TESTING A SMARTPHONE APPLICATION INTERVENTION TO IMPROVE MEDICATION ADHERENCE IN AFRICAN AMERICAN FEMALE CLINIC PATIENTS WITH UNSTABLE HIGH BLOOD PRESSURE:
A TWO-GROUP RANDOMIZED CONTROL TRIAL

A DISSERTATION
SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN THE GRADUATE SCHOOL OF THE TEXAS WOMAN’S UNIVERSITY COLLEGE OF NURSING

BY

VANESSA D. MONROE, MSN

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DEDICATION

To my parents, Henry Collins, Jr. and Eunice Inez Smith Collins, thanks for your guidance, love, and support.

To my sisters, Carol, Ruby, Frieda, Sharon, Diana, and Judy, thanks for your advice given to me over the years.

To my brothers Forrest and Henry III thanks for helping me to expand my imagination.

To my husband, Carl W. Monroe, thanks for helping me to achieve this dream.

To my children, Enjoli, Tara, and Sean, thanks for inspiring me to keep moving this project forward.
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It really did take a village to develop and complete this growing body of research. My personal village was composed of the following individuals and entities who have contributed time, guidance, expertise, physical space, and financial support from the inception of this research study to its conclusion. I gratefully acknowledge the collective contributions of these individuals and entities on the completion of this research study.

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The Baptist Church is located in Harris County, Texas. Access Health Clinic is located in Fort Bend and Waller County, Texas. Both of these organizations assisted in the recruitment, education, and enrollment of research participants. Dr. Thomas Kent, The Lone Star Stroke Consortium, and Texas Nurses’ Association—District 9 provided research grants to purchase software applications, blood-pressure monitors, and other equipment useful to the successful completion of this research study.
ABSTRACT
VANESSA D. MONROE, MSN
TESTING A SMARTPHONE APPLICATION INTERVENTION TO IMPROVE MEDICATION ADHERENCE IN AFRICAN AMERICAN FEMALE CLINIC PATIENTS WITH UNSTABLE HIGH BLOOD PRESSURE: A TWO-GROUP RANDOMIZED CONTROL TRIAL
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The purpose of this study was to determine if selected smartphone applications could improve medication adherence in women who live with unstable high blood pressure. Participants in this study were African American and at least 18 years of age, who sought treatment for unstable high blood pressure in Harris, Fort Bend, or Waller counties in Texas.

The research question addressed in this study was, “Is there a difference in medication adherence for African American women diagnosed with unstable high blood pressure from a community health clinic setting who monitor their blood pressure daily and use the OnTimeRx® smartphone application versus those who use the Omron BP786 monitor?” The theoretical framework for this two-group, posttest only, randomized control trial was an integration of the Technology Acceptance Model, Health Beliefs Model, and Bandura’s Self-Efficacy Theory.

The Stroop Color and Word Test was administered pretest to screen for cognitive deficits that may interfere with the participants‘ ability to operate the equipment that was used in this research study. After achieving t-scores of 30 in all three test areas, participants were consented and randomized into one of two study conditions, the control or treatment group. Instructions on the operation of the equipment and software
applications were made applicable to the participant’s treatment condition. Throughout the study, all participants were contacted on a weekly basis for follow-up and to answer study-related questions. Handouts were provided as a secondary measure to augment verbal instructions. Medication adherence was measured, posttest, with the Morisky Medication Adherence Scale-8. This posttest was administered after the 67 study participants completed 28 days of the study and submitted their blood-pressure values to the primary investigator.

The treatment group demonstrated significantly better medication adherence than the control group (Mann-Whitney U 393, p value 0.037). These findings suggested that smartphone technology could have a positive influence on patients with unstable high blood pressure.
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CHAPTER I
INTRODUCTION

Medication adherence was described by Bond and Hussar (1991) as America’s other drug problem; and, it remains a significant global health care concern for women currently living with unstable high blood pressure. Medication nonadherence contributes to many preventable health consequences, adds $100 billion in avoidable medical expenses, accounts for 33% of hospital or nursing home admissions, and is responsible for 124,000 deaths annually (Sansbury, Dasgupta, Guthrie, and Ward, 2014). Recent technological advancements have created the possibility for researchers, physicians, and nurse specialists to develop innovative strategies to improve medication adherence among patients living with unstable high blood pressure.

The main hypothesis advanced in this research study asserts that smartphone technology could become an integral part of blood pressure management for patients in any health care setting on a global perspective. Medical personnel could use smartphone technology to record medication self-administration and as a reminder for health care patients to take their high blood pressure medications as prescribed. The use of smartphone technology could lead to an innovative health care strategy to improve medication adherence among patients living with unstable high blood pressure.

Problem of the Study

Solomon et al. (2015) suggested medication nonadherence to be one of the main reasons for poorly controlled high blood pressure in African Americans. Members of this cultural group were more likely to suffer from hypertension (47.5%) and hypertension-
related chronic health conditions (Taylor, Peternell, and Smith, 2013), as compared to a reported rate of 28.0% hypertension for non-African American populations as reported by Still et al. (2015).

African American women experienced a higher incidence of high blood pressure than African American men (37% versus 31%) (Nemesure, Wu, Hennis, Leske, and BESs Study Group, 2008). Thus, gender and role differences of these women may influence their attitudes and behaviors toward adherence to recommended treatment therapies for their unstable high blood pressure (Fongwa, Nandy, Yang, and Hays, 2015).

The high percentage of hypertension diagnoses for African American women serve as the rationale for targeting women from this cultural group for this research study. For African American women, medication nonadherence can exacerbate complications that arise from unstable high blood pressure, which is defined as systolic differences of 12 mm/hg and diastolic differences of 9mm/hg, independent of average blood-pressure values (Yu et al., 2014). A medication adherence cut point of 80% is needed to control unstable high blood pressure (Hyman and Pavlik, 2015). The current cut point for noncompliant individuals is currently measured at 50% for patients who are currently taking prescriptive medications (Sansbury, Dasgupta, Guthrie, and Ward, 2014). Smartphone technology represents an untapped potential for an innovative approach to blood pressure management (http://www.pewinternet.org/fact-sheet/mobile/)

**Rationale for the Study**

Medication nonadherence is projected to grow and contribute to the global burden of chronic disease (Culig, Leppée, Boskovic, and Eric, 2011). This situation is
expected to occur in two related ways. First, Rolley (2008) suggested that within 24 months of the initiation of the prescribed medication order, providers could expect to observe incremental increases in medication nonadherence in their patients. Second, Sansbury et al. (2014) suggested that medication nonadherence could lead to the onset of many preventable health conditions and pose high economic burdens to a large number of American families.

Conn, Enriquez, Ruppar, and Chan (2014) averaged data from several studies related to medication adherence to arrive at a national medication nonadherence rate of 50%, which is well below the acceptable medication-adherence standard of 80% (Hyman and Pavlik, 2015). Tamura et al. (2014) suggested that it was urgent for health care providers to reverse these harmful trends through early prevention, early diagnosis, or effective management of this chronic disease. The reason for this urgency is a lowering of high blood pressure could reduce the risk of stroke by approximately 38%, congestive heart failure by 42%, and coronary heart disease by 28% (Crim et al. (2012); Roberie and Elliott, 2012).

**Theoretical Framework**

The theoretical framework for this research study was an integration of the Technology Acceptance Model (Davis, 1986), Self-Efficacy Theory (Bandura, 1977), and the Health-Beliefs Model (Hochbaum, 1958). Investigators of this study used these three theories to predict, explain, and understand participants’ acceptance or rejection of computer technology as a tool for blood-pressure management (Davis, Bagozzi, and Warshaw, 1989).
Davis et al. (1989) first introduced the Technology Acceptance Model (TAM) in 1986 as a more specific adaptation of the more generalized Theory of Reasoned Action (TRA). A key purpose of TAM as described by Davis et al. (1989) was to provide investigators with a basis for tracing the impact of external factors on internal beliefs, attitudes, and intentions of participants to use computer technology to benefit their own health care needs. Key components of the TAM include perceived usefulness of the Internet, perceived ease of use of the technology, participants’ attitude toward Internet use, health-related Internet use for health-information seeking, and Internet use for communication. The TAM helped study participants identify internal and external behaviors necessary for them to implement use of software applications into their health care regimens.

