

THE INFLUENCE OF SPIRITUALITY ON MEDICATION ADHERENCE AND BLOOD  
PRESSURE AMONG OLDER ADULTS WITH HYPERTENSION

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## **ABSTRACT**

AMICA SIMMONS YON: The Influence of Spirituality on Medication Adherence and Blood Pressure Among Older Adults With Hypertension  
(Under the direction of Mary T. Roth McClurg)

Despite the effectiveness of pharmacological therapies, medication nonadherence is prevalent among older adults with chronic disease. Established correlates of adherence (e.g., access, race/ethnicity, education) do not fully explain the differences in adherence. This study examines whether spirituality contributes to older adults' medication adherence and blood pressure, as well as the indirect pathways by which spirituality may be linked to self-reported adherence behavior, with social support and active coping as putative mediators.

A cross-sectional analysis was performed on data from surveys on spirituality, social support, active coping, and adherence behavior administered to a convenience sample of Black and White hypertensive, older adults ( $\geq 65$  years) visiting senior community centers in North Carolina, along with demographic characteristics and blood pressure measurements.

Multivariate logistic and linear regressions were used to examine the relationship between spirituality and self-reported medication adherence and blood pressure, respectively, after adjusting for the psychosocial and demographic characteristics.

Results revealed that perceived spiritual intensity and active spiritual health locus of control (SHLC) were significantly and positively associated with medication adherence. The psychosocial variables were significantly related to both perceived spirituality and medication adherence but were not significant mediators. High spirituality and active SHLC

beliefs were also significantly related to lower systolic and diastolic blood pressures after controlling for adherence and the psychosocial and demographic variables.

These findings highlight the importance of spirituality in adherence behavior and health outcomes for some older adults with chronic disease. Better understanding of the mechanisms and role of spirituality in medication-taking behavior and health outcomes will aid researchers and health professionals in the development of culturally sensitive and patient-centered interventions to improve medication adherence and cardiovascular outcomes.

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## **PREAMBLE**

Despite the effectiveness of pharmacological therapies upon hypertension, medication nonadherence is prevalent among older adults, whose adherence can be influenced by numerous factors including income, health literacy, medication cost, race/ethnicity, and regimen complexity. These established correlates of adherence do not exhaust its variance, however, and inconsistent results have been reported in the literature. Although spirituality has been associated with improved physical and mental health, and some positive lifestyle behaviors, its role in medication adherence has not been well studied. This study seeks to address this gap by determining whether spirituality, via its known associations with social support and active coping, contributes to older adults' medication adherence and thus to lower blood pressure.

This dissertation is organized around three primary research aims, which are described in detail in Chapter 1. Chapter 2 includes a review of the literature on spirituality and adherence, other relevant literature on spirituality and health, and two recognized attributes of spirituality: social support and active coping. The conceptual model that guides this research is also described in Chapter 2. Chapter 3 details the research methods describing the study setting, participant eligibility, the study data, measurements, and analysis by aim, as well as the methods and results for Aim 1, which served as a pilot study. Chapter 4 presents the study results for aims 2 and 3. Finally, Chapter 5 summarizes the major findings of the present study and discusses their implications as well as possible directions for future research.

## **Chapter 1**

### **INTRODUCTION**

#### **Overview**

Medication adherence is a major public health challenge. The World Health Organization (WHO) reports that adherence to long-term therapy for chronic diseases in developed countries averages about 50%.<sup>1</sup> The consequences of nonadherence include poorer health outcomes, severe adverse events (e.g., hospitalizations and death), and increased health care expenditures.<sup>1-3</sup> These consequences are particularly evident in chronic conditions such as hypertension, diabetes, heart failure, and multiple co-morbidities in which pharmacological therapy is the foundation for optimal disease management.<sup>4-6</sup> Nonadherence is a tremendous problem in the United States, where more than half of Americans report not taking their prescribed medications as instructed<sup>7,8</sup> and studies have shown that poor medication adherence accounts for approximately 125,000 deaths annually (342 per day) and 28% of all emergency room visits.<sup>2,9-13</sup>

Adherence can especially be challenging in older adults, who may be prescribed multiple medications for their chronic conditions. Across different disease states and definitions of adherence, it is estimated that up to 70% of chronically ill older adults do not adhere to their prescribed regimens.<sup>5,14-20</sup> As Americans continue to live to more advanced ages, live with multiple chronic conditions, and rely on more medications for disease control, it becomes necessary to recognize and understand factors that contribute to medication-taking behaviors in order to optimally encourage therapeutic adherence.

A review of the literature reveals several factors that may be associated with nonadherence, including age, race/ethnicity, income, education, health literacy, access/cost, and others.<sup>9,21,22</sup> However, these factors do not fully explain the variance in adherence and there are “relatively few consistent predictors” in the literature.<sup>21,23</sup> Therefore, adherence research has been broadening its focus to other patient-level factors (e.g., personal and cultural beliefs about disease) that influence medication-taking behaviors.<sup>24-26</sup>

### **Definition of Spirituality**

No agreement has been reached in the literature on the exact definition of the terms *spirituality* and *religiosity*. However, scholars from a wide range of disciplines do agree that these constructs share overlapping meanings; in addition, they so frequently appear together in medical literature that they are written as a combined term (religiosity/spirituality, or R/S) .<sup>24,27,28</sup> Spirituality is often described as the broader term—that is, as being more universal, more inclusive, and at times less offensive (because it has been less stigmatized by institutionalization).<sup>29-32</sup> Spirituality is often equated with traditional religious practices and beliefs, although it is considered to be more encompassing and personal.<sup>29,31</sup> It comprises feelings of connection to others and the search for meaning and purpose in life beyond the corporeal.<sup>33</sup> Spirituality is often considered a personal phenomenon, meaning that spiritual people have, and cultivate within themselves, an intimate connection or relationship with a higher power or sacred entity.

In essence, spirituality relates to the subjective, individualized experience of transcendence. In this way it differs from religion, which is usually viewed as a societal phenomenon or institutionalized expression and is commonly defined as an organized system of beliefs and practices that involve and determine the collective spiritual experiences of a group of people.<sup>32,35</sup> Thus, religiosity (or religious involvement) refers to the degree of participation or commitment to these organized beliefs and practices.<sup>30,34-36</sup> The



vast majority of Americans are said to not distinguish between spirituality and religiosity, especially in certain regions (e.g., the Southeast).<sup>24,30</sup> This dissociation may be due to the popular perception that spirituality is rooted in an established religious tradition or belief system; in any case, religion is one way that people experience or express spirituality.

Although spirituality is viewed more broadly and defined less strictly than religiosity, scholars tend to agree that these two constructs share very similar characteristics that involve the quest for life's meaning and purpose, transcendence of the present and/or ordinary, connection with other people and with a Divine power, and specific values and behaviors.<sup>25,32,34,35</sup> Because spirituality and religiosity are considered more alike than different, and with the goal of remaining consistent with the spirituality and health literature, in the present study the term *spirituality* will be used to connote both spiritual and religious practices and beliefs. Spirituality in the present study is defined as the personal quest for understanding ultimate questions about life and events, about meaning, and about relationship with the sacred or transcendent; these aims may or may not involve religious practices and beliefs. The term "religiosity" will be used in reference to previous research that has differentiated it from spirituality and/or has specifically used the term religiosity.

Because spiritual traditions and beliefs may affect the decisions individuals make about their health, illnesses, and treatment choices, research on spirituality and health has begun to garner more attention and researchers have become more interested in the ways that spirituality impacts health.<sup>25,34,37-43</sup> The majority of past research on spiritual characteristics, including religious involvement, has shown positive relationships between spirituality and health outcomes.<sup>24,29,30,34,44,45</sup> However, the positive cast of this literature may have resulted from author or publication bias.

The majority of studies examining various aspects of spirituality (mostly in terms of religiosity) in relation to health have been cross-sectional and unable to differentiate cause

and effect; however, research also suggests that the patterns seen in these cross-sectional studies have also been observed in prospective studies and in studies that have compared secular to spiritually based interventions.<sup>40,46-52</sup> For example, Strawbridge and colleagues found in their 28-year prospective study of more than 5000 adults that weekly religious service attendance decreased the relative risk of dying during follow-up by 36% (relative hazard = 0.64; 95% CI 0.53–0.77).<sup>46</sup> This association between attendance and mortality remained statistically significant even after adjusting for health conditions, body mass index (BMI), social connections, and health practices (e.g., smoking, exercise, alcohol consumption). After adjusting for similar control variables, Koenig and colleagues found similar effects on survival in a six-year study of 4000 older adults (relative hazard = 0.72;  $p < 0.001$ ).<sup>53</sup>

Affirmation of the notion that spirituality positively influences health outcomes has varied. Reactions have ranged from cynical skepticism to supportive advocacy (i.e., when researchers contend that spirituality has health-promoting effects).<sup>41,54</sup> Some researchers remain skeptical because the majority of past studies have focused on religious involvement (usually worship service attendance) to the exclusion of other factors or dimensions such as self-perceptions of spirituality, agnosticism, and spiritual well-being. For example, some studies have suggested that individuals who struggle with their faith may be at higher risk for certain emotional and physical health challenges.<sup>55-58</sup> In addition, several of these studies were clouded or confounded by pre-existing mental health disorders (e.g., depression, PTSD) within the study populations. Doubt also stems from the fact that most studies have not been designed to test conceptual models or theory. For all of these reasons, the mechanisms that underlie the positive associations found in some studies, but not in others, are not well understood.<sup>41</sup>

Although there is support for the premise that spirituality positively influences health outcomes and behaviors, little research has examined the role of spirituality in medication adherence. Nonetheless, understanding the role of spirituality in medication adherence is important because it may help explain some of the positive associations that have been observed between spirituality and health. To date, there have been limited studies examining the relationship between spirituality and medication adherence in community-dwelling older adults with hypertension. Past research is mostly comprised of small qualitative studies that have only suggested or implied that aspects of spirituality may facilitate medication management and adherence in chronic diseases such as hypertension.<sup>43,59-61</sup> For example, qualitative results of a recent study that involved in-depth interviews with 21 older African American women suggested that they perceive spirituality as a positive resource that helps them adhere to their antihypertensive medication regimens.<sup>59</sup> If spiritual beliefs do in fact affect the decisions that a significant number of older patients make about their health and behavior choices, it is critical that health care providers listen and recognize all aspects of their patients' lives.

A better understanding of these issues is likely to guide the development of interventions to improve or maintain adherence—which would ultimately improve health outcomes. In addition, understanding whether a patient's spirituality functions as an enhancement of or barrier to adherence may lead to care that is more patient-centered and culturally appropriate; in any case, it will foster better patient-provider communication around disease management. More-specific interventions could also be targeted to high-risk patients and community groups whose adherence to prescribed therapies is challenged.

The objective of this study was to assess the influence of older adults' spiritual characteristics on self-reported medication adherence and blood pressure. In addition, to explore the mechanisms by which spirituality might influence adherence, social support and

active coping were assessed as possible mediators in the pathway between spirituality and self-reported adherence. This study is a cross-sectional analysis of data collected from questionnaires administered to older adults with hypertension. Its specific aims are described in more detail below.

### **Specific Aims**

**Aim 1: To assess three spiritual measures and select the measure (based on internal consistency, association with adherence and sample size efficiency) to test the hypothesis that spirituality is positively associated with medication adherence.**

**Aim 2: To examine the relationship between spirituality and self-reported medication adherence among community-dwelling older adults with hypertension.**

#### ***Hypothesis 2:***

- Older adults who report high spirituality versus those who report low spirituality are more likely to report being adherent to their anti-hypertensive medication(s).
- Older adults with high active spiritual health locus of control (SHLC) beliefs versus those with low active SHLC are more likely to report being adherent to their anti-hypertensive medication(s).

**Aim 2a: To examine the relationships among spirituality, social support, active coping, and self-reported medication adherence in community-dwelling older adults with hypertension.**

#### ***Hypothesis 2a:***

- Spirituality is positively associated with self-reported medication adherence, and this association is mediated through social support and active coping.

**Aim 3: To examine the relationship between spirituality and blood pressure among community-dwelling, older adults with hypertension.**

### ***Hypothesis 3:***

- Older adults who report high spirituality will have lower systolic and diastolic blood pressures compared to older adults who report low spirituality.

Aim 1, the pilot study, involved a cross-sectional study of 62 hypertensive older adults who had already been recruited into a larger study (hereafter, the parent study). A series of questionnaires about spiritual characteristics (i.e., organized religiosity, non-organized religiosity, spiritual health locus of control beliefs, and self-reported level of spirituality) that may influence medication adherence was administered to this group. The goal of Aim 1 was to select the spiritual measure(s) to be used in Aims 2 and 3 for hypothesis testing. Selection of one or more suitable spiritual measures to examine in relation to medication adherence included examining scale reliability; assessing the observed effect sizes (odds ratios); and estimating sufficient sample sizes to efficiently and feasibly test associations between the spiritual variables and medication adherence. Relevance of the spiritual measure to the study population was also considered.

The next part of this project was to design and conduct a larger study (aims 2 and 3), based on the results of Aim 1. Aims 2 and 3 were to 1) test the hypothesis that high spirituality leads to greater medication adherence among older adults with hypertension; 2) examine the relationships among spirituality, social support, active coping, and medication adherence—that is, to test whether social support and active coping mediate the relationship between spirituality and adherence; and 3) to examine the relationship between spirituality and blood pressure.

Data for this project was derived from two main sources: questionnaires administered to a sample of older adult patients enrolled in the parent study, at Chatham

Crossing Medical Center in Chapel Hill, North Carolina (Aim 1), and questionnaires administered to a convenience sample of community-dwelling older adults with hypertension at local senior centers (aims 2 and 3) in the Research Triangle Park region of North Carolina. Logistic regression methods were used to examine the relationships between spirituality and medication adherence in aims 1 and 2, and OLS regression was used to examine the effect of spirituality on blood pressure in Aim 3.

## **Chapter 2**

### **BACKGROUND AND SIGNIFICANCE**

#### **Prevalence of Prescription Drug Use**

Medications are the most common and one of the most important health care interventions to prevent disease, morbidity, and mortality.<sup>21</sup> According to recent data from the U.S. Department of Health and Human Services (DHHS), 50% of all Americans take at least one prescription medication and 10% use five or more.<sup>62</sup> In 2008, over \$234 billion was spent in the United States for prescription drugs. Data for 2007–2008 also reveal that more than 76% of Americans age 60 and older used two or more prescription drugs in any given month and that 37% had used five or more in the preceding month.<sup>62</sup>

#### **Medication Adherence**

Medication adherence is generally defined as the extent to which an individual's medication-taking behavior corresponds to prescribed recommendations from a health care provider.<sup>1,12</sup> Despite the availability of effective medical therapies for chronic disease and specific interventions to improve adherence, medication adherence rates remain low—by some estimates, between 50% and 60%.<sup>21,63</sup> However, according to different definitions of adherence, the literature contains estimated rates of medication nonadherence from 40% to 93% across various chronic diseases.<sup>64-67</sup> The problem is so severe that in 1998, poor adherence to therapeutic and beneficial medication regimens was described as the world's "other drug problem" in *The New York Times*.<sup>68</sup>

Evidence also reveals that poor adherence to medication regimens accounts for preventable worsening of disease, hospitalizations, death, and increased health care costs in the United States.<sup>3,69-79</sup> According to a recent New England Healthcare Institute (NEHI) study, the estimated cost of nonadherence to the U.S. health care system is \$290 billion annually, which translates to 13% of the nation's total health care expenditures.<sup>78</sup>

### **Adherence in Vulnerable Populations**

Poor adherence to prescribed therapy is a significant healthcare issue for vulnerable population groups, especially minorities and the elderly.<sup>80</sup> Many older adults are not only diagnosed with multiple chronic conditions but also have to manage complex medication regimens prescribed by various physicians. Therefore, the consequences of medication nonadherence and/or adverse drug events can be serious or life-threatening. Nonadherence accounts for more than 10% of older adult hospital admissions,<sup>11</sup> nearly 25% of nursing home admissions, and 20% of preventable adverse drug events among older persons in ambulatory settings,<sup>12</sup> and results in thousands of preventable deaths annually.<sup>9</sup> As noted by the American Society on Aging and the American Society of Consultant Pharmacists Foundation, "...of all age groups, older persons with chronic diseases and conditions benefit the most from taking medications, and risk the most from failing to take them properly."<sup>81</sup>

Racial differences in medication adherence have also been reported among the elderly, with Blacks tending to be less adherent.<sup>82,83</sup> Researchers recently found that medication-related problems (6.2 vs. 4.9;  $p < 0.01$ ) and higher rates of nonadherence (68% vs. 42%;  $p < 0.01$ ) were more prevalent in older Black, community-dwelling adults than in Whites, despite the fact that Whites used more medications (11.6 vs. 9.7;  $p < 0.01$ ).<sup>84</sup> In another study of Medicare enrollees, researchers found that Blacks were more likely than Whites to report "not always following physician instructions on how to take medications"



(adjusted OR = 1.60; 95% CI 0.74–3.42), which may reflect differences in patients' attitudes or lay health beliefs that, in turn, influence their medication decisions.<sup>85</sup>

Researchers have also noted that even when controlling for access barriers to medications, Blacks remain more likely to be nonadherent than Whites.<sup>66,80,82,86</sup> For examples, racial/ethnic differences in medication adherence are reported within the veterans' healthcare system despite equal access and cost.<sup>87-92</sup> This discrepancy indicates that poor adherence is more than a problem of access to services or cost of medications, which are two of the most-cited reasons for nonadherence in the literature. Findings of racial differences in medication adherence have profound implications for health disparities, especially because lower adherence often contributes to significant disparities in chronic disease outcomes.

