Implementing a Home-Based Blood Pressure Monitoring Program to Improve Hypertension Management

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Acknowledgement

I would like to express my sincere gratitude to my Advisor and Committee Chair, Dr. Sheryl Winn for her continuous support throughout the Doctor of Nursing Practice (DNP) graduate program. I appreciate your patience, motivation, and immense knowledge toward the planning and implementation of this DNP project. Besides my advisor, I would like to recognize the rest of my committee: Dr. Leslie Moore and Dr. Susan Steele, for their insightful comments and encouragement, as well as their statistical expertise in the analysis and evaluation of this study. Earnest appreciation goes to Dr. Dinesh Chatoth, for sparing valuable time to provide a community perspective to the research project at hand. I'd like to thank the office managers, providers and staff members for their precious support, it would not have been possible to complete this research project without you. I also would like to appreciate Professor Don Morisky and Dr. Rosalind Peters for authorizing me to utilize their published measurement instruments for the evaluation of this study.

I'd like to attribute my personal growth to my fellow classmates, "The Synergist," for their stimulating discussions during class and on Whatsapp, and for the sleepless nights we were working together to meet coursework deadlines. I'd like to acknowledge and thank my family and friends for supporting me throughout the DNP program and my life in general. Most importantly, I would like to thank each and every individual whom donated funding for my blood pressure monitoring program through my "Go Fund Me", as well as, the Carolyn M. Maynard Nursing Scholarship fund and Marjorie G. Prentice Graduate Research Scholarship fund provided through the Georgia College & State University Alumni Foundation. Without the assistance and guidance of all the individuals aforementioned, the successful completion of this project would not be feasible.

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Abstract

Hypertension is a major problem in the United States. It is critical to identify effective strategies to treat and manage hypertension. An experimental design was utilized to determine the effectiveness of home-based blood pressure monitoring (HBPM) in the management of pre-hypertension, newly diagnosed, or uncontrolled hypertension. A randomized convenience sample of 20 adults was recruited into a control (n=9) and experimental (n=11) group. The translational care project was conducted over 60 days where participants measured their blood pressures as instructed for the intervention and control groups. An independent t-test was conducted to analyze the effectiveness of HBPM on the participants' blood pressure, blood pressure knowledge, self-care, and medication adherence utilizing subsequent scales. There was a statistically insignificant increase in systolic blood pressure, but a statistically significant increase in diastolic blood pressure between the experimental and control groups at 60 days. There was no statistical significance in the improvement of HBPM adherence, knowledge, self-care, or medication adherence between the two groups at 60 days. While there is limited statistical support for this translational research project, other resources support HBPM as an innovative program that has the potential to provide healthcare providers an avenue for more timely, effective, and individualized patient care. Literature demonstrates that improved blood pressure control has the potential to decrease the prevalence of co-morbid conditions and decrease health care costs. With an increase in successful studies legislation could be challenged to increase coverage and reimbursement cost for blood pressure monitors and more HBPM programs in practice. Continued research related to HBPM and patient adherence is necessary to improve patient access to affordable care and overall self-care outcomes.

Keywords: hypertension, home, blood pressure, monitoring, self-care

Implementing a Home-Based Blood pressure Monitoring Program To Improve Hypertension Management

Chapter I

Introduction

According to the National Health and Nutrition Examination Survey (NHANES) (2011-2012), approximately 70 million people in the United States (US) have high blood pressure, clinically known as hypertension (Nwankwo, 2014). Complications as a result of hypertension and rising health care costs make this an important issue to address. Best practices demonstrate that daily blood pressure monitoring in the home setting, also known as Home-Based Blood Pressure Monitoring (HBPM), increases patient awareness of the disease process and allows patients to monitor their blood pressure in their natural setting (Parati et al., 2010). Results from home blood pressure monitoring allows for providers to analyze home data trends and provide appropriate feedback. The purpose of this translational research project is to determine the effectiveness of home-based blood pressure monitoring in the management of those diagnosed with pre-hypertension, newly diagnosed, or uncontrolled hypertension.

Problem

Currently, hypertension diagnosis and management is based on several blood pressure readings conducted in various clinical settings at random times of the day. However, a single blood pressure reading in the conventional office or emergency room setting does not reflect whether the patient is hypertensive or if hypertension is being managed properly. High blood pressures in the office setting could be related to stress and the white-coat phenomenon. White-coat refers to a false elevation in blood pressure in the provider's office, hence white-coat (Parati et al., 2010). Daily blood pressure monitoring in the home setting increases patient awareness of

disease process, allows patients to monitor their blood pressure in their normal setting, helps detect white-coat or masked hypertension, and provides several measurements where blood pressure trends can be evaluated (Parati et al., 2010). Results from daily monitoring allows for providers to analyze home data trends and provide appropriate feedback. Therefore, implementation of a home-based blood pressure monitoring program has the opportunity to improve hypertension management and encourage self-management practices among hypertensive patients.

Background

The American Heart Association (AHA, 2016a) describes blood pressure as the force of the blood within the heart, which is measured by a fraction of two numbers. The systolic blood pressure (numerator) measures the pressure in the arteries when the heart contracts and the diastolic blood pressure (denominator) measure the relaxation phase of the heart when it refills with blood (AHA, 2016a). Blood pressure results are usually obtained using a sphygmomanometer in the upper arm above the elbow. Normal blood pressure is considered anything less than 120/80 and anything greater than this is considered pre-hypertensive or hypertensive. Pre-hypertension constitutes an increased blood pressure level between 121/81 and 139/89 where providers may consider further evaluation. Hypertension is an elevated blood pressure, greater than 140/90, where the force of blood pushing against the vessels of the heart is too high and requires prompt evaluation and treatment (AHA, 2016b).

With the large prevalence of Americans having hypertension, the US experiences an health care spending cost of over $46 billion dollars annually for the management of hypertension and associated comorbidities (Nwankwo, 2014). According to the American Heart Association (AHA), uncontrolled hypertension results in end-organ damage, which includes

heart disease, heart failure, stroke, and renal death (AHA, 2016b). In the US, hypertension and diabetes are the leading causes of kidney disease resulting in end-stage renal disease (ESRD) and death (CDC, 2014). In 2012, over $29 billion of the Medicare budget was used in the management of kidney disease and failure (CDC, 2015). Among African Americans, one of the leading causes of Chronic Kidney Disease (CKD) is uncontrolled hypertension with a prevalence rate of approximately 45% among men and women (Nwankwo, 2014). African Americans also have a 2-fold higher incidence of uncontrolled hypertension and an eight-time higher risk of stroke (Piper et al., 2015).

The CDC developed quality initiatives for the prevention, treatment and control of hypertension (CDC, 2015). With the substantial evidence of the prevalence of hypertension and its associated costs for comorbid conditions, it is imperative to implement evidence-based research strategies for improving hypertension management. A literature review demonstrated the potential for Home-based blood pressure monitoring (HBPM) to improve the care of those with hypertension. HBPM is the act of taking an individual's blood pressure in the comforts of the patients' home and recording results for later evaluation by the patients' provider. The objective of this translational research project was to disseminate evidence-based care practices for blood pressure management through implementing home-based blood pressure monitoring into the health care setting.

Terms and Definitions

Ambulatory blood pressure Monitoring (ABPM) is a diagnostic procedure where an automatic cuff is given to the patient from an outpatient lab source and measurements are taken every 15-20 minutes during the day and 20-30 minutes at night through a 24-hour period (Cohen, Huan, and Townsend, 2014).

Chronic Kidney or Renal Disease is a condition involving the decline of the kidney function, which normally cleans and filters the blood (CDC, 2014). In relation to hypertension it is important for blood pressures to remain stable to prevent further kidney damage.

Diabetes Mellitus is a condition where the blood's sugar levels remain elevated for long periods of times (CDC, 2011). Due to the ability of this condition to cause further damage to multiple organs including the heart, it is important that blood pressures remain stable.

Electronic blood pressure Monitoring (EBPM) is similar to HBPM, but includes transmitting the blood pressure results electronically to the health care provider via email or into the patient's electronic medical record (EMR) (Cohen, Huan, and Townsend, 2014).

Home-Based Blood pressure Monitoring (HBPM) is defined as the act of taking an individual's blood pressure in the patient's home twice daily (Cohen, Huan, and Townsend, 2014).

Office blood pressure Monitoring (OBPM) occurs in the office setting where measurements are taken at the patients' appointment for objective vital signs (Cohen, Huan, and Townsend, 2014).

Purpose

The purpose of the translational research project was to determine the effectiveness of home-based blood pressure monitoring in the management of pre-hypertension, newly diagnosed, or uncontrolled hypertension. Since uncontrolled hypertension is one of the leading causes of end-organ damage, which includes heart disease, stroke, and renal death predominantly in African Americans, the objective was to disseminate evidence-based care practices for blood pressure management into the health care setting. The primary investigator (PI) developed a home-based blood pressure monitoring program utilizing an educational program and the Omron

sphygmomanometer, a blood pressure monitoring device. The Omron blood pressure monitor records and stores blood pressure results and downloads results to an Omron Wellness application ("10 Series Upper Arm Blood Pressure Monitor," 2016). Though this mobile application blood pressure results are transmitted to the health care provider via a secure email. The goal was to provide an easily adaptable implementation process for the home-based monitoring system in practice and to improve monitoring compliance and blood pressure results. This innovative technology has the potential to help health care providers deliver individualized patient care based on accurately reported blood pressure results. Improved blood pressure control has the potential to decrease complications of uncontrolled blood pressure and decrease health care costs.

Aims and Clinical Questions

There were three main aims for this translational research project:

1. To reduce resting blood pressure to less than 140/90, in Diabetics (individuals with elevated blood sugars) and Renal disease (individuals with a decline kidney in kidney function) 130/80, or demonstrate a 5% reduction in blood pressure among men and women with primary hypertension.
    a. In adults' age 18-60 years old with primary hypertension, what is the effect of a home-based blood pressure monitoring program compared to conventional outpatient blood pressure monitoring in the health care setting within 60 days?
2. To increase adherence to home blood pressure monitoring among men and women with primary hypertension.
    a. Does HBPM in patients with primary hypertension increase adherence to home blood pressure monitoring?

3. To increase adherence to hypertension lifestyle changes.
    a. Does HBPM in patients with primary hypertension increase adherence to self-care lifestyle changes?
4. To increase adherence to hypertension medication therapy.
    a. Does HBPM in patients with primary hypertension increase adherence to medication compliance?

Opportunities and Challenges

Since uncontrolled hypertension is one of the leading causes of CKD in African Americans, the objective is to disseminate evidence-based care practices for blood pressure management into the primary care setting. Research demonstrates that home-based blood pressure monitoring can increase the diagnosis and management of hypertension as opposed to office blood pressure monitoring (Crabtree & Stuart-Shor, 2014). This translational research project provides a roadmap to implementing HBPM into practice. The PI developed a home-based blood pressure monitoring program that facilitated a step-wise approach to tackling hypertension monitoring and management. The future goal is to have an interface system for every primary care or hypertension clinic. This would allow remote management of hypertension and increase productivity for other acute or chronic visits. HBPM has the potential to minimize follow-up visits related to blood pressure rechecks and allows the patient to conserve resources related to transportation or time off work. This innovative technology has the potential to health care providers deliver individualized patient care based on accurately reported blood pressure results (Young et al., 2015). Improved blood pressure control potentially decreases associated co-morbid conditions and thereby decreases health care expenditures and expenses (CDC, 2015).