As described in Figure 1, Davis et al. (1989) described TAM as a person’s attitude toward using a technological system (A) and the person’s belief of the perceived usefulness of the technological system (U) determined their behavioral intent (BI) to use computers, represented by the formula: BI = A + U). The acceptance (A) part of the formula was jointly determined by perceived usefulness (U) and perceived ease of use (EOU), represented by the formula A = U + EOU. Davis et al. (1989) suggested the acronym EOU was an important concept in the TAM, as it influenced attitudes and behavior of participants through self-efficacy and instrumentation. The TAM does assume a certain level of anxiety associated with the use of technology; thus, this model helped research participants identify these factors, whereas the software applications used in this study will be more readily used.
Bandura’s Self-Efficacy Theory (1977) evolved from the Social-Cognitive Theory, which explained psychological procedures involved in the successful achievement of personal health goals. Bandura (1977) suggested that people are able to process, weigh, and integrate diverse sources of information, which thereby capture their abilities and help regulate their choice behavior pattern and effort expenditure accordingly. Bandura (1977) further suggested that these behaviors commonly reduce defensive behavior and create expectations of mastery, which was further described by expectations of personal efficacy. Self-efficacy theory was expected to increase a participant’s level of confidence, where it would be possible to envision the use of a new treatment regimen.

Bandura (1977) discussed differences between efficacy expectations (self-efficacy) and outcome expectations. Both of these concepts are necessary to execute behavioral change such as medication adherence. Efficacy expectation is a strong held belief that a behavioral change can be possible, and the person has the ability to demonstrate with confidence the necessary competence to successfully execute actions to produce this behavioral change. Bandura (1977) suggested that outcome
expectations are a psychological estimation used by a person to determine if this behavioral change could lead to a desired health care outcome.

Bandura (1977) suggested expectations of personal efficacy rest on four sources of information: performance accomplishments, vicarious experiences, verbal persuasion, and emotional arousal. The mode of induction for performance accomplishments through which sources of information operate include participant modeling, performance desensitization, performance exposure, and self-instructed exposure. The mode of induction for vicarious experience through which sources of information operate and increase the observer’s sense of self-efficacy include live modeling and symbolic modeling. The mode of induction for verbal persuasion through which sources of information operate and provide support for task mastery include suggestion, exhortation, self-instruction, and interpretive treatments. Lastly, Bandura (1977) suggested the mode of induction for emotional arousal are influenced by stress, anxiety, and fear, which may lead to avoidance behaviors; and hence, a lower likelihood of task achievement that includes attribution, relaxation, biofeedback, symbolic desensitization, and symbolic exposure.

Individuals who successfully master prior tasks are more likely to have greater self-efficacy and be willing to try something new. Self-efficacy has a central role in analyzing behavioral changes because of its association with fearful and avoidance behavior (Bandura, 1997). Further suggestions by Bandura (1997) indicated that self-efficacy supports a person’s belief about their ability to complete a certain task. The cognitive processes associated with this type of behavior represents a significant role in the acquisition and retention of new behavior patterns.
The HBM was developed by Hochbaum (1958), Rosenstock, Leventhal, and others as a part of a project at the U.S. Public Health Service. It was later adapted and extended by Rosenstock (1974). This theory attempts to integrate cognitive and stimulus-response theories to explain people’s behaviors. Specifically, the HBM described how a person’s perceptions of severity and susceptibility to disease processes, and the balance of perceived benefits and barriers to seek treatment influence their health behaviors. A number of individual characteristics may modify a person’s perceptions. Ultimately a cue to act triggers the person to engage in health-promoting behaviors.

Through genetics or lifestyle choices, unstable high blood pressure can lead to the development of other long-term health care issues. Patient response to unstable high blood pressure and the ensuing health care issues are partially guided by the individual’s own belief in their perceived susceptibility/severity to develop unstable high blood pressure. This patient might ask their health care provider, “What is this diagnosis? Is it even possible for me to contract this unstable high blood pressure?” If the response to the second question is yes, then the patient might also want to know, “How severe will this illness be for me?” In essence, individuals will want to know the impact of unstable high blood pressure on their life. Without the belief (cue to action) that unstable high blood pressure may cause a negative impact on their life, the patient may spurn into inaction.

As described in the previous section of this report, unstable high blood pressure could lead to long-term health care issues. The HBM suggests a need to believe (cue to action) software applications, Bluetooth technology, and computer technology will benefit
the patient's life. To proceed with the use of these innovative health care options, the positive aspects of removing or delaying unstable high blood pressure or long-term health issues must be clearly described. The HBM also describe the perceived barriers that may occur in using software applications, Bluetooth technology, and computer technology to manage unstable high blood pressure. If the patient perceives the barrier to use this new technology is too great, then the patient may spurn the cue to action.

In summary, the use of software applications, Bluetooth technology, and computer technology in this research study supported the integration of TAM, Self-Efficacy Theory, and HBM. Collectively, these three components of the theoretical framework offered insight to internal and external factors that could impact willingness to participate in this research study. The theoretical framework allowed study participants to believe or feel capable of successfully manipulating the applications and new technology to affect medication adherence and unstable high blood pressure.

**Assumptions**

This study was based on the following assumptions:

1. Uncontrolled hypertension represents a significant lifetime burden for African American women.

2. African American women are interested in controlling their high blood pressure.

3. Smartphone technology represents an untapped potential for an innovative approach for blood pressure management (http://www.pewinternet.org/fact-sheet/mobile/).
**Research Question**

This study addresses the following research question: Is there a difference in *medication adherence* for African American women diagnosed with unstable high blood pressure from a community health-clinic setting who monitor their blood pressure daily and use the OnTimeRx® smartphone application and a reminder service versus those who only use the Omron BP786 monitor?

**Definition of Terms**

The following definitions were used in this study:

1. Garner (2014) described medication adherence as a range of patient behaviors that coincide with provider recommendations and mutually agreed plans of care. In this study, the compliance score recorded on OnTimeRx® medication Log at 2-week and 4-week intervals reflect medication adherence.

2. African American women are women of African ancestry. In this study African American women reflected those of African ancestry who had reached at least 18 years of age and received care from the study clinic or Baptist church.

3. Unstable high blood pressure is an upward or downward deviation of normal blood-pressure values, up to 40–50 mm/hg, that persist for more than 2 days (Ostfeld and Lebovits, 1960; Varon, 2007). In this study, unstable high blood pressure was reflected by ≥ 10 mm/hg change in daily blood-pressure values.

4. Baumgart (2011) described a software application as a critical aspect of the smartphone, because it determines usability, usefulness, and user adoption.
In this study, participants in the treatment group received the OnTimeRx® ProSoftware application installed onto their smartphones.

5. A reminder service consisted of text messages sent daily to participants’ smartphones to maintain a one-sided or interactive relationship, as a reminder to take their medication (Maslakpak and Safaie, 2016). In this study, participants in the treatment group received the following message before they were due to take their medications: “It is time to take your medicine. Have a nice day.”

6. Self-measurement of blood pressure with validated devices and proper training was less subject to interference commonly observed in measurements performed by health care professionals and more closely relate to the patient’s real blood-pressure value (Souza, Jardim, Brito, Araújo, and Sousa. 2012). In this study, each participant was validated and provided with an Omron BP786 blood-pressure monitor to measure their blood pressure at least once daily.

**Study Limitations**

Limitations of the study included the following:

1. This sample was a small voluntary convenience sample. Therefore, the results were not generalizable beyond participants in this research study.

2. Participants from the control and intervention groups may have interacted with one another, which could cause a crossover effect that may dilute the intervention effect.
3. Possible equipment or user malfunction of the software application may have occurred, which could affect the accuracy of results.

Summary

The purpose of this study was to investigate a technological intervention to improve medication adherence in African American women with unstable high blood pressure. African American women experience higher rates of hypertension than non-African American women and African American men. The theoretical framework that served as a foundation for this research study represented an integration of the TAM, the HBM, and the Self-Efficacy Theory. Technologies used in this research study were the OnTimeRx® reminder service, Omron BP786 monitor, and the Internet. This research study sought to harness the growth of technology use and propose an intervention that could reduce the effects of nonadherence to hypertensive medications.
CHAPTER II

REVIEW OF LITERATURE

The purpose of this study was to investigate the use of a technology-based intervention on medication adherence of African American women with unstable high blood pressure. Literature was reviewed for information related to technological interventions for hypertension, high blood pressure, medication compliance, and medication adherence. This chapter presents an overview of the literature-search process and a summation and analysis of related literature. Major topics include software application, medication adherence, hypertension, and cognitive testing.