### **Adherence to Hypertension Medications**

Hypertension affects approximately 75 million Americans (1 of every 3).<sup>93,94</sup> Data from the Framingham Heart Study<sup>95</sup> suggest normotensive individuals at age 55 have a 90% lifetime risk of developing hypertension. Moreover, hypertension increases patients' risk of heart disease and stroke (the first and third leading causes of death in the U.S., respectively).<sup>93,96</sup> In 2010, researchers estimated that high blood pressure alone results in more than \$76 billion nationwide in direct and indirect health care services costs.<sup>96</sup>

Although persistent adherence to prescribed antihypertensive medication regimens is essential to reduce the risks of stroke, cardiovascular disease, renal disease, and even death, medication adherence is low among hypertensive patients regardless of their race or ethnic background.<sup>60</sup> Only about half of patients who are being treated for hypertension actually have their blood pressure under control.<sup>96,97</sup> Furthermore, researchers report that only 50% of patients for whom medication therapy has been initiated persist with this treatment after one year.<sup>98,99</sup> Risk factors of hypertension, such as age and comorbid

conditions, pose an excess risk to cardiovascular morbidity and mortality, a relationship that emphasizes the importance of persistent adherence in vulnerable populations.

Low antihypertensive medication adherence has been proposed as an important barrier to achieving hypertension control and reducing morbidity and mortality in older adults. Most large clinical trials, such as the Systolic Hypertension in the Elderly Program (SHEP) have reported improvements in blood pressure control and patient outcomes, in both community and ambulatory care settings, with adherence to prescribed medications.<sup>100</sup> These and other trials have associated antihypertensive drug therapy with a 35%–45% reduction in stroke incidence, myocardial infarction reduction of 20%–25%, and heart failure reduction of more than 50%.<sup>95</sup>

As the U.S. population continues to age, the prevalence of hypertension will increase and many more people will be prescribed and required to take anti-hypertensive medications. Persistent adherence is the cornerstone for control and for reducing morbidity and mortality. Therefore, it is crucial to understand the factors that affect adherence and to institute a variety of proactive and responsive strategies that help older adults with hypertension to improve and maintain medication adherence.

### **Factors Associated with Medication Nonadherence**

Since the 1970s, literature on medication adherence has grown substantially.<sup>101</sup> In general, medication adherence is believed to be a multidimensional phenomenon. The WHO has grouped relevant factors into five dimensions: (1) social and economic, (2) health care system-related, (3) condition-related, (4) therapy-related, and (5) patient-related.<sup>1</sup> Particularly in older populations, the most frequently examined potential determinants of adherence include variables related to sociodemographics, health status, medications, and prescribers.<sup>101,102</sup> The literature also suggests specific patient-related factors (e.g.,

involvement with their care, disease knowledge, beliefs and attitudes about their chronic illness and treatment) may also be associated with adherence.<sup>1,14,63,102,103</sup>

Although studies associated adherence with an array of sociodemographic characteristics, links have typically been modest and findings have been inconsistent.<sup>21,101,104,105</sup> For example, researchers recently examined the correlates of medication adherence among older adults and found little consensus regarding the sociodemographic and medication-related variables that are associated with adherence in this population,<sup>101</sup> but also concluded that individual choices and beliefs regarding health and treatment may be stronger determinants.

Some researchers have suggested that nonadherence to antihypertensive medications is influenced by a complex set of factors beyond the health care system and general sociodemographics.<sup>22,66,106-109</sup> For example, Steiner and colleagues<sup>104</sup> conducted a retrospective cohort study of more than 100,000 hypertensive patients in which they attempted to develop clinical prediction rules for adherence based on a combination of sociodemographic and clinical patient characteristics. Multivariate logistic models based on the study's predictors, however, could not accurately discriminate adherent from nonadherent individuals (C statistic indice range 0.56–0.61); as a result, these researchers concluded that health providers should not rely only upon their patients' sociodemographic or clinical characteristics to predict which ones will be adherent.<sup>104</sup> Overall, the numerous factors that have been shown to influence patients' adherence to antihypertensive therapies have not fully explained variances in adherence; moreover, most of the study findings have been modest.<sup>8,101,110</sup>

Some studies have indicated that psychosocial and cultural beliefs may be important contributors to medication adherence and blood pressure control,<sup>100,109,111,112</sup> and have suggested their further investigation.<sup>26,60,111,113,114</sup> Accordingly, more research is being

conducted to understand the effects of personal and/or cultural beliefs on adherence behavior and to help understand different adherence rates among various groups of hypertensive patients.<sup>26,112,115,116</sup> Such research is warranted, given that the U.S. population is not only growing older and showing an increased prevalence of hypertension but it is also becoming more racially, ethnically, and culturally diverse.

### **Spirituality: Important Personal/Cultural Beliefs**

Spirituality has been identified as an important personal and/or cultural belief in many communities. It is an important part of the lives of most Americans; recent surveys have estimated that more than 90% (including older adults and the medically ill) claim to believe in God or some higher power and to value such beliefs.<sup>117,118</sup> For some, spirituality plays a prominent role and affects every aspect of life—including health.<sup>24,26,29,39,113,116,119,120</sup> The following sections present a review of relevant literature on spirituality and health outcomes and behaviors. In addition, a conceptual framework through which to assess the general impact of spirituality on medication adherence in hypertension is presented. This literature review and conceptual framework form the basis for the generated hypotheses of the present study.

### **Spirituality, Health Behaviors, and Medication Adherence**

Research suggests that spirituality is an important variable that can both influence and explain health behaviors.<sup>34,38,47,121-123</sup> For example, spiritual involvement has been associated with health-promoting behaviors such as physical activity or exercise, proper nutrition, improved communication with health providers and caregivers, lower smoking and alcohol prevalence, greater use of preventive services, and medical treatment compliance.<sup>34,123-130</sup> These associations have been observed across race/ethnic backgrounds and the age spectrum from adolescents to older adults.<sup>131-135</sup> Religious

affiliation/involvement and frequency of religious service attendance have been the most frequently examined spiritual variables; however, the positive associations between these characteristics and various behaviors probably stem from the notion that religious beliefs and practices condemn risky or unhealthy actions and instead provide behavioral guidelines that “reduce self-destructive tendencies.”<sup>38</sup>

Spiritual transcendence and well-being have also been examined in relation to health-promoting behaviors.<sup>122,136,137</sup> Greater physical activity, exercise adherence, better diet/nutrition regimes, and significantly improved weight loss have been shown to be successful in several faith-based behavioral interventions.<sup>138-145</sup> Researchers suggest that community interventions at church level, where consistent support and reinforcement can be found, have a reasonable chance of influencing the health of vulnerable populations at high risk for cardiovascular disease.<sup>141</sup>

Most people with chronic diseases are required to take medications on a daily basis, which makes adherence one of the most important health behaviors. Nonetheless, medication adherence has been less studied in relation to spirituality and, despite evidence that spirituality has a positive effect on various health outcomes, investigations of direct links between spirituality and medication-taking behavior are scarce. Numerous studies and systematic reviews have suggested, however, that personal beliefs and cultural factors, including spirituality, are important in relation to adherence for patients with chronic illnesses and have concluded that these factors warrant further investigation.<sup>26,59,146,147</sup> For example, researchers have found that faith and reliance on God frequently helped members of a focus group of 28 older adults to manage and cope with chronic illnesses.<sup>147</sup> That spirituality and close ties to religious organizations strengthen patients’ coping ability, increase their compliance with health care visits, and even increase their compliance with treatment recommendations have also been suggested.<sup>148-150</sup> Research that indicates an association

between spirituality and adherence is scant, however, and mostly found in the HIV literature. For prevalent chronic diseases such as diabetes and hypertension, few studies have been done; most of these have been small-scale and qualitative and have indicated only a possible relationship between spirituality and medication adherence. Only a small number of studies suggest that spirituality may enhance medication adherence in some patients with chronic diseases such as diabetes and hypertension. Most of these were qualitative, conducted in minority populations, and stemmed from church-based interventions designed to promote healthy lifestyle behaviors. Spirituality has been suggested to possibly play a role in medication adherence among patients diagnosed with hypertension.<sup>26,151-153</sup> It has also been indicated that spirituality influences patients' thoughts about hypertension, how they manage the disease, and how they follow medication recommendations.<sup>26,60,66,151</sup>

In a qualitative study of 20 hypertensive black Americans, the majority of participants were found to use their religious beliefs as protective, control, and coping mechanisms in their disease management.<sup>151</sup> Informants attributed their hypertension to "God's plan," a conclusion that enhanced their own sense of personal control because they believed that God would provide the necessary means to handle their situation (e.g., "God created doctors", "God has the medication there for me").<sup>151</sup> The authors of this study suggested further investigation into the relationship between spirituality and medication use and stated that whether different dimensions of spirituality are associated with different levels of medication compliance behavior should be determined.<sup>151</sup> In a more recent qualitative study, researchers assessed the role of spirituality in self-management practices among community-dwelling older women (age  $\geq$  65–96 years).<sup>43</sup> Their informants reported using a combination of spiritual and traditional methods as therapeutic approaches to manage their chronic illnesses and that their spirituality guided them in what allopathic therapies to use.

Respondents also reported the importance of spirituality in empowering them to practice health-promoting activities.

Although evidence from other small qualitative studies also indicates that spirituality positively influences treatment preferences and how some patients therapeutically manage their chronic diseases, these have mostly been conducted in the Black population.<sup>108,113,154-</sup>

<sup>159</sup> However, these exploratory qualitative studies (as well as the more abundant HIV literature) represent the first stages of inquiry into the links between spirituality and self-management (particularly medication adherence) in chronic illness. The relationship and potential benefits of spirituality to medication-taking behavior requires further study.

### **Spirituality and Health**

Although a direct relationship between spirituality and medication adherence has not been found, links between spirituality/religiosity and health (e.g., that spiritual beliefs and practices may improve general health, benefit specific health outcomes, and facilitate health-promoting behaviors in some patients) have been much more firmly established. The current increase of interest in the association between spirituality and health and health behaviors among lay and research communities is largely due to scientific evidence of positive associations.<sup>24,34,41,124,160-163</sup> To date, more than 1200 studies have examined clinical and epidemiological relationships between spirituality and health and at least two-thirds have found significant positive associations.<sup>24,29,37,39,55,149,163,164</sup> However, most of these studies concern positive associations between religiosity and improved deleterious health outcomes;<sup>44,165</sup> whereas other researchers attribute the positive and protective affects that spirituality exerts on health simply to lifestyle changes.<sup>34,37</sup> The following sections describe some of the associations found between spirituality and health.

## **Mortality**

For many years, researchers have attempted to demonstrate the importance of spirituality in long life and decreased mortality rates.<sup>162,166,167</sup> It has often been revealed that spiritual or religious involvement is inversely related to mortality. Such studies, which include both cross-sectional and large longitudinal designs,<sup>34,46,53,166,168-172</sup> most often use the spiritual variable of religious service attendance.<sup>162</sup> Other variables include membership in a religious congregation, self-reported spirituality or religiosity, frequency of prayer or meditation, spiritual well-being (particularly strong senses of meaning/purpose, inner peace, and faith)<sup>124</sup> and living within a religious or spiritual community.<sup>34,162</sup> Inverse relationships have been found between spirituality and mortality even after controlling for demographics, socioeconomic status, health status, and health behavior variables.<sup>34,166,170</sup> Overall, the assessment of spiritual factors in mortality research has resulted in significant results that show a favorable effect of spirituality on survival.<sup>163</sup>

## **Physical and Mental Health**

Research has also linked spirituality to physical and psychological well-being along with other health-related outcomes.<sup>39,40,173,174</sup> Such connections seem to be stronger in older patients and patients with severe, terminal, or chronic illnesses.<sup>33,175</sup> As in the spirituality and mortality research, most of these studies have used measures of religiosity or religious involvement; fewer have used other measures of spirituality. This gap has been attributed to a greater consensus by researchers about how to define and measure religious involvement.<sup>29,34</sup>

Some psychiatric researchers claim that spirituality plays a role and is positively linked to mental health. Studies of different racial/ethnic populations, in different settings and age groups, have shown that spirituality (mostly in the form of religious involvement) is related to lower rates of depression, anxiety, suicide, and psychotic disorders.<sup>34,38,126,176</sup>



Since the early 1970s, the number of empirical studies examining the relationship between spirituality and mental health has increased dramatically; most have found significantly lower rates of depressive symptoms and disorders, improved courses of depression, and less anxiety among subjects who identify as spiritual or religious.<sup>34,39,127,177,178</sup> These studies, which have included longitudinal and randomized control trials, have revealed that a higher baseline of spirituality or religiosity predicts fewer depression symptoms and faster remission of symptoms at follow-up compared to control participants and recipients of secular therapies.<sup>38,176</sup> People with chronic and terminal illnesses have reported that their spirituality not only mitigates feelings of fear, worthlessness, and hopelessness, but also replaces such feelings with a clearer understanding of meaning and increased strength to deal with the demands of their health condition(s).<sup>164</sup> The general conclusion of well-conducted scientific investigations into the relationship between spirituality and mental health is that higher levels of spiritual involvement and self-rated spirituality positively impact psychological well-being.<sup>34,38,176</sup>

### **Cardiovascular Disease**

Spirituality has also been studied in patients with cardiovascular disease,<sup>121</sup> the leading cause of death in the United States.<sup>179</sup> Because adults with heart disease face complex physical, psychological, and social stressors resulting from a decrease in general well-being and loss of physical functioning,<sup>180</sup> qualitative and quantitative research has noted that spirituality is important to patients with a range of cardiovascular diseases and that these individuals tend to incorporate their spirituality into their disease coping and management.<sup>37,40,121,164,181</sup> Several observational studies have demonstrated positive impacts of numerous expressions of spirituality (e.g., religious involvement, as sense of hope, inner peace, feelings of strength, and overall spiritual well-being) on the health

outcomes of cardiovascular patients, including adjustment to diagnosis and progression of disease.<sup>182-185</sup>

## **Spirituality and Hypertension**

Spirituality has been shown to be important to hypertensive patients, and some patients have indicated that they use their spirituality for coping and disease management.<sup>115</sup> After adjusting for age, ethnicity, sex, education, functional status, BMI, and previous blood pressures, spiritual involvement has been specifically associated with lower blood pressure and hypertension.<sup>34,174,186-190</sup> Because most of these studies have been observational, which means that causality cannot be inferred, researchers have posed explanations for their positive findings (e.g., the promotion of health-related behaviors, the healthful psychosocial effects of spiritual practice, and the beneficial psychodynamics of belief systems and faith).<sup>189,191</sup>