The primary stakeholders for this project were the patients and patients' families. Other

stakeholders include health care providers, nurses, and medical assistants. There were no major financial burdens to incur with the implementation of HBPM to the health care clinics or patients. The PI enlisted funding through a “Go Fund Me” account, which solicited donations. Funding from the “Go Fund Me”, Carolyn M. Maynard Nursing Scholarship fund and Marjorie G. Prentice Graduate Research Scholarship provided blood pressure monitors to participants and covered the cost related to educational materials. However, the cost of monitors may become a challenge for practices without grant or governmental assistance. Training and education on the proper procedure for taking the blood pressure and the Omron Wellness application for the staff and patients was necessary. The PI conducted educational sessions demonstrating the appropriate frequency of blood pressure monitoring, proper body mechanics when taking blood pressure, and documentation with the Omron Wellness application. This could also commence a challenge, for this would require additional staffing or time dedicated to patient education and staff training that would deduct from regularly scheduled patient care. Most importantly, the patients must be fully invested in their own health and assume responsibility for adhering to the treatment plan.

Chapter II

Review of Literature and Synthesis

This chapter will review current literature regarding HBPM in relation to the management of hypertension. The chapter discusses the search criteria utilized to obtain literature and defines terms related to HBPM and blood pressure management. Lastly, a synthesis of the major themes identified and critical analysis of literature is detailed in this section.

Search for Evidence

The investigation consisted of a search of research-based articles in CINHAL, MEDLINE, MEDLINE Plus Text, and PubMed published in 2010 or later. The search terms used were “home blood pressure monitoring” AND “hypertension” AND “African Americans” OR “Chronic Kidney Disease”. Some articles revealed alternate forms of HBPM. Therefore, alternate terms were searched including “ambulatory blood pressure monitoring,” “home-based blood pressure monitoring,” “self-blood pressure monitoring,” “office blood pressure monitoring,” and “electronic blood pressure monitoring.” Articles were eliminated based on the amount of relevance to HBPM in the management of hypertension and evidence strength. 23 articles were reviewed and 12 were selected for the inclusion in this synthesis of research.

Summary of Evidence

The literature reviewed consisted of literature reviews (4), randomized controlled trials (4), and case/cohort studies (3) that supported the use of either HBPM or ambulatory blood pressure monitoring (ABPM). The synthesis of literature revealed three major themes: 1) HBPM improves blood pressure control, 2) HBPM provides prognostic and diagnostic value of high blood pressure and decreases the progression of co-morbid conditions, including Chronic Kidney

Disease (CKD), 3) SMBP or HBPM provided an equivocal measurement of blood pressure as compared to ABPM. The following provides a summary of the research evidence discovered in the literature review in support of the implementation of the translational research project.

The main theme discovered was that HBPM demonstrated a significant improvement in blood pressure management. McManus et al. (2010) reports a prospective-randomized control trial of 480 Caucasian patients that compared HBPM to traditional office based care. Results showed an average decrease of 30.5 mmHg in systolic blood pressure, which was statistically significant (p=0.002) (McManus et al., 2010). The same author conducted a similar randomized clinical trial to determine the effect of self-measured blood pressure monitoring (SMBP); results showed a 12-point reduction in systolic blood pressure after 12 months (McManus et al., 2014). The randomized control trial by Margolis et al. (2012) was a HBPM program that involved a pharmacist dosing and titrating antihypertensive medications based on blood pressure results received from a blood pressure telemonitoring system. In 228 patients from the telemonitoring intervention, an average reduction of 18 mmHg was noted in the systolic blood pressure (Margolis et al., 2012). Crabtree and Stuart-Shor (2014) developed an HBPM program in a community health center; results showed that among 50 patients, 60% experienced blood pressure improvement and 84% stated the program helped increase their knowledge and understanding of blood pressure management. In a case study of 46 CKD patients, White (2009) focused on increasing patient involvement in a HBPM program. The case study showed a 50% improvement in blood pressure management among CKD patients with hypertension (White, 2009). A literature review of 52 prospective comparative studies on SMBP monitoring in adults with hypertension by Uhlig, Patel, Ip, Kitsios, and Balk (2013) provided supportive evidence of

the use of SMBP alone or in combination with medication regimen improved blood pressure control compared to office setting monitoring.

The second theme identified was that ABPM and HBPM alike provided prognostic and diagnostic value in high blood pressure. Researchers were able to diagnose masked or white-coat hypertension, as well as predict end-organ damage from uncontrolled hypertension with HBPM. Another prospective cohort studied the prognostic ability of ABPM in 436 CKD patients (Minutolo et al., 2011). After approximately four years of tracking and trending this group of patients, 86 of the patients progressed to ESRD (20%), 63 experienced non-fatal cardiovascular events (14%) and 52 succumbed to cardiovascular death (12%) (Minutolo et al., 2011). This study demonstrated that nighttime blood pressure with ABPM proved to be an accurate prediction of renal and cardiovascular risk (Minutolo et al., 2011). A similar literature review by Cohen, Huan, and Townsend (2014) showed that HBPM and ABPM were useful instruments in the diagnosis of hypertension. Stergiou, Kollias, Zeniodi, Karpettas, and Ntineri (2014) conducted a literature review revealing the advantages and limitations of HBPM in clinical practice; the evidence exhibited that HBPM has prognostic and diagnostic ability, and improved medication adherence. Piper et al (2015) also conducted a literature review that examined the benefits of ABPM for diagnostic and predictive value; a review of 27 articles showed strong evidence that ABPM is more accurate in the diagnosis of hypertension.

Lastly, evidence demonstrated that HBPM provided an equivocal measurement of blood pressure as compared to ABPM, a more expensive diagnostic monitoring technique (McGowan & Padfield, 2010). McGowan and Padfield (2010) conducted a comparative study among 87 participants whom had recently undergone ABPM. The researchers provided blood pressure monitors and education to the individuals and compared SMBP to ABPM. Results demonstrated

that there was no difference in blood pressure results obtained via ABPM versus SMBP (McGowan & Padfield, 2010). Stergiou, et al. (2014) not only provided diagnostic value of HBPM as previously stated, but research also exhibited that HBPM is reflective and consistent with ABPM. This summary of evidence provides a foreground in developing a framework to disseminate a home-based blood pressure monitoring program in the care of patients with pre-hypertension, uncontrolled hypertension or newly diagnosed hypertension.

Summary of Expert Evidence

The U.S. Preventive Services Task Force (USPSTF, 2016) published the final recommendation for the utilization of ambulatory blood pressure monitoring (ABPM) in the screening and diagnosis of hypertension, titled "Final Recommendation Statement: High Blood Pressure in Adults: Screening". The study investigated how well home and ambulatory blood pressure monitoring methods predict cardiovascular events compared with clinic-based blood pressure measurement methods. The USPTF (2016) recommends that ambulatory blood pressure monitoring and home blood pressure monitoring be utilized prior to diagnosing hypertension and beginning treatment. The USPTF (2016) also states that "good-quality" evidence demonstrates that HBPM is equally as effective as ABPM in the diagnosis and management of hypertension.

Critical Analysis of Current Evidence

The literature reviewed for the project consisted of literature reviews (Cohen et al., 2014; Parati et al., 2010; Piper et al., 2015; Uhlig et al., 2013), randomized controlled trials (Margolis et al., 2012; McManus et al., 2010; McManus et al., 2014; Stergiou, et al., 2014), and cohort studies (Crabtree & Stuart-Shor, 2014; McGowan & Padfield, 2010; Minutolo et al., 2011; White, 2009) that supported the use of either HBPM or ambulatory blood pressure monitoring (ABPM). Literature reviews and randomized control trials are considered to be the highest

quality of research and made up a majority of this literature review. A critical analysis of the research literature was conducted utilizing Melnyk and Fineout-Overholt (2011) critical appraisal of quantitative research to assess validity, reliability and applicability.

Literature Reviews

A narrative review of blood pressure monitoring in CKD patients conducted by Cohen et al. (2014) discusses the results and findings of several research articles. The review describes only a few of the studies locations, sample sizes, length of follow-up and outcomes. The results discuss the benefit of HBPM in the use of blood pressure management in patients with CKD and predicting end-organ damage. However, this particular literature review was not systematic or methodological in its approach, and lacks an intervention effect or any statistical significance. Cohen et al. (2014) remains applicable to the translational research project at hand by reviewing recent literature that provides guidance on proper blood pressure monitors for HBPM, discussing the importance of ruling out white-coat hypertension and masked hypertension to diagnose true high blood pressure, and providing a foreground for interfacing HBPM into electronic health records.

Parati et al. (2010) another narrative review provides a summary of guidelines necessary for HBPM. While this literature review is not methodological in manner, it does provide supportive national guidelines for the implementation of HBPM into practice. A large component of applicability resides in this review, for it provides information on the advantages and shortcomings to HBPM, validated blood pressure monitors, optimal monitoring schedules, HBPM analysis techniques, and indications for HBPM (Parati et al., 2010). While Parati et al. (2010) provides a strong basis of clinical guideline support, it was important to note that there was some conflict of interest with the authors' relationships with some medical equipment

vendors.

Piper et al. (2014) established a literature review of 27 research articles to demonstrate that elevated OBPM should be confirmed by ABPM to avoid over or under diagnosis of hypertension and improve the diagnostic accuracy of office blood pressure measurement for screening. This literature review was systematic and methodological in nature by detailing the populations, sample sizes, and outcomes. Piper et al. (2014) identified and incorporated solely randomized control trials and graded the literature based on quality. The author also summarized the review in table format that made it particularly simple to evaluate the hazard ratios and positive predictive values of the literature review with the displayed treatment effects and 95% confidence intervals (CI). With HBPM being a more cost-effective way of blood pressure monitoring outside the office similar to ABPM, this review provides applicability to the translational research project in supporting HBPM for the diagnosis and treatment of hypertension.

A systematic review and meta-analysis was conducted by Uhlig et al. (2013) to describe the efficacy of self-measured blood pressure monitoring (SMBP), also known as HBPM. As given its subtitle, the literature review was both systematic and methodological in the processes of data search, extraction and synthesis or research as instituted by the Agency for Healthcare Research and Quality (AHRQ). The author only sequestered randomized control trials (RCTs) and provided each published work's locations, sample sizes, interventions and outcomes. The literature review synthesized the results of 52 studies detailing the relative risk (RR) and statistical significance of each study (Uhlig et al., 2013). Uhlig's et al. (2013) systematic review and meta-analysis provided significant support for the translational research project in that the review corresponded SMBP to notably improve blood pressure management over a six-month

period, especially in the presence of clinical support agents.

Randomized Control Trials

Margolis et al. (2013) is a RCT demonstrating that home-based blood pressure telemonitoring and pharmacist-led antihypertensive management, improved blood pressure (SBP) over a 12 month period compared to OBPM and management. The study consisted of the random assignment of 450 participants into a treatment intervention and control group with explicit inclusion and exclusion criteria; however, the facilitators and stakeholders were not blind to the group assignments. Statistical methods were utilized to obtain an effect size for the prospective sample and authors increased participant recruitment by the calculated odds of patients completing the study over the predetermined length of time. The interventions utilized validated blood pressure telemonitors and a one-on-one meeting with a Pharm-D (Margolis et al., 2013). The study demonstrated an average difference in SBP and DBP of -10.7 mmHg and -6 mmHg at six months from the experimental group to the control group with a CI of 95% (-14.3 - -7.3; -8.6 - -3.4) (Margolis et al., 2013). The results of this study are clinically relevant and imperative to the translational research project of HBPM in hypertension management.

