman, A., Coleman King, M., Fonarow, C., Lawrence, A., Williams, A., & Sanchez, A. (2014). An Effective Approach to High Blood Pressure Control: A Science Advisory From the American Heart Association, the American College of Cardiology, and the

- Centers for Disease Control and Prevention. *Hypertension*, 63(4), 878–885.  
<https://doi.org/10.1161/HYP.0000000000000003>
- Heron, M. (2018). Deaths: Leading Causes for 2016. *National Vital Statistics Reports*, Hyattsville, MD: National Center for Health Statistics. 67(6)
- Institute of Medicine. (2010). *A Population-Based Policy and Systems Change Approach to Prevent and Control Hypertension*. Washington, DC: The National Academies Press.
- Jacob, V., Chattopadhyay, S., Proia, K., Hopkins, D., Reynolds, J., Thota, A., ... Goetzel, R. (2017). Economics of Self-Measured Blood Pressure Monitoring: A Community Guide Systematic Review. *American Journal of Preventive Medicine*, 53(3), e105–e113.  
<https://doi.org/10.1016/j.amepre.2017.03.002>
- James, P., Oparil, S., Carter, B., Cushman, W., Dennison-Himmelfarb, C., Handler, J., ... Ortiz, E. (2014). 2014 evidence-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the Eighth Joint National Committee (JNC 8). *JAMA*, 311(5), 507–520. <https://doi.org/10.1001/jama.2013.284427>
- Khavjou, O., Phelps, D., & Leib, A. (2016). Projections of Cardiovascular Disease Prevalence and Costs: 2015–2035. Research Triangle Park, NC. <https://healthmetrics.heart.org/wp-content/uploads/2017/10/Projections-of-Cardiovascular-Disease.pdf>
- Kim, M. T., Hill, M. N., Bone, L. R., & Levine, D. M. (2000). Development and testing of the Hill-Bone compliance to high blood pressure therapy scale. *Progress in Cardiovascular Nursing*, 15(3), 90-96.
- Krousel-Wood, M., Jannu, A., Re, R. N., Muntner, P., & Desalvo, K. (2005). Reliability of a medication adherence measure in an outpatient setting. *The American journal of the medical sciences*, 330(3), 128-133.

- Lambert, E. V., Steyn, K., Stender, S., Everage, N., & Fourie, J. M. (2006). Cross-cultural validation of the hill-bone compliance to high blood pressure therapy scale in a South African, primary healthcare setting. *Ethnicity and Disease*, 16(1), 286.
- Lavsa, S., Holzworth, A., & Ansani, N. (2011). Selection of a validated scale for measuring medication adherence. *Journal of the American Pharmacists Association*, 51(1), 90–94.  
<https://doi.org/10.1331/JAPhA.2011.09154>
- Lionakis, N., Mendrinos, D., Sanidas, E., Favatas, G., & Georgopoulou, M. (2012). Hypertension in the Elderly. *World journal of cardiology*, 4(5), 135-47.
- McManus, R. J., Mant, J., Franssen, M., Nickless, A., Schwartz, C., Hodgkinson, J., ... TASMINH4 investigators. (2018). Efficacy of self-monitored blood pressure, with or without telemonitoring, for titration of antihypertensive medication (TASMINH4): an unmasked randomised controlled trial. *Lancet (London, England)*, 391(10124), 949–959.  
[doi:10.1016/S0140-6736\(18\)30309-X](https://doi.org/10.1016/S0140-6736(18)30309-X)
- Meraï, R., Siegel, C., Rakotz, M., Basch, P., Wright, J., Wong, B., & Thorpe, P. (2016). CDC Grand Rounds: A Public Health Approach to Detect and Control Hypertension. *MMWR. Morbidity and Mortality Weekly Report*, 65(45), 1261–1264.  
<https://doi.org/10.15585/mmwr.mm6545a3>
- Nasseh, K., Glave Frazee, S., Visaria, J., Vlahiotis, A., & Tian, Y. (2012). Cost of medication nonadherence associated with diabetes, hypertension, and dyslipidemia. *Am J Pharm Benefits* 2012; 4:e41–e47.
- National Association of Community Health Centers. (2018). *Self-measured Blood Pressure Monitoring Implementation Guide for Health Care Delivery Organizations*. Bethesda, Maryland.

- Newhouse, R., Dearholt, S., Poe, S., Pugh, L.C., & White, K. (2007). The Johns Hopkins Nursing Evidence- Based Rating Scale. Baltimore, MD: The Johns Hopkins Hospital, Johns Hopkins University School of Nursing.
- Office of Disease Prevention and Health Promotion. (2013). *Heart Disease and Stroke*. Retrieved from <https://www.healthypeople.gov/2020/topics-objectives/topic/heart-disease-and-stroke/objectives>
- Ogedegbe, G., & Schoenthaler, A. (2006). A Systematic Review of the Effects of Home Blood Pressure Monitoring on Medication Adherence. *Journal of Clinical Hypertension*, 8(3), 174–180. <https://doi.org/10.1111/j.1524-6175.2006.04872.x>
- Ostchega, Y., Berman, L., Hughes, J., Chen, T., & Chiappa, M. (2013). Home Blood Pressure Monitoring and Hypertension Status Among US Adults: The National Health and Nutrition Examination Survey (NHANES), 2009–2010. *American Journal of Hypertension*, 26(9), 1086–1092. <https://doi.org/10.1093/ajh/hpt054>
- Perreault, S. (2018). Global Clinical Consequences of Poor Adherence. In: Burnier M. (eds) *Drug Adherence in Hypertension and Cardiovascular Protection. Updates in Hypertension and Cardiovascular Protection*. (pp. 297- 314). Cham, Switzerland: Springer International Publishing.
- Pickering, T., Miller, N., Ogedegbe, G., Krakoff, L., Artinian, N., & Goff, D. (2008). Call to Action on Use and Reimbursement for Home Blood Pressure Monitoring: Executive Summary A Joint Scientific Statement From the American Heart Association, American Society of Hypertension, and Preventive Cardiovascular Nurses Association. *Journal of Clinical Hypertension*. Malden, USA: Blackwell Publishing Inc. <https://doi.org/10.1111/j.1751-7176.2008.08418.x>

- Piette, J. D., Datwani, H., Gaudio, S., Foster, S. M., Westphal, J., Perry, W., Rodríguez-Saldaña, J., Mendoza-Avelares, M. O., ... Marinec, N. (2012). Hypertension management using mobile technology and home blood pressure monitoring: results of a randomized trial in two low/middle-income countries. *Telemedicine journal and e-health : the official journal of the American Telemedicine Association*, 18(8), 613-20.
- Polgreen, A., Suneja, L., Tang, M., Carter, M., & Polgreen, M. (2015). Increasing Trend in Admissions for Malignant Hypertension and Hypertensive Encephalopathy in the United States. *Hypertension*, 65(5), 1002–1007.  
<https://doi.org/10.1161/HYPERTENSIONAHA.115.0524>
- Prochaska, J., & Di Clemente, C. (1982). Transtheoretical therapy: Toward a more integrative model of change. *Psychotherapy: Theory, Research and Practice*, 19(3), 276-288
- Prochaska, J., Velicer, W., Rossi, J., Goldstein, M., Marcus, B., Rakowski, W., ... Matthews, K. (1994). Stages of Change and Decisional Balance for 12 Problem Behaviors. *Health Psychology*, 13(1), 39–46. <https://doi.org/10.1037/0278-6133.13.1.39>
- Professional Research Consultants, Inc. (2016). *2016 Community Health Needs Assessment Bergen County, New Jersey*. Retrieved from  
<https://www.holyname.org/includes/files/CHNA-Bergen-County-2016.pdf>
- Soni, R. K., Porter, A. C., Lash, J. P., & Unruh, M. L. (2010). Health-related quality of life in hypertension, chronic kidney disease, and coexistent chronic health conditions. *Advances in chronic kidney disease*, 17(4), e17–e26. doi:10.1053/j.ackd.2010.04.002
- Souza, W.K., Jardim, P.C., Brito, L.P., Araújo, F.A., & Sousa, A.L. (2012). Self measurement of blood pressure for control of blood pressure levels and adherence to treatment. *Arquivos*

- Brasileiros de Cardiologia*, 98(2), 167-174. <https://doi.org/10.1590/S0066-782X2012005000010>
- State of New Jersey Department of Banking and Insurance. (2016). *2016 New Jersey HMO and PPO Performance Report*. Retrieved from [https://www.state.nj.us/dobi/lifehealthactuarial/hmo2016/getbetter\\_2.html](https://www.state.nj.us/dobi/lifehealthactuarial/hmo2016/getbetter_2.html)
- Stergiou, G., & Bliziotis, I. (2011). Home Blood Pressure Monitoring in the Diagnosis and Treatment of Hypertension: A Systematic Review. *American Journal of Hypertension*, 24(2), 123–134. <https://doi.org/10.1038/ajh.2010.194>
- Target: BP. (2016). BP Improvement Program. Retrieved from: <https://targetbp.org/blood-pressure-improvement-program/>
- Target: BP. (2018). SMBP Training Video. Retrieved from: [https://targetbp.org/tools\\_downloads/self-measured-blood-pressure-video/](https://targetbp.org/tools_downloads/self-measured-blood-pressure-video/)
- Topouchian, J., Agnoletti, D., Blacher, J., Youssef, A., Chahine, M., Ibanez, I., ... Asmar, R. (2014). Validation of four devices: Omron M6 Comfort, Omron HEM-7420, Withings BP-800, and Polygreen KP-7670 for home blood pressure measurement according to the European Society of Hypertension International Protocol. *Vascular Health and Risk Management*, 10, 33–44. <https://doi.org/10.2147/VHRM.S53968>
- Tucker, K., Sheppard, J., Stevens, R., Bosworth, H., Bove, A., Bray, E., ... McManus, R. (2017). Self-monitoring of blood pressure in hypertension: A systematic review and individual patient data meta-analysis. *PLoS Medicine*, 14(9), e1002389–e1002389. <https://doi.org/10.1371/journal.pmed.1002389>
- Uchmanowicz, I., Jankowska-Polańska, B., Chudiak, A., Szymańska-Chabowska, A., & Mazur, G. (2016). Psychometric evaluation of the Polish adaptation of the Hill-Bone Compliance



- to High Blood Pressure Therapy Scale. *BMC cardiovascular disorders*, 16, 87.  
doi:10.1186/s12872-016-0270-y
- Uhlig, K., Patel, K., Ip, S., Kitsios, G., & Balk, E. (2013). Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis. *Annals of Internal Medicine*, 159(3), 185–194. <https://doi.org/10.7326/0003-4819-159-3-201308060-00008>
- U.S. Department of the Treasury. Internal Revenue Service. (2019). *Additional Preventive Care Benefits Permitted to be Provided by a High Deductible Health Plan*. (NOTICE 2019-45). Retrieved from <https://www.irs.gov/pub/irs-drop/n-19-45.pdf>.
- Whelton, P., Carey, R., Aronow, W., Casey, D., Collins, K., Dennison Himmelfarb, C., ... Wright, J. (2018). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Hypertension*. 71:e13–e115. DOI: 10.1161/ HYP.0000000000000065.
- Williams, B., Mancia, G., Spiering, W., Agabiti Rosei, E., Azizi, M., Burnier, M., ... Dominiczak, A. (2018). 2018 ESC/ESH Guidelines for the management of arterial hypertension. *European Heart Journal*, 39(33), 3021–3104.  
<https://doi.org/10.1093/eurheartj/ehy339>
- World Health Organization. (2013). *A global brief on hypertension*. Retrieved from [https://www.who.int/cardiovascular\\_diseases/publications/global\\_brief\\_hypertension/en/](https://www.who.int/cardiovascular_diseases/publications/global_brief_hypertension/en/)
- Xu, W., Goldberg, S., Shubina, M., & Turchin, A. (2015). Optimal systolic blood pressure target, time to intensification, and time to follow-up in treatment of hypertension: population

based retrospective cohort study. *BMJ: British Medical Journal*, 350(feb05 9), h158.