For example, preliminary findings from one study<sup>192</sup> indicate that religious and spiritual participation and practice are beneficial to blood pressure. In the Jackson Heart Study,<sup>187,188</sup> researchers examined the prevalence, awareness, treatment, and control of hypertension among 5302 Black participants aged 21 to 94 years and ascertained, in a sub-analysis, associations among organized and non-organized religion, religious coping, and daily spiritual experiences and participants' blood pressure.<sup>192</sup> Findings revealed that participants with more religious activities and participation had significantly lower diastolic and systolic blood pressure (77.8 vs. 84.7 mmHg and 137.2 vs. 149.5 mmHg, respectively) after adjusting for demographic, sociocultural, and psychological variables. Interestingly, these researchers noted that the link between spirituality and blood pressure remained consistent even though religious and spiritual subjects were more likely to have higher BMI scores and were less likely to take their medications as directed.<sup>187,192</sup> Researchers also found that people who engaged in religious activities had lower levels of cortisol (a biological marker of

stress).<sup>192</sup> This finding is similar to others that have linked spirituality to better lipid profiles,<sup>191,193</sup> glucose control,<sup>194,195</sup> and immune function.<sup>33,186,191,196,197</sup>

### **Negative Effects of Spirituality on Health**

There is also a smaller body of literature that has related spirituality (especially religious involvement) to negative physical and mental health outcomes or found no association between spirituality and improved physical and mental health.<sup>34,37,39,54,149,162,198,199</sup> Such outcomes have also included negative coping behaviors and inappropriate use of health services. For example, particularly among older adults, mental health disorders often remain undetected (and, therefore, untreated) when people feel that their mental health is “unworthy of professional help.”<sup>200,201</sup> Older adults who frame and view mental health issues as evidence of personal weakness, failure, and spiritual inadequacy also tend to have issues with access to and utilization of medical health treatment and services.<sup>200,202</sup> Some reports indicate spiritual beliefs and practices—particularly in the context of religiosity—can negatively affect patients’ health outcomes (e.g., increased anxiety and guilt, lower self-esteem, and greater psychological distress).<sup>56,58,203-205</sup>

More germane to the focus of the present study is research that has found negative or no associations between spirituality and blood pressure or hypertension. For example, in a longitudinal study (Fitchett et al., 2009) of the relationship between daily spiritual experiences (DSES; e.g., a feeling connection to God or transcendent, inner peace) and systolic blood pressure and hypertension among 1658 Black and White middle-aged women<sup>206</sup> DSES neither provided protective effects on blood pressure nor was associated with hypertensive status (OR = 0.90, 95% CI 0.42–1.93; OR = 1.03, 95% CI 0.52–2.06, respectively). Studies of similar relationships have found negative or no associations between spirituality and blood pressure or hypertension.<sup>127,195,207,208</sup> Medication adherence was not examined or adjusted for, however, in favor of examining the influence of religious

affiliation (i.e., service attendance) on blood pressure rather than any broader aspects of spirituality. These limitations, and the inconsistent findings about blood pressure, support the premise of the current study.

For some individuals, leading a spiritual life or maintaining a spiritual orientation can involve interpersonal struggles and/or struggles with God or the Divine that may have important implications for their health and overall well-being.<sup>149</sup> Several empirical studies have related spiritual struggles to poorer quality of health and longer hospitalizations, as well as higher rates of mortality, psychological distress, and suicide.<sup>56-58,149,209</sup> Pargament and colleagues' (2001), two-year longitudinal cohort study of 596 patients aged 55 years or older who were receiving medical inpatient services at a hospital and VA medical center<sup>56</sup> assessed patients' positive religious coping and religious struggles in relation to their mortality and found that religious struggle was associated with greater risk of mortality (RR for death, 1.06;  $p = 0.02$ ), particularly for patients who "wondered whether God had abandoned" them and those who "questioned God's love" for them (RR for death, 1.28 and 1.22, respectively). In this study, the magnitude of the effects associated with religious struggle was relatively small (from 6% to 10% increased risk of mortality) but remained significant even after controlling for demographics and physical and mental health variables.<sup>56</sup> In another study of medically ill hospitalized older adults, indicators of religious struggle (e.g., anger toward God, feeling punished by God) were associated with poorer health indicators including number of medical diagnoses (Std.  $\beta$ , 0.15;  $p < 0.001$ ), ADL impairment (Std.  $\beta$ , 0.12;  $p \leq 0.01$ ), and cognitive function (Std.  $\beta$ , -0.10;  $p \leq 0.01$ ). Results of this study also significantly related negative religious coping methods with greater depression and lower quality of life.<sup>203</sup>

It has been suggested that certain belief systems or spiritual practices may adversely affect a person's health by encouraging avoidance or discontinuance of allopathic

treatments, failure to seek medical care, and avoidance of effective preventive health measures such as immunizations and blood transfusions.<sup>34,39,210</sup> Other people may not comply with medical recommendations because they believe that a higher power has caused their disease, or that illness in general is the result of bad behavior.<sup>211-213</sup> Because such convictions can influence self-efficacy or willingness to adhere to chronic disease management, these findings cannot be negated in general and especially not for people who experience spiritual/religious struggles in relation to their health and behavior or who are members of faith groups that hold fatalistic views of health, life, and death. Similarly, individuals who rely on faith alone for their healing or endorse prayer as a medical substitute experience higher levels of negative outcomes for most chronic diseases.<sup>214-217</sup>

The few empirical studies that have indicated certain forms of spirituality negatively impact health have mostly focused on religiosity; been conducted on mental health, hospitalized, and/or terminally ill patients (as opposed to community-dwelling adults); and have not provided sufficient evidence of spirituality's relationship to medication adherence in chronic disease. This information strongly influenced the research focus, population of interest, and hypotheses of the present study; moreover, it affirms the necessity of extending prior research into the relationship between spirituality and health as well as the importance of being mindful of potentially negative findings.

## **Summary**

Medication adherence is a serious public health issue that is extremely challenging in older adults with chronic disease. Personal and cultural beliefs may play a role in adherence to medications. Spirituality, an important personal/cultural factor in many communities, is especially expressed in patients with chronic illnesses. A summary of the literature indicates support for the positive effects of spirituality upon health and health behaviors, ranging from positively impacting mortality to serving as a resource in chronic disease management.

However, negative associations have also been found between spirituality and health, and these findings must be considered—especially in light of the possibility of publishing bias toward positive findings.

Research has clearly shown that many patients rely on a spiritual framework to guide them in making decisions, understanding their health condition(s), and increasing their self-efficacy and coping skills when dealing with chronic disease.<sup>26,34,60,158</sup> Given the major issues with medication nonadherence in chronic illness, however, it is important for researchers and health providers to be cognizant of the role spirituality may play in medication-taking behaviors and patients' adherence or nonadherence to prescribed therapies. As a background factor, spirituality has been largely overlooked in prior studies of medication adherence, particularly in older adults. This gap is evidenced by the dearth of research on the role of spirituality in adherence rates, although the positive associations that have been found between spirituality and health outcomes may have resulted from the greater adherence of spiritual patients. In order to clarify these relationships in older patients with chronic diseases, it is important for clinicians and researchers to understand which aspects of spirituality predict better medication adherence or function as barriers.

Less specifically, recognition and clarification of how spirituality influences medication-taking behaviors among older adults with chronic disease(s) is an important part of providing patient-centered and culturally appropriate care. For these reasons, the present study sought to examine the influence of a range of spiritual dimensions on self-reported medication adherence in older adults with hypertension. To our knowledge, this is one of the first quantitative studies to examine this relationship in this population. Its findings can not only be used to further our understanding of the influence of spirituality on adherence, and the beliefs that patients consider important in their health behaviors, they also may help

researchers design future studies to further clarify the relationship among spirituality, adherence, and chronic disease control.

### **Conceptual Model**

The conceptual model for this doctoral project was adapted from an innovative conceptual model proposed by Lewis and Ogedegbe (2008) of possible mechanisms by which spirituality may increase medication adherence and decrease blood pressure in hypertensive African Americans (Figure 1).<sup>26</sup> Although it focuses on spirituality qualified as uniquely African American, its developers emphasized that the influence of spirituality on adherence may also operate in other minority populations as well as Whites.<sup>26</sup> This model is largely based on data from small qualitative studies that have suggested a positive relationship between spirituality and medication adherence in African Americans. The model is also based upon systematic reviews of adherence research that have suggested personal beliefs about hypertension and its treatments influence how African Americans manage and follow medical recommendations.<sup>26,66,108,154-156,218,219</sup> The model includes three dimensions of African American spirituality (faith in a transcendent force; relationships with God, others, and self; and transformation and consolation) that may work together or independently to influence medication adherence in African Americans. The first dimension, faith in a transcendent force or higher power, provides direction and guidance for maintaining health, which in turn helps patients make positive decisions about adherence to prescribed medications. The second dimension (relationships with God, others, and self) involves the notion that such relationships provide increased social support that in turn increases self-efficacy to overcome barriers associated with medication adherence. The third dimension (transformation and consolation) provides strength to actively cope with disease and the barriers associated with adherence.

## **Mechanisms of Spirituality: Social Support and Active Coping**

In the literature, there are several mechanisms of spirituality that may help explain its positive impacts on health and health behaviors. In particular, social support and active coping have been suggested to facilitate the importance and benefits of spirituality in health and health-promoting behaviors.<sup>26,61,79,99,167,220-222</sup> Some researchers have found that spiritual beliefs and practices tend to improve social support and coping skills across many chronic diseases, especially in vulnerable populations.<sup>43,119,151,194,221,223,224</sup>

The link between spirituality and social support appears in studies that have significantly related measures of spirituality to larger social networks and to tangible/instrumental and emotional support.<sup>225-228</sup> Social support has also been shown to mediate the relationships between a number of spiritual dimensions and health outcomes (e.g., lower psychological distress, increased life satisfaction, improved quality of life, enhanced coping, reduced levels of pain, and lower rates of mortality).<sup>169,226,229</sup> It is generally accepted that spiritual participation, especially public spiritual involvement, can facilitate social support by providing avenues for increased social contact and development of close social bonds outside the nuclear family. Particularly in older adults, researchers have observed that spiritual/religious involvement often provides a close network of family, friends, and others with similar values and experiences who provide support in times of stress and during decision making about health.<sup>223</sup> These support networks have been found to offer positive assistance that facilitates or promotes healthy lifestyle behaviors, protects health, and aids recovery from illness in older adults.<sup>228</sup>

Social support has also been associated with medication adherence in older adults with chronic illnesses.<sup>108,230-234</sup> A study of Medicare enrollees with histories of hypertension revealed perceived social support to be associated both with following physician instructions on how to take medications and not forgetting to take medications (adjusted OR = 0.51; 95%



CI, 0.35–0.76).<sup>85</sup> Other studies have found similar associations across various health conditions,<sup>11,67,235</sup> which suggests that the involvement of others in providing knowledge, offering reminders, and giving other types of support may help to overcome barriers to medication adherence.<sup>85</sup>

Active coping, another proposed mechanism by which spirituality positively impacts health in chronically ill people,<sup>229,236-240</sup> refers to the strategies whereby “individuals accept and actively attempt to deal with” their illness and other stressors related to health problems.<sup>224,240</sup> It is generally accepted that active coping, in contrast to avoidant or maladaptive coping, is the most adaptive response to stress; as such, it includes strategies such as problem solving, planning, and seeking emotional and tangible/instrumental support.<sup>224</sup> Active coping is primarily perceived as positive because it involves effectively reframing stressful situations (e.g., health challenges) to lessen the impact of stressors.<sup>241-243</sup> Active coping has also been associated with patient adherence to treatment across numerous health conditions.<sup>244-247</sup> Patients with multiple chronic conditions must balance many priorities and make daily decisions about illness management; these tasks become even more complicated for older adults who suffer from multiple health conditions that may interrupt normal routines, diminishes finances, affects psychological well-being, and even creates situations of dependency.<sup>34,43,45</sup> In the face of such obstacles, not only do many people rely on their spiritual beliefs but they also tend to cope more effectively than those without spiritual beliefs.<sup>38,43,243,248-250</sup>

Studies have shown spiritual beliefs and practices to be significantly and positively correlated with active coping, even after controlling for health status and demographic variables.<sup>224,240,251,252</sup> A survey of 330 hospitalized medical patients aged 60 and over revealed that 90% reported using religion to cope, at least to a moderate extent,<sup>253</sup> and that more than 40% indicated their religious faith was the most important factor that enabled

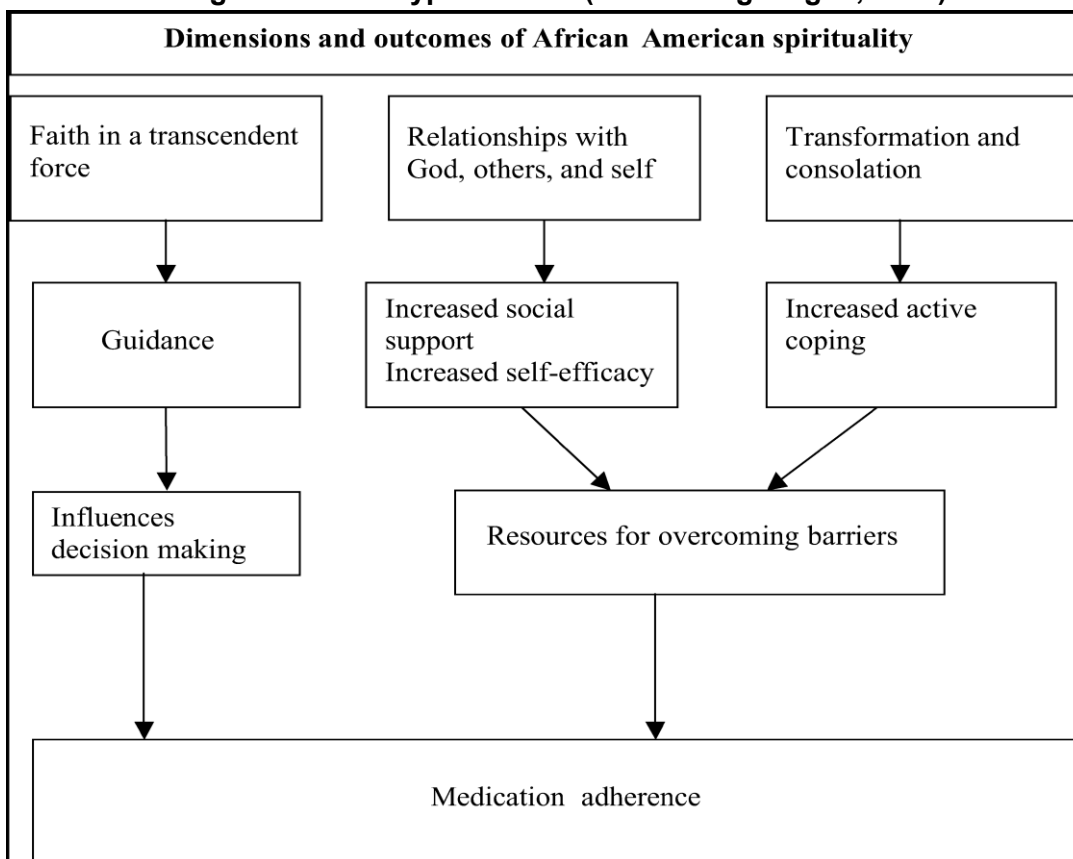
them to cope.<sup>253</sup> Chronically ill patients with greater reliance on spiritual beliefs are more likely to use an active coping style in which they accept their illness and try to deal with it positively and purposefully.<sup>39,226</sup>

Because social support and active coping have been shown to be attributes of spirituality and also to influence health outcomes and behaviors,<sup>39,224,226</sup> it is important to investigate whether social support and active coping are mechanisms through which spirituality influences medication adherence. For this reason, another aim of the present study is to examine whether social support and active coping mediate the relationship between spirituality and medication adherence in the target population.