Literature-Review Process

Organizing Knowledge Synthesis: A Taxonomy of Literature Reviews (Cooper, 1988) served as a guide to evaluate literature related to smartphone applications, medication adherence, and unstable high blood pressure. The literature review was conducted using online searches of PubMed and ScienceDirect databases between the years 2010 and 2015. Key words used in the search included smartphone, cellphone, mobile phone interventions, medication adherence, medication compliance, technology acceptance model, health belief model, cognitive function, cognitive decline, unstable high blood pressure, and unstable hypertension.

There were thirty-five journal articles located in this search; but only seventeen of these articles were included in this literature review. To be included in this review, the journal articles needed to cover concepts related to the independent and dependent variables of this study. The remaining eighteen articles were excluded because they
lacked specific focus on smartphone applications or medication adherence. These journal articles were listed in the following paragraph by the topic areas of software application, medication adherence, cognitive testing, hypertension, and theoretical framework.

Software Application

The following research studies provided support that software applications are a useful tool in the management of hypertension. These applications include bidirectional text messaging, mobile short-message service (SMS), web-based home health care systems, and enhancement of evidence-based health care services.

Anthony et al. (2015) conducted a prospective randomized control trial to evaluate bidirectional text messaging as a potential intervention to increase the number of blood-pressure measurements by patient after their routine clinic visits. The researchers randomized participants into three groups: electronic medical record (EMR)-only \((n = 22)\), EMR + reminders \((n = 26)\), or bidirectional text messaging \((n = 42)\). The researchers’ (Anthony et al., 2015) main goal was to determine if the participants would record 14 blood-pressure measurements within 15 days.

The bidirectional text messaging group reported the full 14 measurements; and, in contrast, the EMR + reminder group outperformed the EMR-only group (Anthony et al., 2015). Findings from this study suggested text-message-based reminder services are an effective way to encourage patients to record their blood-pressure measurements. Anthony et al. (2015) suggested that future research should help care providers to determine if this software platform could be used to record other disease states in order to send patient reminders and instructions.
Ahadzadeh, Sharif, Ong, and Khong (2015) examined the interrelationship of the TAM and HBM on perceived health risk and health-related consciousness on Internet use. Both offered valid and reliable models that have been used for many years; but, independently they were unable to explain cognition and related mechanisms necessary to explain why participants used the Internet for health-related purposes (Ahadzadeh et al., 2015).

Study participants were 293 Malaysian women living in the State of Selangor on the west coast of Malaysia (Ahadzadeh et al., 2015). Purposive sampling was used with the women who were educated, married, and living in urban areas of the country. They used a drop-and-collect method to distribute a questionnaire that contained questions related to reflective and formative constructs (Ahadzadeh et al., 2015).

The HBM combined with the TAM was able provide insight and a broad understanding of perceived usefulness of the Internet for health information and attitude toward Internet use for health-related purposes that could act as a mediator on the effect of health-related factors on health-related Internet use (Ahadzadeh et al., 2015). The integrated model proposed in this study was able to predict Internet use for health-related purposes. The model suggested that women were able to subjectively evaluate their health as vulnerable to diseases that would further help them make positive decisions toward health-related Internet use (Ahadzadeh et al., 2015).

Bobrow et al. (2016) conducted a pragmatic, single-blind, three-arm, randomized trial to assess the effect of an automated treatment adherence support delivered through a mobile phone SMS text message. The participants were randomized into three groups: information-only SMS text messages \(n = 457\), interactive SMS text messages...
(n = 458), or usual care (n = 457). All participants received written information about hypertension and healthy living as part of the research protocol. Additionally, Bobrow et al. (2016) developed the taxonomy for text messages from a library of messages geared toward behavior-change techniques, such as goals and planning, repetition and substitution, social support, and natural consequences.

There was a small reduction in systolic blood-pressure control in the SMS text-message group compared to the usual-care group at 12 months; however, there was no evidence emerged that the interactive intervention increased this effect. Bobrow et al. (2016) suggested future research should determine optimal frequency of text messages, cost of modifying the messages to remain effective, and use of SMS text messages in different communities for people with different or multiple comorbid long-term health conditions. In the present research study, participants in the treatment group received the following text message: “Hello, (participant number), it is time to take your medicines. Have a nice day.”

Heinrich and Kuiper (2012) conducted a pilot study (n = 27) to determine the usefulness of handheld devices such as smartphones to promote medication adherence for individuals with chronic disease processes. These handheld devices delivered an electronic reminder at the times patients were due to take their medications. This study had two key objectives. The first was to determine the relationship between cognitive abilities and medication adherence. The second was to determine medication-adherence rates after the use of the medication reminders (Heinrich and Kuiper, 2012).

The researchers programmed the participants’ list of medications into the handheld device and provided oral and written instructions to participants on device
operation, followed by retrieval of compliance data from the drug-activity Log of the
device at 6-week and 12-week intervals (Heinrich and Kuiper, 2012). The OnTimeRx®
software application was added to a smartphone device that reported a range of 62.5%–
100% for participants with a mean average adherence rate of 89.64% on activity logs
(Heinrich and Kuiper, 2012). Future research on these types of handheld devices should
consider a much larger population sample and also consider the cost of these handheld
devices to the health care consumer (Heinrich and Kuiper, 2012). This issue can be
easily overcome with the use of smartphones and the use of the OnTimeRx® software
application.

Mosa, Yoo, and Sheets (2012) conducted a systematic literature review to
classify smartphone-based technologies according to their functionality. They reviewed
55 journal articles that discussed 83 software applications. This research study found
that medical applications make smartphones useful tools in the practice of evidenced-
based health care because of their growing use in society. Mosa et al. (2012) suggested
future researchers to assess guidelines that may be used for standardizing smartphone-
based health care applications. The goal of this activity is to determine if these
applications could be used together seamlessly for specific purposes, integrated with
hospital information systems such as EMR and patient-monitoring systems to maximize
the power of mobile applications (Mosa et al., 2012).

Tamura et al. (2014) conducted an investigative study ($n = 219$) on the
effectiveness of a web-based health care system’s ability to enhance specific health
checkups and guidelines, that was recently introduced by the Japanese government.
The researchers separated participants into three groups: the information group
(n = 180), the incentivized-support group (n = 14), and the positive-support group (n = 25). Tamura et al. (2014) evaluated the positive-support group every three months, whereas they evaluated the incentivized and information groups every six months. These evaluations involved physical examinations that measured body weight, blood pressure, and levels of particular chemicals in the blood. Tamura et al. (2014) also arranged health guidance and a system of self-management and e-mail consultations for participants on an individual basis.

The investigators found that existing health check-ups and monitoring systems were not sufficient to prevent disease; however, they suggested a new and innovative web-based health-checkup system should be developed that would be more familiar to patients (Tamura et al., 2014). This meant that current web-based mechanisms were ineffective in enhancing health check-ups. Tamura et al. (2014) suggested future researchers consider social factors, including aging populations, cost, and implications of medical insurance required to improve the effectiveness of these health care-monitoring systems.

These studies suggest smartphone software or web-based applications represent viable and innovative options for the management of medication adherence. A potential limitation could be the training required to properly operate these applications. Smartphones are an effective tool to use for patient education, disease self-management, and remote patient monitoring (Mosa et al., 2012). The next section of this paper describes why these applications are important to the health care management of medication adherence and unstable high blood pressure.
Medication Adherence and Hypertension

Blood pressure control directly links to a patient’s ability to take their medications. Medication adherence reflects a patient’s intent to follow agreed recommendations from their health care provider (Lehmann et al., 2014). Three operational and quantifiable parameters define medication adherence: initiation, implementation, and disconnection. Initiation is the commencement of medication therapy (Lehmann et al., 2014). Implementation is the continuation of the dosing regimen, which includes the patient’s dosing history (Lehmann et al., 2014). Discontinuation is the completion of time-limited prescribed regimens or the continuation of chronic medications (Lehmann et al., 2014). The following research studies address these operational parameters and describe how medication adherence affects hypertension.