<https://doi.org/10.1136/bmj.h158>

YMCA. (2019). *Blood Pressure Self Monitoring*. Retrieved from <http://www.ymca.net/blood-pressure-self-monitoring>

Zhang, D., Wang, G., Zhang, P., Fang, J., & Ayala, C. (2017). Medical Expenditures Associated With Hypertension in the U.S., 2000–2013. *American Journal of Preventive Medicine*, 53(6), S164–S171. <https://doi.org/10.1016/j.amepre.2017.05.014>

## Appendix A

**DNP Project Chair:** Dr. Irina Benenson, DNP,FNP-C

**DNP Project Title:** Improving Blood Pressure Control and Hypertension Management With A Self- Measured Blood Pressure Monitoring Intervention

**EBP Question:** The following appraisal of literature, contributed to the project's clinical question: "In community dwelling adults with a previously established diagnosis of HTN, will SMBP combined with educational support help to improve BP control and promote adherence to anti-hypertensive medications?"

Table of Evidence

Article #1	Aekplakorn, W., Suriyawongpaisal, P., Tansirisithikul, R., Sakulpipat, T., & Charoensuk, P. (2015). Effectiveness of Self-Monitoring Blood Pressure in Primary Care: A Randomized Controlled Trial. <i>Journal of primary care &amp; community health</i> , 7(2), 58-64.				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
Aekplakorn, Suriyawongpaisal, Tansirisithikul, Sakulpipat, & Charoensuk (2015)	Randomized clinical trial (RCT)	<i>Inclusion criteria:</i> patients w/ systolic BP $\geq 140$ mmHg or diastolic BP $\geq 90$ mmHg. <i>Exclusion criteria:</i> <35 years, immigrants, or had deficiencies/ disorders in communication skills. 224 patients were enrolled and allocated to an intervention or control group via concealed block randomization (113 control group, 111 in the intervention group). 34% male, average age 59 years, all of the patients in the study were on at least one antihypertensive drug. The study was conducted from May 2013 to June 2015, in an urban community hospital in the Bang phli district, in Thailand.	At 12 months, a statistically significant benefit of SMBP was found in the population age $\geq 60$ years, with an 8.9 mmHg decrease in SBP (95% CI: -15.1, -2.7), and the proportion of those with uncontrolled BP ( $>140/90$ mm Hg) decreased from 90% (n= 50) at baseline to 38.2% (n=21) at month 12 (p= 0.02). 84.1% of participants regularly recorded their BP (everyday, twice a day, three readings for each time) for an average of 123.9 days and 54.7% of the subjects recorded their daily BPs for $>135$ days. Percentage of regular recorders was slightly higher among those aged $\geq 60$ years compared with those $<60$ years (61% versus 47%). The amount of antihypertensive medications prescribed increased in both the control group and intervention group.	Homogenous population (low- to low- middle socioeconomic status Thais), external validity would be applicable only to populations with similar characteristics, and findings may not be generalizable. Sample size was small which contributed to non-significant results. Details of the medications at the follow- up periods were not available. Low adherence to SMBP (low percentage of completed records of BP) may to a certain extent have reduced the effectiveness of the intervention.	Level I/ good quality. Strong study design, that randomized participants and characteristics were similar in both control and intervention groups.

Article #2	Bosworth, H., Olsen, M., Grubber, J., Neary, A., Orr, M., Powers, B., ... Bosworth, H. (2009). Two self-management interventions to improve hypertension control: a randomized trial. <i>Annals of Internal Medicine</i> , 151(10), 687–695. <a href="https://doi.org/10.7326/0003-4819-151-10-200911170-00148">https://doi.org/10.7326/0003-4819-151-10-200911170-00148</a>				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
Bosworth et al. (2009)	2 by 2 factorial design RCT	<p><i>Inclusion criteria:</i> diagnosis of HTN; enrollment with a primary care physician at one of the two primary care clinics; self- report currently taking anti-hypertensive medications; have a scheduled non- lab primary care provider appointment; reside in one of 32 specified zip codes.</p> <p>2060 potentially eligible participants were mailed letters, of those 656 were enrolled and consented, after baseline interviews a total of 636 were deemed eligible and were randomized to one of four groups: usual care (n=159), behavioral intervention (n= 160), home BP monitor intervention (n=158), and combined intervention of home BP monitor and behavioral (n=159). Of the 636 participants, the mean age was 61 years, 49% were African Americans, 66% were female, and 73% had their BPs controlled at baseline. At the 24 month follow up there were 475 participants remaining (75%). The study was conducted in two primary care clinics affiliated with the [REDACTED] Health System in Durham, NC.</p>	<p>Participants in the combined intervention group had the greatest improvement in BP control over the 24-month study period. A statistically significant improvement in BP control of 11% (95% CI: 1.9%, 19.8%; p= 0.012) was observed for patients in the combined intervention group versus the usual care group. The combined intervention group had a clinically meaningful decrease in SBP of 3.3 mmHg and 3.9 mmHg compared to the usual care group, at 12 and 24 months, respectively.</p> <p>Compared to the usual care group and the home BP intervention alone, at the 12-month follow-up, SBP decreased by 3.7 mmHg (CI 95%: -6.1, -1.2) and DBP decreased by 3.1 (95% CI: -4.4, -1.8). At 6 and 24 months, self- reported medication adherence and exercise improved slightly.</p>	<p>At baseline there was a high rate of BP control in the study population. 25% of the population sample was not available at the 24 month follow up, but a mixed effects model was used as the primary analysis tool, leading to valid inferences.</p>	<p>Level I/ high quality.</p> <p>636 patients were enrolled, and the sample size estimation showed that 570 patients were needed in order to detect significant results and avoid a type- I error (good sample size).</p> <p>Research assistants, who measured BP at various time points, were blinded to the patient's randomization assignment.</p> <p>Results of this study are consistent with another meta-analysis of 18 RCTs.</p>

Article #3	Bosworth, H., Powers, B., Olsen, M., Mccant, F., Grubber, J., Smith, V., ... Oddone, E. (2011). Home Blood Pressure Management and Improved Blood Pressure Control: Results From a Randomized Controlled Trial. <i>Archives of Internal Medicine</i> , 171(13), 1173–1180. <a href="https://doi.org/10.1001/archinternmed.2011.276">https://doi.org/10.1001/archinternmed.2011.276</a>				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
Bosworth et al. (2011)	RCT	<p>Participant inclusion criteria: HTN diagnosis; using an anti- hypertensive medication; inadequate BP control (&gt;140/90 mm Hg) based on the average of the prior 12 months.</p> <p>Letters were mailed to 1893 potentially eligible patients, of those 611 consented, and 591 were eligible and randomized into four different groups: usual care/ control group (n=147), behavioral management intervention group (n=148), medication management intervention group (n=149), and combined intervention group (n=147). Of the 591 participants, 48% were African American, 49% were White, 92% were male, and 59% (n=348) had their baseline BP under control.</p> <p>At the 18-month follow-up there were 503 participants remaining (85%). Study participants were selected from general internal medicine clinics at a Veterans Affairs Medical Center in Durham, NC.</p>	<p>At 12 months: statistically significant improvement in BP control in the behavioral management group of 12.8% (95% CI: 1.6%, 24.1%; p= 0.03) and in the medication management group of 12.5% (95% CI: 1.3%, 23.6%; p=0.03). Combined intervention group BP control improved 8.3% (95% CI: -3.3%, 19.9%; p=0.16).</p> <p>At 18 months: Compared to the usual care group ONLY the combined intervention group had improved BP control by 7.7% (95% CI: - 4.1%, 19.5%; p=0.20), but the difference was not statistically significant.</p> <p>Post hoc analyses of baseline BP control, found that individuals with poor BP control in the behavioral group had a decrease in their SBP by 8.3 mmHg (95% CI: -15.1, -1.6; p=0.02) at the 12 month follow up.</p> <p>Decreases in DBP were present among all three-intervention groups but were not statistically significant.</p>	<p>Despite the inclusion criteria, 59% had their BP under control at baseline.</p> <p>Majority of study participants were male and the results may be only generalizable to hypertensive American males.</p> <p>Post hoc analyses of baseline BP control were not initially planned.</p>	<p>Level I/ high quality. 600 patients were needed to detect a 15% improvement in BP control at 18 months compared to the control group, with a 80% power and type- I error rate of 5% (sufficient sample size)</p> <p>No cross- over among study groups.</p> <p>Compared to past studies, this study was more diverse in literacy levels, education, and race/ ethnicity.</p>

Article #4	Fikri-Benbrahim, N., Faus, M., Martínez-Martínez, F., Alsina, D., & Sabater-Hernández, D. (2012). Effect of a pharmacist intervention in Spanish community pharmacies on blood pressure control in hypertensive patients. <i>American Journal of Health-System Pharmacy</i> , 69(15), 1311–1318. <a href="https://doi.org/10.2146/ajhp110616">https://doi.org/10.2146/ajhp110616</a>				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
Fikri-Benbrahim, Faus, Martínez-Martínez, Alsina, & Sabater-Hernández (2012)	Quasi-experimental with a control group	<p>Inclusion criteria: hypertensive patients &gt;18 years on anti-hypertensive treatment.</p> <p>The study was conducted in thirteen community pharmacies in the provinces of Jaen and Granada in Spain. 209 patients who visited the community pharmacies were invited to participate, 17 declined, 12 met exclusion criteria, and 4 left before the study completed. The intervention group (n=87) consisted of three components: education about HTN by trained pharmacists, HBPM, and referral to a physician, when necessary. The control group (n=89) did not receive pharmacist education or home BP monitors. The average age of participants was 62 years, 37.5% of participants were males, and 51.7% of participants had controlled BP (&lt;140/90 mmHg).</p>	<p>The intervention group had significant reductions from baseline in SBP (6.8 mm Hg; <math>p &lt; 0.001</math>) and DBP (2.1 mm Hg; <math>p = 0.032</math>), which were significantly greater than in the control group.</p> <p>The control of BP in the intervention group also increased to 71.3% (<math>p = 0.009</math>).</p> <p>Significant changes in BP control were NOT observed from baseline to endpoint in the usual care group, 50.6% to 55.1% respectively (<math>p = 0.481</math>).</p> <p>The odds of achieving BP control in the intervention group was 2.46 times higher than in the control group (95% CI: 1.15, 5.24; <math>p = 0.020</math>).</p>	<p>Results are based on a specific population of patients that was not completely randomized.</p> <p>Pharmacists who provided the intervention were not blinded.</p> <p>Possible contamination between the control and intervention group.</p> <p>BP control was assessed over a relatively short time period (6 months).</p>	<p>Level II- high quality.</p> <p>Valid design for assessing the impact of an intervention program. The estimated sample size was 116, based on a type II error of 20% and a priori level of significance of 0.05.</p>