Both McManus et al. (2010) and McManus et al. (2014) are un-blinded RCTs that measure the effectiveness of SMBP and self-titration of antihypertensive therapy versus usual care. McManus et al. (2010) simply studied SMBP among primary care practices (n= 480) and McManus et al. (2014) studied the intervention among those with increased cardiovascular risks (n=522). Despite the fact that neither studies provided effect size data, both studies' participants were recruited and randomly assigned to the treatment and control group with reasons given for those subjects who did not complete the study in a flow-chart figured in each manuscript. The intervention groups received blood pressure monitors that were verified and reliable and

developed self-titration algorithms with their nationally certified primary care providers (McManus et al., 2010; McManus et al., 2014). In the initial McManus et al. (2010) study there was a -12.9 mmHg (95% CI 10.4-15.5) decrease in SBP among the experimental group versus the control groups -9.2 mmHg (95% CI 6.7-11.8). In the study involving at-risk cardiovascular participants, SBP/DBP was -9.2 mmHg/-3.4 mmHg lower in the intervention group versus the control group respectively (95% CI 5.7-12.7)/(95% CI 1.8-5.0) (McManus et al., 2014). The findings of these studies help support the importance of instituting HBPM into practice.

The last RCT was conducted in a hospital outpatient clinic to compare HBPM to ABPM management (Stergiou, et al., 2014). Participants were blindly randomized into a treatment and control group based on a statistically identified effect size of 122 participants (Stergiou, et al., 2014). One strength of the study is the strategic placement of a flow diagram outlining the recruitment phase of participants and those whom withdrawn from the study, which supports the use of a flow diagram for this translational research project. The use of this flow diagram motivated the researcher to construct a similar diagram for this translational research project. The treatment group received home blood pressure monitors and antihypertensive medications were titrated based on HBPM results, while the control group utilized either OBPM or ABPM and had medications titrated based on the clinic or ABPM results (Stergiou, et al., 2014). End-organ diagnostic testing and blood pressure results were assessed pre and post-intervention to determine the reliability of HBPM versus ABPM. Stergiou, et al. (2014) provides a visual of the relationships between the various treatment methods with elements describing the standard error and confidence intervals. The study demonstrated that HBPM is comparable to ABPM and clinic management showing no statistical difference between treatments.

Cohort Studies

Crabtree and Stuart-Shor (2014) is a cohort study to implement HBPM into practice at a health care facility. Participants were recruited from a single primary care office whom were diagnosed with a high blood pressure of >140/90 mmHg. Participants were given validated blood pressure monitors and education on proper blood pressure monitoring and treatment. Crabtree and Stuart-Shor (2014) indicated a 60% improvement in blood pressure control (BP<130/80), of which, 84% of patients felt that the HBPM program helped them understand and manage their blood pressure, enhanced their doctor visits, and added value to their care. Although blood pressure management improved with HBPM, there was no magnitude of relationship indicators, *p*-values or CIs documented in the results. However, there was a strong applicability and correlation to the presented translational research project in that the study demonstrates Home-based blood pressure monitoring is valuable in the improvement of hypertension knowledge and disease management adherence among patients.

McGowan and Padfield (2010) conducted a comparative cohort study among 87 participants whom had recently undergone ABPM. The researchers provided validated blood pressure monitors and education to the individuals and compared SMBP to ABPM. Results demonstrated that there was no difference in blood pressure results obtained via ABPM versus SMBP (McGowan & Padfield, 2010). HBPM matched ABPM results in 87% of the individuals. Statistical analysis demonstrated a correlation and repeatability coefficient of 0.72 (CI 95%, 0.57-0.82) and 5.2 (CI 95%, 4.1-6.2) respectively for SBP (McGowan & Padfield, 2010). For the DBP the correlation and repeatability coefficient was 0.89 (CI 95%, 4.1-6.2) and 5 (CI 95%, 4.1-6.2) respectively (McGowan & Padfield, 2010). Subjectivity of the study was limited, however, no adjustments were made to rule out confounding variables. The applicability of the study in

HBPM provides reassurance that HBPM can be substituted for ABPM in the clinical setting and provides accurate results in the care of hypertensive patients.

Specifically in chronic kidney disease, Minutolo et al. (2011) a cohort study, determined that nighttime ABPM demonstrated precise prediction of renal and cardiovascular risk (n=436). ABPM was compared to OBPM for predicting the time to end-stage renal death or cardiovascular complications. Elevated nighttime blood pressure (>137 mmHg SBP) during ABPM is associated with increased risk of end stage organ death unlike OBPM (Minutolo et al., 2011). The magnitude of relationship indicators, p-values and CIs are documented in the results providing reliability to the results. With ABMP being proven to be comparable to HBPM, HBPM holds similar predictive and prognostic value. While the purpose of the translational research project is to demonstrate that HBPM improves the management of hypertension, the applicability in this study lies in the support of HBPM and its role in preventing the progression of chronic diseases.

White (2009), cohort study conducted at a nephrology practice, recruited 46 CKD patients with hypertension to perform HBPM. Participants were selected by the clinical staff and provided with validated blood pressure monitors. Participants submitted HBPM results on a monthly basis and results demonstrated approximately a 50% improvement in hypertension over a six-month period. There were subjective statements by the researcher noted in the study report that could introduce bias to the results. The data analysis did not adjust for risk factors or confounding variables such as race, age, and gender. Unfortunately, the White (2009) study is statistically frail with insufficient statistical data and data analysis to support the study of HBPM. Yet, the results of the study help provide important educational and implementation techniques for the HBPM translational research project.

Limitations of Current Evidence

This literature synthesis provides an abundance of research on the topic of HBPM and has supported the use of various types of self-monitoring techniques for the diagnosis, management and prognosis of blood pressure control (Cohen et al., 2014; Crabtree & Stuart, 2014; McManus et al., 2014; McManus et al., 2010; Piper et al., 2015; Minutolo et al., 2011; Margolis et al., 2012; Stergiou et al., 2014; Uhlig et al., 2013; White, 2009). Palatini and Frick (2012) discuss limitations to the implementation of HBPM into practice to include lack of methodological implementation, utilization of invalidated blood pressure monitoring equipment, result inaccuracy related to misreporting, and inadequate staff and patient education. The gap in the literature was identified with only a few studies having been conducted on the use of HBPM with the influence of hypertension education on the improvement of hypertension management and medication adherence.

While national organizations such as the CDC (2015) and USPSTF (2016) support and provide guidance for the use of HBPM or SBPM alike, there is limited research that demonstrates that HBPM is effective and worth the efforts of instituting into practice. Some literature lacks critical quantitative evidence and strength. Of the literature reviewed, common research limitations were related to the introduction of bias with un-blinded RCTs, inadequate participant recruitment and under-represented patient samples. Other limitations discovered in the literature review included: lack of evaluation of confounding variables, inconsistent medical management and treatment of hypertension, limited study length and follow-up, research generalizability and reproducibility in multiple settings, and no cost analyses were conducted. The translational research project addressed several of these factors in effectively implementing HBPM into practice.

Strengths of Current Evidence

All the studies examined in this literature review were applicable to the study of HBPM in the management or improvement of hypertension. A majority of the studies discovered in the appraisal of literature were systematic reviews or randomized control trials, which are methodologies that more accurately exemplify the entire population. Several studies like McManus et al. (2010) and McManus et al. (2014) contained large sample sizes with statistically supportive results demonstrating that HBPM is effective in blood pressure control and decreases the risk of end-organ damage. Several studies also provided evidence demonstrating that HBPM is a more cost effective and reliable substitution for OBPM and ABPM (McGowan & Padfield, 2010; Minutolo et al., 2011; Piper et al., 2015; Stergiou, et al., 2014). Other research studies provide statistically significant evidence representing that HBPM provides prognostic and diagnostic value in high blood pressure (Cohen et al., 2014; McManus et al., 2010; McManus et al., 2014; Minutolo et al., 2011; Piper et al., 2015; Stergiou, et al., 2014). The synthesis of research provides a framework of support implicating HBPM as a potential factor in the management of hypertension.

Apply the Evidence

Given the prevalence of cardiovascular disease, kidney disease, and increased health care costs; it is beneficial to explore HBPM use in the primary care setting where the initial diagnosis and management of hypertension most often occurs. Utilization of HBPM should be initiated in the primary care setting to screen, diagnose and manage hypertension on a continuous basis. Evidence demonstrates that it is imperative to create and apply a methodological approach to HBPM as to successfully implement in practice. An important step in the methodology is to ensure patient and staff are properly educated in accurate HBPM procedures. Another important

concept in HBPM is the need of an interface or software system similar to the pharmacist-led study due to the fact that electronic results improve evaluation, accuracy and efficiency of blood pressure outcomes (Margolis et al., 2013). Further investigation is necessary to determine a systematic way to effectively implement HBPM into practice.

Theoretical Framework

Translational/Change Theory

"Translating Evidence into Practice: A model of large-scale knowledge translation" by Pronovost, Berenholtz, and Needham (2008) introduces a model that enables evidence-based research to be implemented into practice. This theory provides an organized way to implement home-based blood pressure monitoring for patients with hypertension. The Translating Evidence into Practice theory is aimed at large-scale research projects and includes four phases: summarize evidence for improving a specific outcome, identify local barriers of implementation, identify outcomes of the implementation and performance measures, and finally ensure all patients reliably receive the intervention (Dudley-Brown, White, & Ebooks, 2012). The change theory orchestrates the synthesis of research to translate HBPM into practice. The plan is to utilize evidence-based practice to engage and educate staff on the importance of monitoring blood pressure outside the primary care clinic on a consistent basis. The PI will implement a program that records electronic home blood pressure readings and facilitate the electronic submission of those results. To evaluate the study, a baseline comparison of blood pressures prior to the intervention and blood pressures post intervention over an eight-week period will be conducted.

Hill-Levine Conceptual Model

According to Young et al. (2015), medication non-adherence (70%) was the most common cause of uncontrolled hypertension in low income African Americans. According to the survey, causes of medication non-adherence included: expensive medications, prescription side effects, forgetfulness, no noted blood pressure improvement, lack of access to a physician, lack of transportation, and high pill frequency. Since adherence is the most common issue for uncontrolled hypertension in African Americans, it is important to consider the Hill-Levine Conceptual model (1999) for improving patient adherence to the individual's treatment plan (Figure 1) (Hill et al., 1999). Greer and Ostwald (2015) adapted the Hill-Levine's Conceptual Model to provide an educational hypertension program sensitive to the cultural attitudes and beliefs of African American women. This conceptual model was utilized in the formation of the educational phase of the HBPM program implemented in this translational research project.