Extent. Khan, Shah, and Hameed (2014) conducted a prospective cross-sectional study with random selection to evaluate the extent of nonadherence to antihypertensive medications and the reasons participants \( n = 200 \) provided for their nonadherence. The study used the Morisky Medical Adherence Scale-4 (MMAS-4), which measured intentional and unintentional adherence based on forgetfulness, carelessness, stopping medication when feeling better, and stopping medication when feeling worse. Overall adherence rates were 79%. Rates in women were lower than in men (74.7% versus 85.7%); and, participants 50–60 years of age experienced 100% adherence compared to younger-aged groups. Investigators concluded future researchers should address tailored therapy to maximize medication adherence to accomplish the eventual goal of controlling blood pressure in all age, cultural, and gender groups (Khan et al., 2014).
**Measurement.** Ayoade and Oladipo (2012) investigated the degree of correlation ($n = 75$) between the MMAS and the electronic pill bottle cap (eCap) on medication adherence, which was an important determinant in blood-pressure control. Investigators administered the MMAS to each participant and trained and evaluated patients on the use of the eCap. Participant scores ranged from 0 to 100% (MMAS) and 6.6–100% (eCap). These findings suggested that eCap offers greater objectivity in medication-adherence evaluation; however, there were factors such as cost, technological requirements, and logistic constraints that limited its use. The MMAS self-reported scale remains a useful tool for health providers to use in resource-poor communities. Any future comparative studies should use periodic administration of these self-reported measures to obtain time-trends and confer prospective quality for participants (Ayoade & Oladipo, 2012).

de Oliveira-Filho, Morisky, Felizardo, Costa, and de Lyra Junior (2014) conducted a cross-sectional survey to translate the MMAS-8 to analyze its psychometric properties and assess suitability for measuring medication adherence in hypertensive patients ($n = 937$). Data was accrued from participants through home interviews and blood-pressure measurements. MMAS-8 scores < 6 indicated low adherence, 6 to < 8 indicated medium adherence, and 8 (maximum score) indicated high adherence. Participants' results indicated 46.7% were low adherers, 33.0% were medium adherers, and 20.3% were high adherers (de Oliveira-Filho et al., 2014). Investigators found a significant relationship between patient scores on the MMAS-8 and blood-pressure control. de Oliveira-Filho et al. (2014) suggested future research broaden the scope of this research to incorporate intentional and unintentional medication nonadherence.
de Oliveira-Filho et al. (2014) conducted a cross-sectional study with structured interviews to determine the association between the treatment adherence of patients who were validated on the Portuguese version of the MMAS-8 and measures of blood-pressure control \((n = 223)\) for hypertensive patients. Data accumulated through home interviews and home blood-pressure measurements. At the conclusion of the study, the researchers found 19.7% of participants adhered to their medication regimen and 34.0% had their blood pressure under control. Future research studies should include conducting a broader investigation on the extent of medication adherence and the ability to supply cost-free medications to hypertensive patients (de Oliveira-Filho et al., 2014).

Medication adherence is a significant problem that is inextricably linked to unstable high blood pressure. No one panacea would fix this problem, but the MMAS is a valid and reliable tool to identify and tackle this significant health care issue.

**Interventions.** Alhalaiqa, Dean, and Gray (2013) conducted the qualitative leg of a mixed-methods study to investigate the experience of noncompliant hypertensive patients \((n = 10)\) who had received seven sessions of adherence therapy as part of a randomized control trial. One-on-one 20-minute interviews helped researchers understand participants’ experience and views on adherence therapy. Five major themes emerged from these interviews: modifying attitudes and beliefs, positive impact on self-efficacy, motivational therapist, positive impact on well-being, and description of well-intention research design. Findings suggested an improvement in beliefs and attitudes toward medications. Finding solutions to barriers that prevent adherence will help patients become more compliant with their medications, which will have a positive impact on clinical outcomes (Alhalaiqa et al., 2013). Recommended future studies
should expand the sample size to identify the myriad reasons for medication adherence (Alhalaiqa et al., 2013).

Burla et al. (2014) conducted a prospective randomized control trial to compare the effects of usual care versus more intensive blood-pressure management ($n = 65$ in control; $n = 58$ in intervention). The intervention group had visits at baseline (initial visit), 3, 6, 9, and 12 months, during which time the researchers measured their blood pressure three times in order to obtain average clinic blood-pressure values. Researchers titrated blood-pressure medications according to patients’ respective groups’ assignment. To make a group wise comparison, investigators calculated a therapeutic intensive score (TIC) at each visit. This calculated TIC score was a composite measure of therapy derived from the sum of each individual medication-intensity ratio, which was the prescribed dose divided by the maximum dose. Study findings suggested that more intensive hypertensive therapy did not negatively impact participants’ perceived health status. Future studies should develop a multi-institutional cohort to evaluate the health status of participants over a long-term follow-up period to compare data with health controls of the same demographic background (Burla et al., 2014).

Kumar, Khunger, Gupta, and Garg (2015) conducted a cross-sectional study to determine the content of medical applications designed for hypertension management. The researchers found a great need for more oversight in medical applications developed and used for hypertension management. Although Kumar et al. (2015) screened 200 software applications, they only reviewed only 107 applications in this study. The majority of the applications employed functionality that included tracking for
blood pressure, pulse, weight, and body-mass index. These applications also provided
general information on hypertension and medication adherence, but only 3% of these
applications were developed by health care agencies. Future studies at universities and
professional organizations should develop high-quality, adequately powered randomized
control trials to evaluate the effectiveness of mobile-health interventions to enhance
clinical outcomes for hypertension (Kumar, Khunger, Gupta, and Garg, 2015).

**Cognitive Testing**

Chronic hypertension aligns with an increased risk for cognitive decline and
dementia (Rouch et al., 2015). As the length of time increases when the blood pressure
is not within a therapeutic range, cognitive decline may worsen even further. Participants
in the treatment group must use software technology, Bluetooth technology, and operate
a blood-pressure monitor and investigators of this study must assure participants can
independently operate these devices. Cognitive testing was an important part of the
inclusion and exclusion criteria of this study and was also discussed in the next three
research studies.

Pase et al. (2013) conducted a cross-sectional study ($n = 493$) to determine the
association of central systolic pressure, central-pulse pressure, and pulse-pressure
amplification with cognitive performance to examine whether these associations
between the blood pressure variables and cognition were stronger for brachial or central
pressures. Pase et al. (2013) found that central aortic pressure and amplification were
sensitive indicators of cognitive aging, cognitive decline, and dementia, unassociated
with brachial blood-pressure values. Pase et al. (2013) suggested future studies include
cognitive function of young adults who live with unstable high blood pressure.
Spinelli et al. (2014) conducted a correlation study \((n = 302)\) to evaluate the effect of blood-pressure (doctor’s office or daily activities) control on cognitive functioning in adults treated for hypertension. Participants underwent testing with the Mini Mental State Examination, Frontal Assessment Battery, and tests for attention and executive function. The Stroop Color and Word Test were part of this battery of testing. The investigators found that poorly controlled hypertension in adult treated hypertensives aligned with impaired global cognitive functions, especially with respect to executive and attention functions of the brain. The Stroop Color and Word Test is comprised of three test sections administered over 45 seconds each; and, it is an appropriate evaluation tool for the population of participants who comprised the sample in this present study. Spinelli et al. (2014) suggested that future studies should explore the effect of blood-pressure control on peculiar cognitive functions and potential mechanisms where hypertension could align with neuropsychological impairments.

Yano et al. (2015) conducted a secondary analysis of data from the Coronary Artery Risk Development in Young Adults study to assess nocturnal and dipping blood-pressure levels in young adults and the association with cognitive function 20 years later in midlife for these young adults, which were independent of long-term office values \((n = 2326)\). Yano et al. (2015) were able to find that less nocturnal systolic blood pressure dipping and higher diastolic blood-pressure levels aligned with lower executive function in midlife, independent of multiple measures of office blood-pressure values during long-term follow-up care. Yano et al. (2015) believed that larger sample sizes were warranted to direct potential strategies for preventing lower cognitive function for individuals in middle age and older.
These studies indicated that unstable high blood pressure could lead to cognitive decline. One set of researchers followed participants over a 25-year period. This study introduced the concept of dipping and diastolic blood pressures, which tend to lower executive functioning in the mid-life period. Blood-pressure values normally dip during the hours of sleep, but a dipping pattern greater than 10% over a prolonged period could lead to cognitive decline for the participant.