Article #5	Fikri-Benbrahim, N., Faus, M., Martínez-Martínez, F., & Sabater-Hernández, D. (2013). Impact of a community pharmacists' hypertension-care service on medication adherence. The AFenPA study. <i>Research in Social and Administrative Pharmacy</i> , 9(6), 797–805. <a href="https://doi.org/10.1016/j.sapharm.2012.12.006">https://doi.org/10.1016/j.sapharm.2012.12.006</a>				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
Fikri-Benbrahim, Faus, Martínez-Martínez, & Sabater-Hernández (2013)	Quasi-experimental with a control group	<p>Inclusion criteria: hypertensive patients &gt;18 years on anti-hypertensive treatment</p> <p>The study was conducted in thirteen community pharmacies in the provinces of Jaen and Granada in Spain. 209 patients who visited the community pharmacies were invited to participate, 17 declined, 12 were excluded, and 4 left before the study completed. The intervention group (n=87) consisted of three components: education about HTN by trained pharmacists, HBPM, and referral to a physician, when necessary. The control group (n=89) did not receive pharmacist education or home BP monitors. The average age of participants was 62 years, 37.5% of participants were males, and 51.7% of participants had controlled BP (&lt;140/90 mmHg).</p> <p>Adherence to antihypertensive medication was evaluated by manual pill counts at baseline and at study completion.</p>	<p>At baseline 86.3% (n=115) of patients were considered to be adherent to their medications.</p> <p>Intervention group: adherence increased from 86% at baseline to 96.5% at endpoint (p= 0.022).</p> <p>Control group: adherence was similar from baseline to the endpoint and not statistically significant (86.5% to 85.4%; p= 0.928).</p> <p>The odds of adherence to antihypertensive medications in the intervention group was 4.07 (95% CI: 1.04, 15.95; p= 0.044) times higher than the control group.</p>	<p>Results are based on a specific population of patients that was not completely randomized</p> <p>Due to the relatively small sample of patients, results may not be generalizable.</p> <p>Pharmacists who provided the intervention were not blinded.</p> <p>Possible risk of contamination between the control and intervention group.</p> <p>Adherence was assessed over a relatively short time period (6 months), longer time period is needed to confirm the sustainability of the positive impact of the intervention.</p>	<p>Level II- high quality.</p> <p>Valid design for assessing the impact of an intervention program. The estimated sample size was 116, based on a type II error of 20% and a priori level of significance of 0.05.</p> <p>Study accounted for Hawthorne effect (in order to minimize bias).</p>

Article #6	Fuchs, S.C., Ferreira-Da-Silva, A.L., Moreira, L.B., Neyeloff, J.L., Fuchs, F.C., Gus, M., ... Fuchs, F.D. (2012). Efficacy of isolated home blood pressure monitoring for blood pressure control: randomized controlled trial with ambulatory blood pressure monitoring – MONITOR study. <i>Journal of Hypertension</i> , 30(1), 75–80.				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
Fuchs et al. (2012)	RCT	<p>Inclusion criteria: hypertensive adults aged 18-80 years, with uncontrolled office BP (<math>\geq 140/90</math> mmHg) and 24 hour ambulatory BP (<math>\geq 130/80</math> mmHg), and on anti-hypertensive treatment.</p> <p>There were 558 possible participants screened for the study. Eligible participants were randomly assigned to four different groups: HBPM (n=36), pharmacist care (n=35), HBPM with pharmacist care (n=32), or usual care (n=33). The results were reported in a pooled analysis of differences between the intervention group (HBPM and HBPM with pharmacist care) and control group (pharmacist care and usual care), since there was no interaction with the pharmacist care intervention.</p> <p>Study groups were similar for most characteristics, with the exception of age. Average age in the control group was 61.2 years and in the study group it was 56.6 years. 89% of the participants (n=121) completed the trial. The overall total population of participants was 60% female.</p> <p>The study was conducted in an outpatient clinic in Rio Grande do Sul, Brazil.</p>	<p>Efficacy of HBPM measured by ABPM: Deltas of decreases in BP measured by ABPM between baseline and endpoint were significantly higher in the HBPM intervention group. 24 hour systolic ABPM delta was 8.8 mmHg (<math>\pm 13.1</math>) with a p value of 0.02. 24 hour diastolic ABPM delta was 5.6 mm Hg (<math>\pm 8.4</math>) with a p value of 0.002.</p> <p>At the end of the study, 32.4% of participants in the HBPM group and only 16.2% of participants in the control group had their 24 hour SBP <math>&lt; 130</math> mmHg (p=0.03).</p> <p>Differences assessed in BP values between the control and intervention groups by office BP measurements, did not show statistically significant variations.</p> <p>Adherence to HBPM measurements was 84.6% at the end of the trial, indicates its feasibility and acceptance by the population. Complexity of the intervention could have affected adherence, thus simplification of HBPM process can promote long-term adherence to this intervention.</p>	<p>Predominantly female population, findings may not be applicable to men.</p> <p>Participants were followed for 60 days (short follow up).</p>	<p>Level I/ high quality.</p> <p>Equal randomized allocation ratio and parallel groups. Research team was blinded to the randomization.</p> <p>Adequate sample size: the estimated sample size was 48 individuals for an effect size of 2mmHg on SBP, with 90% power and p= 0.05.</p> <p>Outcomes were evaluated by 24-hour ABPM and a parallel group with office monitoring (there was no modifications to anti-hypertensive medications)</p>



Article #7	Souza, W.K., Jardim, P.C., Brito, L.P., Araújo, F.A., & Sousa, A.L. (2012). Self measurement of blood pressure for control of blood pressure levels and adherence to treatment. <i>Arquivos Brasileiros de Cardiologia</i> , 98(2), 167-174. <a href="https://doi.org/10.1590/S0066-782X2012005000010">https://doi.org/10.1590/S0066-782X2012005000010</a>				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
Souza, Jardim, Brito, Araújo, & Sousa (2012)	RCT	<p>Inclusion criteria: adults between the ages of 18 and 70 years w/ HTN under drug treatment</p> <p>Sample consisted of 57 patients in Brazil, 38 in the study group (SG) and 19 in the control group (CG). Average age in the SG was 62.05 years (<math>\pm 10.78</math>) and in the CG it was 55.42 years (<math>\pm 11.87</math>).</p> <p>Participants were followed for 12 months, with quarterly medical visits and other examinations at random and every 6 months.</p>	<p>SG reached faster BP treatment goals than the CG, with a significant difference in the sixth month for both SBP (135.49 mmHg; <math>\pm 12.73</math>; <math>p=0.022</math>) and DBP (81.69 mmHg; <math>\pm 10.88</math>; <math>p=0.020</math>).</p> <p>At the endpoint of the study, the SG had 100% adherence to the regular use of antihypertensive medications, whereas the CG had 88.2% adherence (<math>p=0.031</math>).</p> <p>Compared to the CG the SG also had a significant decrease in the number of types of antihypertensive medications used (<math>p=0.043</math>). That can be attributed to identification of white- coat HTN through SMBP, and reduced need for medications.</p>	<p>Population sample consisted of patients from a referral center, which provides guidance to them on the importance of effective BP and metabolic control and adherence to HTN treatment. This may have limited major observable differences between the two groups.</p> <p>Unequal allocation of the sample may affect internal validity.</p>	<p>Level I/ good quality.</p> <p>Smaller sample size, and unequal allocation ratio.</p>

Article #8	Piette, J. D., Datwani, H., Gaudioso, S., Foster, S. M., Westphal, J., Perry, W., Rodríguez-Saldaña, J., Mendoza-Avelares, M. O., ... Marinec, N. (2012). Hypertension management using mobile technology and home blood pressure monitoring: results of a randomized trial in two low/middle-income countries. <i>Telemedicine journal and e-health : the official journal of the American Telemedicine Association</i> , 18(8), 613-20.				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
Piette et al. (2012)	RCT	<p>Participants were eligible if they were between the ages of 18-80 years with high SBP (<math>\geq 140/90</math> mmHg if non diabetic and <math>\geq 130/80</math> mmHg if diabetic).</p> <p>The study took place in clinics in Cortes, Honduras and Real del Monte, Mexico.</p> <p>The participants had limited health insurance.</p> <p>67.4% female (66.3% IG; 68.4% CG)</p> <p>Average age: 57.6 years <math>\pm</math> 0.8 (58 years <math>\pm</math> 1.3 IG; 57.1 <math>\pm</math> 1.1 CG)</p> <p>200 patients were recruited and 181 completed follow-up (83 from Honduras, 98 from Mexico).</p> <p>Patients were randomly assigned to either an intervention group (n=89, given a home BP monitor, provided with instructions on how to check their BP, and received weekly automated calls with information on self- monitoring and self-care) or control group (n=92).</p>	<p>Compared to the control group, the intervention subgroup with low-literacy and high information needs had a decrease in SBP by 8.8 mmHg (95% CI: -14.2, -3.4; <math>p=0.002</math>).</p> <p>Based on JNC7 BP control guidelines, 57% of intervention patients had controlled BP at follow- up compared to 38% of the control group (<math>p=0.006</math>).</p> <p>Compared to the control group, the intervention group also reported at follow- up to have fewer medication related problems, such as uncertainty of the importance of their medication regimen, worry about the long-term effects of their medications, and confusion related to medication regimen complexity (-1.1; 95% CI: -1.7, -0.5; <math>p&lt;0.0001</math>).</p> <p>Intervention patients reported at follow-up better overall health, greater satisfaction with care specifically related to their HTN management (<math>p&lt;0.004</math>).</p> <p>94% of participants in the intervention reported using their home BP monitors at least several times a week.</p>	<p>Short follow up period of 6 weeks.</p> <p>The intervention had two components (home BP monitoring and automated self- care support calls) and it is difficult to determine the relative benefit contribution of each.</p> <p>Participants were from low-middle income countries.</p>	<p>Level I/ high quality.</p> <p>Strong study design (RCT) with an adequate sample size.</p>

Article #9	Tucker, K., Sheppard, J., Stevens, R., Bosworth, H., Bove, A., Bray, E., ... McManus, R. (2017). Self-monitoring of blood pressure in hypertension: A systematic review and individual patient data meta-analysis. <i>PLoS Medicine</i> , 14(9), e1002389–e1002389. <a href="https://doi.org/10.1371/journal.pmed.1002389">https://doi.org/10.1371/journal.pmed.1002389</a>				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
Tucker et al. (2017)	Systematic review and meta-analysis	<p>25 studies that included a total of 10,487 participants were identified to be eligible and included in the review.</p> <p>The studies were published from 2005 to 2014, and were conducted in North America (11 USA, 1 Canada) Europe (6 UK, 3 Italy, 1 Netherlands, 1 Spain, 1 Finland), 1 Australia.</p> <p>The review only included randomized trials. All of the studies compared SMBP to control groups without SMBP. Studies were required to have at least 100 patients who were followed up for at least 24 weeks. Rates of follow up at 12 months in the included studies were between 58% and 98%, with most studies following up around 90%.</p>	<p>Compared to usual care, at 12 months SMBP was associated with reduced clinic SBP by 3.2 mmHg (95% CI: -4.9, -1.6).</p> <p>Meta- analysis provided strong evidence to support that the reduction in BP is related to the intensity of the co- intervention (self- management, systematic medication titration, lifestyle counseling) that is combined with self- monitoring. Most significant reduction in SBP was when SMBP was combined with intensive support, which resulted in a 6.1 mm Hg decrease (95% CI: -9.0, -3.2). A similar pattern was seen in DBP.</p> <p>SMBP was most effective in individuals with a higher baseline systolic BP up to 170 mm Hg and those on fewer anti-hypertensive medications.</p>	<p>There was significant heterogeneity between studies, which was attributed to different inclusion criteria, self-monitoring regimens, and target BPs in the individual studies.</p> <p>Only half of the studies used a blinded assessment of the outcomes.</p>	<p>Level I/ high quality.</p> <p>The included studies had low risk of bias, and had an adequate quality due to randomization sequences, allocation concealment, and analyses.</p> <p>A wide range of self-monitoring protocols, co- interventions and populations was used.</p>