Although Lewis and Ogedgbe (2008) noted that their conceptual framework is a complex paradigm that warrants additional study, its use in the present study is appropriate as a way to clarify whether aspects of spirituality positively influence adherence. Figure 2 presents an adapted version of this framework as the basic conceptual model of the present study, whose interest and primary objective was to examine characteristics of spirituality (i.e., organized and non-organized religious activity, spiritual health locus of control beliefs, and self-ranking of spirituality) and their possible relationships to medication adherence. These spiritual characteristics, which were chosen in an effort capture the dimensions of spirituality described by Lewis and Ogedegbe, include the premise that spirituality may increase patients' social support and active coping that function as resources for overcoming some barriers (e.g., limited personal control over chronic illness) associated with medication adherence. Spirituality may work in conjunction with these two attributes to influence adherence, or it may have a more proximal or direct impact. For the purposes of clarification, the present study also sought to explore the effect of spirituality on blood pressure after adjusting for self-reported adherence, social support, and active coping as potentially confounding and/or explanatory variables. Given that the conceptualization of

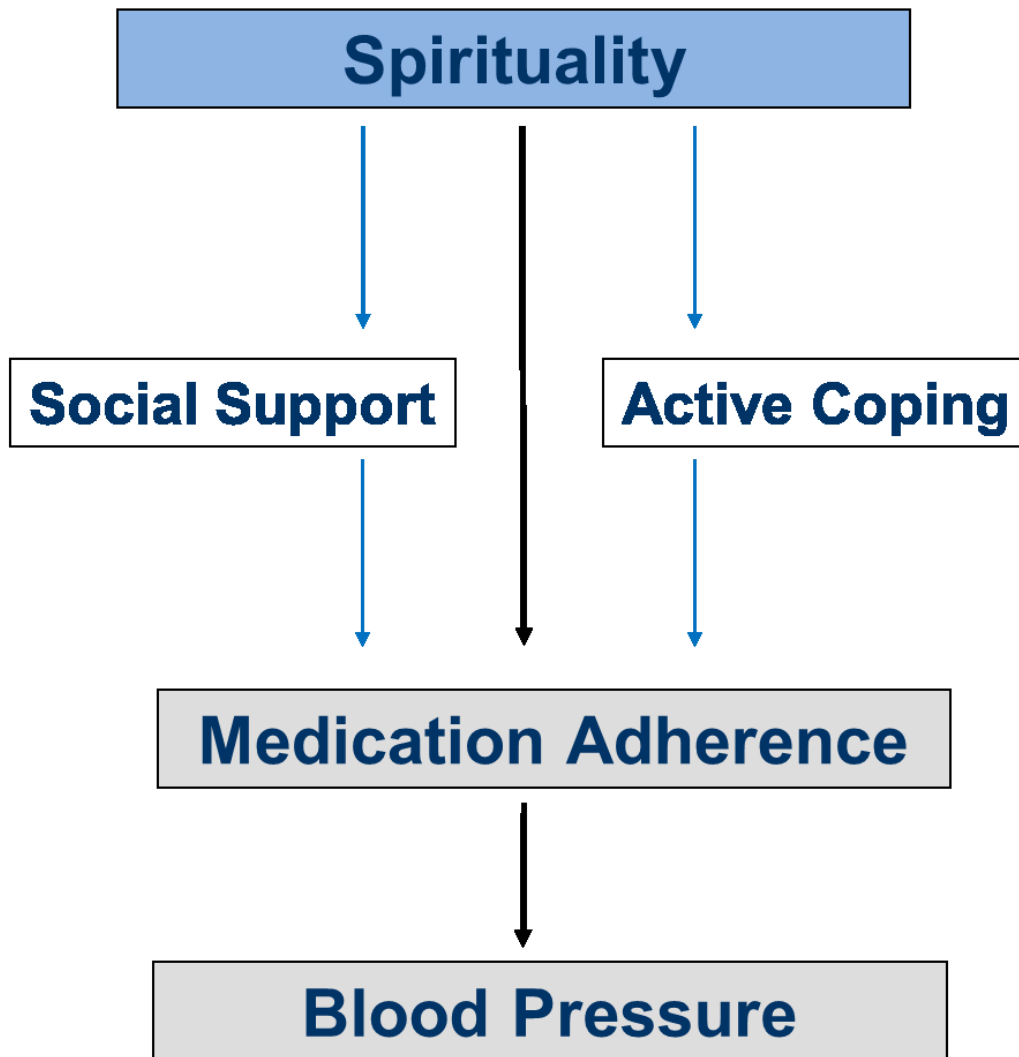
spirituality may be similar across races/ethnicities, both Whites and Blacks were included as subjects in the present study.

**Figure 1. Conceptual Model of Spirituality and Medication Adherence for African Americans Diagnosed with Hypertension (Lewis & Ogedegbe, 2008)**



Adapted from; Lewis, L and Ogedegbe, G. Understanding the Nature and Role of Spirituality in Relation to Medication Adherence; *Holistic Nursing Practice*, Sept/Oct 2008.

**Figure 2. Conceptual Model of the Present Study**



Adapted from Lewis, L and Ogedegbe, G. (2008) Understanding the nature and role of spirituality in relation to medication adherence. *Holistic Nursing Practice*, Sept/Oct 2008.

## CHAPTER 3

### METHODS

#### Overview

The present study examined the influence of spirituality on medication adherence and blood pressure in community-dwelling White and Black older adults with hypertension in a two-phase process. The first phase (Aim 1) involved a pilot study of a sub-sample of hypertensive patients (N = 62) who were already enrolled in a larger study (i.e., the parent study). The performance of three spiritual/religious measures were examined in relation to medication adherence. Enacting the first aim involved selecting the spiritual measure(s) to be used for hypothesis testing (Aims 2 and 3). Selection of the spiritual measure(s) for the project's second phase consisted of examining their reliability, comparing their observed effect sizes, and estimating sample sizes in order to sufficiently power the larger study. Description of the methods for each phase is presented below as follows: the results of Aim1 (the pilot study), and then the methods and results of aims 2 and 3.

#### Aim 1 Methods (Pilot Study)

**Aim 1: To assess three spiritual measures and select the measure (based on internal consistency, association with adherence and sample size efficiency) to test the hypothesis that spirituality is positively associated with medication adherence.**

#### Description of Parent Study

Data for Aim 1 (the pilot study) was collected as part of an ongoing parent study conducted by researchers at the UNC-Eshelman School of Pharmacy (Effects of a Medication Management Program on the Quality of Medication Use in Older Adults, IRB

Study #10-0874). Aim 1 was conducted using 62 hypertensive patients selected from the 73 participants in the parent study, which was a prospective, longitudinal study of the feasibility and effectiveness of a clinical pharmacist-led medication management program in improving the quality of medication use in Black and White older adults. In the parent study, patients were seen three times (baseline, 3, and 6 months) at a community-based, academically affiliated clinic, by one of two study pharmacists. As per the parent study protocol, baseline assessment consisted of meeting with a research assistant and a subsequent interview with the assigned clinical pharmacist. During the baseline assessment visit, the research assistant (RA) collected self-reported information on the participants' demographics, health literacy, functional status, and medication management. Following this assessment, patients met with the study pharmacist who collected detailed information about medical history, current health status, medications, and adherence behavior and also provided medication management services.

For the purposes of the present study, three measures were added to the parent study at the baseline assessment and collected by the RA in order to explicate the significance of spirituality and/or religiosity in the study subjects and the relationship of these qualities to subjects' medication adherence. The additional measures were the Duke University Religion Index (DUREL), the Spiritual Health Locus of Control Scale (SHLCS), and a one-item measure of overall self-ranking of spirituality (or spiritual intensity) which was administered along with a newly developed survey. These measures were chosen to capture relevant dimensions (i.e., faith in a transcendent force, relationship with God, and transformation and consolation) of spirituality described in the framework of the present study (Figure 1).<sup>26</sup> Scale brevity and cultural appropriateness were strong considerations in the selection these measures, in part because many of the spirituality measures in the literature contain up to 150 items and because many of the older people in the geographical

region (Southeast United States) from which the sample population was drawn experience spirituality within the context of religion or religious beliefs.

Two additional measures were added to the parent study in order to assess social support and active coping as depicted in the conceptual model (Figure 2): an adapted version of the Tangible, Informational, Emotional and Social Support (TIES) survey and the John Henry Active Coping scale (JHAC12). These were added to report the distribution of responses given by participants in the pilot study and to assess the approximate time required to complete all the questionnaires. All five of the additional measures are presented in the appendices of this dissertation.

### **Setting**

The setting for the pilot study was Chatham Crossing Medical Center, a community-based outpatient physician practice affiliated with the University of North Carolina at Chapel Hill and serviced by the UNC Health Care system that provides medical care to a diverse population of adults and children with chronic medical conditions and special needs. Available services, which include preventive health care, chronic health management, same-day sick care, and minor procedures, are provided by seven physicians who specialize in Internal Medicine and Pediatrics and serve on the faculty of the UNC Department of Medicine and Pediatrics. Approximately one-third of the older adults serviced at Chatham Crossing are Medicare-eligible ( $\geq 65$  years of age).

### **Patient Eligibility and Recruitment**

Patients in the parent study were eligible to participate in the pilot study if they met the following criteria: (1) racially identified as Black or White, (2) aged 65 years or older, (3) taking at least five medications (prescription, nonprescription, and/or herbal), (4) living independently in the community without a terminal illness, (5) English-speaking, and (6) under the care of a primary care provider (attending physician or mid-level practitioner) at

Chatham Crossing Medical Center. Eligibility criteria for five medications or more was based upon verified evidence of older adults' higher risk of adverse drug events, patient errors and nonadherence.<sup>254-256</sup> Individuals with cognitive impairments (e.g., dementia or mental function deficit) were included in the study with appropriate proxy consent. Patients were excluded if they were non-English-speaking, non-community-dwelling, children, pregnant, terminally ill, or if their primary care provider at Chatham Crossing was a resident in training in the UNC healthcare system.

Participants were recruited from referrals by primary care providers at the Chatham Crossing Medical Center (as per the enrollment protocol of the parent study). Providers at the clinic were given an overview of the parent study and a list of eligibility criteria and asked to generate a list of patients who they felt could benefit from medication therapy management services; they also referred participants to the medication management program based on patient need and medication complexity. Providers who generated lists of potential participants left the completed referral forms for the study team in a designated box at the clinic at the beginning of the study and at any time during enrollment that they identified potential participants. At the end of the enrollment period of the parent study, physicians had referred 139 patients for the medication management program; of these, 73 were eligible and agreed to participate.

All referred patients were entered into the study database, which tracked everything from the point of referral through enrollment. Using WebCIS (the UNC Health Care System electronic medical record database), the RA verified that referred patients met study eligibility criteria. Next, eligible patients were mailed a letter from their provider at Chatham Crossing that informed them of the study as well as a forthcoming phone call from study personnel at the UNC Eshelman School of Pharmacy. A total of three calls were made within one week of the mailing date of the invitation letter; after three with no response, an



individual was considered to be unreachable. When the RA was able to contact an eligible individual by phone, s/he described the study in greater detail, confirmed eligibility criteria, and invited participation. At the time of the call, patients were at liberty to decline participation in the study. If the patient expressed interest in participating, the RA arranged a meeting with the RA and a clinical pharmacist at the clinic for consent and baseline assessment.

### **Baseline Study Visit**

The baseline assessment comprised meeting with the RA and then being interviewed by the clinical pharmacist. All interviews were conducted in a designated private examination room at Chatham Crossing Medical Center.

### **Visit with the RA**

At the beginning of the initial meeting, the RA described the study and explained the informed consent document. After the individual or proxy provided written, informed consent, the RA administered a series of measures (Table 1) that included patient demographics, health literacy, functional status, spirituality, social support, and active coping.

The RA collected demographic information (e.g., age, marital status, gender, race/ethnicity, education, primary health care provider, and specialist physicians) from the patient and/or proxy using the demographic questionnaire designed for the parent study and then asked patients to complete the following self-report surveys/questionnaires:

- Duke University Religion Index (DUREL)<sup>257</sup> (Appendix 1)
- Spiritual Health Locus of Control Scale (SHLCS)<sup>258</sup> (Appendix 2)
- Self-Ranking of Spirituality<sup>259</sup> (Appendix 3)
- John Henryism Active Coping Scale (JHAC12)<sup>260</sup> (Appendix 4)
- Tangible, Informational, Emotional Social Support Survey (adapted version of TIES)<sup>261</sup> (Appendix 5)

Prior to the administration of each survey, the RA read its instructions aloud. Then the RA stepped away (usually into the hallway outside the exam room) to allow the patient to complete each survey on his/her own or with help from his/her proxy. However, the RA did ask each patient whether he/she needed assistance with reading and completing the surveys. If the participant had visual impairment or requested assistance, the RA read each survey item aloud, solicited a response, marked the patient's response, and then repeated it aloud to ensure that it had been documented properly. All other participants read, answered, and marked their own responses. Only 4 participants needed assistance from the RA or proxies.

### **Visit with the Clinical Pharmacist**

Immediately after the baseline visit, each patient was interviewed by the clinical pharmacist, who collected information about income, health/disease conditions, number of medications, medication-taking behavior, and medication adherence, and entered this information onto the Baseline Comprehensive Medication Review Form that had been designed for the parent study. This transcription was preceded by a thorough review of each patient's electronic medical record by the same pharmacist, using WebCIS. The information contained in these medical records, which included medical history, laboratory values, and other pertinent health history, helped the pharmacist to verify information given by the patients during their interviews and in formulating her assessment of their medication use and medication-related problems.

All of the information gathered during the medication review was documented by the clinical pharmacist on the parent study's Baseline Comprehensive Medication Review Form, which included the 4-item Morisky Compliance Assessment scale (Appendix 6). The parent study assessed adherence in three ways: 1) pharmacist clinical assessment, 2) the Morisky instrument, and 3) patient self-reports of adherence on each medication, from 0% to 100%

(visual analog scale). However, for the purposes of the pilot study (Aim 1), the Morisky Compliance Assessment Scale was used to assess overall medication adherence. The Morisky Compliance Scale<sup>262</sup> is a self-reported, 4-item measure of medication-taking behavior over the previous 4 weeks (Appendix 6).

The Morisky Compliance Scale was chosen over the other two measures of adherence used in the parent study after careful consideration. The clinical pharmacist's assessment and self-reported adherence via visual analog was not judged to be ideal because both assessed adherence to *each prescribed medication*, which made it difficult to calculate a composite score of adherence. In the parent study, the clinical pharmacist marked whether a participant was adherent to a specific medication, based on the pharmacist's clinical assessment, with 'Yes' or 'No.' For the visual analog scale, participants indicated the percentage (0% to 100%) that best reflected his/her compliance to each medication that had been prescribed during the previous 4 weeks. The focus of analysis for the pilot study (Aim 1) was the subset of hypertensive patients from the parent study rather than a specific hypertension medication type, in order to use as much of the sample as possible from the parent study (N = 73). Given the small sample size of the parent study and the inability to obtain an overall composite score for these measures, the 4-item Morisky scale was determined to be most efficient.

## Description of Measures

This section describes the measures that were administered and utilized for Aim 1.

**Table 1. Outline of Measures Administered at Baseline**

<u>Measure</u>	<u>Baseline</u>	<u>Conducted by</u>
Demographics	X	RA
Health literacy (s-TOFHLA) <sup>a,b</sup>	X	RA
Functional status <sup>b</sup>	X	RA
Spirituality/Religiosity (DUREL; SHLCS; Self-Ranking of Spirituality)	X	RA
Active coping (JHAC12)	X	RA
Social support (TIES)	X	Pharmacist
Comprehensive medication review	X	Pharmacist
Adherence	X	Pharmacist
Assessment of quality medication Use <sup>b</sup>	X	Pharmacist
Health services utilization <sup>b</sup>		

<sup>a</sup> This measure was given to the proxy if the participant had a documented diagnosis of cognitive impairment or dementia.

<sup>b</sup> These measures were used in the parent study but not the pilot study.

## Measures

- **Demographic Questionnaire:** Age, race/ethnicity, gender, marital status and education were obtained for each patient during the baseline visit by the RA, using the parent study's demographic questionnaire. Other patient information (e.g., number of medications and health conditions) was collected by the clinical pharmacist during the baseline assessment and was recorded on the parent study's Baseline Comprehensive Medication Review Form.