**Summary**

This literature review was accomplished through a search of two online-related nursing databases: PubMed and Science Direct. After using key search terms, seventeen journal articles were selected. The journal articles included in this report group under the major headings of software applications, medication administration, and hypertension.

Information provided in these studies suggested that software applications could be an effective tool to assist in the management of unstable high blood pressure. Additional information suggested medication administration closely associated with hypertension. If a participant does not routinely take their prescribed antihypertensive medication, uncontrolled hypertension can result from this inactivity. In a subtopic of this literature review process, evidence does suggest that uncontrolled hypertension could lead to cognitive decline.
CHAPTER III

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

A true experimental, posttest-only, control-group design was used to investigate the influence of an intervention using the OnTimeRx® software application and reminder service to measure medication adherence. The Omron BP786 blood-pressure monitor facilitated blood-pressure monitoring. This chapter presents procedural information regarding the study setting, population and sample, protection of human participants, instruments, data collection, and treatment of data.

Setting

Participants were recruited from a large multi-location private not-for-profit health clinic that provides primary care health services to low-income populations of patients who lived in Fort Bend County and Waller County in the State of Texas. Participants were also recruited from a large Baptist Church located in Harris County, Texas.

The main Fort Bend County clinic is well-staffed and has three entrances and associated admission desks. The main work areas in this clinic are administration, adult health, pediatrics, pharmacy, and laboratory services. Abundant free parking allowed this clinic to be easily accessible to patrons. Once signed into the clinic, providers see a patient within one hour. Most employees in this clinic are bilingual, but this is not a requirement for employment. Physicians, nurse practitioners, and licensed vocational nurses staff this clinic. These nurses must have ongoing and in-service trainings to maintain their certifications. This main Fort Bend County clinic provides several community activities to raise funds for patients who are at-or-below 200% of the federal
poverty level, where income levels could be a possible barrier to medication adherence (Access Health, 2015).

The east Fort Bend County clinic was much smaller and was staffed equally well as the other clinics. This clinic was in a building that shared office space with two other entities, one of which was a sheriff’s substation. Participants were more likely to visit the clinic with the presence of police security. The parking lot at this facility was much smaller and more difficult for patrons to obtain sufficient parking. This clinic had one entrance and one exit, with much longer wait times to be seen by medical and nursing staff. A wall-to-wall glassed-in area separates staff at this clinic from patients. Patrons must speak through a small opening in the glass to communicate with front-desk employees. For this clinic site, participants were recruited from the waiting room area.

The Baptist Church, located in Harris County, offered First Responder services to each parishioner at the 8:00 am and 11:00 am church services or for any church-sponsored event. First Responder services include observations and assessments of the emotional and physical needs of all church members (Riceville Baptist Church, 2017). The First Responders attended to emergent/urgent situations and made appropriate referrals to health care clinics or hospital facilities, as needed (Riceville Baptist Church, 2017). First Responders report assessments of fainting spells, nausea, dizziness, or chest pains, which are often caused by extremely high blood pressure (Riceville Baptist Church, 2017).

Population and Sample

Participant recruitment was guided by the number of patients from the target population at one location and the availability of interview space to provide information
and enroll patients in this study guided participant recruitment for this study. There was one Waller County clinic, two Fort Bend County Clinics, and one Baptist church used to recruit study participants. Access to participants was gained through clinic staff referrals, presentations to the church choir, advertisement in the church bulletin, and recruitment in the clinic waiting room at the various clinics. Through these venues, prospective respondents were invited to participate in this research study.

A systematic review of a similar research study described their estimated effect size to be 0.71. This effect size was adopted because of similar independent and dependent variables as this research study. Using this effect size of 0.71, alpha of .05, and power of .80, it was determined that a sample of 66 participants was sufficient for to answer the research question of this research study. Inclusion criteria included (a) African American women at least 18 years of age with a diagnosis of blood-pressure lability, unstable high blood pressure, or an 401.9 ICD –10 code in the medical records, and prescribed one or more medications for high blood-pressure management- (b) a t-score of ≥ 30 on all sections of The Stroop Color and Word test-(c) e-mail and smartphone access with specific ownership of Android 2.3 or iOS 4.2 platforms or higher- and (d) an ability to speak, read, and understand the English language. The exclusion criteria included (a) pregnant women and (b) hospital admission during the study.

After obtaining Institutional Review Board–Houston approval, a convenience-sampling technique was used to identify and recruit prospective study participants, who met the inclusion/exclusion criteria of this study. A sample of 77 participants volunteered as participants. Of this number, 39 participants were randomized to the control group
and 38 were randomized to the intervention group. There were ten participants, who
failed to complete the study, leaving a total of 36 participants in the control group and 31
participants in the treatment group, for a total sample size of 67 participants. An analysis
of selected characteristics revealed no significant differences among completers and
non-completers with regard to age, education, baseline blood pressure, or number of
hypertension medications. Greater than 60% of the participants did not record their
household income and greater than 70% of them failed to record their height and weight
status. These variables were not considered any further in the analysis. Of the
participants who did not complete the study, they do not appear to be statistically
different from those who completed the study.

Protection of Human Participants

In compliance with the current rules and regulations of the Institutional Review
Board, approval was received for the use and protection of human participants from the
clinic site, church, and study institutions. All participants who volunteered to participate in
this study signed consent forms. All research materials were stored in a double-locked
file cabinet and steps were taken to enhance benefits and limit any disadvantages
resulting from research participation.

Instruments

A demographic and clinical data sheet, health-history form, smartphone, blood-
pressure-use survey, and the Morisky Medication Adherence Scale-8 (MMAS-8) were
administered to all participants in this study. The MMAS-8 instrument had a score range
of zero to 8 points for the eight questions. Questions one through four, six, and seven
were scored one point each for each No response and zero points for each Yes
response. Question number five was scored zero for each No response and one point for each Yes response. Question number eight was scored on a Likert-type scale. On the Likert-type scale: Option four was scored 1.0, Option three was scored 0.75, Option 2 was scored 0.50, Option one was scored 0.25, and Option 0 was scored 0.00. The overall or final MMAS-8 score for the participant was a summated score.

Adherence levels score were as follows: Low Adherence: < 6.0; Medium Adherence: 6.0 – < 8.0; and High Adherence: 8.0. de Oliveira-Filho et al. (2014) have assessed this instrument for face validity, content validity, construct validity, and criterion validity, and the instrument demonstrated adequate test–retest reliability (alpha .682).

Four additional forms were used to collect the needed data for this study: The Demographic and Clinical Data sheet contained questions related to age, height, weight, marital status, annual household income, highest education level, length of time with a diagnosis of high blood pressure, and the number of blood-pressure medications that were prescribed. The Medication Information Sheet provided a written record of each participant’s prescribed medication dose, frequency, and route of administration. The Smart Phone and Blood Pressure Use Survey identified each participant’s comfort level in manipulating a smartphone. The Health-History form asked for medical diagnosis, medical history, surgical history, and any pertinent laboratory values. Lastly, control-group participants received a written Log to record medication-taking behaviors and blood-pressure values.

Data Collection

Recruitment was done in the following manner: (a) Recruitment flyers and recruitment letters were distributed in the clinics and lobby of the Baptist Church, (b)
Study related questions were answered from the pastor, First Responders, church parishioners, clinic staff, physicians, and nurse practitioners about the study, (c) Discussed future plans for the research study as a tool for the management of unstable high blood pressure, and (d) Discussed administration of The Stroop Color and Word Test as a screening tool.

After potential participants met inclusion and exclusion criteria and agreed to be in the study, they signed the consent form. The participants were then randomized into the treatment group or control group. Participants then completed the demographic and clinical data sheet, the health history, the medication-information sheet, and a smartphone and blood-pressure-use survey. Written copies of the procedural instructions on device operation were also provided to each study participant.