Article #10	Uhlig, K., Patel, K., Ip, S., Kitsios, G., & Balk, E. (2013). Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta- analysis. <i>Annals of Internal Medicine</i> , 159(3), 185–194. <a href="https://doi.org/10.7326/0003-4819-159-3-201308060-00008">https://doi.org/10.7326/0003-4819-159-3-201308060-00008</a>				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
Uhlig, Patel, Ip, Kitsios, & Balk (2013)	Systematic review and meta-analysis	<p>52 prospective comparative studies (with over 13,603 participants) of SMBP with or without additional support versus usual care or an alternative SMBP monitoring intervention. All studies searched on MEDLINE were before February 2013, and on CENTRAL/ Cochrane were the fourth quarter of 2012.</p> <p>Studies had to have at least 8 weeks of follow up.</p> <p>Most studies had included patients with uncomplicated HTN and without acute disease.</p> <p>All but two studies were conducted in North America, Australia and Western Europe.</p>	<p>SMBP versus usual care: resulted in significantly lower BP at six months, with a net difference for systolic BP of -3.9 mmHg, and -2.4 mmHg for diastolic BP in 12 comparisons; the net difference was not significant at 12 months in nine comparisons. The strength of evidence was considered moderate. There was evidence of statistical heterogeneity for all the analyses. Results remained similar when analyses were restricted to high and moderate quality studies.</p> <p>Self-measured monitoring plus additional support versus usual care: resulted in significantly lower blood pressure with net differences ranging from -3.4 to -8.9 mmHg for systolic BP and from -1.9 to -4.4 mmHg for diastolic BP at 12 months in good quality studies.</p> <p>Some studies found more medication changes and greater medication adherence with SMBP.</p>	<p>Minorities were underrepresented.</p> <p>Duration of follow up in some trials was &lt;12 months.</p> <p>Many studies were rated Quality C, and were likely underpowered to detect any effect of the intervention.</p> <p>Data was minimal on clinical outcomes.</p> <p>Clinical heterogeneity was present in protocols for SMBP (limiting ability for specific comparisons)</p>	<p>Level II/ high quality</p> <p>Although a majority of the studies were RCTs, the review also allowed non-randomized studies.</p> <p>3 category grading system from the AHRQ denoted the methodological quality of each study for each outcome (10 Quality A, 15 Quality B, 26 Quality C)</p>

Article #11	Fletcher, B., Hartmann-Boyce, J., Hinton, L., & McManus, R. (2015). The Effect of Self- Monitoring of Blood Pressure on Medication Adherence and Lifestyle Factors: A Systematic Review and Meta-Analysis. <i>American Journal of Hypertension</i> , 28(10), 1209–1221. <a href="https://doi.org/10.1093/ajh/hpv008">https://doi.org/10.1093/ajh/hpv008</a>				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
Fletcher, Hartmann-Boyce, Hinton, & McManus (2015)	Systematic review and meta-analysis	<p>Databases were searched through February 2014, included only randomized and quasi-randomized studies.</p> <p>Evaluated studies that compared SMBP to usual care in ambulatory hypertensive patients and reported adherence to medication or other forms of non-pharmacologic treatments.</p> <p>28 trials with 7,021 participants fulfilled the inclusion criteria.</p> <p>Studies were conducted in USA, Australia, Brazil, Germany, Canada, Iran, Spain, UK, Finland, Nigeria, Netherlands, and Belgium.</p> <p>Medication adherence was assessed in 25 trials (89%) and medication persistence in one (4%). BP was assessed in 26 trials (93%).</p> <p>Measures of medication adherence included: electronic monitoring, pill counts, self-reports, and pharmacy fill data.</p> <p>Follow up of the trials ranged from 2 weeks to 12 months (median 6 months), and was deemed to be adequate in 75% of studies (&gt;80% of participants available for outcome assessment).</p>	<p>Results from 13 studies were in favor of SMBP and its positive effect on medication adherence (standard mean deviation 0.21, 95% CI: 0.08, 0.34).</p> <p>Electronic monitoring of medication adherence detected a significant effect in favor of SMBP (SMD 0.45, 95% CI: 0.10, 0.79).</p> <p>Analysis of 3 out of 7 studies showed that office SBP significantly improved and so did medication adherence.</p>	<p>Tested interventions were heterogeneous, with varying target populations, SMBP protocols, medication titration protocols, and other co-interventions.</p> <p>12 studies were judged to have had a high risk of bias in one domain, and in 14 studies risk of bias was unclear.</p>	<p>Level I/ high quality.</p> <p>Only randomized trials were included.</p> <p>Comprehensive search strategy that captured more than double the amount of studies compared to previous reviews.</p> <p>Sufficient data allowed for estimation of effect size.</p> <p>No language restriction allowed for representation of more evidence.</p>

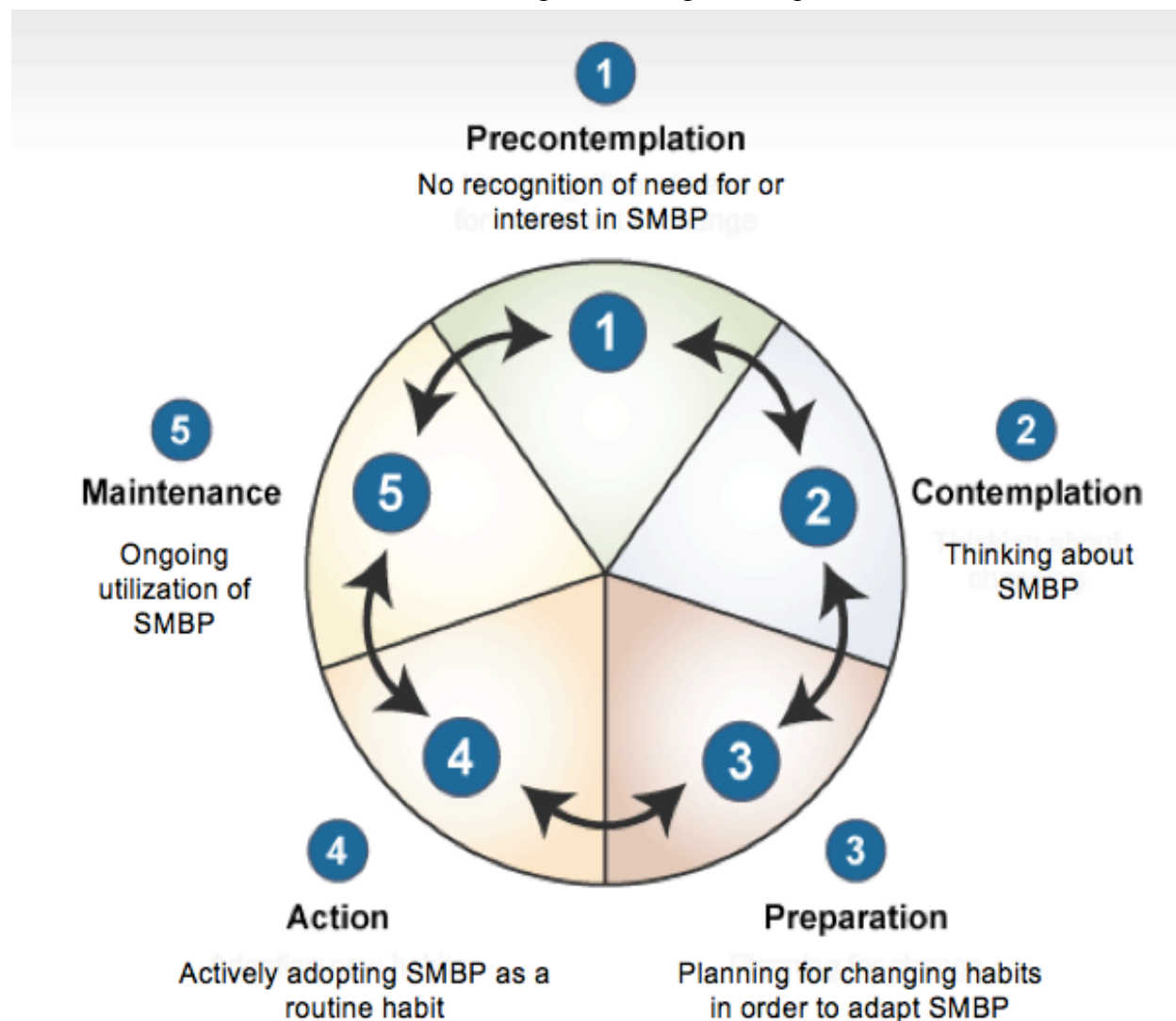
Article #12	Pickering, T., Miller, N., Ogedegbe, G., Krakoff, L., Artinian, N., & Goff, D. (2008). Call to Action on Use and Reimbursement for Home Blood Pressure Monitoring: Executive Summary A Joint Scientific Statement From the American Heart Association, American Society of Hypertension, and Preventive Cardiovascular Nurses Association. <i>Journal of Clinical Hypertension</i> . Malden, USA: Blackwell Publishing Inc. <a href="https://doi.org/10.1111/j.1751-7176.2008.08418.x">https://doi.org/10.1111/j.1751-7176.2008.08418.x</a>				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
Pickering et al. (2008).	Non-research Scientific Statement	Not applicable. This is a joint statement from the AHA, American Society of Hypertension, and Preventive Cardiovascular Nurses Association, on the call to action on use and reimbursement of HBPM	Provides detailed recommendations on HBPM and reasons why it is beneficial in the management of HTN.  It validates the fact that HBPM is part of evidence-based care and urges to make it a routine in HTN treatment.  HBPM can predict clinical outcomes and improve clinical care.	Not applicable to this body of literature.	Level IV/ high quality  Recommendations were supported by evidence from prospective studies.

Article #13	Whelton, P., Carey, R., Aronow, W., Casey, D., Collins, K., Dennison Himmelfarb, C., ... Wright, J. (2018). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>Hypertension</i> . 71:e13–e115. DOI: 10.1161/ HYP.0000000000000065.				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
Whelton et al. (2018)	Non- research Clinical practice guideline	Not applicable.  Strong recommendation based on level A quality of evidence. Benefit greatly outweighs risk	Discusses procedures for the use of HBPM.  Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults	Not applicable to this body of literature.	Level IV/ high quality

Article #14	Centers for Disease Control and Prevention. (2014). Self-Measured Blood Pressure Monitoring: Actions Steps for Clinicians. Atlanta, GA: Centers for Disease Control and Prevention, US Dept of Health and Human Services.				
Author/ Date	Study Type	Sample/ Sample Size/ Setting	Findings that help answer the EBP question	Limitations	Evidence Level/ Quality
CDC (2014)	Non research  Action steps	Not applicable  Initiative developed by the US Department of Health and Human services and co-led by the CDC and CMS	Reinforces scientific evidence on the significance and effectiveness of SMBP.  Facilitates the implementation of SMBP by providing actions with corresponding resources to assist with these actions.  Based on literature review done by Uhlig et al.	Not applicable.	Level IV/ high quality

## Appendix B

### Transtheoretical Model- Stages of Change Conceptual Framework



Adapted from: Prochaska, J., & Di Clemente, C. (1982). Transtheoretical therapy: Toward a more integrative model of change. *Psychotherapy: Theory, Research and Practice*, 19(3), 276-288. Figure 2, p. 283.



## Appendix C

### Recruitment Flyer

#### **ARE YOU AN ADULT WHO HAS HIGH BLOOD PRESSURE?** *VOLUNTEER PARTICIPANTS WANTED FOR A RESEARCH STUDY*



Recruiting adults between the ages of 18 and 90 years with an established high blood pressure diagnosis to participate in a study aimed at improving the control of blood pressure by training participants on self- measured blood pressure monitoring.

#### **Participants will be asked to:**

- attend a total of **three brief sessions every two weeks**, in order to participate in all of the study activities (duration of sessions: first- 1 hour, second- 15 minutes, third- 30 minutes)
- routinely check their own blood pressures at home or at the YMCA and log them

#### **Additional eligibility criteria:**

- participants must be prescribed at least one high blood pressure medication
- participants must be willing and able to take their own blood pressure twice a day

#### **Benefits**

- (1) learn about blood pressure self-monitoring
- (2) have your blood pressure checked

#### **Location**



#### **Time/ Date**

*To Be Determined*

*Refreshments will be served at all three sessions.*

**Study Title:** Improving Blood Pressure Control and Hypertension Management With A Self- Measured Blood Pressure Monitoring Intervention

**Principal Investigator:** Caterina Reshetnyak, Doctorate Nurse Practitioner Student at Rutgers University

**Contact the principal investigator for more information at any time via email**

**[Redacted Email Address]** or by phone **[Redacted Phone Number]**



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## Appendix D

### Informed Consent



#### CONSENT TO TAKE PART IN A RESEARCH STUDY

**Title of Study:** “Improving Blood Pressure Control and Hypertension Management With A Self-Measured Blood Pressure Monitoring Intervention”

**Principal Investigator:** Caterina Reshetnyak, RN, BSN, Doctorate Nurse Practitioner Student at Rutgers University

**STUDY SUMMARY:** This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. The purpose of the research is to: provide education about self- measurement of blood pressure and its benefits, as well as train you on how to accurately measure blood pressure. If you take part in the research, you will be asked to measure your blood pressure twice a day for 2 weeks, and log the measurements on a provided log. Your time in the study will take approximately 2 hours, split into 3 sessions, each held 2 weeks apart. The first session will be one hour long, the second session will be 15 minutes long, and the third session will be 30 minutes long. Participating in this research study will pose no risk of physical harm or discomfort. There will be a very minimal risk related to a possible breach in confidentiality and a potential inconvenience of having to dedicate time to participate in the study. Possible benefits of taking part may be having your blood pressure measured and learning about the self-measurement of blood pressure intervention. Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After all of your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

#### Who is conducting this research study?

I, Caterina Reshetnyak, am the principal investigator of this research study, and may be reached via phone at [REDACTED] or via email at [REDACTED]. A principal investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. My faculty advisor, Dr. Irina Benenson, may also be contacted via telephone at [REDACTED] or via email at [REDACTED].