The conceptual model (Figure 1) identifies predisposing, enabling, and reinforcing factors as the foundation of the framework when building a culturally competent educational program. This diagram represents the framework of the Hill-Levine Conceptual Model and the steps it takes to improve medical adherence and achieve controlled hypertension. This foundation helps the PI address current knowledge and positive or negative beliefs about hypertension (predisposing factors). The conceptual model ensures the individual is provided with the resources necessary to succeed in the program by assessing and providing health behavioral skills (enabling factors). Lastly, the model incorporates the subject's environment and support systems for motivational help and guidance (reinforcing factors).

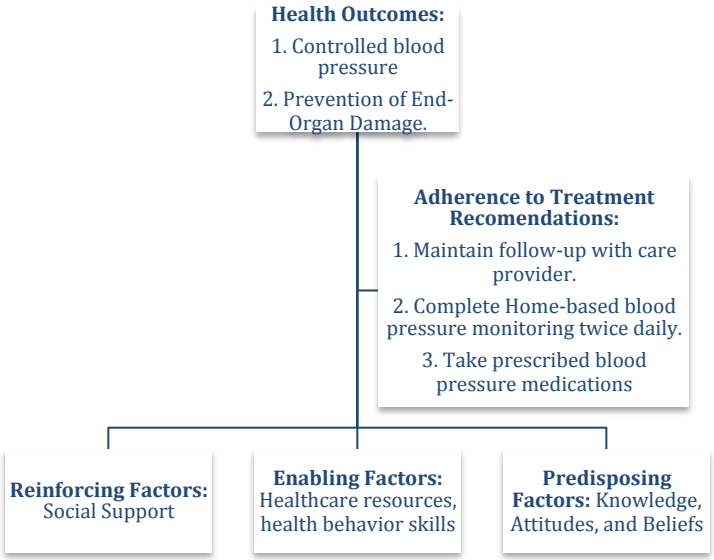

Figure 1: Hill-Levine's Conceptual Model for Hypertension Management Adherence.

With these supportive factors the individual is provided with the recommendations for successful program completion resulting in positive health outcomes. In this case it would be controlled blood pressure and prevention of end-organ damage. This is a culturally effective model, because it addresses the individuals' issues and helps to reshape the person's beliefs while providing social support from their own environment. Greer and Ostwald (2015) study of a culturally sensitive high blood pressure educational program among African American women demonstrated a statistically significant (p=.006) decrease in blood pressure over six months without any loss of participants, but the association between blood pressure and education were not statistically significant (p>.05). While this theoretical framework focuses on the behaviors of African American women, it provides practices that can benefit various cultures and individuals. Nonetheless, the theoretical framework was utilized to formulate the educational platform for the HBPM program to improve blood pressure monitoring adherence.

Chapter III:

Project Design

The translational research project is a pre-test and post-test clinical trial of the effectiveness of HBPM. Consent of the Georgia College & State University Institutional Review Board (IRB) was obtained prior to beginning the recruitment of participants for this study. Consent and site approval was obtained from a primary care non-profit community clinic in rural North Georgia and a medical practice in suburban Central Georgia to implement study.

Sample

A convenience sample of participants 18 to 60 years old with pre-hypertension, newly diagnosed or uncontrolled hypertension was identified for the project. The age group is limited to 18 to 60 based on the JNC VIII guidelines. According to the JNC VIII recommendations, elderly persons greater than 60 years old are given a higher threshold of blood pressure (150/90) (Abel et al., 2015). Physicians and practitioners from the two practices identified potential participants and provided them with unmarked folders. The folders contained the proposed project with HBPM education and consent forms for subjects to sign. Each informed consent was labeled with an identification number, but however concealed until participant opened and signed consent. The subjects were asked to read contents, sign informed consent, and submit consent forms to the clinic manager. The researcher retrieved consents from clinic manager and verbally confirmed consent with participants. The even numbered participants were a part of the experimental group and the odd numbered participants a part of the control group.

Inclusion Criteria. The study sample included adult patients, male and female, 18 to 60 years old with pre-hypertension (>130/80), newly diagnosed or uncontrolled essential hypertension (>140/90). The participants must have a pre-hypertension or hypertension diagnosis

and be under the care of a physician for management. Each subject must be proficient in English or have a professional interpreter, have access to email and Internet or be able to travel to the clinic to submit results on a monthly basis. Lastly, participants must be physically capable of taking their own blood pressure twice a day or have a family member willing to participate.

Exclusion Criteria. Subjects less than 18 years old or greater than 60 years old, pregnant, blood pressure greater than 200/100, terminal disease, dementia, or hypertension not managed by a physician.

Variables

Descriptive data was obtained from medical records and a demographic survey (Appendix B). Descriptive variables defined in the study sample included gender, age, ethnicity, quantity of blood pressure medications prescribed (QoBPM), weight, height, Body Mass Index (BMI), tobacco use, pre-study HBPM use (PHU), past medical history (PMH), socio-economic factors (SEF). Outcomes variables include Systolic Blood pressure (SBP), Diastolic Blood pressure (DBP), high blood pressure knowledge scale (HBPKS), high blood pressure self-care scale (HBPSCS), and Morisky's Medication Adherence Scale (MMAS-8).

Project Phases

The translational care project was conducted over eight-weeks and was divided into three phases: Educational Phase, Monitoring Phase, and Evaluation Phase. The healthcare providers referred patients with pre-hypertension, newly diagnosed or uncontrolled hypertension to participate in the project and given project information with informed consent. Once participants signed and submitted informed consent, the PI contacted participants to schedule educational sessions. Even numbered participants were a part of the experimental group and received blood pressure monitors with their educational session, whereas the odd numbered participants were a

part of the control group and received educational session only. Educational courses were scheduled weekly on Tuesday's from 5-7pm. Due to time constraints participants were scheduled for education in small groups immediately upon enrollment. Due to low participation, an additional practice site was added under the same guidelines as the initial practice site.

Phase 1: Staff Education. Education was provided to the clinical staff of each facility to include: proper measurement techniques, monitoring home readings, and providing timely advice for medication titration and lifestyle changes from the Eighth Joint National Committee (JNC VIII) (James et al., 2014). The JNC VIII Algorithm was provided to physicians and providers as a standard guide to follow in the treatment of hypertension (Figure 2).

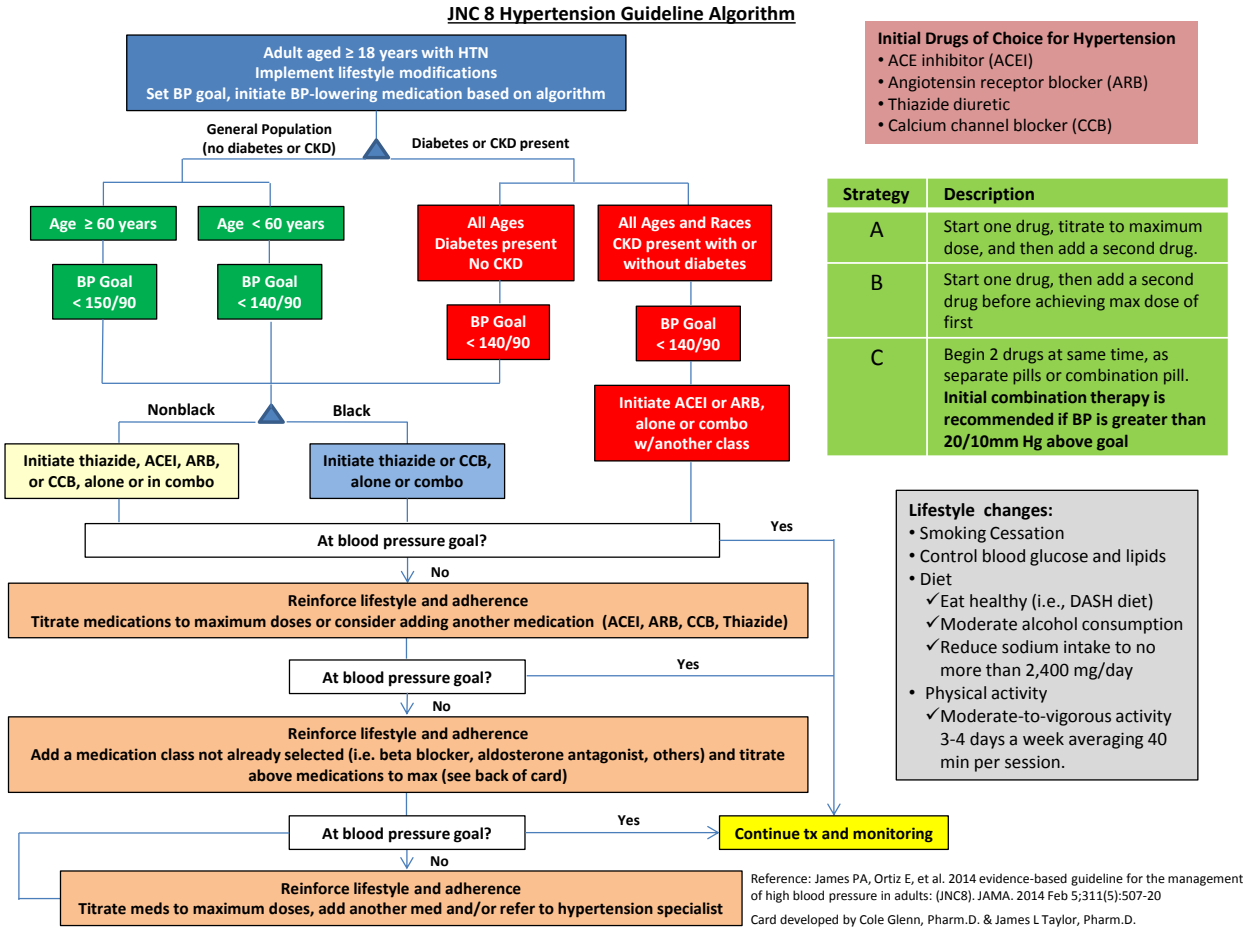

Figure 2: JNC VIII Medication and lifestyle change algorithm (James et al., 2014).

Phase 1: Participant Education. Participants recruited were assigned to their educational course based on their assigned identification number. The experimental group was provided with the same blood pressure monitors to minimize variance. Both groups received the same education regarding: definition of hypertension, importance of blood pressure management, proper measurement techniques, frequency of blood pressure monitoring, and blood pressure management protocol. Patient and staff educational materials included:

Agency for Healthcare Research and Quality's (AHRQ) Measuring Your Blood pressure at Home: A Review of the Research for Adults (2012);

- American Heart Association's (AHA, 2012) How to Monitor and Record Your Blood pressure;
- AHA's (2012) Instructional Video: Monitoring Blood pressure at Home.

All tools utilized for education were created and supported by the CDC (2014) and are available free of charge on the CDC's website "Self-Measured Blood pressure Monitoring Action Steps for Clinicians." A pre-education baseline test was conducted to assess participants' blood pressure knowledge and self-care abilities utilizing Peters and Templin (2008) Blood pressure Knowledge Scale and Blood pressure Self-Care Scale.

All participants were provided with a Flagging system using the American Heart Association's hypertension categories will be provided to participants to assure patients are aware of what their blood pressure means and how they should act upon the results (Figure 3).

Blood pressure Category	Systolic mm Hg (upper #)		Diastolic mm Hg (lower #)
Normal	less than **120**	and	less than **80**
Prehypertension	**120 – 139**	or	**80 – 89**
High Blood pressure (Hypertension) Stage 1	**140 – 159**	or	**90 – 99**
High Blood pressure (Hypertension) Stage 2	**160** or higher	or	**100** or higher
Hypertensive Crisis (Emergency care needed)	Higher than **180**	or	Higher than **110**

Figure 3: Flagging System (AHA, 2016a).