**Treatment Group**

After completing data forms, the OnTimeRx® PROversion software application was downloaded onto the smartphone of the treatment group and enrolled the participants in the 100 phone/SMS reminder and e-mail service. Instructions were provided on the operation of the equipment, which was followed by return demonstrations of the procedures by the participants. The primary investigators then assisted participants to enter their blood-pressure medications into the OnTimeRx® application. Each participant in the treatment group received the same text message when they were due to take their medication, “Participant (Code Number), it is time to take your medication. Have a nice day.” In addition to the text message, the smartphone would set off an alarm when the medication was due.
Treatment group participants received the Omron BP786 blood-pressure monitor and the Omron Wellness application was downloaded to participants’ smartphones with instructions on its use. The primary investigator demonstrated how to transmit data from the blood-pressure monitor to the smartphone. Participants were instructed to measure their blood pressure daily with the Omron BP786 monitor and to transmit blood-pressure values from the monitor to their smartphone. The medication and blood-pressure Log provided an alternative documentation source to prevent loss of data. In this Log, participants manually recorded blood-pressure values onto the data sheet. All blood-pressure values from the data sheet and compliance data from the Log folder on the OnTimeRx® application was retrieved every two weeks for four weeks and the participants was cautioned not to clear any of the data from the software applications.

Control Group

Participants in the control group received the Omron BP786 blood-pressure monitor and the primary investigator downloaded the Omron Wellness application onto participants’ smartphones. Participants were taught how to transmit data between the blood-pressure monitor and smartphone. As an alternative to data transmission from the blood-pressure monitor to the smartphone, the primary investigator provided the medication and blood-pressure Log. Participants were then instructed to measure their blood pressure daily. Blood-pressure values were collected every two weeks for four weeks.
Treatment of Data

The appropriate descriptive statistics were used to analyze categorical variables. The likelihood ratio was used to accommodate the small number of cases in some of the categories. The Mann Whitney U test was used to analyze the research question.
CHAPTER IV
ANALYSIS OF DATA

The purpose of this two-group posttest-only study was to evaluate the efficacy of a technology intervention on medication adherence for hypertensive African American women. All participants had unstable high blood pressure and were taking medications for blood-pressure control. The sample was drawn from county health clinics and a large Baptist church that offered screening assessments for church members.

Participants in the treatment group used the OnTimeRx® software application and reminder service on their smartphones as a mechanism to remind them to take their blood pressure on the Omron BP786 monitor. Control-group participants received the Omron BP786 and the Omron Wellness application to download onto their smartphones. Medication Adherence was measured by using the MMAS-8. This chapter provides a description of the sample and presentation of the study findings.

Description of Sample

Although 77 participants were enrolled in this research study, the final sample consisted of 67 participants, with 31 participants in the treatment group and 36 in the control group. Frequencies and percentages were used to analyze demographic and select health data for the final sample of participants. Significant differences in demographic variables were assessed between treatment and control groups using likelihood ratios for categorical variables, and independent samples t-tests for continuous variables. The following tables summarize characteristics of the sample.
Overall, sample participants were well represented in each descriptive category (see Tables 1 and 2). Most participants were in their 50s with a range of 40–90 years of age. The control group was significantly older than the treatment group by approximately 5 years. The majority of participants were either married, divorced, or widowed. Education levels were evenly dispersed across categories from high school to graduate school. Most were taking one or two medications for their hypertension. Likelihood ratios revealed no significant differences between the treatment group on the selected variables. Pre-enrollment values of systolic and diastolic blood pressures averaged 140 mm/hg over 85 mm/hg with no significant differences between the groups.

Table 1
Marital Status, Education, and Number of Prescribed Medications

<table>
<thead>
<tr>
<th>Variable</th>
<th>All</th>
<th>Treatment</th>
<th>Control</th>
<th>Likelihood-ratio p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Percent</td>
<td>N</td>
<td>Percent</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/Partner</td>
<td>23</td>
<td>36.5</td>
<td>10</td>
<td>36.5</td>
</tr>
<tr>
<td>Divorced/Separated</td>
<td>19</td>
<td>30.2</td>
<td>11</td>
<td>30.2</td>
</tr>
<tr>
<td>Single/Never Married</td>
<td>9</td>
<td>14.3</td>
<td>6</td>
<td>14.3</td>
</tr>
<tr>
<td>Widowed</td>
<td>12</td>
<td>19.0</td>
<td>3</td>
<td>19.0</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High School or Less</td>
<td>19</td>
<td>28.8</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>Some College</td>
<td>15</td>
<td>22.7</td>
<td>8</td>
<td>26.7</td>
</tr>
<tr>
<td>College graduate</td>
<td>17</td>
<td>25.8</td>
<td>10</td>
<td>33.3</td>
</tr>
<tr>
<td>Graduate School</td>
<td>15</td>
<td>22.7</td>
<td>7</td>
<td>23.3</td>
</tr>
<tr>
<td># HTN Meds</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>24</td>
<td>36.9</td>
<td>13</td>
<td>43.3</td>
</tr>
<tr>
<td>2</td>
<td>23</td>
<td>35.4</td>
<td>9</td>
<td>30</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>6.2</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>&gt; 3</td>
<td>14</td>
<td>21.5</td>
<td>6</td>
<td>20</td>
</tr>
</tbody>
</table>

34
Table 2
Age and Blood Pressure Ranges at Start of Study

<table>
<thead>
<tr>
<th>Variable</th>
<th>All</th>
<th>Treatment (n = 36)</th>
<th>Control (n = 31)</th>
<th>t-test p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Age</td>
<td>59.3</td>
<td>9.1</td>
<td>56.5</td>
<td>7.7</td>
</tr>
<tr>
<td>HTN in years</td>
<td>14.7</td>
<td>11.0</td>
<td>12.1</td>
<td>9.8</td>
</tr>
<tr>
<td>Systolic B/P pre-study</td>
<td>140.0</td>
<td>24.1</td>
<td>138.3</td>
<td>21.7</td>
</tr>
<tr>
<td>Diastolic B/P pre-study</td>
<td>84.7</td>
<td>16.7</td>
<td>86.1</td>
<td>16.1</td>
</tr>
</tbody>
</table>

Note. HTN = hypertension, B/P = blood pressure.

The Health History document asked questions such as a report of all medical diagnoses, health history, surgical history, previous blood pressure valves, or any pertinent laboratory values that may impact blood pressure values and medication adherence. This document was completed at the beginning of the study and indicated 50% of participants in the treatment group had two or more comorbid cardiac conditions; and, 51.6% of participants, in the control group, had two or more comorbid cardiac conditions. The Health History document was also used to determine the reported frequency of blood pressure checks and their values. Some participants reported that they did not check their blood pressure, some participants commented that they only checked their blood pressure on retail store machines, while others only had blood pressure checks when visiting their healthcare provider. The majority could not recall the actual values of any previous blood pressure readings.

The Survey: Smartphone and Blood Pressure Use document was designed to assess comfort level with using smartphones and measuring blood pressures. As illustrated in table 3, nearly half of the treatment-group and control-group participants never download applications and most of the rest were infrequent downloaders. A
majority of both groups reported sending and receiving text messages, although the treatment group did this activity almost universally. Over three-quarters of respondents stated they could access the Internet using their smartphones with the treatment group reporting greater ability than the control group. When examining the sample’s access to and use of blood pressure monitors, approximately half of the treatment group and three quarters of the control group had a blood pressure monitor at home. Frequency measurements of blood-pressure varied widely from not at all to twice a day. There were no significant differences between the groups.