The principal investigator will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

#### Why is this study being done?

The purpose of this study is to educate you on how to self-measure and monitor your blood pressure and its benefits on blood pressure control. Approximately one in three American adults have high blood pressure, and only about half of them have their condition under control. High blood pressure is a major risk factor for heart disease and stroke, which are the first and fourth leading causes of death in the United States of America. Data has demonstrated that better



control of high blood pressure can reduce the risk of stroke by 18% to 40% and the risk of heart attack by 15%.

**Who may take part in this study and who may not?**

The following individuals will be able to take part in this study: 1) male and female adults over 18 years of age but less than 90 years with a current high blood pressure diagnosis, 2) currently taking high blood pressure medications, 3) proficient in English, 4) have their own blood pressure monitor or be able to come to the fitness facility and measure their blood pressures with monitors provided by the principal investigator, 5) be physically capable of taking their own blood pressure twice a day. The following individuals may NOT participate in this study: 1) individuals without a current high blood pressure diagnosis, 2) individuals not under the treatment of any high blood pressure medications, 3) pregnant females, 4) individuals with cognitive impairment, 5) individuals with a diagnosis of arrhythmia.

**Why have I been asked to take part in this study?**

You are being asked to participate in this voluntary study because you qualify based on the eligibility criteria.

**How long will the study take and how many subjects will take part?**

You are approximately one of twenty people who are eligible to participate in this study. We expect the study to take three sessions, which will each be held 2 weeks apart. The first session will be one hour long, the second session will be 15 minutes long, and the third session will be 30 minutes long. The overall length of the study will be about 3-6 months between data collection and final analysis.

**What will I be asked to do if I take part in this study?**

After completing the informed consent you will be asked to fill out a seven question demographic survey and a medication survey. After that the principal investigator will check your blood pressure and give a brief presentation on self-measurement of blood pressure. You will be asked to go home, measure your blood pressure twice a day (morning and evening) for seven days, and log the values. You will then return in two weeks, bring in your blood pressure log, and have any questions answered. You will then measure your blood pressure for another seven days (twice a day), and return two weeks later. At the third session you will be asked to bring in your second completed blood pressure log, fill out the same medication survey as you did at the initiation of the study, and have your blood pressure re-measured by the principal investigator.

**What are the risks and/or discomforts I might experience if I take part in this study?**

Participating in this research study will pose no risk of physical harm or discomfort. There will be a very minimal risk related to a possible breach in confidentiality and a potential inconvenience of having to dedicate time to participate in the study intervention.

**Are there any benefits to me if I choose to take part in this study?**

The possible benefits of taking part in this study are having your blood pressure measured, learning about the benefits of self-measurement of blood pressure, and receiving training on the correct technique to measure your own blood pressure.

**What are my alternatives if I do not want to take part in this study?**

Your alternative to taking part in the research study is not to take part in it. You may choose not to be in the study. Your decision not to participate will not involve any penalty or loss of benefits to which you are entitled.

**How will I know if new information is learned that may affect whether I am willing to stay in the study?**

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

**Will there be any cost to me to take part in this study?**

There is no associated cost with participating in this study.

**Will I be paid to take part in this study?**

You will not be paid to take part in this study.

**How will information about me be kept private or confidential?**

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. The principal investigator will assist each participant to create a unique identification code. That code will be used to identify any collected data (surveys, demographic questionnaire, blood pressure logs). A master list with the identification codes and corresponding names will be kept secure and separately from the collected data. All of the collected paperwork, including signed informed consents, code lists, surveys, questionnaires, and logs will only be accessible by the principal investigator and will be kept in a locked cabinet in room 1115, at Rutgers University School of Nursing campus located at 65 Bergen Street, Newark, NJ, 07107.

**What will happen to my information or biospecimens collected for this research after the study is over?**

The information collected about you for this research will not be used by or distributed to investigators for other research.

**What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?**

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

**Who can I call if I have questions?**

If you have questions about taking part in this study, you can contact the study investigator, Caterina Reshetnyak, via phone [REDACTED] or via email at [REDACTED]. You may



also contact my faculty advisor, Dr. Irina Benenson, via telephone at [REDACTED] or via email at [REDACTED]

If you have questions about your rights as a research subject, you can call the IRB Director at: Newark HealthSci (973)-972-3608 or the Rutgers Human Subjects Protection Program at (973) 972-1149.

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### AGREEMENT TO PARTICIPATE

#### 1. Subject consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name: \_\_\_\_\_

Subject Signature: \_\_\_\_\_ Date: \_\_\_\_\_

#### 2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed name): \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## Appendix E

### Demographic Survey



ID #: \_\_\_\_\_

*Improving Blood Pressure Control and Hypertension Management With A Self- Measured Blood Pressure Monitoring Intervention*

#### Demographic Survey for Research Study

Please select the most appropriate answer to each question.

1. **What is your age?**
  - A. 18- 24 years old
  - B. 25- 34 years old
  - C. 35- 44 years old
  - D. 45- 54 years old
  - E. 55- 64 years old
  - F. 65- 74 years old
  - G. 75 years or older
2. **What is your gender identity?**
  - A. Male
  - B. Female
  - C. I prefer not to answer
  - D. I prefer to self describe:  
\_\_\_\_\_
3. **What is your race or ethnicity?**
  - A. White
  - B. African-American or Black
  - C. Hispanic or Latino
  - D. Asian or Pacific Islander
  - E. Native American or American Indian
  - F. Other
4. **What is the highest degree or level of school that you have completed? *If currently enrolled, select the highest degree received.***
  - A. Some high school, no diploma
  - B. High school graduate, diploma or the equivalent (GED)
  - C. Some college, no degree
  - D. Associates degree
  - E. Bachelor's degree
  - F. Master's degree
  - G. Doctoral degree
5. **How long have you been diagnosed with high blood pressure (hypertension)?**
  - A. Less than 1 year, newly diagnosed
  - B. 1-5 years
  - C. 5-10 years
  - D. Greater than 10 years
6. **How many high blood pressure medications (antihypertensives) are you currently prescribed?**
  - A. One
  - B. Two
  - C. Three or more
  - D. I am not sure
7. **Do you currently check/ monitor your own blood pressure?**
  - A. Yes, everyday
  - B. Yes, a couple of times a week
  - C. Yes, once a week
  - D. Yes, once a month
  - E. Yes, I randomly check it
  - F. No

## Appendix F

## Medication Adherence Scale



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ID #: \_\_\_\_\_

## Hill-Bone Medication Adherence Scale (HB-MAS)

No	Item	Response:			
		<i>All of the Time</i>	<i>Most of the Time</i>	<i>Some of the Time</i>	<i>None of the Time</i>
1	How often do you forget to take your <b>high blood pressure</b> medicine?	1	2	3	4
2	How often do you decide NOT to take your <b>high blood pressure</b> medicine?	1	2	3	4
3	How often do you forget to get prescriptions filled?	1	2	3	4
4	How often do you run out of <b>high blood pressure</b> pills?	1	2	3	4
5	How often do you skip your <b>high blood pressure</b> medicine before you go to the doctor?	1	2	3	4
6	How often do you miss taking your <b>high blood pressure</b> pills when you feel better?	1	2	3	4
7	How often do you miss taking <b>your high blood pressure</b> pills when you feel sick?	1	2	3	4
8	How often do you take someone else's <b>high blood pressure</b> pills?	1	2	3	4
9	How often do you miss taking your <b>high blood pressure pills</b> when you are careless?	1	2	3	4

## Appendix G

### Permission to Use Tool

Thank you for your interest in using the Hill-Bone Scale.

Please consider this email as permission to use the Hill-Bone Scale.

We have attached the Hill-Bone Compliance Scale along with several relevant articles reporting on the validation and use of the scale. Please cite the scale using the references provided. We would appreciate you sharing the findings of your research with us.

We wish you the very best in your project and please don't hesitate to reach out to us if you have any follow-up questions.

Best,  
The Hill-Bone Scales Team

\* Note: Please do not share these documents with anyone else outside your project. We ask that anyone who wishes to use the scale should submit a formal request using the link provided for proper authorization

Dear Sir or Madam,

I am a doctoral student from Rutgers University writing my dissertation titled *Improving Blood Pressure Control and Hypertension Management With A Self- Measured Blood Pressure Monitoring Intervention* under the direction of my dissertation committee chaired by Dr. Irina Benenson who can be reached at [REDACTED]. The Rutgers University IRB Committee can be contacted by phone at 973-972-3608.

I would like your permission to use the Hill Bone MAS survey/questionnaire instrument in my research study. The purpose of this study is to improve blood pressure control in hypertensive adults and ultimately reduce hypertension-related complications. I would like to use and print your survey under the following conditions:

- I will use the surveys only for my research study and will not sell or use it with any compensated or curriculum development activities.
- I will include the copyright statement on all copies of the instrument.
- I will send a copy of my completed research study to your attention upon completion of the study.

If these are acceptable terms and conditions, please indicate so by replying to me through e-mail: [reshetn@gmail.com](mailto:reshetn@gmail.com).

Sincerely,




Caterina Reshetnyak

Doctoral Candidate



## Appendix H

## What is High Blood Pressure? Handout

## What Is High Blood Pressure?

Blood pressure is the force of blood pushing against blood vessel walls. It is measured in millimeters of mercury (mm Hg).

High blood pressure (HBP) means the pressure in your arteries is higher than it should be. Another name for high blood pressure is hypertension.

Blood pressure is written as two numbers, such as 112/78 mm Hg. The top, systolic, number is the pressure when the heart beats. The bottom, diastolic, number is the pressure when the heart rests between beats.

Normal blood pressure is below 120/80 mm Hg. If you're an adult and your systolic pressure is 120 to 129, and your diastolic pressure is less than 80, you have elevated blood pressure. High blood pressure is a pressure of 130 systolic or higher, or 80 diastolic or higher, that stays high over time.

High blood pressure usually has no signs or symptoms. That's why it is so dangerous. But it can be managed.

Nearly half of the American population over age 20 has HBP, and many don't even know it. Not treating high blood pressure is dangerous. HBP increases the risk of heart attack and stroke.

Make sure you get your blood pressure checked regularly and treat it the way your doctor advises.

BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (upper number)		DIASTOLIC mm Hg (lower number)
<b>NORMAL</b>	<b>LESS THAN 120</b>	and	<b>LESS THAN 80</b>
<b>ELEVATED</b>	<b>120 – 129</b>	and	<b>LESS THAN 80</b>
<b>HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 1</b>	<b>130 – 139</b>	or	<b>80 – 89</b>
<b>HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 2</b>	<b>140 OR HIGHER</b>	or	<b>90 OR HIGHER</b>
<b>HYPERTENSIVE CRISIS (consult your doctor immediately)</b>	<b>HIGHER THAN 180</b>	and /or	<b>HIGHER THAN 120</b>

### Am I at higher risk of developing HBP?

There are risk factors that increase your chances of developing HBP. Some you can control, and some you can't.