- **Duke University Religion Index (DUREL):** The Duke University Religion Index (DUREL)<sup>257</sup> (Appendix 3) is a widely used five-item measure, divided into three subscales, that assesses organized religious activity (frequency of attending religious services), non-organized religious activity (frequency of praying, meditating, or studying religious text) and intrinsic religiosity (internalization of and commitment to religious practices and beliefs). The five single items measure organizational and non-organizational religiosity; the three-item subscale measures intrinsic religiosity. Items in the subscales are scored on a five-to-six-point Likert-type scale. The overall scale has been shown to have high test-retest reliability (intra-class correlation = 0.91), high internal consistency (Cronbach's  $\alpha$  = 0.78–0.91) and high convergent validity with other measures of religiosity ( $r$ 's = 0.71–0.86); DUREL's factor structure has been demonstrated and confirmed in separate samples by different investigative teams.<sup>39,257</sup>
- **Spiritual Health Locus of Control (SHLCS):** The Spiritual Health Locus of Control Scale (Appendix 2) is a 13-item, two-dimensional scale that assesses active and passive spiritual health locus of control beliefs. It was adopted from Holt and colleagues (2003, 2007).<sup>160,258,263</sup> Item responses are scored on a four-point Likert-type scale that ranges from strongly disagree (1) to strongly agree (4). The SHLCS is an expanded scale based largely on the concepts of Rotter's (1966) social learning theory;<sup>264</sup> previous work was done with other locus of control measures (the Health Locus of Control Scale,<sup>265</sup> the Multidimensional Health Locus of Control Scale,<sup>266</sup> and the God Locus of Control Scale<sup>267</sup>) of internal and external locus of control beliefs found to be predictive of health-related behaviors and outcomes.<sup>258,263</sup> On the SHLCS, Cronbach's  $\alpha$  for the active dimension (11 items) ranges from 0.78 to 0.89 and from 0.56 to 0.76 for the passive dimension (2 items).<sup>258,263,268</sup> The active spiritual dimension was found to be positively correlated with the internal dimension of the Multidimensional Health Locus of Control

(MHLC) Scale<sup>266</sup> and negatively associated with the external dimension, whereas the passive spiritual dimension was found to be positively associated with the external dimension.<sup>258,263</sup> The SHLC subscales have demonstrated significant predictive validity, evidenced by negative correlations between the passive spiritual dimension and knowledge about mammography, breast cancer and breast cancer treatment, and mammography utilization.<sup>258</sup> From a theoretical standpoint, spiritual health locus of control beliefs are thought to be predictive of health-related behaviors or outcomes. This measure is being further evaluated in various populations by the developers and for confirmation of its factor structure.

- Self-Ranking of Spirituality:** Overall self-ranking of spirituality (i.e., perceived level of spirituality) is a one-item assessment of spiritual intensity that asks participants to rate the extent that they consider themselves to be spiritual/religious. Responses range from 4 (very spiritual/religious) to 1 (not spiritual/religious at all). This item was adopted from the Brief Multidimensional Measure of Religiousness/Spirituality (BMMRS) developed by a panel of experts on spirituality and health research at the Fetzer Institute and the National Institute on Aging<sup>259</sup> and has been included on numerous spiritual surveys in combination with other spiritual measures; it has also been used as a single-item measure of spirituality.<sup>259,269</sup> Self-ranking of spirituality has been correlated with other spiritual domains in health research, including daily spiritual experiences, spiritual/religious practices and beliefs, and positive spiritual coping.<sup>259,270</sup> This item was administered along with a newly developed tool, which will be used for further development and future analysis (Appendix 3).
- John Henryism Active Coping Scale (JHAC12):** Active coping was assessed using the John Henryism Active Coping Scale (Appendix 4).<sup>260</sup> This measure was used in the pilot study to describe the distribution of responses from the study sample about coping

and to assess feasibility of administration. The JHAC12 is a 12-item Likert-type scale consisting of statements that assesses a person's behavioral or personality predisposition to persistently and actively cope with difficult psychosocial stressors and barriers; its active coping score is the sum of the values assigned to each of the 12 responses, which range from 1 (completely false) to 5 (completely true). Possible total scores range from 12 to 60, with higher scores indicating a greater John Henryism trait (or predisposition to actively cope). Higher scores (i.e., those above the study's sample median) predict mental and physical vigor, tenacity, and a strong sense of personal efficacy when confronted with stressors/barriers.<sup>260,271</sup> The JHAC12 has been examined with other psychometrically validated coping and psychosocial measures. Evidence supports its validity and reliability among both Black and White Americans, and similar patterns of correlations have been found for these subgroups in other psychosocial measures.<sup>271,272</sup> In these populations, the JHAC12 has been found to be correlated with the active coping and suppression of competing activities subscales of the COPE Inventory<sup>273</sup> but negatively correlated with the Marlowe-Crowne Social Desirability Scale,<sup>274</sup> which demonstrates support for convergent validity.<sup>271</sup> In addition, the JHAC12 has been shown to be positively correlated with the Life orientation Test (LOT),<sup>275</sup> which assesses individual differences in generalized optimism versus pessimism.<sup>271</sup> Discriminant validity for the JHAC12 as an active coping scale has been demonstrated by its lack of correlation with the emotion-focused subscales of COPE, which are related to venting emotions and mental disengagement. Confirmatory factor analysis of JHAC12 has suggested two similar and meaningful factors among Blacks and Whites that consist of two dominant themes: commitment to succeed through hard work, and personal efficacy.<sup>271</sup> Reliability coefficients for the JHAC12 from community-based adult samples range from the low 0.70s to the low 0.80s. As discussed in Chapter 1, active coping

behaviors have been positively associated with spirituality and patient adherence across numerous chronic health conditions; moreover, the JHAC12 has been positively correlated with spirituality/religiosity, health behaviors, and life satisfaction.<sup>276,277</sup> For aims 2 and 3, active coping was assessed in relation to spirituality, medication adherence, and blood pressure.

- **Social Support with Medications and Health:** Social support was assessed using a 7-item questionnaire (Appendix 5) to describe the distribution of responses from the study sample about social support for health issues and obtaining medications as well as to assess feasibility of administration. The questionnaire consisted of 6 questions adapted from the 16-item Tangible, Informational and Emotional Social Support Survey (TIES),<sup>261</sup> with one additional question (“Is there someone, other than your doctor, you could turn to for general advice regarding your medications?”). The six questions that were abstracted from the original 16-item TIES Survey (a reliable and valid social support survey) were items that specifically relate to support with medications and health; the original survey was developed to measure the types of social support that are necessary in cardiovascular disease prevention and management. For validation of the original TIES survey, researchers used the Medical Outcomes Study Social Support Survey (MOS)<sup>278</sup> because it includes a broad range of items on tangible, information, and emotional support that are more specific to the social support needs of medically ill patients. Exploratory factor analysis revealed a four-factor solution that accounted for 54% of total variance and correlated with the tangible ( $r = 0.77$  and  $r = 0.51$ ), the emotional/informational ( $r = 0.80$ ), and positive social interaction ( $r = 0.60$ ) subscales of the MOS. Scores on the original TIES have been correlated with the total scores on the MOS ( $r = 0.82$ ).<sup>261</sup> For the purposes of the pilot study, the adapted seven-item questionnaire was used to assess patients’ level of support with obtaining and taking



their medications. Item responses ranged from 0 (none of the time) to 2 (all or most of the time), with higher scores indicating more support with medications. Although this adapted version of TIES has not been validated, it was used in the pilot study (Aim 1) for descriptive purposes to report the distribution of responses and to help estimate the time of administration, taking into account the various questionnaires that were to be administered in the larger study (aims 2 and 3).

- **Baseline Comprehensive Medication Review (BCMR)** was conducted by the clinical pharmacist during the baseline assessment and documented on the Medication Review Form used in the parent study. It consisted of the patient or proxy presenting all current medications (prescription, nonprescription, complementary, and alternative) to the clinical pharmacist and the clinical pharmacist reviewing each medication, inspecting their containers, and discussing/recording (1) medical conditions and related information, (2) information on all medications (e.g., strength, directions, indication, use), (3) medication-taking behaviors, (4) medication allergies and adverse drug events, (5) method of payment for medications, including prescription drug insurance or assistance, (6) the dispensing pharmacy, (7) use of medication adherence aids (e.g., pill boxes, medication calendars), (8) estimated out-of-pocket spending per month on medications, (9) number of prescribers, and 10) additional medication-related information provided by the older adult or his/her caregiver as per the protocol of the parent study. For Aim 1 of the present study, data were taken from the medication review form for descriptive purposes and included number of chronic medical conditions, number of current medications, prescription drug insurance coverage, and yes-or-no answers to “Was there a time in the past 6 months when you needed prescription medication but could not purchase it because of the cost?”

- **Morisky Compliance Assessment Scale:** For Aim 1, medication adherence (dependent variable) was evaluated using the Morisky instrument<sup>262</sup> (Appendix 6), which assesses medication-taking behavior over the previous 4 weeks. Morisky is a four-item scale that asks: (1) Do you ever forget to take your medicine?, (2) Are you careless at times about taking your medicine?, (3) When you feel better do you sometimes stop taking your medicine?, and (4) Sometimes if you feel worse when you take the medicine, do you stop taking it? Its score is calculated by assigning one point for each answer of “no” and zero points for each answer of “yes.” Patients answering “yes” to one or more questions are viewed as possibly having problems with medication adherence.<sup>262</sup> The Morisky scale has been shown to be reliable (Cronbach’s  $\alpha = 0.61$ ) and to demonstrate both concurrent and predictive validity,<sup>262</sup> but it does not capture behavior for specific medications. This measure is a general assessment of adherence and is not disease or medication-specific. It was selected for its feasibility, considering that the data for Aim 1 was collected in the context of a larger study.

### **Data Collected and Variables**

Data for Aim 1 was taken from the participants’ baseline visit with the RA and clinical pharmacist, using the measures described in the previous section. Table 2 presents the key variables, measures, sources, and their type or range.

**Table 2. Variables Used in Aim 1**

Variable	Measure	Source <sup>a</sup>	Type/Range	Definition
<b>Dependent Variable</b>				
Medication adherence	Self-report	Morisky (4-item) Scores range from 0 to 4	1 = adherent 0 = non-adherent (Scores < 4 defined as nonadherent)	Overall adherence to meds over past 4 weeks <i>Nonadherence</i> : Yes for $\geq 1$ items on Morisky Compliance Scale.
<b>Key Independent Variables (Spirituality/Religiosity)</b>				
Organized religious activity (ORA)	Self-report	DUREL	1 = High ORA 0 = Low ORA	Frequency of religious service attendance. High = ( $\geq$ few times/mth)
Non-organized religious activity (NORA)	Self-report	DUREL	1 = High NORA 0 = Low NORA	Frequency of private religious activity. High = ( $\geq$ two times/week)
Intrinsic religiosity (IR)	Self-report	DUREL	1 = High Intrinsic 0 = Low Intrinsic	Internalization/commitment to beliefs. Scores at median or higher on the IR subscale will be 'High IR.' Scores below median will constitute low.
Active spiritual	Self-report	SHLCS	1 = High Active 0 = Low Active	Involves idea that God empowers self-care; both God and self are responsible for health. Responses: 4 (Strongly Agree) to 1 (Strongly Disagree)
Passive spiritual	Self-report	SHLCS	1 = High Passive 0 = Low Passive	Involves idea that God has control over one's health. Responses: 4 (Strongly Agree) to 1 (Strongly Disagree)
Self-ranking of spirituality	Self-report	1-item measure	Recoded: 1 = High 0 = Low/No	Overall perceived spirituality via a 1-item measure asking "To what extent do you consider yourself a spiritual/religious person?" Responses: 4 (very spiritual) to 1 (Not spiritual)
<b>Control Variable</b>				
Race/ethnicity	Self-report		0 = Black 1 = White	Collected at baseline assessment by the RA
<b>Patient Characteristics (variables used for descriptive purposes)</b>				
Gender	Self-report	Demographic form of parent study	0 = Male 1 = Female	Collected at baseline assessment by the Research Assistant
Age			Continuous	
Education			Categorical	
Difficulty paying for meds in past 6 months?		Comprehensive Medication Review	Categorical 0 = No 1 = Yes	Collected at baseline assessment by the PharmD.
No. of medications	Chart/Med Record	Comprehensive Medication	Continuous	Documented by PharmD and verified electronically

		Review		medical records review
Social support	Self-report	TIES (adapted)	1 = High Support 0 = Low Support	Scores at median or higher on the adapted TIES measure will be 'high social support'. Scores below median will constitute low.
Active coping	Self-report	JHAC12	1 = High Active 0 = Low Active	Scores $\geq$ median connotes 'high active coping'. Scores $<$ median constitute low.

<sup>a</sup>**Source acronyms:** *Morisky* (Morisky Compliance Assessment scale); *DUREL* (Duke University Religion Index); *SHLCS* (Spiritual Health Locus of Control scale); *TIES* (Tangible, Informational, Emotional, Social Support scale); *JHAC12* (John Henryism Active Coping scale)

## Definition of Dependent Variable

**Medication Adherence:** Adherence was measured using the Morisky self-report questionnaire that was administered during the baseline assessment with the clinical pharmacist. Response scores were recoded and dichotomized to “adherent” and “non-adherent,” where a score  $< 4$  was categorized as non-adherent to medication regimen(s). That is, nonadherence was defined as a “yes” answer to one or more of the four questions on the Morisky scale. Adherent to medications was defined as a “no” answer to every question (score = 4). Patients who answered “yes” to one or more of the Morisky items were viewed as possibly having problems with medication adherence.<sup>262</sup>

## Definition of Independent Variables

**Spirituality/Religiosity:** To capture spirituality/religiosity, subscales from three different measures were used: the Duke University Religion Index (DUREL), the Spiritual Health Locus of Control Scale (SHLCS), and the one-item measure of overall self-ranking of spirituality. From the DUREL, organized religious activity (ORA), non-organized religious activity, (NORA), and intrinsic religiosity (IR) were measured. The ORA subscale asks participants to indicate how often they attend church or other religious meetings; responses range from “never” to “more than once/wk.” The ORA variable was dichotomized as high ORA (attendance  $\geq$  few times a month) and low ORA ( $\leq$  a few times a year). The NORA

subscale asks participants how often they spend time in private religious activities, such as prayer, meditation or Bible study. The NORA variable was dichotomized to high NORA ( $\geq$  two times/week) and low NORA ( $\leq$  once a week). The IR subscale is measured with three items on the DUREL that ask participants to mark the extent to which each of the following statements is true or not true: “In my life, I experience the presence of the Divine (i.e., God); “My religious beliefs are what really lie behind my whole approach to life”; and “I try hard to carry my religion over into all other dealings in life.” Item responses range from definitely true (4) to definitely not true (0). Total scores on the IR subscale were dichotomized at the sample’s median to categorize participants into high and low intrinsic religiosity groups. These subscales have previously been dichotomized in the literature.

The Spiritual Health Locus of Control Scale measures active spiritual (11 items) and passive spiritual beliefs (2 items). Item responses for these subscales range from 4 (strongly agree) to 1 (strongly disagree). Each of these variables was recoded to be dichotomous. Total scores for both the active and passive spiritual dimensions were dichotomized at the sample’s median to categorize participants into the high and low spiritual groups. Currently, there is no established cut-off score for the active and passive subscales; in previous work the scores have been both measured continuously and dichotomized at a median split (however, a median split in one sample does not necessarily correlate to another –thus, the scoring system was reevaluated for the main study for meaningful cut-offs).<sup>160,279,280</sup> (Dr. Cheryl Holt, personal communication, February 16, 2011). This measure is being further evaluated by the developers for confirmation of its factor structure and for establishment of the scale’s scoring scheme.

**Self-ranking of spirituality:** A categorical variable measured from a one-item question that asks participants to what extent they consider themselves to be spiritual/religious. Responses range from 4 (very spiritual/religious) to 1 (not

spiritual/religious at all). This variable was recoded to be dichotomous: high spirituality (1) and low spirituality (0). High spirituality consisted of responses of either 4 (highly spiritual/religious) or 3 (moderately spiritual/religious) and low spirituality consisted of responses of either 2 (slightly spiritual) or 1 (not spiritual at all).

All of the following variables were collected by the research assistant on the demographic form during the baseline assessment, except where noted.

**Control Variable: (only one, due to small sample size of pilot study)**

**Race:** Two-category variable indicating the best description of the participant's self-reported racial/ethnic background (either Black or White).

**Patient characteristics.** The following patient characteristics were examined for descriptive purposes in the pilot study. These characteristics were considered as potential control variables to be used in analysis for the larger study (aims 2 and 3).