The OnTimeRx® software application recorded compliance rates for the treatment group. This rate reflected how well the participant was taking and recording their high blood pressure medications. This rate was provided to the primary investigator every two weeks. The mean of the compliance rate was 97.13% at two weeks; drifting downward to 93.70% at four weeks.
## Table 3

*Survey Responses*

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>Treatment</th>
<th>Control</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>How often download apps?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>29 47.5</td>
<td>11 37.9</td>
<td>18 56.3</td>
<td>.222</td>
</tr>
<tr>
<td>Less than every other day</td>
<td>24 39.3</td>
<td>14 48.3</td>
<td>10 31.3</td>
<td></td>
</tr>
<tr>
<td>Every other day</td>
<td>2 3.3</td>
<td>1 3.4</td>
<td>1 3.1</td>
<td></td>
</tr>
<tr>
<td>Every day</td>
<td>6 9.8</td>
<td>3 10.3</td>
<td>3 9.4</td>
<td></td>
</tr>
<tr>
<td><strong>Able to access internet on smartphone?</strong></td>
<td></td>
<td></td>
<td></td>
<td>&lt; .001</td>
</tr>
<tr>
<td>No</td>
<td>14 23.7</td>
<td>1 3.4</td>
<td>13 43.3</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>45 76.3</td>
<td>28 96.6</td>
<td>17 56.7</td>
<td></td>
</tr>
<tr>
<td><strong>Send/Receive texts?</strong></td>
<td></td>
<td></td>
<td></td>
<td>.002</td>
</tr>
<tr>
<td>No</td>
<td>7 11.5</td>
<td>0 0</td>
<td>7 21.2</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>54 88.5</td>
<td>28 100</td>
<td>26 78.8</td>
<td></td>
</tr>
<tr>
<td><strong>Have home BP monitor?</strong></td>
<td></td>
<td></td>
<td></td>
<td>.072</td>
</tr>
<tr>
<td>No</td>
<td>24 40.0</td>
<td>15 51.7</td>
<td>9 29</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>36 60.0</td>
<td>14 48.3</td>
<td>22 71</td>
<td></td>
</tr>
<tr>
<td><strong>How often measure BP?</strong></td>
<td></td>
<td></td>
<td></td>
<td>.475</td>
</tr>
<tr>
<td>Not at all</td>
<td>8 13.3</td>
<td>4 14.3</td>
<td>4 12.5</td>
<td></td>
</tr>
<tr>
<td>Monthly</td>
<td>16 26.7</td>
<td>8 28.6</td>
<td>8 25</td>
<td></td>
</tr>
<tr>
<td>Weekly</td>
<td>9 15.0</td>
<td>5 17.9</td>
<td>4 12.5</td>
<td></td>
</tr>
<tr>
<td>Every other day</td>
<td>1 1.7</td>
<td>0 0</td>
<td>1 3.1</td>
<td></td>
</tr>
<tr>
<td>Daily</td>
<td>17 28.3</td>
<td>8 28.6</td>
<td>9 28.1</td>
<td></td>
</tr>
<tr>
<td>Twice Daily</td>
<td>9 15.0</td>
<td>3 10.7</td>
<td>6 18.8</td>
<td></td>
</tr>
<tr>
<td><strong>Recharge smartphone daily?</strong></td>
<td></td>
<td></td>
<td></td>
<td>.146</td>
</tr>
<tr>
<td>No</td>
<td>11 18.3</td>
<td>3 10.7</td>
<td>8 25</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>49 81.7</td>
<td>25 89.3</td>
<td>24 75</td>
<td></td>
</tr>
</tbody>
</table>

*Note. p*-values for yes/no questions determined by likelihood ratio tests; p*-values for questions with ordinal responses from Mann-Whitney tests; BP = blood pressure.*
Findings

The following research question was addressed in this study: Is there a difference in medication adherence for African American women diagnosed with unstable high blood pressure from a community health clinic setting who monitor their blood pressure daily and use the reminder service versus those who only use the Omron BP786 monitor? The results were analyzed by using the Mann Whitney U test to examine the differences between the control and treatment group on medication, as measured by the MMAS-8. The total possible MMAS scores ranged from 0.0 to 8.0. Sample scores for this study ranged from 0.50 to 8.0. The median MMAS-8 score for the treatment group was 6.80 (IQR 5.8—7.8) and the median for the control group was 5.8 (IQR 4.8—7.0) indicating the scores in both groups ranged from low to medium adherence with the treatment group showing greater adherence than the control group. The Mann Whitney U test revealed a significant difference in the median scores between the two groups (MWU=393.0; p-value=0.037). So, the answer to the research question is Yes. The use of software applications that has a reminder service could significantly and positively impact medication adherence.

Summary of Findings

This chapter provided a description of the sample and results of statistical testing specific to the research question. Of the 77 participants randomly assigned to either the treatment or control group, this study assessed the impact of smartphone technology on medication adherence. Tables in this chapter reported the outcomes from the 67 participants who completed the study. Findings revealed that smartphone technology could have a positive impact on medication adherence.
CHAPTER V
SUMMARY OF STUDY

The purpose of this posttest-only control-group research study was to investigate a software application’s ability to improve medication adherence in African American women with high blood pressure. The dependent variable of this study was medication adherence, which was measured by the Morisky Medication Adherence Scale-8 (MMAS-8) scores. Women in the treatment group used the OnTimeRx® smartphone application, reminder service, and Omron BP 786 blood pressure monitor. Women in the control group used the Omron BP786 monitor to check their blood pressure. OnTimeRx® is a commercial software platform that could be downloaded onto a smartphone, iPad, laptop computer, or desktop computer. Along with this application, the user could also purchase a reminder service that offer various levels of reminder services. This chapter provides a summary of the research study, discussion of findings, conclusions, implications, and recommendations for future research.

Summary

There were seventy-seven participants who were randomized into one of two treatment conditions. Of this number, 67 participants completed this study ($n = 31$ for treatment; $n = 36$ for control). Thirty-one treatment group participants had the OnTimeRx® software application downloaded onto their smartphones, required teaching on all software applications (OnTimeRx® and Omron BP786), and receive instructions on how to transmit their blood pressure values to the primary investigator. The 36 control participants only required instructions on how to operate the Omron BP 786 blood pressure monitor.
pressure monitor and how to transmit their blood pressure values to the primary investigator.

As a secondary measure, participants who had difficulty in transmission of their blood-pressure values were asked to record their blood-pressure values on a blood pressure Log, which was provided to them. All participants in the study received weekly telephone calls or text messages for four weeks to answer any study related questions. After 28 days, all blood pressure data were collected and the Morisky Medication Adherence Scale-8 was administered to the participants.

The median MMAS-8 score for the treatment group was 6.80 (IQR 5.8—7.8) and the median for the control group was 5.8 (IQR 4.8—7.0). This indicates that the scores in both groups ranged from low to medium adherence, with the treatment group showing greater adherence than the control group. The Mann Whitney U test revealed a significant difference in the median scores between the two groups (MWU–393.0; p-value–0.037). This study has found that the treatment group, using the OnTimeRx® application and reminder service, demonstrated significantly better adherence scores than the control group participants.

**Discussion of Findings**

Findings of this study demonstrated greater medication adherence for those in the treatment group. This finding was congruent with those of Anthony et al. (2015) who demonstrated that use of a text-based reminder service increased blood-pressure measurement. Ahadzadeh et al. (2015) and Mosa et al. (2012) indicated that software applications could be useful tools in blood-pressure management. Bobrow et al. (2016) found a small reduction in systolic blood pressure was achieved by participants using
smartphone applications for blood pressure. This effect was enhanced by using interactive messages. Heinrich and Kuiper (2012) found the participants in their investigations achieved medication-adherence rates greater than 80% through the use of handheld devices that was programmed with the participant’s medication list.

However, findings from this study were not congruent with one by Tamura et al. (2014) who used a web-based health care system that allowed participants to record measurements of their blood pressure, body weight, and the number of steps walked per day. Their study by Tamura et al (2014) found that current monitoring systems were not effective in preventing disease. Many of the participants lost interest and stopped measuring the study variables, which caused the investigators to conclude that the intervention’s effectiveness was associated with participants’ levels of motivation (Tamura et al., 2014).

In the present research study, one-way text messages and alarm reminders on smartphones supported participants’ motivation to take their medications. Weekly telephone calls provided needed reinforcement for blood-pressure management. These activities helped to explain a different set of result findings in this study than was found in the literature.

Smartphone technology has continued to grow and improve human lives since its inception in 1992. Actionable insights gleaned from this research study suggest that smartphone technology has the possibility of improving medication adherence in relationship to unstable high blood pressure. The software applications used in this study offered a platform to record and monitor medication-taking behavior and also provided the user with an electronic log to view their own medication-adherence percentages. The
reminder service sounded an alarm in 15-minute intervals during the hour the participant was scheduled to take their medication, serving as a memory aide during the hour for the 31 treatment-group members who completed the study. After the hour passed, the application recorded the medication as a missed dose. Over time, missed doses of medication lowered adherence scores.