Those that can be controlled are:

- Smoking and exposure to secondhand smoke
- Diabetes
- Being obese or overweight
- High cholesterol
- Unhealthy diet (high in sodium, low in potassium, and drinking too much alcohol)
- Physical inactivity

*(continue on d)*

**ANSWERS**  
by heart



Lifestyle + Risk Reduction  
High Blood Pressure

## What Is High Blood Pressure?

Factors that cannot be modified or are difficult to control are:

- Family history of high blood pressure
- Race/ethnicity
- Increasing age
- Gender (males)
- Chronic kidney disease
- Obstructive sleep apnea

Socioeconomic status and psychosocial stress are also risk factors for HBP. These can affect access to basic living necessities, medication, healthcare providers, and the ability to adopt lifestyle changes.

### How can I tell I have it?

The only way to know if you have high blood pressure is to get it checked regularly by your healthcare provider.

For proper diagnosis of high blood pressure, your healthcare provider will use an average based on two or more readings obtained on two or more occasions.

### What can I do about HBP?

- Don't smoke and avoid secondhand smoke.
- Reach and maintain a healthy weight.
- Eat a healthy diet that is low in saturated and *trans* fats and rich in fruits, vegetables, whole grains, and low-fat dairy products.
- Aim to consume less than 1,500 mg/day of sodium (salt). Even reducing your daily intake by 1000 mg can help.
- Eat foods rich in potassium. Aim for 3,500 – 5,000 mg of dietary potassium per day.
- Limit alcohol to no more than one drink per day if you're a woman or two drinks a day if you're a man.
- Be more physically active. Aim for at least 90 to 150 minutes of aerobic and/or dynamic resistance exercise per week, and/or three sessions of isometric resistance exercises per week.
- Take medicine the way your doctor tells you.
- Know what your blood pressure should be and work to keep it at that level.

### HOW CAN I LEARN MORE?

- 1 Call 1-800-AHA-USA1 (1-800-242-8721), or visit [heart.org](http://heart.org) to learn more about heart disease and stroke.
- 2 Sign up to get *Heart Insight*, a free magazine for heart patients and their families, at [heartinsight.org](http://heartinsight.org).
- 3 Connect with others sharing similar journeys with heart disease and stroke by joining our Support Network at [heart.org/supportnetwork](http://heart.org/supportnetwork).

### Do you have questions for the doctor or nurse?

Take a few minutes to write your questions for the next time you see your healthcare provider.

For example:

**Will I always have to take medicine?**

**What should my blood pressure be?**

### My Questions:

We have many other fact sheets to help you make healthier choices to reduce your risk, manage disease or care for a loved one. Visit [heart.org/answersbyheart](http://heart.org/answersbyheart) to learn more.



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## Appendix I

## What is High Blood Pressure Medicine? Handout





Lifestyle + Risk Reduction  
High Blood Pressure



American Heart Association  
life is why™

## What Is High Blood Pressure Medicine?

Your doctor has prescribed medicine to help lower your blood pressure. You also need to make the other lifestyle changes that will help reduce blood pressure, including: not smoking, reaching and maintaining a healthy weight, lowering sodium (salt) intake, eating a heart-healthy diet including potassium-rich foods, being more regularly physically active, and limiting alcohol to no more than one drink a day (for women) or two drinks a day (for men). Following your overall therapy plan will help you get on the road to a healthier life!



Taking your medicine the way your doctor tells you to is key to getting your blood pressure down where it belongs!

**What should I know about taking medicine?**

- Your doctor may prescribe one or more drugs to bring your blood pressure down to normal.
- The medicines work in different ways to help lower blood pressure.
- Medicine only works when you take it regularly.
- Don't ever stop taking medicine on your own.
- Even after your blood pressure is lowered, you may still need to take medicine — perhaps for your lifetime — to keep your blood pressure normal.

**How can I remember to take it?**

Sometimes it's hard to keep track of your medicine. But to be safe, you must take it properly. Here are some good ways:

- Take your medicine at the same time each day.
- Take medicine along with daily events, like brushing your teeth.

- Use a weekly pill box with separate sections for each day or time of day.
- Ask family and friends to help remind you.
- Use a medicine calendar.
- Set a reminder on your smartphone.

**What types of medicine may be prescribed?**

One or more of these medications are initially used to treat high blood pressure:

- **THIAZIDE DIURETICS** — rid the body of excess sodium (salt) and water and help control blood pressure. These are sometimes called "water pills".
- **ANGIOTENSIN-CONVERTING ENZYME (ACE) INHIBITORS, ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs) and CALCIUM CHANNEL BLOCKERS** — relax and open up the narrowed blood vessels and lower blood pressure.

(continue d)

**ANSWERS**  
by heart



Lifestyle + Risk Reduction  
High Blood Pressure

What Is High Blood Pressure Medicine?

### What are their side effects?

For many people, high blood pressure medicine can effectively lower blood pressure, but some types may cause side effects. Tell your doctor if you have side effects, but don't stop taking your medicine on your own to avoid them. Your healthcare provider can work with you to find the medication or dose that works best for you.

Here are some of the common side effects that may occur:

- Weakness, tiredness or drowsiness
- Erectile dysfunction
- Trouble sleeping
- Slow or fast heartbeat
- Skin rash
- Feeling thirsty
- Cough
- Muscle cramps
- Headache, dizziness or light-headedness
- Constipation or diarrhea



### HOW CAN I LEARN MORE?

- 1** Call 1-800-AHA-USA1 (1-800-242-8721), or visit [heart.org](http://heart.org) to learn more about heart disease and stroke.
- 2** Sign up to get *Heart Insight*, a free magazine for heart patients and their families, at [heartinsight.org](http://heartinsight.org).
- 3** Connect with others sharing similar journeys with heart disease and stroke by joining our Support Network at [heart.org/supportnetwork](http://heart.org/supportnetwork).

### Do you have questions for the doctor or nurse?

Take a few minutes to write your questions for the next time you see your healthcare provider.

For example:

**Should I avoid any foods or medicines?**

**What reactions or side effects should I expect?**

**My Questions:**

We have many other fact sheets to help you make healthier choices to reduce your risk, manage disease or care for a loved one. Visit [heart.org/answersbyheart](http://heart.org/answersbyheart) to learn more.



**American  
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## Appendix J

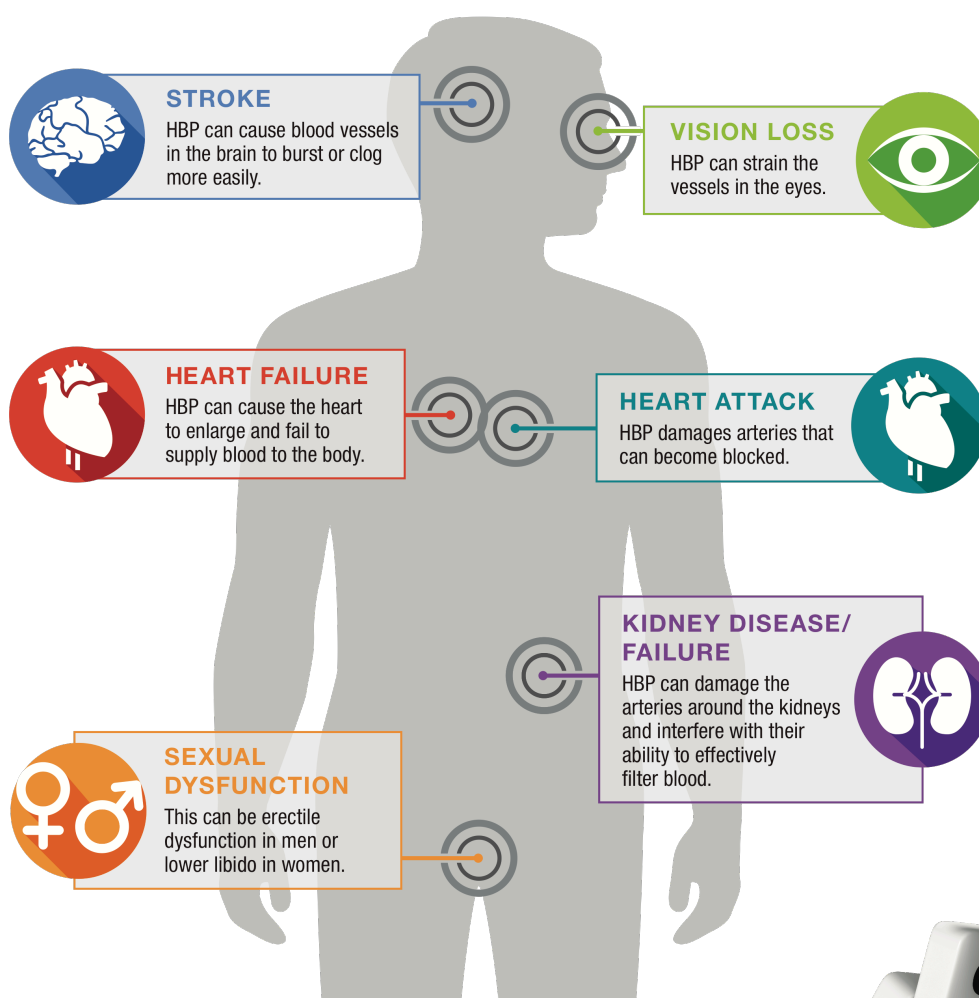
## Consequences of High Blood Pressure Handout

# CONSEQUENCES

## of High Blood Pressure

TARGET: **BP**<sup>™</sup>

High blood pressure is often the first domino in a chain or “**domino effect**” leading to devastating consequences, like:



A simple **blood pressure check** is the first step to preventing the “domino effect.”

Learn more at [heart.org/hbp](http://heart.org/hbp).



## Appendix K

### What is Self- Measured Blood Pressure? Handout

TARGET:BP™



# What is self-measured blood pressure?

Self-measured blood pressure (SMBP) is when you measure your blood pressure outside of the doctor's office or other health care settings.



## Why do I need to measure my blood pressure if my blood pressure was already measured at the doctor's office?

SMBP allows you to measure at different times throughout the day and over a longer period of time, helping your doctor get a more complete picture of your blood pressure.

## How does SMBP help me with my health?

By using SMBP you and your care team can come up with a treatment plan to better control your blood pressure, which can prevent more serious health problems.

The consequences of hypertension can be costly ... and deadly.



of Americans with high blood pressure are **not** controlled



## What do the numbers mean when I take a blood pressure reading?

**Systolic blood pressure** (SBP or SYS): Top number of your blood pressure measurement, indicates how much pressure your blood is exerting against your artery walls when the heart beats

**Diastolic blood pressure** (DBP or DIA): Bottom number of your blood pressure measurement, indicates how much pressure your blood is exerting against your artery walls while the heart is resting between beats

**Pulse:** Number of times the heart beats per minute

## What are some important things to know before I start measuring my own blood pressure?

Use an SMBP device and blood pressure cuff that are recommended by your doctor or care team.

If you purchase your own device, ask your care team to check it for accuracy.