1. Green * (Normal)- Great job, your blood pressure is normal. Keep monitoring your bp twice daily.
2. Yellow (Pre-Hypertension)- Your blood pressure is slightly elevated. Did you take your bp medications, have a high sodium meal, are you stressed? Keep monitoring your bp twice daily and taking medications as prescribed.
3. Orange (Stage 1)- Your blood pressure is elevated. Did you take your bp medications, have a high sodium meal, are you stressed? Your provider may need to change your blood pressure medication. Keep monitoring your bp twice daily and taking medications as prescribed.
4. Red (Stage 2)- Your blood pressure is very elevated. You should call your provider to schedule an appointment or discuss your bp medication regimen. Keep monitoring your bp twice daily.
5. Red (Hypertensive Crisis)- Caution, CALL 911

*if your pressure is <100/50, please notify your physician. If you begin to experience lightheadedness or dizziness please go to your nearest emergency department or call 911.

Phase 2: Monitoring. After the educational phase patients were given the tools needed to monitor their blood pressures at home twice daily at 12 hours a part. The experimental group was expected to submit results to researcher for review monthly. The results were able to interface into Omron's Wellness App, a HIPAA approved health information technology program accessible to those provided with the Omron blood pressure monitor. The Participants' pre HBPM implementation blood pressure results were compared to post HBPM results to determine effectiveness of HBPM program. The PI was available in the clinic once a week and via phone for troubleshooting needs and for those without access to Internet or email. If participants were

unable to submit results via email or during PIs available hours at the clinic, individuals were contacted to schedule a time to retrieve records.

The control group received the same education as the experimental group, but did not receive blood pressure monitors. Participants among the control group were encouraged to obtain a home monitor and monitor home results with a blood pressure results handout to write in results twice daily. Blood pressure results were submitted to their health care provider during follow-up and the researcher reviewed the results in the EHR.

Instruments

Demographic Data

The socio-demographics of the study sample were examined utilizing a demographic survey constructed by the researcher (Appendix A). The demographic information that was collected on the participants included: gender, age, ethnicity, quantity of blood pressure medications prescribed, weight, height, Body Mass Index (BMI), tobacco use, pre-study HBPM use, past medical history, socio-economic factors (education, marital status, employment status, household income and health insurance status). This information was used to describe the sample and for later data analysis.

Blood Pressure Monitor

Omron medical equipment has a reputation of providing quality medical grade equipment. The Omron BP786 monitor was tested and passed according to the protocols of The Association for the Advancement of Medical Instruments (AAMI) and the European Society of Hypertension (ESH) ("10 Series Upper Arm Blood Pressure Monitor," 2016). The Omron 10 Series has the ability to take three consecutive blood pressure readings over ten minutes, and averages the results for an accurate and reliable reading. The blood pressure monitor features an

“easy wrap ComFit Cuff, extra large display, and is able to save 200 readings” ("10 Series Upper Arm Blood Pressure Monitor," 2016, p. 1). The Omron BP786 is a sphygmomanometer model that is capable of transmitting data to the Omron Wellness application. Participants are then able to submit results via email through the application and to the patient's provider via a HIPAA approved information system. This eliminates the tediousness of writing and need for patients to keep a written log, which helps prevent the misinterpretation of results due to poor writing legibility or lack of memorization. The monitor is able to store results by keeping an electronic record of accurate blood pressure results that can be easily accessed and reviewed. This will allow the practitioner to be able to utilize supporting data to institute the best intervention necessary for treatment of the patient’s blood pressure. Topouchian et al. (2014) documents the validity of the Omron BP786 demonstrating less than 5 mmHg differences in SBP and DBP results based on the AAMI’s and ESH’s protocol.

Knowledge and Self-care Scale

Peters and Templin (2008) developed the Blood Pressure Knowledge (KS) and Self-Care (SC) scales utilizing the self-care deficit nursing theory by Orem (Appendix B). The scales were utilized in this translational research project to measure participants’ knowledge and self-care practices pre-education and post-HBPM intervention. This instrument helps measure the effectiveness of the phase one participant educational session to determine if hypertension lifestyle (low fat and salt diet, diet high in fruits and vegetables, daily 30-min physical activity, minimal stress, healthy weight, minimal alcohol and tobacco use, doctor follow-up, and medication adherence) changes had improved.. The Blood Pressure Knowledge Scale and the Blood pressure Self-Care Scale were 11 and 10-item questionnaires respectively (Peters & Templin, 2008). The Knowledge Scale assesses the comprehension and belief that particular

behaviors improve blood pressure results and the Self-care Scale assesses how often the participants perform the specific behaviors (Peters & Templin, 2008). The behaviors analyzed included: maintaining a healthy diet, increased physical activity, stress management, weight management, avoiding alcohol or tobacco use, doctor follow-up and medication adherence. The scales utilized a seven-point bipolar scale from 1 to 7, measuring from "strongly disagree" to "strongly agree" for the knowledge scale and "never" to "always" for the self-care scale (Peters & Templin, 2008) (Appendix C). Some of the items are reverse coded with a total scale range from 11 to 77 for the Knowledge scale and 9 to 70 for the Self-Care scale (Peters & Templin, 2008). The scales are valid and reliable demonstrating a Cronbach's alpha of 0.85 (KS) and 0.7 (SC) (Peters & Templin, 2008). The authors gave the researcher permission to utilize these scales in this translational research study.

Morisky's Medication Adherence Scale

Medication adherence was measured pre and post intervention to answer the clinical question of whether HBPM in patients with hypertension increase adherence to blood pressure monitoring and medication compliance. Krousel-Wood et al. (2009), Morisky, Ang, Krousel-Wood, and Ward (2008), and Morisky and DiMatteo (2011) established Morisky's Medication Adherence Scale (MMAS-8), which is an eight-item scale to assess medication adherence in patients with various chronic diseases including hypertension (Appendix C). The scale utilizes a "yes" and "no" response for items 1-7 and for item 8 a five-point Likert scale is utilized measuring from "never/rarely" to "all the time" (Krousel-Wood et al., 2009; Morisky et al., 2008; Morisky & DiMatteo, 2011). Some of the items are reverse coded with a total scale range from 0 to 8, with 8 equivocating to high adherence, 6 to 8 medium adherence, and less than 6 low adherence (Krousel-Wood et al., 2009; Morisky et al., 2008; Morisky & DiMatteo, 2011).

The MMAS-8 has shown to be valid and reliable according to Pérez-Escamilla, Franco-Trigo, Moullin, Martínez-Martínez, and García-Corpas (2015). The Pérez-Escamilla et al. (2015) literature review compared several medication adherence instruments, but Morisky's had the highest validity and reliability with a Crohnbach's alpha of 0.83. Appendix D displays the questionnaire developed by Krousel-Wood et al. (2009), Morisky et al. (2008), and Morisky and DiMatteo (2011), which is copyrighted. The authors gave the researcher permission with a written agreement to utilize this scale for this translational research study.

Protection of Human Subjects

Informed consent was obtained prior to the initiation of the translational research project (Appendix F). The information and consent forms were provided to the prospective participants. The participants signed and submitted consent forms to the clinic manager and were returned to the PI. Each participant was provided a copy of the informed consent for his or her records. Information security and patient information protection is important in the process of this translational project. To ensure data is protected in accordance to the Health Insurance Portability and Accountability Act (HIPAA) privacy rule and the Georgia College & State University's Institutional Review Board (GCSU IRB) by which this project was approved, the researcher did the following:

1. The clinician established an ID number for each participant. The ID number and code-list will be kept separately on paper and via an electronic file.
2. All paper work, code-list, signed consents, and written surveys will be kept in a locked file drawer in a locked and secure office.

3. Any electronic files kept on the clinician's computer will be password protected as well as the computer itself. Data files on the computer will be encrypted by Apple's OS X folder encryption software.
4. Any back-up files and data that will be saved on a portable drive will also be password protected. Again, data files on the computer will be encrypted by Apple's OS X folder encryption software.
5. Any lost or stolen information or property will be reported to GCSU's IRB immediately and handled per the institution's protocol.
6. All patient data will be kept and securely stored for three years following the research study. After three years the data will be deleted and destroyed.

There were no immediate risks associated with home-based blood pressure monitoring. However, being diagnosed and treated for hypertension comes with risks of psychological stress and physical damage to the heart and arteries. The researcher facilitated emotional and psychological support throughout the study of HBPM. The introduction of the study began with HBPM education. The participants were encouraged to bring family or friends to the education for social support. The education provided the participants with an introductory knowledge basis to HBPM and an opportunity to become comfortable with home monitoring and also provides and opportunity of social support with other individuals with a similar diagnosis.

The flagging system was a proactive measure to ensure patients were equipped with the materials necessary to monitor and evaluate their blood pressures on a daily basis. The flagging system was a reference tool with the necessary advisory instructions for the participant to reference every time the blood pressure was taken. The reference tool also provides supportive measures to help prompt the patient in critically analyzing reasons for changes in BP. Signs and

symptoms that were discussed with participants that would require immediate medical attention included: chest discomfort, shortness of breath, facial drooping, sudden severe headache, arm weakness, speech difficulty, nausea/vomiting, lightheadedness, or dizziness. If any of these symptoms occurred, patients were instructed to call 911, immediately. One participant was discontinued from the study for safety measure.

Data Analysis Plan

Phase 3: Post Evaluation

Descriptive and outcomes data was first cleaned and evaluated for missing data and outliers. Missing data was identified via exploratory analysis and outliers via scatterplots, boxplots and Z-scores. Descriptive statistics were used to describe the demographics of the sample. Descriptive statistics included frequencies for nominal and ordinal level measurements (gender, ethnicity, BMI, tobacco use, SEF, PMH, and PHU). For ratio level measurements (age, weight, height, QoBPM, HBPKS, HBPSCS, MMAS, SBP, and DBP) mean, median, mode, standard deviation, confidence intervals, kurtosis and skewness will be obtained to assess for normality and central tendency. Internal consistency reliability of both instruments were evaluated and discussed in the instruments section of this manuscript.

Clinical Question 1. Patients receiving the HBPM program will have lower blood pressures at 60 days. SPSS Version 24 was used to conduct inferential statistics with the two-tailed paired t-test. The two-tailed paired t-test is most operative in showing whether or not the HBPM program is effective since this is a pre-test and post-test quasi-experimental study. A two-tailed paired t-test will provide enough power to show whether the HBPM program is or is not effective in the management of uncontrolled hypertension. The dependent variable, blood pressure, is a ratio level of measurement and if normal distribution is true, this variable fits the

assumptions for parametric testing. Results were assessed at multiple time points (four weeks and eight weeks) to assess the progression of the study among the experimental group. Pre and post HBPM intervention blood pressure results were compared among the experimental and control groups. Analysis of Covariance (ANCOVA) testing was conducted to rule-out confounding variables, for example, the variables age, kidney disease, and African American men.

Clinical Question 2. Patients receiving the HBPM program will have increased adherence to HBPM monitoring at 60 days. The number of missed data entries was tabulated for each participant to evaluate monitoring adherence. Of the 60 days (120 data entries) the project was implemented, each participant was allotted 12 missed data entries (10%). Greater than 12 missed data entries over the course of the project was considered decreased adherence to the HBPM program.