**Gender:** This two-category variable (male or female) was taken from the demographic form of the parent study.

**Age:** A continuous variable indicating the participant's age in years at the time of the baseline assessment.

**Education:** A seven-category variable ranging from the highest grade or year of school completed (postgraduate work) to "never attended school or only attended kindergarten." An additional category included a response of "refuse to answer."

**Total number of prescribed medications:** Continuous variable measured on the BCMR (of parent study) by the clinical pharmacist. Total number of medications included any herbals, vitamins, and over-the-counter medications approved by the participants' prescribing physician(s).

**Difficulty paying for medication:** Two-category variable (yes/no) indicating whether the participant needed prescription medication over the past six months but could afford it, taken from the BCMR completed by the clinical pharmacist.

**Social support with medications:** Measured from items adapted from the TIES survey and consisting of three categories that indicate how often the participant has sufficient support with health and medication-taking. Support includes anyone other than the participant's primary health care provider. Responses to the items include "all or most of the time," "some of the time," and "none of the time," with corresponding item scores of 2, 1, and 0, respectively. Responses to all seven items were summed to create a total social support score ranging from 0 to 14 and were recoded as dichotomous (high or low support). Total scores for this adapted version of TIES were dichotomized at the sample's median which was a score of 11. The TIES measure has previously been dichotomized at a median split by the developers.<sup>281</sup> However, this was an adapted version of the original TIES, and use of this unvalidated version and its scoring scheme was further considered for the main study (aims 2 & 3).

**Active coping:** Dichotomous variable indicating high and low active coping, measured via the John Henryism Active Coping scale (JHAC12), a 12-item self-report measure. The active coping score is the sum of the values assigned to each of the 12 responses. In keeping with the methodology proposed by the developers and other researchers who have used the JHAC12 measure, scores were dichotomized at the sample median, which was a score of 50 for the pilot study, to categorize respondents into "high" and "low" active coping groups.<sup>260,271,282-284</sup>

## **Aim 1 Analysis**

### **Overview**

Results from Aim 1 helped determine the spiritual variable(s) that were used in aims 2 and 3 (to test for the association between spirituality and medication adherence and spirituality and blood pressure, respectively). A cross-sectional analysis of data collected during the baseline visit (i.e., the spirituality/religiosity surveys, social support and active coping measures, patient demographics, and adherence behavior) was conducted. Prior to conducting analyses, three criteria were determined as the basis for selecting the primary spiritual measure to use in the larger study. It was also determined a priori that these criteria would be examined collectively. However, the ultimate decision for selection of the measure would be based on sample size efficiency.

Criteria for selecting the key spiritual variable(s) for hypothesis testing involved examining (1) the internal consistency of the different spiritual instruments and comparing these instruments to the one-item self-ranking of spirituality measure, (2) the odds ratios (effect sizes) of each spiritual variable on adherence, and (3) the required sample sizes for each spiritual variable, based on the effects observed in the pilot study. A threshold of 0.70 was set for the internal consistency criterion. A Cronbach's  $\alpha$  value greater than 0.70 is generally desired and typically connotes acceptable overall scale reliability in the medical and social science fields.<sup>285,286</sup> If all measures had acceptable reliability, the observed effect sizes (odds ratios) in relation to adherence would be the next determining factor. Given that this was an exploratory study, it was of interest to examine which spiritual measure produced the largest detectable effect in relation to adherence. Although a test of significance of the spiritual measures in relation to adherence was not of primary concern given the pilot's small sample, it was considered an added benefit. Overall, sample size efficiency was of the upmost importance in the selection process. Due to the limited



resources for this project, a sample size that would yield adequate power and would be feasible for primary data collection was considered essential.

### **Statistical Analyses**

For Aim 1, the outcome variable was medication adherence as measured by a validated self-report instrument.<sup>262</sup> The independent spiritual variables were (1) organized religious activity, (2) non-organized religious activity, (3) intrinsic religiosity (all measured via DUREL); (4) the active spiritual and (5) passive spiritual dimensions of the SHLCS; and (6) the 1-item self-reported spiritual/religious measure (Table 2). Given the small size of the pilot study, race was the only control variable used in the logistic regression analyses.

Racial/ethnic differences in medication adherence have been observed across various chronic conditions,<sup>84,85,287</sup> where Blacks have been shown to be less adherent than Whites; accordingly race has been suggested as one of the strongest and most consistent predictors of adherence (even within elderly populations).<sup>82,84,90,288-290</sup> Although race was used as the main control variable in the pilot study's analyses, other patient characteristics (age, gender, education, number of medications, and difficulty obtaining medications due to cost) were examined for descriptive purposes and to explore as potential covariates for the larger study. These characteristics were selected a priori because they have been suggested to be correlates of medication adherence in older populations, although this suggestion has not been consistently verified.<sup>19,21,82,103,290-294</sup>

All data were entered into the study database using Microsoft Access and cleaned for missing or nonsensical values prior to analyses. Next, data were converted to STATA 11 (StataCorp LP, 2009) for analyses. Descriptive statistics were calculated for all variables. Bivariate relationships with medication adherence were examined using chi-square statistics for categorical variables and t-tests for continuous variables. Chi-square statistics were calculated for the cross-tabulation of adherent versus nonadherent patients and categorical

variables. Standard two-tailed *t*-tests were conducted to test the association between adherent versus nonadherent patients and the continuous variables. Because of the small sample size of the pilot study, no definitive conclusions about significance of these analyses were made. Bivariate relationships were not assessed to draw meaningful conclusions from the results themselves but rather to examine the trends and potential impact of the spiritual variables on medication adherence. Results were examined to assess whether the adherence outcome differed across the spiritual variables. Logistic regression models were conducted to examine, after adjusting for race, how each spiritual variable was related to whether patients reported being adherent to their prescribed medications.

In the multivariate analyses, five separate logistic regression models were constructed to examine the relationship between the spiritual variables and adherence while adjusting for race: three regressions for the DUREL subscales, one regression for the two SHLCS dimensions, and one model for the one-item overall self-ranking of spirituality measure. DUREL's developers do not recommend summing all three subscales into a total overall religiosity score but instead suggest that investigators examine each subscale score independently in separate regression models to prevent subscale scores canceling out each other's effects.<sup>257</sup> The dimensions of the SHLCS have previously been run in the same model to control for the effects of each dimension (Dr. Cheryl Holt, personal communication, February 16 and March 8, 2011).<sup>160,258,263,268</sup> The one-item overall self-ranking of spirituality variable was run as its own regression model while controlling for race.

After obtaining the logistic regression estimates of the spiritual variables on adherence while controlling for race, sample size estimations were generated from power analysis using SAS 9.2 (SAS Institute Inc, Cary, NC). To power the larger study, selection of the spiritual measure(s) that were used as the independent variables for hypothesis testing

in aims 2 and 3 was based on examination of the performance of each measure, the effects observed in relation to adherence, and the feasibility of the sample size.

## **Aim 1 Results: Pilot Study**

### **Overview**

The pilot study was conducted to determine the spiritual variable(s) to be used in aims 2 and 3. Because Aim 1 helped inform the design of the larger study, the pilot study results (descriptive statistics, bivariate analyses, and logistic regression models predicting medication adherence) are presented prior to the description of method for aims 2 and 3. They are based upon the hypertensive patients enrolled in the parent study.

### **Descriptive Data: Characteristics of Hypertensive Patients**

Because older adults with hypertension were the population of interest for hypothesis testing in aims 2 and 3, patient characteristics for the subset of hypertensive patients (N = 62) for the pilot study are presented in Table 3. A total of 73 older adult participants enrolled in the parent study; of these, the majority (62, 85%) had hypertension. The mean age of this subset was 75.0 (SD = 6.4); 58% were women; and 29% identified themselves as Black/African American. The majority were married and highly educated, and most had had high active coping and social support scores. The mean number of chronic health conditions was 8 (median = 8.5) and the mean number of medications was 14 (median = 13). Only one (1.6%) hypertensive patient answered “yes” to the question “Was there a time in the past 6 months when you needed prescription medication but could not purchase it because of the cost?”. In addition, only two patients reported lacking prescription drug coverage at the time of consent. Fifty-seven percent of patients were nonadherent to prescribed medications (score < 4 on Morisky four-item). The most common reasons for nonadherence were forgetting to take medicines (82.9%) and occasional carelessness (37.1%).

Spiritual characteristics of the study sample are presented in Table 4. When patients were asked to rank their spirituality, 46 (74%) reported being moderately to very spiritual/religious; 35 (56%) attended church (or other religious meeting) a few times a month or more; and 10 (16%) reported never attending church or religious meetings. Half of the patients reported spending time in private prayer or meditation two or more times a week and 21 (34%) patients reported rarely or never spending time in private religious activities. The majority of patients (37, 60%) had high intrinsic religiosity. On the intrinsic religiosity subscale, the majority (71%) reported that their religious beliefs underlie their whole approach to life and 73% reported carrying their beliefs over into all other dealings in life. Similarly, more than half (56%) had high active spiritual locus of control beliefs and only 17% had high passive spiritual locus of control beliefs.

**Table 3. Characteristics of Hypertensive Patients (N = 62) in Aim 1**

<b>Characteristics</b>	<b>Hypertensive sample (N = 62) No. (%) unless otherwise specified</b>
<b>Age</b> , mean (std. deviation), range	75.0 ( $\pm$ 6.4), 66–92
<b>Women</b>	36 (58.1)
<b>Race</b>	
Black	18 (29.0)
White	44 (71.0)
<b>Marital status</b>	
Never married	3 (4.8)
Married	39 (62.9)
Widowed	16 (25.8)
Divorced	3 (4.8)
Separated	1 (1.7)
<b>Education</b>	
Grades 1-8 (Elementary)	4 (6.5)
Grades 9-11 (Some high school)	5 (8.1)
Grades 12 or GED (High school grad)	10 (16.1)
College 1 to 3 years (some college)	23 (37.1)
College 4 years (College graduate)	11 (17.7)
Postgraduate work	9 (14.5)
<b>No. of medications</b> , mean (range)	14.1 (5–30)
<b>No. chronic conditions</b> , mean (range)	8.3 (3–14)
<b>Could not purchase Rx b/c of cost</b>	1 (1.6)
<b>Chronic health conditions</b>	
Hyperlipidemia	46 (74.2)
Diabetes	30 (48.4)
<b>Active coping score</b> , mean (std. deviation), range	49.3 (7.0), 23–60
Low active coping (< 50, median score)	27 (43.6)
<b>Social support</b> , mean (std. deviation), range	10.4 (3.5), 1–14
Low social support (< 11, median score)	27 (43.5)
<sup>a</sup> <b>Adherence</b> (score 4 = adherence)	
Adherent (scored 4 on Morisky)	27 (43.6)
Non-adherent (scored < 4 on Morisky)	35 (56.5)

<sup>a</sup>Because this patient population had pre-existing medication-related issues, adherence was coded strictly with a cutoff of 4 on the Morisky (score < 4 = nonadherent).

**Table 4. Spiritual Characteristics of Patients (N = 62) in Aim 1**

<b>Characteristic</b>	<b>Frequency (%)</b>
<b>Self-ranking of spirituality<sup>a</sup></b>	
High (moderately to very spiritual/religious)	74.2
Low (not at all to slightly spiritual/religious)	25.8
<b>ORA (frequency of church attendance)<sup>b</sup></b>	
≥ a few times per month	56.5
≤ a few times per year	43.6
<b>NORA (private religious activity, e.g., prayer, meditation)<sup>b</sup></b>	
(≥ two times/week)	50.0
(≤ once/week)	50.0
<b>Intrinsic (internalization of and commitment to religious beliefs)<sup>b</sup></b>	
High (≥ 10, sample median)	59.7
Low (< 10, sample median)	40.3
<b>Active spiritual (God empowers one to take healthy actions)<sup>c</sup></b>	
High (≥ 28, sample median)	55.8
Low (<28, sample median)	44.2
<b>Passive spiritual (God or higher power is in control of health)<sup>c</sup></b>	
High (> 4 score on 2 items)	17.3
Low (< 4 score on 2 items)	82.7

<sup>a</sup>One-item measure of the extent participants consider themselves spiritual/religious. <sup>b</sup>DUREL subscale.

<sup>c</sup>SHLCS; sample totals (active and passive spiritual) are < 62 due to missing data. The SHLCS instrument was administered after the study had begun and 12 patients had been enrolled, so SHLCS was administered to only 52 patients.

## **Bivariate Results**

Table 5 shows the differences in spiritual variables and patient characteristics by adherent and nonadherent patients. Overall, no significant differences in adherence were found by whether patients had high or low scores across the spiritual variables (i.e., ORA, NORA, intrinsic religiosity, self-ranking of spirituality, active and passive spiritual locus of control beliefs). The percentage of patients who had high intrinsic religiosity and reported being adherent was similar to the percentage who had low intrinsic religiosity and were adherent (43.2% vs. 44.4%). Notably, a higher percentage of patients who self-reported high spirituality were adherent compared to those who reported being slightly or not at all spiritual (50% vs. 25%). Similarly, 48% of the patients who had high active spiritual locus of control beliefs reported being adherent compared to 39% of patients who reported having low active spiritual health locus of control beliefs and being adherent. A higher percentage of patients with high passive spiritual locus of control beliefs reported being adherent than those with low passive spiritual beliefs who were adherent (56% vs. 42%).

No significant differences across age, race, gender, or education were found in the pilot study in terms of patient adherence. However, those reporting being adherent were slightly older (mean age = 76.7 vs. 73.7 years). A higher percentage of females than males reported being adherent (47.2% vs. 38.5%) and a higher percentage of Whites than Blacks reported being adherent (50% vs. 27.8%). Furthermore, a higher percentage with less than a college education reported being adherent than those with some college or more (57.9% vs. 37.2%).

**Table 5. Medication Adherence (Morisky Score of 4 = Adherent) by Spiritual Variables and Characteristics of Patients with Hypertension (N = 62) in Aim 1**

Medication Adherence <sup>a</sup>			
Variables	Adherent (n=27) Frequency (%)	Nonadherent (n=35) Frequency (%)	p value
<b>Spiritual independent variables</b>			
<b>DUREL (N=62)</b>			
ORA (church attendance)			
High ( $\geq$ few times/mth)	16 (45.7)	19 (54.3)	0.70
Low ( $\leq$ few times a year)	11 (40.7)	16 (59.3)	
NORA (private prayer)			
High ( $\geq$ 2 times/week)	13 (41.9)	18 (58.1)	0.80
Low ( $\leq$ once a week)	14 (45.2)	17 (54.8)	
Intrinsic (commitment to beliefs)			
High ( $\geq$ 10, sample median)	16 (43.2)	21 (56.8)	0.95
Low ( $<$ 10, sample median)	11 (44.4)	14 (56.0)	
<b>1-Item measure of spirituality (N=62)</b>			
Self-ranking of spirituality			
High (moderately to very spiritual)	23 (50.0)	23 (50.0)	0.07 <sup>b</sup>
Low (slightly to not spiritual at all)	4 (25.0)	12 (75.0)	
<b>SHLCS (N=52)<sup>c</sup></b>	<b>(n=23)<sup>c</sup></b>	<b>(n=29)<sup>c</sup></b>	
Active spiritual locus of control			
High ( $\geq$ 28, sample median)	14 (48.3)	15 (51.7)	0.51
Low ( $<$ 28, sample median)	9 (39.1)	14 (60.9)	
Passive spiritual locus of control			
High ( $>$ 4 score of 2 items)	5 (55.6)	4 (44.4)	0.45 <sup>b</sup>
Low ( $<$ 4 score of 2 items)	18 (41.9)	25 (58.1)	
<b>Patient characteristics (N = 62)</b>			
<b>Age, mean (std dev)</b>	76.7 (6.3)	73.7 (6.3)	0.06
<b>Race</b>			
Black	5 (27.8)	13 (72.2)	0.11
White	22 (50.0)	22 (50.0)	
<b>Gender</b>			
Male	10 (38.5)	16 (61.5)	0.49
Female	17 (47.2)	19 (52.8)	
<b>Education</b>			
Less than college	11 (57.9)	8 (42.1)	0.13
Some college or more	16 (37.2)	27 (62.8)	
<b>No. of medications, mean (std dev)</b>	13.4 (5.6)	14.7 (4.8)	0.33

<sup>a</sup>Significance level of the chi-square statistic for categorical variables, two-tailed *t*-test for continuous variables: \**p* < 0.05. <sup>b</sup>Fisher's exact test was performed and *p*-value reported when the cells reached an expected frequency of  $\leq 5$ . <sup>c</sup>Totals for the SHLCS variables are < 62 due to missing data; the SHLCS instrument was administered after the study had begun and 12 patients had been enrolled.