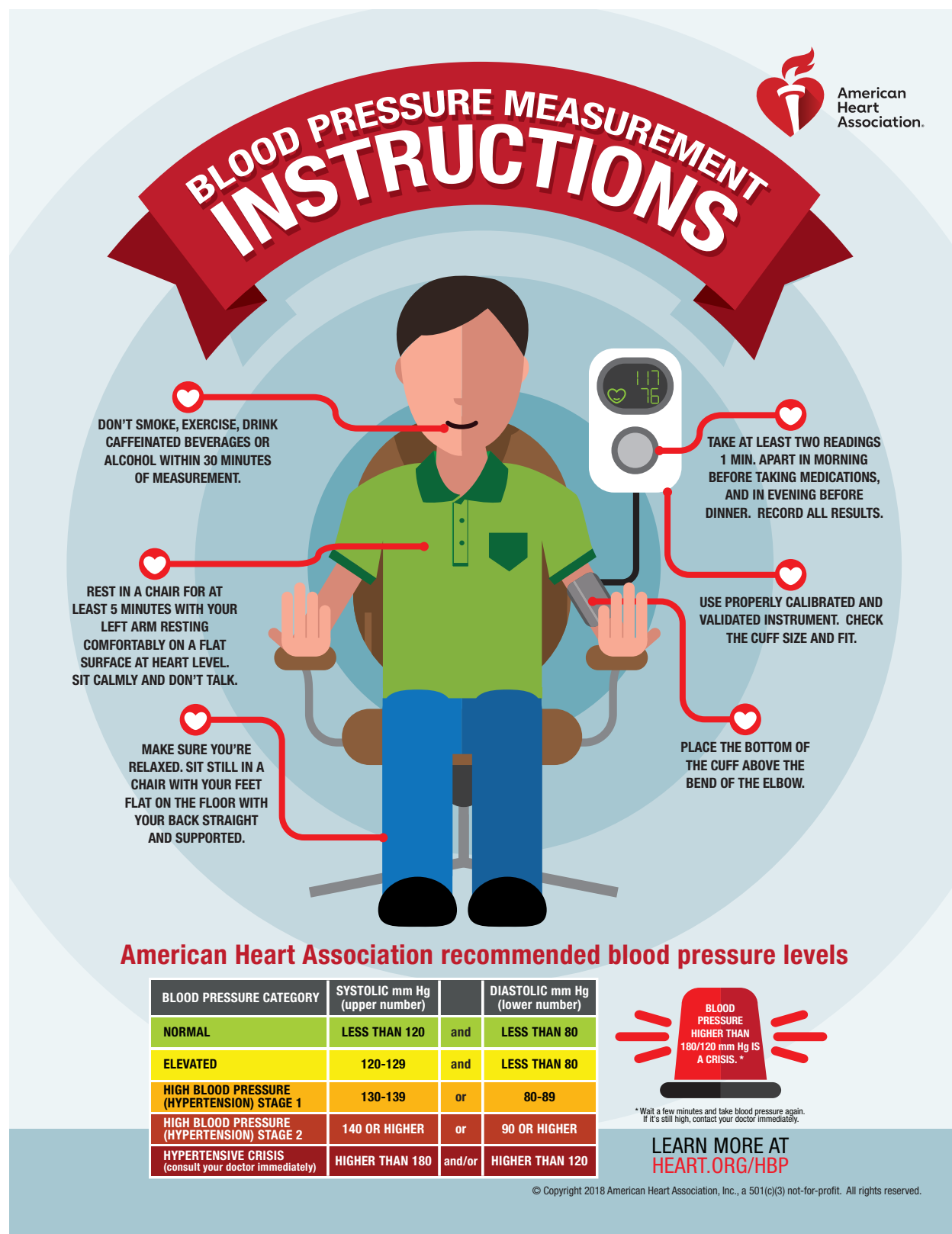
Understand the correct way to take a blood pressure reading.

Know when and how you will share your blood pressure readings with your doctor.

Make sure you have instructions from your care team on what to do if your blood pressure is out of the expected range.

## Appendix L

## Blood Pressure Measurement Instructions Infographic



**BLOOD PRESSURE MEASUREMENT INSTRUCTIONS**

**AMERICAN HEART ASSOCIATION**

- DON'T SMOKE, EXERCISE, DRINK CAFFEINATED BEVERAGES OR ALCOHOL WITHIN 30 MINUTES OF MEASUREMENT.**
- REST IN A CHAIR FOR AT LEAST 5 MINUTES WITH YOUR LEFT ARM RESTING COMFORTABLY ON A FLAT SURFACE AT HEART LEVEL. SIT CALMLY AND DON'T TALK.**
- MAKE SURE YOU'RE RELAXED. SIT STILL IN A CHAIR WITH YOUR FEET FLAT ON THE FLOOR WITH YOUR BACK STRAIGHT AND SUPPORTED.**
- TAKE AT LEAST TWO READINGS 1 MIN. APART IN MORNING BEFORE TAKING MEDICATIONS, AND IN EVENING BEFORE DINNER. RECORD ALL RESULTS.**
- USE PROPERLY CALIBRATED AND VALIDATED INSTRUMENT. CHECK THE CUFF SIZE AND FIT.**
- PLACE THE BOTTOM OF THE CUFF ABOVE THE BEND OF THE ELBOW.**

**American Heart Association recommended blood pressure levels**

BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (upper number)		DIASTOLIC mm Hg (lower number)
<b>NORMAL</b>	<b>LESS THAN 120</b>	<b>and</b>	<b>LESS THAN 80</b>
<b>ELEVATED</b>	<b>120-129</b>	<b>and</b>	<b>LESS THAN 80</b>
<b>HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 1</b>	<b>130-139</b>	<b>or</b>	<b>80-89</b>
<b>HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 2</b>	<b>140 OR HIGHER</b>	<b>or</b>	<b>90 OR HIGHER</b>
<b>HYPERTENSIVE CRISIS (consult your doctor immediately)</b>	<b>HIGHER THAN 180</b>	<b>and/or</b>	<b>HIGHER THAN 120</b>

**BLOOD PRESSURE HIGHER THAN 180/120 mm Hg IS A CRISIS. \***

\* Wait a few minutes and take blood pressure again. If it's still high, contact your doctor immediately.

**LEARN MORE AT [HEART.ORG/HBP](http://HEART.ORG/HBP)**

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## Appendix M

### Self- Measured Blood Pressure Training Checklist

TARGET:BP™



# Self-measured blood pressure Patient training checklist

Instructions: To ensure all necessary steps and components are covered, use this checklist when training your patient's on how to perform self-measured blood pressure (SMBP).

#### ☐ Gather supplies

- ☐ Tape measure
- ☐ [What is SMBP?](#) (PDF)
- ☐ [SMBP infographic](#) (PDF in English or Spanish)
- ☐ [SMBP recording log](#) (PDF)
- ☐ [SMBP device accuracy test](#) (PDF)

#### ☐ Provide background information on SMBP to the patient (if not explained by provider)

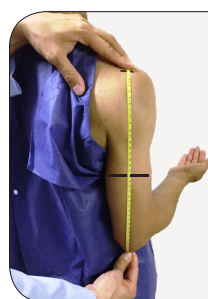
- ☐ Explain how SMBP allows the provider to get a more accurate and complete picture of the patient's blood pressure outside of the office (more readings, over a longer period of time, in the patient's normal environment)

*Tip: Hand out the "What is SMBP?" document.*

#### ☐ Determine SMBP cuff size

- ☐ Use tape measure to measure the circumference of the patient's mid-upper arm in centimeters (see image for more detail)

*Tip: Ideally, this is done before the patient purchases a device so you can ensure the device and cuff purchased are appropriate for the patient.*



#### Locate mid-upper arm

Using a measuring tape, place one end on the bony prominence at the shoulder (acromion process) and measure the length of the arm to the bony protuberance at the elbow (olecranon process). Divide this distance in half and that is the mid-upper arm where you should measure the arm circumference for determining cuff size.

Source: [https://www.cdc.gov/nchs/data/nhanes/2017-2018/manuals/2017\\_Anthropometry\\_Procedures\\_Manual.pdf](https://www.cdc.gov/nchs/data/nhanes/2017-2018/manuals/2017_Anthropometry_Procedures_Manual.pdf)

#### ☐ Check patient's SMBP device for accuracy

*Tip: Use the SMBP device accuracy test.*

#### ☐ Determine the patient's blood pressure arm (if not currently identified)

- ☐ Measure the patient's blood pressure in each arm and use the arm with the higher reading for all future readings

#### ☐ Teach patient how to properly prepare for self-measurement

- ☐ Avoid caffeine, tobacco and exercise for at least 30 minutes before measurement
- ☐ Empty bladder if full
- ☐ Take BP measurements before blood pressure medications

*Tip: Show [SMBP training video](#) and hand out the SMBP infographic.*

#### ☐ Teach patient the proper positioning for self-measurement

- ☐ Back supported
- ☐ Feet flat on the floor or a firm surface
- ☐ Legs uncrossed
- ☐ Cuff placed on bare upper arm
- ☐ Arm supported with middle of the cuff at heart level

*Tip: Refer to the SMBP video and/or infographic.*

☐ **Teach patient how to use device\* (if applicable)**

- ☐ How to turn on device
- ☐ How to start measurement
- ☐ How to troubleshoot

*\* Refer to device manual as needed.*

☐ **Teach patient how to properly self-measure**

- ☐ Rest quietly for five minutes
- ☐ Take two measurements, one minute apart
- ☐ Avoid conversations and electronic devices during measurement
- ☐ Perform this process once in the a.m. and once in the p.m. for seven consecutive days

*Tip: Provide patient with [link to SMBP training video](#) to reference later (also available in [Spanish](#)).*

☐ **Teach patient how to use SMBP recording log**

- ☐ Reminder: Complete the "For Office Use" section
- ☐ How to document systolic and diastolic blood pressure
- ☐ What to do if blood pressure is too high or too low
- ☐ What to do with log when week of measurements is complete

☐ **Use teach back or return demonstration methods to ensure patient understands how to properly self-measure**

☐ **Ensure all necessary office paperwork is complete**

## Appendix N

## Inaccurate Blood Pressure Measurement Handout

## Common problems that account for inaccurate blood pressure measurement

<i>When the patient has ...</i>	<i>BP can appear higher by ...<sup>1,2</sup></i>
<b>Cuff over clothing</b>	<b>10-40 mm Hg</b>
<b>A full bladder</b>	<b>10-15 mm Hg</b>
<b>A conversation or is talking</b>	<b>10-15 mm Hg</b>
<b>Unsupported arm</b>	<b>10 mm Hg</b>
<b>Unsupported back</b>	<b>5-10 mm Hg</b>
<b>Unsupported feet</b>	<b>5-10 mm Hg</b>
<b>Crossed legs</b>	<b>2-8 mm Hg</b>

1. Pickering, et al. *Circulation* 2005

2. O'Brien, et al. *J Hypertens*. 2003



**JOHNS HOPKINS**  
MEDICINE

## Blood Pressure Log



ID #:

[illegible]

- Avoid checking your blood pressure if you have eaten a big meal, exercised, smoked, used caffeine or taken decongestants in the past 30 minutes.
- If you need to use the bathroom, do so before you begin.
- Sit quietly for five minutes in a comfortable position.
- Sit in a chair with your back supported.
- Sit with your legs uncrossed and your feet flat on the floor. Use a step stool if necessary to make sure you support your feet on a flat surface.
- Support your arm on a table or other surface at heart level.

Take your blood pressure as directed by your doctor.

Write down the date and time of your blood pressure measurement in the appropriate column.

Write the top number of your blood pressure reading in the "systolic" column.

Write the bottom number of your blood pressure reading in the "diastolic" column.