Clinical Question 3. Patients receiving the HBPM program will have increased adherence to hypertension lifestyle (low fat and salt diet, diet high in fruits and vegetables, daily 30-min physical activity, minimal stress, healthy weight, minimal alcohol and tobacco use, doctor follow-up, and medication adherence) changes than those in the control at 60 days. Again, SPSS Version 24 was used to conduct inferential statistics with the two-tailed paired t-test. A pre-test and post-test of the knowledge scale and self-care scale was conducted to determine whether or not the HBPM education and monitoring process improved patient education and self-care skills. The dependent variables are the responses to the HBPKS and HBPSC surveys which are ratio levels of measurement and if normal distribution is true, this variable fits the assumptions for parametric testing. Pre and post survey responses will be compared among the

experimental and control groups to evaluate the effectiveness in improving hypertension management adherence.

Clinical Question 4. Patients receiving the HBPM program will have higher adherence to medication therapy than those in the control group at 60 days. Again, SPSS Version 24 was used to conduct inferential statistics with the two-tailed paired t-test. A pre-test and post-test medication adherence questionnaire was utilized to determine whether the HBPM program improved medication adherence. Again, SPSS Version 24 was used to conduct inferential statistics with the two-tailed paired t-test. The dependent variables are the responses to the MMAS-8 survey, which are ratio levels of measurement. If normal distribution is true, this variable fits the assumptions for parametric testing. Pre and post survey responses will be compared among the experimental and control groups to evaluate the effectiveness in improving hypertensive medication adherence.

Feasibility

Timeline

The timeframe was eight-weeks to successfully implement the translational care project. The staff was educated on the HBPM process involving proper body mechanics and hypertension management prior to the beginning of the study in person and via web-ex on July 26th. Due to time constraints, participant recruitment and project implementation occurred simultaneously in small groups. As the provider referred participants, classes were assigned based on the number labeled in their education and informed consent packer. The even numbered participants were a part of the experimental group and the odd numbered participants were a part of the control group. Educational courses were scheduled weekly on Tuesday's from 5-7pm and Thursday's from 4-5:30pm for three months (August 2nd to October 11th). At the beginning of

each seminar a pre-test Blood Pressure Knowledge Scale, Self-care Scale was completed and MMAS-8 was conducted. HBPM began the day after education, where blood pressures were to be taken twice daily, 12-hours a part. Each participants start date was recorded and tracked to ensure prompt follow-up. The results were examined on a monthly basis by the researcher and forwarded to the participants' care provider. After eight-weeks of HBPM implementation, post-test Blood Pressure Knowledge Scale, Self-care Scale, and MMAS-8 was conducted in person, via phone or email and data analysis began.

Budget

The researcher developed a Go Fund Me account (https://www.gofundme.com/HBPM2016) and collected $1,920 to purchase blood pressure monitors for the participants. The researcher also received two scholarships through Georgia College and State University from the Carolyn M. Maynard Nursing Scholarship fund and the Marjorie G. Prentice Graduate Research Scholarship fund for a total of $893. Funding helped provide blood pressure monitors to patients and cover costs related to educational materials. The total cost of the blood pressure monitors was $3041.48 for the entire sample population after a discount provided by Omron Healthcare.

Benefit

Home-based blood pressure monitoring is innovative technology that will help health care providers deliver individualized patient care based on accurately reported blood pressure results. This project is the beginning of future large scaled projects. A HBPM program can be costly and therefore proper implementation is essential. Yet, compared to the billions of dollars spent on hypertension, treatment, and co-morbid conditions; improved blood pressure control will decrease the prevalence of co-morbid conditions and decrease health care costs. The HBPM

program decreases patient expenditures due to decreased in-office visits and co-pays and decreased transportation needs or time off work. HBPM also has the potential to increase revenue to the health care practice for virtual visits. Often patients are lost to follow-up due to conflicting schedules and transportation (Young et al., 2015). HBPM with telecommunication management provides an avenue for more timely, effective, and individualized patient care. According to the CDC (2014), Medicare Part B, Medicare Part C, Medicaid, and private insurance provide coverage for Ambulatory Blood Pressure Monitoring for diagnostic accuracy of hypertension, whereas, in most insurance plans, HBPM coverage is limited. With an increase in successful studies, such as the one proposed, legislation could be initiated to increase coverage and reimbursement cost of HBPM programs.

Chapter IV:

Results

The results of this pre-test and post-test clinical trial of HBPM are discussed in this chapter. Findings reported here include descriptive statistics concerning the sample of participants and data addressing the research questions. Data screening was performed prior to conducting the statistical analyses in SPSS Version 24. Data was verified utilizing a double entry method where two separate databases were created and compared to identify discrepancies. Inconsistencies were then reconciled with the participants' original data and a substitution method was utilized for missing data.

Examination of all continuous variables was conducted to determine normal distribution using descriptive statistics for central tendency, Fisher's exact for skewness and kurtosis, histogram, Q-Q normality plots, Kolmogorov-Smirov test, and Shapiro-Wilk test. Each variable either exhibited normality or near normal distribution and therefore parametric testing was utilized to evaluate the results. The student t-test and Chi-square (X^2) test were conducted to determine whether a covariate existed among the variables of age, gender, ethnicity, and past medical history of chronic kidney disease. The results were insignificant for all potential covariates and therefore no covariates were controlled for in hypothesis testing.

Sample Characteristics

A total of 20 adults participated in the HBPM program. While initially the inclusion criteria for the study limited the participant age range to 18-60 years old, in the interest of the protection of human subjects and the ethical principle of justice, all ages were accepted into the study. Data was collected and analyzed for the entire sample since the purpose of the HBPM program was to demonstrate an improvement in blood pressure and adherence to the program, not to achieve a specific threshold as designated by the JNC VIII guidelines. Those meeting the

inclusion criteria were randomized into the experimental (n=11) and control group (n=9) as demonstrated in Figure 4, the CONSORT Flow Diagram (Altman et al., 2001). The flow diagram outlines the flow of participants throughout the project revealing the forfeiture of two participants both due to lost to follow up. One participant did not submit results and researcher was unable to reach participant and the other discontinued due to hospitalization for hypertensive emergency. Data analysis was completed on all 20 participants. For the two participants whom did not complete the study, post-intervention data entries were substituted using their pre-intervention results.

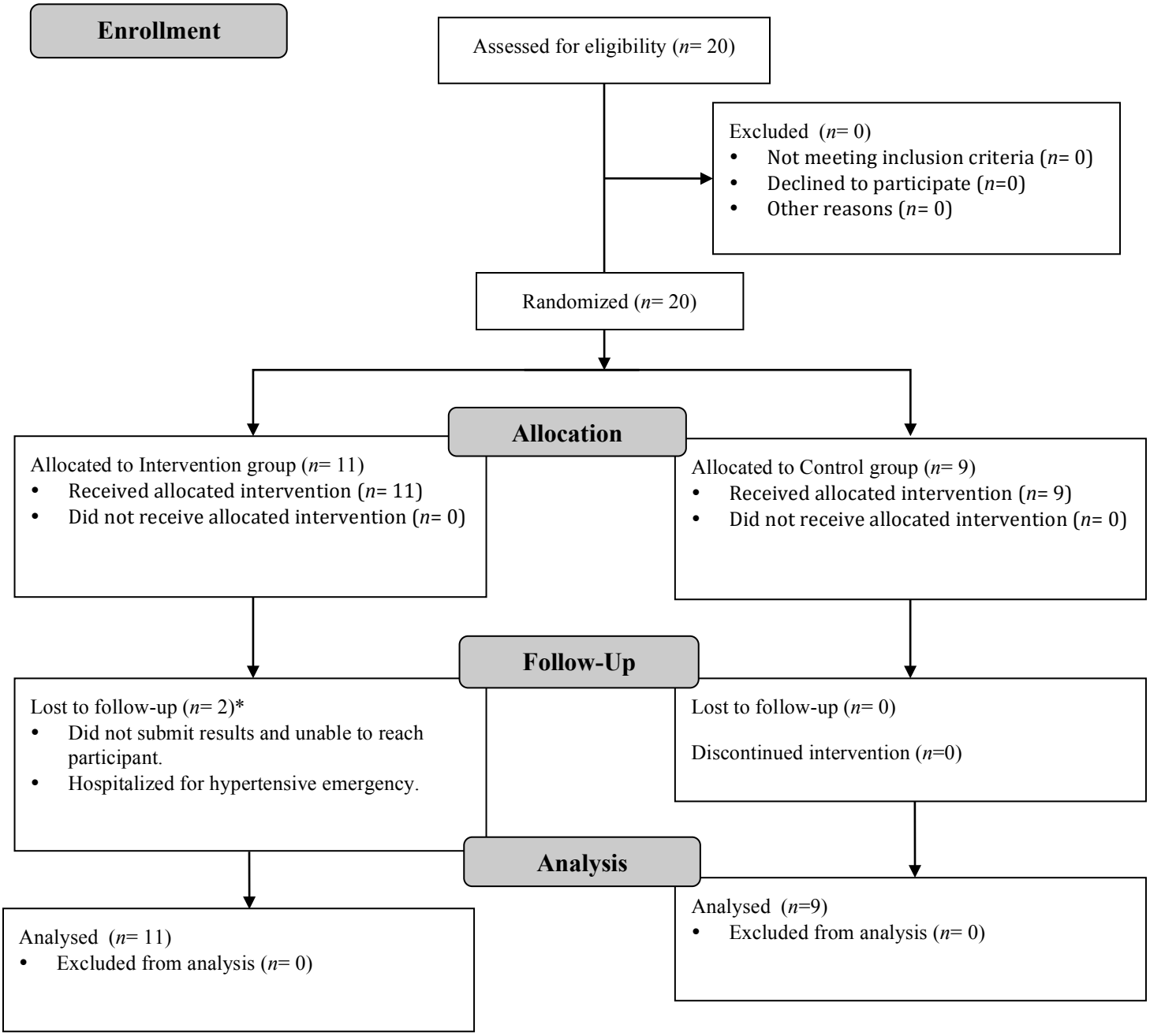

Figure 4: CONSORT Flow Diagram (Altman et al., 2001).
*Participants were lost to follow-up at 30 days. All participants' pre-intervention data was analyzed; the two participants lost to follow-up had missing data for the 60-day data analysis.

The participant's demographics, medical history, lifestyle, and socio-economic status are described in detail in Table 1. The study participants were primarily male (55%), Caucasian (45%), or African American (40%). Two participants were Hispanic (10%) and one "Other" (5%). Participants' ages ranged from 35 to 82 with a mean age of 58.05 (SD = 12.88). Regarding lifestyle, a majority of the sample was considered overweight (50%) with a BMI of 25 to 29.9 (*M* = 31.0) and weight ranging from 141lbs to 270lbs; only one participant was a normal BMI (5%). A large percentage of participants did not use tobacco products (75%). Concerning pre-existing conditions that could cause hypertension, participants were positive for a history of Type 2 Diabetes Mellitus (75%), hyperlipidemia (50%), CKD (55%) and sleep apnea (20%). Participants on average had 2.8 (*SD* = 1.9) blood pressure medications prescribed. Regarding the sample's socio-economic status, a majority were high school graduates/GED equivalent (30%) or had a Bachelor's degree (25%), married (50%), employed (40%) or retired (40%), uninsured (35%) or under a federally funded insurance program like Medicare (35%) with a mean household income of $34363.20 (*SD* = 25033.40). Overall, prior to the initiation of this research project, sixty percent of the sample had been performing some type of blood pressure monitoring at home.