## Internal Consistency of Spiritual Measures

The internal consistencies (reliability) of the various spiritual instruments were examined using Cronbach's  $\alpha$ . This test statistic is used to examine whether several items that propose to measure the same general construct produce similar scores (i.e., how well the different items hang together). Internal consistency ranges between 0 and 1 and a coefficient of 0.70 or higher is acceptable in most social science research.<sup>286</sup> Table 6 reveals the Cronbach's  $\alpha$  reported in the literature for the validated measures (DUREL and SHLCS) and also the Cronbach's  $\alpha$  that were calculated for the different measures (where applicable) in this pilot study sample.

It is not recommended to obtain a single composite score for DUREL and SHLCS<sup>257</sup> (Cheryl Holt (developer), personal communication, February 16, 2011) but rather to explore the subscales independently. However, some researchers have used single composite scores for these instruments and have reported the Cronbach's  $\alpha$  (Table 6). The  $\alpha$  reported in the literature for DUREL range from 0.78 to 0.91. For this study sample the DUREL (when examined as one scale) had a Cronbach's  $\alpha$  reliability of 0.87, which falls in the range reported in the literature.<sup>257</sup> For the SHLCS, Cronbach's  $\alpha$  reported in the literature range from 0.66 to 0.78 for the active spiritual subscale and 0.51 to 0.76 for the passive subscale.<sup>258,268,279</sup> The calculated Cronbach's  $\alpha$  for this study sample was a little higher than those reported for the active and passive subscales (0.90 and 0.82, respectively). Because Cronbach's  $\alpha$  cannot be calculated for individual items, it is not reported for the one-item measure assessing overall self-ranking of spirituality.

**Table 6. Reliability of Spirituality Measures (Cronbach's  $\alpha$ ) used in Aim 1**

Measure <sup>a</sup>	Reported $\alpha$ in literature	Calculated $\alpha$ for study sample
<b>DUREL</b>		
ORA (1 item) + NORA (1 item)	0.57–0.79	0.66
Intrinsic religiosity (3 items)	0.75–0.94	0.88
Single composite index	0.78–0.91	0.87
<b>SHLCS</b>		
Active spiritual (11 items)	0.66–0.78	0.90
Passive spiritual (2 items)	0.51–0.76	0.82
Single composite index	Blacks = 0.80 Whites = 0.89	0.89
<b>Self-ranking of spirituality<sup>b</sup></b>	---	---
Single item	---	---

<sup>a</sup>Measure acronyms: *DUREL* (Duke University Religion index); *SHLCS* (Spiritual Health Locus of Control scale).

<sup>b</sup>The self-ranking of spirituality measure could not be examined for reliability because it is a 1-item measure.

### Logistic Regression Models

Logistic regression was performed to determine the effect of each spiritual variable on medication adherence after controlling for race (Table 7). Five separate logistic regression models were constructed in order to assess the relationship between each spiritual variable and self-reported medication adherence.

#### DUREL subscales (ORA, NORA and Intrinsic Religiosity)

Three separate logistic regression models were performed to examine the relationships between (1) organized religious activity and adherence, (2) nonorganized religious activity and adherence, and (3) intrinsic religiosity and adherence. Consistent with the literature and the recommendations of by the developers of the DUREL instrument, each subscale was examined independently in separate regression models to inhibit subscale scores canceling out each other's effects.<sup>257</sup> After controlling for race, none of the DUREL subscales were significant at the  $p < 0.05$  level. However, a positive relationship with adherence was seen for organized religiosity (OR = 1.79; 95% CI 0.58–5.46), non-organized religiosity (OR = 1.05; 95% CI 0.37–2.99), and for intrinsic religiosity (OR = 1.41; 95% CI,

0.46–4.34), where patients with high religiosity had higher odds of reporting adherence than those with low religiosity.

### **Spiritual health locus of control subscales (active spiritual and passive spiritual)**

One logistic regression to evaluate the effects of SHLC (active spiritual and passive spiritual) on medication adherence included both dimensions while controlling for race; the dimensions of the SHLCS have previously been run in the same model to control for the effects of each dimension<sup>160,258,263,268</sup> (Cheryl Holt, personal communication, February 16, 2011). To ensure that there were no issues of collinearity when including these dimensions in the same regression model, the variance inflation factor (VIF) and tolerance (1/VIF) values were examined (a variable whose VIF values are > 10 may merit further investigation to rule out linear combination of other independent variables). The VIF and tolerance (1/VIF) values for active spiritual were 1.22 and 0.82 and for passive spiritual the VIF was 1.04 and the tolerance value was 0.96. These results suggest that no issues of collinearity arise from including these dimensions in the same model.

After controlling for race, neither the active nor passive spiritual locus of control dimensions were significant at the  $p < 0.05$  level. However, a positive relationship with adherence was seen for the active spiritual dimension (OR = 2.77; 95% CI 0.77–10.04), which suggests that patients with high active spiritual locus of control beliefs are more likely to report being adherent to their medications. Interestingly, the same trend was seen for the passive spiritual dimension, which suggests that patients who believe that a higher power is in control of their health are more likely to report being adherent (OR = 2.66; 95% CI, 0.52–13.52).

### **Self-ranking of spirituality**

A separate logistic regression (using the one-item measure of spirituality) was performed to evaluate the effect of patients' self-ranking of their spirituality on medication

adherence. After controlling for race, self-ranking of spirituality was significant in relation to self-reported adherence ( $p = 0.04$ ). Patients who rated themselves as highly spiritual had higher odds of reporting adherence to their medications than those with low spirituality (OR = 4.12; 95% CI 1.09–15.61).

### **Estimated Sample Sizes**

Another purpose of the pilot study (Aim 1) was to determine the sample size to sufficiently power the study in Aim 2, which tested the hypothesis that hypertensive older adults who report being highly spiritual are more likely to report being adherent to their anti-hypertensive medication(s) than those who report low spirituality. In order to calculate the necessary sample size, three values were required: (1) significance level ( $\alpha$ ), (2) desired power, and (3) effect size. The pilot data were used to estimate the population distribution of the variables used in the logistic regression models. The  $\beta$  coefficients (estimates) and standard errors for each spiritual variable (Table 7) were then used to determine the required sample size to test for the effect observed in the pilot study at 80% power and a 0.05 significance level. It is generally accepted that power should be 0.80 or greater.<sup>295</sup> That is, there is an 80% chance of finding a significant effect that actually exists. Also, an alpha level of less than 0.05 is commonly accepted in most social science fields as statistically significant.<sup>295</sup> Sample calculations were based on the assumption that the sample in Aim 2 would be similar to the population distribution of the variables observed in Aim 1 (the pilot study). The sample size calculations were performed in SAS 9.2 (SAS Institute, Cary, NC).

Results of the sample size calculations for the DUREL subscales range from 472 to 61,343; this is the number of subjects needed to test for the effects observed for organized, non-organized, and intrinsic religiosity with a power of 0.80 and an alpha of 0.05. The estimated sample sizes needed for the active and passive spiritual subscales from the SHLCS were calculated to be 170 and 295, respectively. For the self-ranking spirituality

measure, the sample size calculation estimated that a total of 113 subjects would be needed to test an odds ratio of 4.12 with a power of 0.80 and an  $\alpha$  of 0.05.

**Table 7. Adjusted Logistic Regression Models for Medication Adherence and Sample Size**

<b>Spiritual Variables<sup>a</sup></b>	<b>OR<sup>b</sup></b>	<b>95% CI</b>	<b><math>\beta</math> Estimates (SE)</b>	<b><i>p</i> value<sup>c</sup></b>	<b>Sample Size (power=0.80, <math>\alpha</math>=0.05)</b>
<b><i>DUREL</i></b>					
ORA	1.79	0.58–5.46	0.58 (0.57)	0.31	472
NORA	1.05	0.37–2.99	0.05 (0.53)	0.93	61343
IR	1.41	0.46–4.34	0.34 (0.57)	0.55	1358
<b><i>SHLCS</i></b>					
Active	2.77	0.77–10.04	1.02 (0.66)	0.12	170
Passive	2.66	0.52–13.52	0.98 (0.83)	0.24	295
<b><i>Self-ranking of spirituality</i></b>	<b>4.12</b>	<b>1.09–15.61</b>	<b>1.88 (0.84)</b>	<b>0.04</b>	<b>113</b>

<sup>a</sup>DUREL: Duke University Religion index; SHLCS: Spiritual Health Locus of Control scale. The logistic models consisted of three separate models for the DUREL subscales and a model that contained the two SHLCS dimensions; the self-ranking of spirituality measure was run in its own model. <sup>b</sup>Each logistic regression model was adjusted for race. <sup>c</sup>Significance level of odds ratio;  $p < 0.05$  was significant.

### Selection of Spiritual Measure(s) for Aims 2 & 3

Table 8 includes a summary of the selection criteria and results of Aim 1 that helped inform the design of the larger study.

**Table 8. Summary of Criteria for Selecting Spiritual Measure to Use in Aims 2 and 3**

Criteria	Cronbach's $\alpha$ Calculated (literature)	Effect on Adherence (odds ratios; 95% CI)	Sample Size Efficiency
<b>Measures<sup>a</sup></b>	$\sqrt{\phantom{x}}$		
<b>DUREL</b>			
ORA (1 item)	----	1.79 (0.58–5.46)	472
NORA (1 item)	----	1.05 (0.37–2.99)	61343
Intrinsic (3 items)	0.88 (0.75–0.94)	1.41 (0.46–4.34)	1358
Composite index	0.87 (0.78–0.91)		
<b>SHLCS</b>		$\sqrt{\phantom{x}}$	$\sqrt{\phantom{x}}$
Active spiritual (11 items)	0.90 (0.66–0.78)	2.77 (0.77–10.04)	170
Passive spiritual (2 Items)	0.82 (0.51–0.76)	2.66 (0.52–13.52)	295
Composite index	0.89 (0.80–0.89)		
<b>Self-ranking of spirituality</b>		$\sqrt{\phantom{x}}$	$\sqrt{\phantom{x}}$
Spirituality (1-item)	----	4.12 (1.09–15.61)	113

<sup>a</sup>DUREL: Duke University Religion index; SHLCS: Spiritual Health Locus of Control scale.

The first criterion for selecting the key spiritual variable for hypothesis testing was the scales' reliability. In addition to calculating the Cronbach's  $\alpha$  for the current study sample for each spiritual instrument, the literature was reviewed for reported Cronbach's  $\alpha$  for the validated measures (DUREL and SHLCS). When examining the internal consistency of each spiritual measure, the Cronbach's  $\alpha$  were all above 0.70 which connoted good reliability of the items on each scale (in addition to the Cronbach's  $\alpha$  reported in the literature for the DUREL and SHLCS subscales). Each measure showed good homogeneity with Cronbach's  $\alpha$  above 0.80 for this study sample. Although a Cronbach's  $\alpha$  could not be obtained for the one-item self-ranking of spirituality variable, it was examined in relation to the other

measures via cross-tabulation; results were comparable and consistent with participants' responses on those measures.

The second criterion for selecting the key spiritual variable was the observed effect of each spiritual variable on adherence in the logistic regression analysis. As conceptualized, the high spiritual characteristics (i.e., organized, non-organized, and intrinsic religiosity; active spiritual health locus of control beliefs, and self-ranking of spirituality) demonstrated a positive trend in relation to adherence for this study sample. The smallest effects in relation to adherence were observed for the DUREL subscale measures (ORA, NORA, and intrinsic religiosity) with odds ratios ranging from 1.05 to 1.79. This relationship may suggest that religious involvement or external expression of spirituality may not benefit or determine whether a patient decides to be adherent. Although the spiritual health locus of control beliefs were not significantly associated with adherence, they had greater observed effects than the DUREL subscales did in that patients who reported high spiritual health locus of control beliefs were on average twice as likely to report being adherent. These results suggest that the role of God or some Supreme Power in individuals' health may be influential in their decisions to adhere to their prescribed regimens and to stay healthy by other means. The largest observed effect, and the only significant association, was seen with the one-item self-ranking of spirituality variable: the odds ratio was 4.12 (95% CI 1.09–15.61). The confidence interval, which was large for this variable, is most likely due to the small sample size. However, these results seem to indicate that the level of perceived spirituality is more associated than the other spiritual measures with self-reported adherence.

Sample size efficiency was also a criterion for selection of the key spiritual measure used for aims 2 and 3. These sample sizes were calculated based on the effects and standard errors observed in the pilot at a significance level of 0.05 and a power of 0.80. The

DUREL subscales required the largest and least feasible sample sizes (range 472 to 61,343) for the purposes of the present study. The most feasible sample size was calculated for the self-ranking of spirituality variable; results estimated that a total of 113 subjects would be needed to test for the effects observed in Aim 1 at a power of 0.80 and an  $\alpha$  of 0.05. The next feasible sample size, for the active spiritual locus of control dimension, was 170 (required).

Considering these results collectively, the one-item self-ranking of spirituality measure was chosen as the key spiritual variable to examine in relation to adherence (Aim 2) and blood pressure (Aim 3). This variable was chosen after careful consideration because it is a concise measure but also, as suggested by the Fetzer Institute and the National Institute on Aging, one of the important domains of spirituality for health research.<sup>259</sup> In addition, the self-ranking of spirituality measure captures the broader phenomenon of spirituality in comparison to the other validated measures, allows inclusiveness of both the spiritual and religious context of individuals, and allows participants to frame the construct within their own experience and to the aspects of spirituality that are relevant for them. For example, although the DUREL is a brief instrument, it focuses on religiosity (i.e., outward expressions of spirituality). The population of interest for the present study (older adults) may be highly spiritual, even if they do not frequently participate in religious activities or consider themselves religious, this would inhibit the capture of their overall self-ratings of spirituality and its effect on their adherence. In other words, one's personal awareness or perceived spiritual state may be more important to health and behaviors than outward expressions of spirituality or connections with a religious group are. Due to the broad and inclusive nature of this measure and its relevance to the study population, the one-item self-ranking of spirituality was judged to be most suitable measure to use as the key spiritual variable.



Moreover, a basic cross-tabulation of the self-ranking of spirituality measure with each of the other spiritual measures showed that self-ranking of spirituality was highly related to spiritual practices and beliefs of the older adults in this study. For example, of the patients with high ORA, 89% also reported high spirituality. Similarly, patients with high NORA and high intrinsic religiosity, and those with high active spiritual locus of control beliefs, also reported themselves of high spirituality (94%, 95%, and 86%, respectively). This result suggests that perceived spiritual intensity may be a suitable indicator of other spiritual characteristics and beliefs or that it may provide a foundation marker for other domains of spirituality.

Finally, the self-ranking of spirituality measure had the largest observed association with adherence and the most efficient required sample size. It is important to note, however, that the effect ( $OR = 4.12$ ) observed for the self-ranked spirituality measure was large and may be imprecise (or an overestimation of the effect), as evidenced by the large confidence intervals. This result may be attributed to the small sample size in the pilot study. Therefore, to be conservative and to avoid overestimation, the observed effect size for the self-reported spirituality variable was arbitrarily decreased by 10% and 25%. At a decrease of 10%, an estimated sample of 133 subjects was needed to maintain a power of 0.80, whereas a 25% decrease resulted in a total of 142 subjects to maintain a power of 0.80.

Although a conservative sample of 142 subjects would provide enough power to detect the relationship between the self-ranking of spirituality measure and adherence, further consideration was given to this estimated sample size. Because self-ranking of spirituality is only a 1-item measure and would provide limited information regarding the participants' spiritual alignment and beliefs, it was believed that the sample size should be further increased to include a secondary measure of spirituality. Inclusion of a secondary measure would provide support for the associations observed with the 1-item measure and

additional information regarding the participants' spiritual beliefs. Thus, the active SHLC subscale was selected as the secondary measure of spirituality to use in the main study, and the sample size needed to observe an effect on that instrument was estimated to be 170. Thus, the sample size of 142 was further increased to account for the inclusion of this second instrument. Furthermore, both the primary and secondary measures aligned with the definition of spirituality used for this study and did not solely focus on religiosity or worship service attendance as has been most often used in prior studies examining spirituality in relation to health and behaviors.