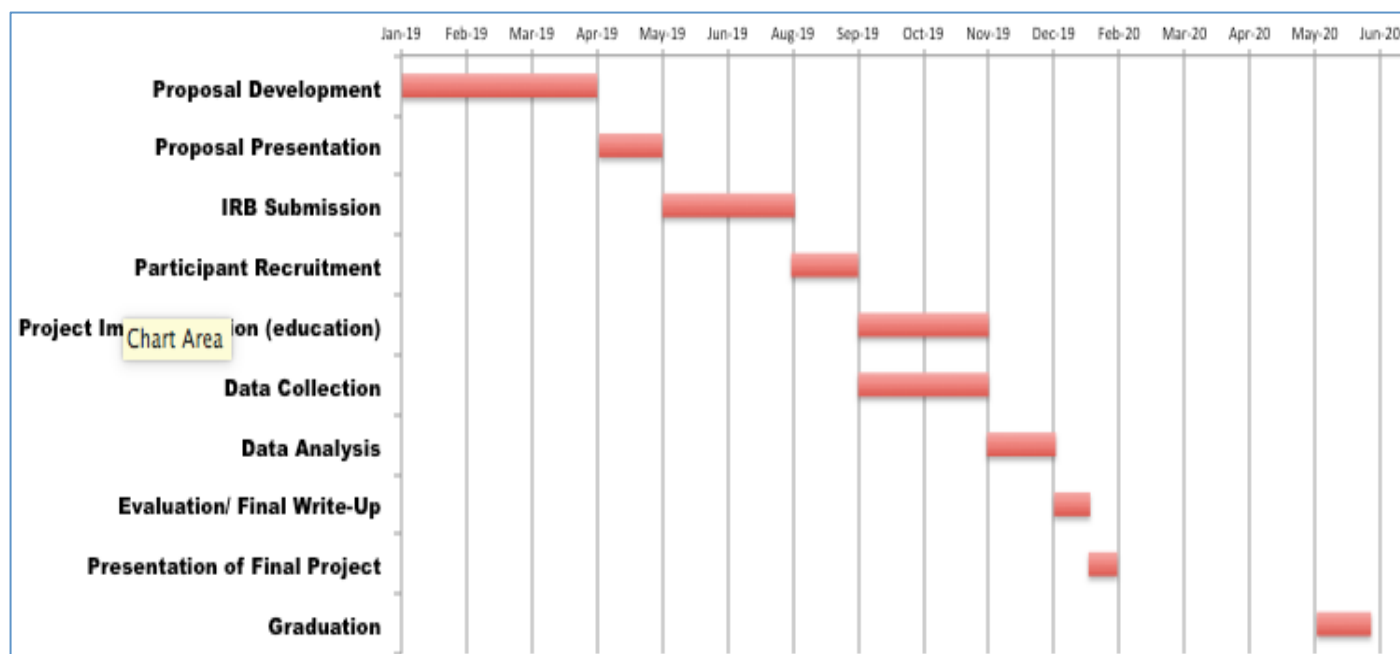
Bring this log with you to your doctor visits or communicate the results by telephone or computer.



Self-measured  
blood pressure  
patient log



This Self Measure Blood Pressure Patient Log was adapted with permission of the American Medical Association and The Johns Hopkins University. All Rights Reserved. The original copyrighted content can be found at <https://millionhearts.hhs.gov/tools-protocols/smbp.html>.

**Appendix P****Project Timeline**

**Appendix Q**

## Budget

<b>Expense Type</b>	<b>Estimated Cost</b>	<b>Estimated Total Cost</b>
Recruitment Flyers/ Consent	<i>90 x \$0.15</i>	\$13.50
Educational Program Materials		
• Various educational handouts	<i>200 x \$0.10</i>	\$20
• Measuring tapes	<i>30 x \$0.05</i>	\$1.50
• Pens	<i>1 x \$10</i>	\$10
• Omron BP monitors	<i>4 x \$60</i>	\$240
• Hand sanitizer (2 liter)	<i>1 x \$10</i>	\$10
• Disinfectant wipes	<i>1 x \$15</i>	\$15
Refreshments	<i>3 Sessions x \$20</i>	\$60
		<b>GRAND TOTAL: \$370</b>

## Appendix R

### Session One Lesson Plan: “BP Self Monitoring”

Total Time: 1 Hour	Activity
15 minutes	Welcome briefing: Purpose Learning Objectives 1) Discuss the importance of SMBP. 2) Provide training on how to accurately measure BP. 3) Offer support and resources for adaptation of the intervention.  Informed Consent
5 minutes	Demographics Questionnaire
5 minutes	Medication Adherence Tool
10 minutes	BP measurement
30 minutes	Education Intervention: Infographics/ Video Presentation/Lecture by Caterina Reshetnyak Handouts Discussion
5 minutes	Question & Answer
<i>Reminder 2-Week Follow-Up</i>	

### Session Two Lesson Plan

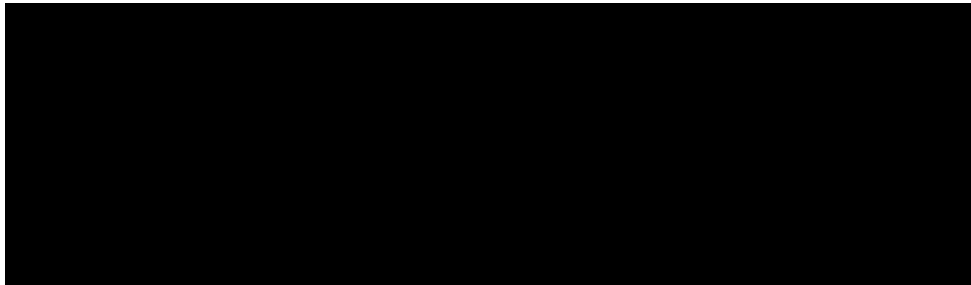
Total Time: 15 minutes	Activity
15 minutes	Collect BP logs Review BP logs Question & Answer
<i>Reminder 2-Week Follow-Up</i>	

### Session Three Lesson Plan

Total Time: 30 minutes	Activity
10 minutes	Collect BP logs Question & Answer
5 minutes	Medication Adherence Tool
10 minutes	BP measurement
5 minutes	Wrap up

## Appendix S

### Site Letter of Cooperation



### Site Letter of Cooperation for Study

Date: 03/26/2019

**Re: Letter of Cooperation For Meadowlands YMCA**

This letter confirms that that I, as an authorized representative of the Meadowlands YMCA, allow the Principal Investigator (PI), **Caterina Reshetnyak**, access to conduct study related activities at the listed site(s), as discussed with the Principal Investigator and briefly outlined below, and which may commence when the Principal Investigator provides evidence of IRB approval for the proposed project.

- **Research Site(s):** [REDACTED]
- **Study Purpose:** This is a pilot study. The purpose of this study is to improve blood pressure control in hypertensive adults and ultimately reduce hypertension-related complications.
- **Study Activities:** The study consists of three sessions. The first session will include a pre- intervention medication adherence survey and measurement of blood pressure by the PI, followed by a group and one-on-one educational session on hypertension and self-measurement of blood pressure. The participants will be provided with blood pressure logs and information to take home with them. They will be asked to return two weeks later for a second session, bring their blood pressure logs for review, and have any questions answered. The third and final session will be conducted two weeks after that, and the participants will have their blood pressure rechecked by the PI and will be given a post intervention medication adherence survey.
- **Subject Enrollment:** Due to the fact that this is a pilot study, a convenience sample of approximately 20 people will be needed. The inclusion criteria for the study will be the following: 1) male and female adults over 18 years with a current diagnosis of hypertension, 2) currently taking antihypertensive medications, 3) able to speak, read, and write in English, 4) able to provide written consent to participate in the study.
- **Site(s) Support:** [REDACTED] will provide an enclosed room with chairs and table to conduct the study activities, authorize site employees to identify persons who might qualify for the study, post flyers notifying [REDACTED] of the upcoming study, and provide an area where study participants can routinely come to measure their blood pressure with the machines provided by the PI, if they do not have their own monitors.
- **Data Management:** The following data will be collected for the study: demographic information (age, race/ ethnicity, gender, level of education, length of their hypertension diagnosis, amount of hypertension medications prescribed), blood pressure values, and medication adherence via a survey. The data will be de-identified prior to analysis and no participant data will be reported. Data will be stored in a locked cabinet, and keys to the cabinet will be kept in a different place. In order to ensure anonymity and privacy, responses from the pre and post intervention surveys and blood pressure logs will be linked based on a unique code. The code will be 7 characters long, the first 2 characters will be the study participant's father's first and last name initials, the 3<sup>rd</sup> character will be



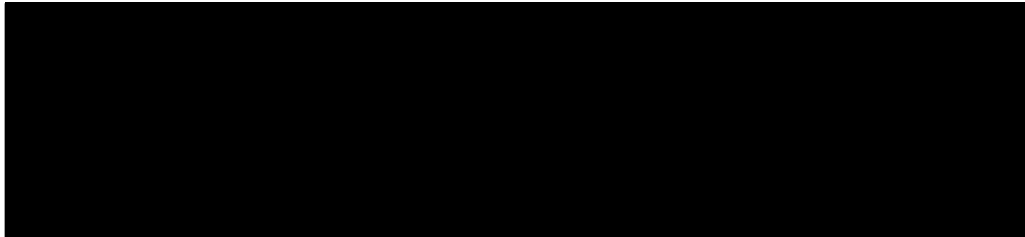
their mother's maiden name initial, the last 4 characters will be their 2-digit month of birth and their 2-digit year of birth. For example, if Jane Lewis is participating in this project and she was born on June 20, 1976, her father's name is John Doe and her mother's maiden name is Smith, her identification code would *JDS0676*.

- **Anticipated End Date:** 10/25/2019

We understand that this site's participation will only take place during the study's active IRB approval period. All study related activities must cease if IRB approval expires or is suspended. I understand that any activities involving Personal Private Information or Protected Health Information may require compliance with HIPAA Laws and Rutgers Policy.

Our organization agrees to the terms and conditions stated above. If we have any concerns related to this project, we will contact the Principal Investigator. For concerns regarding IRB policy or human subject welfare, we may also contact the Rutgers IRB (see [orra.rutgers.edu/hspg](http://orra.rutgers.edu/hspg)).

Regards,



**Appendix T**

Table T1.

*Demographic Characteristics of the Sample Population*

Characteristics	Total ( <i>n</i> =13)	%
Age groups (years)		
35-44	2	15.4
45-54	3	23.1
55-64	2	15.4
65-74	6	46.2
Gender Identity		
Male	7	53.8
Female	6	46.2
Race or Ethnicity		
White	8	61.5
Hispanic or Latino	3	23.1
Asian or Pacific Islander	1	7.7
Other	1	7.7
Highest Degree/ Level of School		
Some high school, no diploma	1	7.7
High school graduate, diploma or GED	1	7.7
Some college, no degree	4	30.8
Bachelor degree	5	38.5
Masters degree	2	15.4
Duration of HTN Diagnosis		
Less than 1 year, newly diagnosed	1	7.7
1-5 years	3	23.1
5-10 years	4	30.8
Greater than 10 years	5	38.5
Amount of Antihypertensives Prescribed		
One	4	30.8
Two	5	38.5
Three or more	4	30.8
Do You Currently Monitor Your Own Blood Pressure?		
Yes, everyday	3	23.1
Yes, a couple of times a week	1	7.7
Yes, once a week	2	15.4
Yes, randomly check it	4	30.8
No	3	23.1

**Appendix U**

Table U1.

*Systolic BP Descriptive Statistics*

	N	Mean	Std. Deviation	Minimum	Maximum	25 <sup>th</sup> Percentile
Pre- Intervention Systolic BP	13	131.08	14.767	110	163	119.50
Post- Intervention Systolic BP	13	124.62	12.494	104	145	112.50

Table U2.

*Diastolic BP Descriptive Statistics*

	N	Mean	Std. Deviation	Minimum	Maximum	25 <sup>th</sup> Percentile
Pre-Intervention Diastolic BP	13	79.54	11.377	59	96	74.00
Post- Intervention Diastolic BP	13	75.85	10.558	54	95	72.00

Table U3.

*Related-Samples Wilcoxon Signed Rank Test Summaries*

	Systolic BPs	Diastolic BPs
Total N	13	13
Test Statistic	10.000	19.500
Standard Error	11.236	12.738
Standardized Test Statistic	-2.047	-1.531
Asymptotic Sig. (2-sided test)	.041	.126

**Appendix V**

Table V1.

*HB-MAS Descriptive Statistics*

	N	Mean	Std. Deviation	Minimum	Maximum	25 <sup>th</sup> Percentile
Pre-Intervention HBMAS Score Total	13	30.54	3.152	24	34	28.00
Post- Intervention HBMAS Score Total	13	35.08	1.320	32	36	34.50

Table V2.

*Related-Samples Wilcoxon Signed Rank Test Summary*

	HB-MAS
Total N	13
Test Statistic	78.000
Standard Error	12.713
Standardized Test Statistic	3.068
Asymptotic Sig. (2-sided test)	.002