Many of the reasons participants in this study stated for not taking their prescribed medications as instructed included being too busy, not fully understanding the medication, or having difficulty managing the side effects. The reminder service prompted the participant to take the medication or to begin a dialogue with their primary care physician about changing their treatment plan.

**Conclusions and Implications**

In most cases, it is difficult to measure medication adherence to prescribed antihypertensive medications (Hyman and Pavlik, 2015). The OnTimeRx® software application has a way to enter all, routine, one-time, and as-needed medications. When it is time to take the medication, the participant indicates under "pill time" if they took the medication. In the Log section of the application, there is a record of the date and time that each medication was take, and the compliance percentage. The treatment group was able to successfully use the reminder device. The knowledge gained from this research study includes the following:

1. Technology reminder devices are an effective way to improve blood pressure medication adherence in African American women.
2. Compliance scores are easily accessible for the OnTimeRx® user.
The implications of this study include the following:

1. The software application use allows individuals living with unstable high blood pressure to be an integral partner in their own blood-pressure management.
2. Healthcare providers should strategically use technology-based options to increase patient medication adherence.
3. Using technology-based applications will require health care providers to provide patient education on blood pressure, medication use, and technology use.

**Recommendations for Further Studies**

Unstable high blood pressure remains a global health care concern. Medication adherence is the *gateway* to controlling the errant blood pressure values.

Recommendations for future research include the following:

1. Expand this research study to a larger group of participants in other parts of the United States; including participants from different races, cultures, men, children, adolescents, and pregnant women.
2. Investigate whether other software applications achieve similar results.
3. Evaluate the effectiveness of coupling additional reminder mechanisms to strengthen adherence.
4. Conduct a study using technology support that specifically addresses hypertension control.
REFERENCES


APPENDIX A

TWU Institutional Review Board Approval

Approval from Access Health Clinic and

Riceville Mt. Olive Baptist Church
DATE: August 21, 2017

TO: Ms. Vanessa Dale Monroe
     Nursing - Houston

FROM: Institutional Review Board (IRB) - Houston

Re: Extension for Testing A Smartphone Application Intervention To Improve Medication Adherence in African American Female Clinic Patients With Unstable High Blood Pressure: A Two-Group Randomized Control Trial (Protocol #: 18428)

The request for an extension of your IRB approval for the above referenced study has been reviewed by the TWU IRB (operating under FWA00000178) and appears to meet our requirements for the protection of individuals’ rights.

If applicable, agency approval letters must be submitted to the IRB upon receipt prior to any data collection at that agency. If subject recruitment is on-going, a copy of the approved consent form with the IRB approval stamp is enclosed. Please use the consent form with the most recent approval date stamp when obtaining consent from your participants. A copy of the signed consent forms must be submitted with the request to close the study file at the completion of the study.

This extension is valid one year from August 31, 2017. Any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any unanticipated incidents. All forms are located on the IRB website. If you have any questions, please contact the TWU IRB.

cc: Dr. Ainslie Nibert, Nursing - Houston
    Dr. Rita A. DelloStritto, Nursing - Houston
    Graduate School
October 17, 2016

Texas Women’s University
Office of Research & Sponsored Programs
PO Box 425619
Denton, TX 76204-5619

To Whom It May Concern,

AccessHealth has granted Vanessa Monroe permission to perform her hypertension research regarding "Testing a Smartphone Application Intervention to Improve Medication Adherence in African American Female Clinic Patients with Unstable High Blood Pressure: A Two-Group Randomized Control Trial".

We look forward to supporting her efforts in this study.

Regards,

Carol V. Edwards
CEO
April 2, 2017

Texas Women’s University
Office of Research & Sponsored Programs
P O Box 425619
Denton, TX 76204-5619

To Whom It May Concern,

AccessHealth has granted Vanessa Monroe permission to perform her hypertension research regarding “Testing a Smartphone Application Intervention to Improve Medication Adherence in African American Female Clinic Patients with Unstable High Blood Pressure: A Two-Group Randomized Control Trial.”

We look forward to supporting her efforts in this study.

Regards,

[Signature]

Rev. Terry E. Mackey
Senior Pastor
APPENDIX B

Morisky Medication Adherence Scale-8
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 [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 [health concern] medication.

<table>
<thead>
<tr>
<th>(Please mark your response below)</th>
<th>No=1</th>
<th>Yes=0</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you sometimes forget to take your [health concern] medication(s)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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 [health concern] medication(s)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Have you ever cut back or stopped taking your medication(s) without telling your doctor, because you felt worse when you took it?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. When you travel or leave home, do you sometimes forget to bring along your [health concern] medication(s)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Did you take your [health concern] medication(s) yesterday?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. When you feel like your [health concern] is under control, do you sometimes stop taking your medication(s)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Taking medication(s) every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your [health concern] treatment plan?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. How often do you have difficulty remembering to take all your medication(s)? (Please circle your answer below)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never/Rarely ...........................................</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Once in a while .......................................</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Sometimes ............................................</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Usually ...............................................</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>All the time .........................................</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Sources:


APPENDIX C

Demographic and Clinical Data Sheet
## DEMOGRAPHIC AND CLINICAL DATA SHEET

<table>
<thead>
<tr>
<th>Age</th>
<th>Height:</th>
<th>Weight:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Sex/Gender</th>
<th>Race</th>
</tr>
</thead>
</table>

**Current Marital Status (circle correct letter):**
- a. Married
- b. Living with someone.
- c. Divorced/Separated
- d. Single/Never married.
- e. Widowed.

**Annual Household Income:**

**Highest education Level (circle correct letter):**
- a. <Grade/Middle School.
- b. Some High School.
- c. High School Graduate
- d. Some College.
- e. College Graduate
- f. Some Graduate School
- g. Graduate Degree

**Systolic (top number) Blood Pressure (mm/hg) at onset of study.**

**Diastolic (bottom number) Blood Pressure (mm/hg) at onset of study.**

**How long have you lived with high blood pressure? (Months/years).**

**What is the number of high blood pressure medications that you take?**
- 0
- 1
- 2
- ≥3
APPENDIX D

Health History
Health History

1. Medical Diagnosis:
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

2. Medical History:
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

3. Surgical History:
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

4. Previous Blood Pressure values:
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

5. Pertinent Laboratory Values:
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

.
APPENDIX E

Survey: Smartphone and Blood Pressure Use
### Survey: Smart Phone and Blood Pressure Use

<table>
<thead>
<tr>
<th>Question</th>
<th>Circle (only) one</th>
</tr>
</thead>
<tbody>
<tr>
<td>How often do you download applications onto your smartphone?</td>
<td>• Every-day. • Every-other-day. • Less-than-every-other-day. • Not-at-all.</td>
</tr>
<tr>
<td>Are you able to access the internet on your smartphone?</td>
<td>• Yes. • No.</td>
</tr>
<tr>
<td>Do you send and receive texts on your smartphone?</td>
<td>• Yes. • No.</td>
</tr>
<tr>
<td>Do you have a home blood pressure monitor?</td>
<td>• Yes. • No.</td>
</tr>
<tr>
<td>How often do you measure your blood pressure?</td>
<td>• Daily. • Twice-daily. • Every-other-day. • Weekly. • Monthly. • Not-at-all.</td>
</tr>
<tr>
<td>If included in this research study, will you be able to measure your blood pressure, at least daily?</td>
<td>• Yes. • No.</td>
</tr>
<tr>
<td>Do you re-charge the batteries on your smartphone, daily?</td>
<td>• Yes. • No.</td>
</tr>
</tbody>
</table>
APPENDIX F
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Dear Mrs. Vanessa Monroe,

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September 30th, 2015

Vanessa Monroe
Texas Woman's University-Houston
6700 Fannin St
Houston, TX 77030
Email: vmonroe@twu.edu

Dear Vanessa,

Stoelting grants you permission to use Golden's Stroop Color and Word Test for your dissertation study "Smartphone Application: A Two-Group Randomized Control Trial of Medication Adherence and Unstable High Blood Pressure." This permission is for research purposes only.

Should you need any other support, please do not hesitate to contact me.

Sincerely,

Katherine Genseke, Psy.D.
Product Manager for Psychological and Special Education Materials