Table 1

Descriptive Statistics of Sample Characteristics (n=20)

Characteristics, *n*	Participants		
	Total Group (*n* = 20)	Experimental Group (*n* = 11)	Control Group (*n* = 9)
Gender, *n* (%)			
Male	11 (55)	5 (45.5)	6 (66.7)
Female	9 (45)	6 (54.5)	3 (33.3)
Age *M,* (SD)	58.1 (12.9)	50.5 (9.3)	67.3 (10.44)
Ethnicity, *n* (%)			
Caucasian	9 (45%)	3 (27.3)	6 (66.7)
Hispanic/Latino	2 (10%)	2 (18.2)	0 (0)
African American	8 (40)	5 (45.5)	3 (33.3)
Native American	0 (0)	0 (0)	0 (0)
Asian	0 (0)	0 (0)	0 (0)
Other	1 (10)	1 (9.1)	0 (0)
Educational Level, *n* (%)			
Some High School (no degree)	1 (5)	1 (9.1)	0 (0)
High School Graduate/GED	6 (30)	5 (45.5)	1 (11.1)
Some College (no degree)	4 (20)	1 (9.1)	3 (33.3)
Trade School	2 (10)	2 (18.2)	0 (0)
Bachelor's	5 (25)	0 (0)	5 (55.6)
Master's	1 (5)	1 (9.1)	0 (0)
Doctoral	1 (5)	1 (9.1)	0 (0)
Marital Status, *n* (%)			
Single	2 (10)	2 (18.2)	0 (0)
Married	10 (50)	4 (36.4)	6 (66.7)
Widowed	2 (10)	0 (0)	2 (22.2)
Divorced	4 (20)	3 (27.3)	1 (11.1)
Separated	2 (10)	2 (18.2)	0 (0)
Employment Status, *n* (%)			
Employed for Wages	8 (40)	7 (63.6)	1 (11.1)
Self-Employed	1 (5)	0 (0)	1 (11.1)
Unemployed	1 (5)	1 (9.1)	0 (0)
Homemaker	1 (5)	1 (9.1)	0 (0)
Retired	8 (40)	1 (9.1)	7 (77.8)
Disabled	1 (5)	1 (9.1)	0 (0)
Total Household Income, *M* (SD)	34363.20 (25033.40)	27528.36 (27776.17)	42716.89 (19524.57)
Health Insurance Status, *n* (%)			
Uninsured	7 (35)	6 (54.5)	1 (11.1)

(Table 1 continued)

Employment-Based Plan	3 (15)	3 (27.3)	0 (0)
Direct-Purchase Private Plan	2 (10)	1 (9.1)	1 (11.1)
Medicare	7 (35)	0 (0)	7 (77.8)
Medicaid	1 (5)	1 (9.1)	0 (0)
Quantity of BP Meds Prescribed, *M* (SD)	2.8 (1.9)	1.9 (1.4)	3.9 (1.97)
Currently Monitoring HBPM, *n* (%)			
Yes	13 (65)	6 (54.5)	7 (77.8)
No	7 (35)	5 (45.5)	2 (22.2)
Past Medical History, *n* (%)			
Diabetes Type 1	0 (0)	0 (0)	0 (0)
Diabetes Type 2	15 (75)	7 (63.6)	8 (88.9)
Hyperlipidemia	10 (50)	3 (27.3)	7 (77.8)
Chronic Kidney Disease	11 (55)	4 (36.4)	7 (77.8)
Sleep Apnea	5 (25)	0 (0)	5 (55.6)
Tobacco Use, *n* (%)			
Yes	5 (25)	3 (27.3)	2 (22.2)
No	15 (75)	8 (72.7)	7 (77.8)
BMI, *M* (SD)	31.0 (5.4)	31.6 (6.7)	30.4 (3.4)
Blood Pressure (BP), *M* (SD)			
Baseline-Systolic BP	158.9 (12.8)	154.5 (8.7)	164.2 (15.2)
Baseline-Diastolic BP	90.2 (13.1)	93.7 (7.2)	85.8 (17.3)
Post-Systolic BP	142.9 (19.1)	145.8 (19.3)	139.2 (19.2)
Post-Diastolic BP	81.6 (12.5)	87.8 (7.9)	74 (13.2)
Knowledge Scale (KS), M (SD)			
Baseline-KS	67.7 (9.8)	69.6 (9.8)	65.4 (9.8)
Post-KS	67 (8.1)	66.5 (8.7)	67.7 (7.7)
Self-Care Scale (SCS), M (SCS)			
Baseline-SCS	46.3 (11.5)	48.0 (13.3)	44.3 (9.1)
Post-SCS	51.0 (8.6)	50.6 (9.7)	51.3 (7.7)
MMAS, M (SD)			
Baseline-MMAS	5.7 (1.9)	5.88 (1.83)	5.4 (2.0)
Post-MMAS	5.9 (1.6)	5.86 (1.64)	5.9 (1.7)

Note. *n* = Total participants, % = percentage, *M* = Mean, *SD* = Standard deviation, meds = medications, MMAS = Morisky's Medication Adherence Scale.

Clinical Question 1

An independent samples t-test was used to test the hypothesis that patients receiving the HBPM program will significantly lower blood pressure at 60 days than those in the control group. This hypothesis was not supported. Patients receiving the HBPM program had higher systolic blood pressures (M = 145.8, SD = 19.3) than those in the control group [(M = 139.2, SD = 19.2), t(18) = -.76, p = .456] at 60 days. Similarly, patients receiving the HBPM program had significantly higher diastolic blood pressures (M = 87.8, SD = 7.94) than those in the control group [(M = 74.0, SD =13.2), t (18) = -2.9, p = .010] at the 60-day blood pressure re-evaluation.

Clinical Question 2

An adherence scale was developed to determine whether patients receiving the HBPM program had increased adherence to HBPM monitoring. For each day the participant checked their blood pressure two points were accumulated, with a total possible score ranging from 0-120. Adherence was split into three categories, Low 0-40 (15%), Moderate 41-80 (15%), and High Adherence >81 (45%). An independent sample t-test was used to determine whether patients receiving the HBPM program had higher adherence to blood pressure monitoring at 60 days. This hypothesis was supported. Patients receiving the HBPM program had higher HBPM adherence scores (M = 70.1, SD = 43.74) than the control group [(M = 46.0, SD = 52.8), t (18) = -1.117, p = .279] at 60 days.

Clinical Question 3

An independent sample t-test was used to determine whether patients receiving the HBPM program had higher adherence to hypertension lifestyle (low fat and salt diet, diet high in fruits and vegetables, daily 30-min physical activity, minimal stress, healthy weight, minimal alcohol and tobacco use, doctor follow-up, and medication adherence) changes at 60 days. This

hypothesis was not supported. Patients receiving the HBPM program had lower self-care survey scores (M = 50.6, SD = 9.74) than the control group [(M = 51.33, SD = 7.66), t (18) = .175, p = .863] at 60 days. Similarly, patients receiving the HBPM program had lower knowledge scale survey scores (M = 66.45, SD = 8.7) than the control group [(M = 67.67, SD = 7.7), t (18) = .326, p = .748] at the end of 60 days.

Clinical Question 4

An independent samples t-test was used to determine whether patients receiving the HBPM program had higher adherence to medication therapy than those in the control group at 60 days. This hypothesis was not supported. Patients receiving the HBPM program had lower medication adherence survey scores (M = 5.86, SD = 1.73) than those in the control group [(M = 5.88, SD = 1.64), t (18) = .033, p = .974] at 60 days.

Summary

An analysis of a sample of 20 hypertensive patients enrolled in a structured HBPM program was completed. For clinical question 1, inferential statistics demonstrate a statistically insignificant increase in systolic blood pressure, but a statistically significant increase in diastolic blood pressure between the experimental and control groups at 60 days. There was no statistical significance in the improvement of HBPM adherence, knowledge, self-care, or medication adherence in clinical questions 2, 3, and 4 between the two groups at 60 days.

Chapter V

Discussion

The rising prevalence and mortality rate of hypertension makes this an important health care issue to address (CDC, 2015). To help address the CDC's (2015) initiatives to prevent, treat and control hypertension, it is necessary to identify strategies like HBPM to improve blood pressure monitoring in the treatment of hypertensive patients. Based on the data analysis, a statistically significant improvement in blood pressure management, monitoring adherence, knowledge, self-care, and medication adherence was not achieved in the implementation of HBPM compared to hypertensive patients who did not receive the intervention. However, while enhanced monitoring adherence was demonstrated among the experimental group, it was not statistically significant.

While the findings suggest there is no statistical support for the use of HBPM in practice, the translational research project is relevant in that it establishes a guide to implementing HBPM into practice and addressing hypertension management. The results are not relative to similar studies in that the study was underpowered and should be re-examined with a larger sample size. In comparison to similar HBPM studies with an adequate sample size, a statistically significant average decrease of 30.5 mmHg (p=0.002) in systolic blood pressure occurred in one study (McManus et al., 2010) and a 12-point reduction in systolic blood pressure was demonstrated at 12 months in another study (McManus et al., 2014). Crabtree & Stuart-Shor (2014) demonstrated a 60% improvement in a 12-month study of HBPM. Differences between these studies and the current study are the implementation timeframe and sample size, demonstrating a few of the constraints of this study.

Limitations

There were several limitations of this study to be discussed. The first obstacle was limited funding for the purchase of blood pressure monitors. A-priori power analysis was conducted for a two-tailed t-test indicated that 128 participants were desired to achieve statistical significance. The initial goal for the study was to have one large cohort of participants to obtain the power analysis. However, funding was required to purchase the amount of blood pressure monitors needed to fulfill the study a-priori sample size. Therefore, the researcher sought grants, investors, and scholarship funding for the purchase of the monitors for 128 participants. The short length of time from the planning phase to implementation of the project made it difficult to sequester the amount of funding necessary to purchase the blood pressure monitors. Many grants that were inquired about required at least a one-year timeframe before funds were distributed. Therefore, a Go Fund Me was established for the procurement of funding, which required additional time for growth. Once the allotted donations and scholarships were obtained a budget was created. The study sample size, a-priori, was reevaluated to preclude developing a control group whom would not receive a blood pressure monitor. The time required to obtain the funding necessary to implement the project delayed the time available for the implementation phase of this translational research project and therefore was shortened to 60 days.

Recruitment of participants for this study was difficult due to practice accessibility. Initially, the researcher contacted several primary practices to implement the study. While there was great interest in the study, it was difficult to find stakeholders in the research project. Specifically, one particular practice declined to participate due to being in between medical directors and not being able to facilitate the study during the timeframe required. Eventually, two sites confirmed interest and provided site approval for the HBPM project. Unfortunately,

one site cancelled their participation just prior to the implementation of the project due to changes in practice dynamics. Therefore, implementation went forward with one practice site approval, making participant recruitment limited. Approximately four weeks in the implementation process a second practice site was added to recruit additional participants however time for recruitment, project implementation, and data analysis was limited for this practice group.

In addition to a small sample size, this is a convenience sample, which has the potential to introduce bias, which decreased the statistical significance of the study. While the participants were randomly assigned to the control and experimental groups, they were recruited from two practice sites that cannot represent the population of hypertensive patients. Convenience samples tend to misrepresent the population as a whole and are not ideal in the research process. A complete randomized control study with an adequate sample size over a longer period of time would strengthen the study design and more likely provide results similar to studies identified in the literature review.

Strengths

While the sample size was inadequate to provide statistical significance of the pre-test and post-test effectiveness of HBPM, it is a potential pilot for future studies. On a small scale, the study conducted helps evaluate practicability, time, cost-effectiveness, complications, and effect size to implement and sustain successful large-scale study designs in the future. Therefore, the potential funding sources for the purchase of blood pressure devices identified in this translational research project would benefit future research opportunities. Also, the methodology of this project provides the phases necessary to incorporate a well-structured HBPM program into practice. For instance, the resources and references identified in this translational research

project can be utilized to construct a hypertension educational program for patients and staff whom are key stakeholders in the success of similar research studies.

Future Research

Future research is necessary to analyze the effectiveness of a HBPM program. Future studies can incorporate the existing HBPM program, model and tools to examine blood pressure results among a larger sample over a longer period of time. Recruiting participants from larger or multiple institutions could expound the sample size. Utilizing multiple facilities allows the experimental and control groups to then be randomized on a per facility basis. For studies with larger sample sizes, more researchers would be necessary to properly distribute the workload. A larger sample size would improve statistical significance and improve generalizability of results. In addition to a larger sample, other studies that demonstrated significant improvement in blood pressure monitored results for 6 to 12 months. A longer study period would allow for the collection of more data for a more accurate data analysis.

The models and tools utilized in this study can be easily replicated to evaluate various settings and cultures. The translating evidence into research model by Pronovost, Berenholtz, and Needham (2008) is a simple model that can be utilized in translating knowledge into practice regardless of setting or culture. Whereas, the Hill-Levine's Conceptual Model for Hypertension Management Adherence was a conceptual model formulated to improve hypertension management strategies among African American women (Hill et al., 1999). For the purposes of this study, this model was utilized to structure a proper educational program, however, future studies would benefit form utilizing this model to analyze HBPM adherence among African Americans.

In relationship to adherence, it appears that HBPM improved monitoring adherence. While the experimental group had higher blood pressure results (with a significantly higher diastolic blood pressure) than the control group, this could be due to the small sample size or possibly due to stressors implicated by having to evaluate blood pressures in the home. Future studies should be challenged to perform qualitative studies to explore patient perceptions of the program. As advances in telemonitoring continue to make large strides, analysis of self-monitoring and self-care in hypertension management should be assessed to ensure patients are receiving quality care and meeting their own health care expectations.

Blood pressure monitors for HBPM can be quite expensive, especially for validated monitors that provide the integration of mobile applications for transmitting data. With a majority of health disparities occurring in underserved areas, future studies should examine the cost effectiveness of HBPM and determine methods in which to increase affordability. Since HBPM provides improved individualized care without the expenditure of excessive resources, governmental agencies should be challenged to increase coverage and reimbursement cost of HBPM programs.

Sustainability Analysis

Training of the staff on the implementation of the home-based blood pressure monitoring program was instrumental in sustaining the life of this project. Incorporating the staff in the patient education of HBPM and providers in the supervision of the program provides a foreground for the stability and future of HBPM in the practices. The program also utilizes protocols and algorithms from national organizations such as the American Heart Association (AHA) and Center's of Disease Prevention and Control (CDC) that will allow for continued

access to reference tools and updates. The researcher will remain available for further assessment and revamping of the program as needed.

Implications for Nursing Practice

With rising difficulties in the access to affordable health care, telemonitoring is essential to the improvement of patient outcomes. HBPM is an innovative intervention that helps providers administer individualized patient care based on accurately reported blood pressure results without frequent in-office follow-ups. Successful HBPM implementation requires social support and the translational research project demonstrates the importance of conducting home monitoring in a supportive environment. Therefore, properly trained nursing staff by doctoral prepared nurse clinicians is instrumental in ensuring patients and staff members are receiving the proper education, instruction and tools necessary to successfully implement HBPM. The translational research project implicates a feasible systematic approach to developing a successful nurse-led HBPM program into practice.

Nurses, researchers, and translational research clinicians play an integral part in the education, prevention, and management of chronic diseases. Nurses are at the forefront in the clinical setting and represent the individuals actively implementing evidence-based practice guidelines. In regards to HBPM, they are responsible for accurately obtaining blood pressures and being able to demonstrate proper HBPM techniques, as well as, acknowledging processes that are ineffective in the clinical setting. Doctor of nursing practice (DNP) researchers disseminate research into practice and are capable of identifying robust evidence-based research to effectively change policy and procedures. DNP researchers may conduct a literature review to identify improved methods of blood pressure monitoring or implementation practices.

Collaboration efforts between PhD and DNP prepared nurses is essential in the development and implementation of new HBPM practices.

Conclusion

The purpose of the translational research project was to determine the effectiveness of home-based blood pressure monitoring in the management of pre-hypertension, newly diagnosed, or uncontrolled hypertension. Based on the data analysis, a statistically significant improvement in hypertension management was not achieved in the implementation of a HBPM program. While there is limited statistical support for this translational research project, other resources support HBPM as an innovative program that has the potential to provide healthcare providers an avenue for more timely, effective, and individualized patient care. Literature demonstrates that improved blood pressure control has the potential to decrease the prevalence of co-morbid conditions and decrease health care costs. With an increase in successful studies legislation could be challenged to increase coverage and reimbursement cost for blood pressure monitors and more HBPM programs in practice. Continued research related to HBPM and patient adherence is necessary to improve patient access to affordable care and overall self-care outcomes.

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Appendices

Appendix A

Demographic Survey

Principle Investigator: Nicole Bello ID #: _____

Date: _____

Carefully read each question answer most appropriately.

1. What is your gender?
   A. Male
   B. Female

2. What is your age?_____

3. Please specify your ethnicity:
   A. White
   B. Hispanic/Latino
   C. Black/African American
   D. Native American/American Indian
   E. Asian/Pacific Islander
   F. Other

4. Weight _____

5. Height _____

6. Use of Tobacco products? Yes/No

7. How many blood pressure medications do you take? _____

8. Do you currently monitor your blood pressure at home? Yes/No

9. What is the highest degree or level of school you have completed? If currently enrolled, highest degree received.
   A. Some high school, no diploma
   B. High school graduate, diploma or the equivalent (GED)
   C. Some college, no degree
   D. Trade/Technical school
   E. Associates degree
   F. Bachelor's degree
   G. Master's degree
   H. Professional degree
   I. Doctoral degree

10. What is your marital status?
   A. Single, never married
   B. Married/domestic partnership
   C. Widowed
   D. Divorced
   E. Separated

11. What is your occupation?
   A. Employed for wages
   B. Self-employed
   C. Unemployed and looking for work
   D. Unemployed and not currently looking for work

E. A homemaker
F. A student
G. Military
H. Retired
I. Disabled

12. What is your total household income?_____

13. What is your health insurance status?

A. Uninsured
B. Employment-based private plan
C. Direct-purchase private plan
D. Medicare
E. Medicaid
F. Military health plan

14. Have you ever been diagnosed with_____? (Select all that apply).

A. Diabetes Mellitus Type I
B. Diabetes Mellitus Type II
C. High Cholesterol
D. Sleep Apnea
E. Chronic Kidney Disease

Appendix B

ID NO. _____

Blood Pressure Knowledge Scale© (revised)

In general, how likely do you believe that the following statements are true? Using the scale below, please choose the number that best matches your answer.

		Strongly disagree						**Strongly Agree**
1	Eating a low fat diet each day will help me keep my blood pressure within normal limits	1	2	3	4	5	6	7
2	Eating a low salt diet will help me keep my blood pressure within normal limits	1	2	3	4	5	6	7
3	Eating a diet with at least five fruits and vegetables each day will help me keep my blood pressure within normal limits	1	2	3	4	5	6	7
4	Physical activity for at least 30 minutes each day will help me keep my blood pressure within normal limits	1	2	3	4	5	6	7
5	Seeing my doctor on a regular basis will help me keep my blood pressure within normal limits	1	2	3	4	5	6	7
6	If someone has high blood pressure the best way to keep their blood pressure within normal limits is by taking medicines every day as prescribed by their doctor	1	2	3	4	5	6	7
7	Avoiding alcohol (such as beer, wine, liquor) will help me keep my blood pressure within normal limits	1	2	3	4	5	6	7
8	Reducing stress will help me keep my blood pressure within normal limits	1	2	3	4	5	6	7
9	Maintaining normal body weight would help me keep my blood pressure within normal limits	1	2	3	4	5	6	7
10	Avoiding tobacco (such as smoking or chewing) would help me keep my blood pressure within normal limits	1	2	3	4	5	6	7
11	I will know if my blood pressure is high (above normal limits) because of how I feel	1	2	3	4	5	6	7

Appendix C

ID NO. _____

Blood Pressure Self-Care Scale© (revised)

In general, how often are the following statements true about you? Using the scale below, please choose the number that best matches your answer

			Never 1	2	3	4	5	6	**Always** 7
1	I am eating a low-fat diet each day		1	2	3	4	5	6	7
2	I am eating a low-salt diet each day		1	2	3	4	5	6	7
3	I am eating a diet with at least five fruits and vegetables each day		1	2	3	4	5	6	7
4	I am physically active at least 30 minutes each day		1	2	3	4	5	6	7
5	I am able to maintain a low level of stress each day		1	2	3	4	5	6	7
6	I am able to maintain a healthy weight		1	2	3	4	5	6	7
7	I am drinking two or more alcoholic drinks each day		1	2	3	4	5	6	7
8	I use tobacco		1	2	3	4	5	6	7
9	I see my doctor as often as he/she tells me to.		1	2	3	4	5	6	7
10	I am taking my blood pressure pills exactly as prescribed by my doctor each day	N/A	1	2	3	4	5	6	7

Appendix D

©Morisky Medication Adherence Scale (MMAS-8-Item). This is a generic adherence scale and the name of the health concern can be substituted in each question item.

You indicated that you are taking medication(s) for your (identify health concern, such as "high blood pressure"). Individuals have identified several issues regarding their medication-taking behavior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience with your high blood pressure medication.

	(Please mark your response below)	
	No=1	**Yes=0**
1. Do you sometimes forget to take your high blood pressure medication(s)?		
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your high blood pressure medication(s)?		
3. Have you ever cut back or stopped taking your medication(s) without telling your doctor, because you felt worse when you took it?		
4. When you travel or leave home, do you sometimes forget to bring along your high blood pressure medication(s)?		
5. Did you take your high blood pressure medication(s) yesterday?		
6. When you feel like your high blood pressure is under control, do you sometimes stop taking your medication(s)?		
7. Taking medication(s) every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your high blood pressure treatment plan?		

8. How often do you have difficulty remembering to take all your medication(s)?

(Please circle your answer below)

Never/Rarely……....**4**

Once in a while……**3**

Sometimes……....**2**

Usually……**1**

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