Thus, it was determined that 170 community-dwelling older adults with hypertension would be surveyed for aims 2 and 3. These samples were estimated to provide sufficient power to test the association between the self-ranking of spirituality measure and self-reported adherence and to allow for control variables other than race (e.g., social support and active coping) in the regression analyses. In addition, the active dimension of the validated SHLCS was chosen as a secondary measure of spirituality. Results from the power analysis revealed that 170 subjects were required to detect the effect observed for the active spiritual dimension of this scale; in addition, this measure yielded the second-largest association with adherence in the pilot study. Therefore, a sample size of 170 subjects was chosen to allow the inclusion of additional control variables and to include a secondary measure of spirituality while maintaining a power of 0.80.

### **Summary of Other Study Findings**

Several other findings from the pilot project (Aim 1) helped inform the design of the larger study (aims 2 and 3). Descriptive results indicated that the pilot sample was well educated and that only one patient had been unable to purchase medication. Nonetheless, approximately 57% of the patients reported being nonadherent to their prescribed medications—a result that suggests other patient-level factors than access or

socioeconomic status may have influenced the adherence of patients in this study population. Similar results have been seen in the work of other researchers who found differences in adherence even after access to care and cost of medications were minimized.<sup>90,287,290,296</sup> It is important to note that the large percentage of patients who reported being non-adherent may be related to the type of patients who were enrolled in the parent study upon which Aim 1 (the pilot study) was based. The subjects of the parent study consisted of older patients who were referred to clinical pharmacists by their primary health providers for medication therapy management (MTM) services based on patient need and medication complexity. Furthermore, although the study sample consisted of patients with hypertension, the adherence measure (4-item Morisky instrument) was not specific to antihypertensive medications, which means that results may have been affected by patient reports of nonadherence to other medications (including acute therapies). Therefore, it was determined that a more specific and reliable measure of adherence should be used for aims 2 and 3.

With regard to the spiritual characteristics of the study sample, most of the patients (74%) reported being very to moderately spiritual and more than half (56%) believed that God empowers them to enact healthy behaviors or take an active role in their own health. The high spiritual culture found in this study sample is consistent with the distribution norms reported in the literature for the southern region of the United States and for patients who are chronically ill.<sup>25,39,162,168,257,297-299</sup> Although no significant relationships were found between the spiritual variables and adherence in the bivariate analyses, a higher percentage of patients with high spiritual characteristics (organized, non-organized, and intrinsic religiosity; self-reported spirituality, and active spiritual locus of control) reported being adherent to their regimens than patients with low spiritual characteristics. This trend is consistent with the project hypothesis that spirituality is positively associated with

adherence. Although no definitive conclusions can be drawn, these results strongly suggest that certain aspects or benefits of spirituality positively impact adherence in some patients. For example, patients who are more spiritual may use their spirituality to manage and cope with the demands taking chronic medications—much as previous studies have associated positive spiritual coping strategies with better health outcomes and other health-promoting behaviors.<sup>241,242,269,300,301</sup>

Self-ranking of spirituality was the only spiritual variable associated with adherence in the logistic regression analyses. After adjusting for race, patients who reported being moderately to very spiritual were more likely to be adherent to their medications than those who reported being slightly or not at all spiritual (95% CI 1.09-15.61). This result is consistent with the study hypothesis and corroborates previous studies that have shown positive associations between higher levels of spirituality and health promoting-behaviors.<sup>34,39,123,137,269</sup> For example, Mellins and colleagues (2009) used a similar measure of spirituality in a study of HIV-infected adults with both psychiatric and substance abuse disorders, with the main objective of examining factors associated with adherence to antiretroviral medications. In that study, researchers asked participants to rate on a 4-point Likert-type scale their level of spirituality/religiosity and found that lower self-reported spirituality was one of the factors significantly and consistently associated with nonadherence. The HIV-infected adults who reported high spirituality had better adherence to their antiretroviral medications than those who reported low spirituality (OR range 1.47–1.92;  $p < 0.01$ ).<sup>269</sup>

Patient characteristics that would be used as control variables in the larger study were the last group of variables to be considered. The majority of the patients in the pilot study had high active coping and high social support scores (both are established attributes/benefits of spirituality). That most of the patients reported high spiritual

characteristics may explain the high perceptions of social support and positive coping strategies, and upholds the conceptual framework for the present study.<sup>26</sup> In bivariate analyses, none of the demographic characteristics were significantly associated with self-reported adherence; however, patients who reported being adherent were slightly older, female, and White—all characteristics that have been noted in the adherence literature<sup>82,103,290,292,302</sup> and shown to be significantly related to spirituality.<sup>39,228,303,304</sup> Therefore, age, race, and gender were considered important demographic characteristics to include in the analysis of the larger study.

## **Conclusion**

The present study began with a limited examination of spiritual measures in relation to medication adherence among a sample of older adults with hypertension. The main purpose of this pilot study (Aim 1) was to select a suitable spiritual measure to use in examining the relationships between spirituality and adherence and the effect of spirituality on blood pressure (aims 2 and 3). The criteria for selecting the spiritual measure consisted of examining and comparing the reliability of the instruments, assessing which spiritual measure(s) had the largest detectable effect on adherence, and determining the sample size (using the effects observed in the pilot study) that would be feasible for conducting hypothesis testing.

Results revealed that each spiritual measure had fairly good homogeneity with a Cronbach's  $\alpha > 0.80$ . In addition, as conceptually hypothesized, each spiritual measure demonstrated a positive trend in relation to adherence. However, after adjusting for race in the logistic regression analysis, the one-item self-ranking of spirituality measure yielded the largest and only statistically significant effect on adherence and required the most feasible sample size that had been calculated in the power analysis (the next feasible sample size was calculated for the active SHLC measure). According to the results from this pilot study

and its relevance to the population of interest, it was determined that self-ranking of spirituality would be the key measure used in the larger study to examine in relation to adherence and blood pressure, and the active SHLC would function as a secondary measure. A conservative sample size of 170 community-dwelling older adults was calculated for the larger study to maintain a power of 0.80 as well as to allow for the inclusion of additional control variables and the second spiritual measure. The following sections describe the methods and results, and present a discussion of aims 2 and 3 (the second phase of the present study).

### **Aims 2 & 3 Methods**

**Aim 2: To examine the relationship between spirituality and self-reported medication adherence among community-dwelling older adults with hypertension.**

#### ***Hypothesis 2:***

- Older adults who report high spirituality versus those who report low spirituality are more likely to report being adherent to their anti-hypertensive medication(s).
- Older adults with high active spiritual health locus of control (SHLC) beliefs versus those with low active SHLC are more likely to report being adherent to their anti-hypertensive medication(s).

**Aim 2a: To examine the relationships among spirituality, social support, active coping, and self-reported medication adherence in community-dwelling older adults with hypertension.**

#### ***Hypotheses 2a:***

- Spirituality is positively associated with self-reported medication adherence, and this association is mediated through social support and active coping.

**Aim 3: To examine the relationship between spirituality and blood pressure among community-dwelling, older adults with hypertension.**

***Hypothesis 3:***

- Older adults who report high spirituality will have lower systolic and diastolic blood pressures compared to older adults who report low spirituality.

**Overview**

The study hypotheses for aims 2 and 3 were tested by conducting a cross-sectional study of a sample of community-dwelling older adults with hypertension. This study involved administering surveys on spirituality, social support, active coping, and medication adherence behavior to a convenience sample of 170 older adults visiting senior community centers in the Triangle area of North Carolina. Demographic characteristics and two blood pressure measurements were also collected from each participant. Data collection began in September 2011 and recruitment/enrollment of participants ended February 2012. The University of North Carolina Institutional Review Board (IRB) approved this study.

**Study Setting**

Participants were recruited from local senior community centers in the Research Triangle Park region of North Carolina. The center directors were contacted to obtain approval to solicit older adults who attend the center(s) for recruitment/enrollment. Four senior centers agreed to participate and they were located in the cities of Chapel Hill, Hillsborough (near Chapel Hill), Raleigh, and Garner (near Raleigh).

These senior center settings were targeted because the centers serve older adults from diverse socioeconomic and racial/ethnic backgrounds and are open to the general, independently living, older adult population aged 55 years and older. These centers were deemed feasible and efficient for capturing older adults who would be able to spend approximately 45 minutes completing the questionnaires. Senior centers in North Carolina

are community facilities that provide services and activities that meet the skills, interests, and needs of the older adult population. These services range from fitness and health promotion to job training. The centers also provide engagement opportunities for older adults through regularly scheduled programs, volunteer opportunities, and other activities, which makes them focal points for their attendees. Most of the centers provide programs/activities at no cost or for a minimal fee, as well as scholarships. According to a report prepared for the Division of Aging and Adult Services by the N.C. Department of Health and Human Services: "The principal goals of senior centers are to improve seniors' access to services that support independence in their later years, to provide a community setting for continuing engagement in meaningful activities, and to serve as a launch pad for advocacy about issues important to seniors."<sup>305</sup>

Targeting older adults at senior community centers rather than other settings such as medical clinics and/or hospitals was considered advantageous for several reasons. First, this population of older adults tend to live and function independently and are therefore more likely to be responsible for managing their own medications with minimal to no assistance. By contrast, clinics and/or hospitals may afford a sicker population of older adults who may already be receiving specialty care and assistance with their health and managing their prescribed medications. Second, targeting senior centers lessened recruitment challenges by eliminating the need to train and depend on medical staff to invite older adults to participate, and also because the reasons that older adults might be visiting medical clinics could include situations and/or conditions that could have influenced their survey responses. Finally, choosing senior centers throughout the Triangle area provided a racial, ethnic, and socioeconomically diverse sample because the site coordinators at the senior centers indicated that their clients are diverse in these areas.



Because the centers are open public spaces for seniors, actual demographic data is unavailable. However, the centers' coordinators and resource directors for seniors provided general characteristics of the seniors who participated in several health and wellness programs in 2012. The two centers in Orange County served more than 9,000 seniors in 2012. Approximately 69% were female, 71% were  $\geq 65$  years, and about 81% reported having a high school diploma or more. Most of the attendees were White (74%), with 13% identifying as Black and 12% as Other. The two Wake County centers served approximately 13,000 seniors in 2012. Of these, 84% were  $\geq 65$  years, 74% female, 58% White, and 29% Black. About 69% reported a high school diploma or higher. Exact income demographics were not available for the four centers, but approximately 7% of each center's clientele were below the 100% poverty level (based on the numbers of older adults who attended the free lunch programs). Overall, the centers' older adult attendees were demographically similar to older adults across the state and in Orange and Wake counties. The seniors in Orange County, however, reported a higher average level of education.<sup>306</sup>

### **Participant Eligibility and Recruitment/Enrollment**

Older adults were eligible for the study if they: (1) self-identified as being Black or White, (2) were age 65 years or older, (3) had been told by a health provider that s/he has hypertension, (4) reported taking at least one anti-hypertensive medication, (5) reported living independently in the community (not in a hospice, nursing and/or assisted housing facility), (6) were English-speaking and able to read or understand English, and (7) agreed to sign a consent form. Individuals were excluded if they had participated in the pilot phase (Aim 1), as were individuals who were unable to give consent without a proxy. Because the target population was older adults, pregnant women and children were also excluded. Older adults were actively and passively recruited from the four senior community centers. The study was consistently advertised and introduced as "a project conducted by UNC

Eshelman School of Pharmacy to understand what is important to older adults when it comes to their health and taking their blood pressure medicines.” Thus, all participants were blinded to the study questions and hypotheses.

Upon approval from the IRB and the senior centers, flyers advertising the study and containing contact information for the principal investigator (PI) were given to center staff, placed in the centers’ newsletters, and posted in the centers’ common areas. Flyers (Appendix 11) were also distributed at the centers’ special events and health programs (e.g., health fairs, informational sessions, and health screenings). At these events the senior centers’ program coordinators distributed flyers, announced the study, and collected contact information from interested older adults for a referral list (Appendix 12) that was provided to the PI after each program or event. If the PI was not at the site when the program coordinator collected the contact information, the referral list was put in a sealed envelope and kept in the office of the site’s coordinator until the PI returned. After the PI obtained the contact information, she contacted each potential participant by phone to invite participation using a conversation flow detailed in the study’s telephone script (Appendix 13). Within two weeks of this contact, interested, eligible individuals met with the PI at a mutually agreed-upon time at the senior center for consent and enrollment. If an older adult on the contact list was not interested, his/her name and telephone number was deleted with a black permanent marker. After all potential participants had been called, the list was shredded and discarded.

A total of 76 potential participants were contacted via the referral lists from the four senior centers. Of these, 58 were eligible and agreed to participate. The exact participation rate cannot be determined, however, because it was difficult to track and account for the individuals who dropped by the study area for additional information as well as the groups who were approached and invited to participate but declined (during active recruitment,

many groups of three to six older adults approached the researcher and expressed interest in the study).

In addition to these recruitment strategies, the main recruitment method involved the PI directly and actively recruiting older adults at the senior centers by waiting in the common areas and approaching attendees as they entered or exited. For this purpose, the PI arranged to be at the senior centers on alternating days and weeks. Eventually, appointments for enrollment were set for interested participants at each of the senior centers, which made recruitment and enrollment easier. The recruitment/enrollment schedule for the centers is shown in Table 9.

**Table 9. Recruitment/Enrollment Schedule for the Senior Centers**

<b><u>Month 1</u></b>			
	<b>Days</b>	<b>Time</b>	<b>Senior Centers</b>
<b>Weeks 2 &amp; 3</b>	Monday & Thursday	8 am–3 pm	Center 1 (Orange County)
	Tuesday & Wednesday	9 am–5 pm	Center 2 (Wake County)
	Friday	9 am–3 pm	Center 3 (Wake County)
<b>Weeks 4</b>	Monday & Tuesday	9 am–3 pm	Center 4 (Orange County)
	Monday & Thursday	5:30 pm–7 pm	Center 1 (Orange County)
	Wednesday	9 am–5 pm	Center 2 (Wake County)
	Friday	9 am–5 pm	Center 3 (Wake County)
<b><u>Month 2</u></b>			
<b>Weeks 1 &amp; 2</b>	Monday & Thursday	9 am–3 pm	Center 1 (Orange County)
	Tuesday & Wednesday	9 am–3 pm	Center 2 (Wake County)
	Saturday	10 am–1 pm	Center 1 (Orange County)
<b>Weeks 3 &amp; 4</b>	Monday & Thursday	9 am–2 pm	Center 3 (Wake County)
	Tuesday & Wednesday	9 am–2 pm	Center 2 (Wake County)
	Wednesday	2:30 pm–5 pm	Center 3 (Wake County)
	Saturday	8 am–12 pm	Center 1 (Orange County)
<b><u>Month 3</u></b>			
<b>Weeks 1 &amp; 2</b>	Mon, Thurs & Friday	9 am–3 pm	Center 3 (Wake County)
	Tuesday & Wednesday	9 am–5 pm	Center 4 (Orange County)
<b>Weeks 3, 4, 5</b>	Monday	9 am–2 pm	Center 1 (Orange County)
	Tuesday & Wednesday	9 am–5 pm	Center 2 (Wake County)
	Thursday & Friday	9 am–5 pm	Center 3 (Wake County)
<b><u>Months 4 &amp; 5: (Open for enrollment appointments. Revisited sites (i.e., Garner and Seymour) that had the most traffic.</u></b>			

After an older adult was identified or demonstrated an interest in the study, the PI led him or her to the private study area within the center and confirmed eligibility with the first six questions on the Demographic Questionnaire (Appendix 7). Next, the PI provided the participant with the study objectives and the potential benefits of the research findings. After consent had been obtained, the PI immediately assigned the participant a subject number (1–170) and wrote it at the top of each study questionnaire. The study visit occurred on the same day consent was obtained and usually lasted 30–45 minutes.

The study visit began with the PI obtaining two blood pressure readings, as per the procedures outlined in the Blood Pressure Measurement Protocol (Appendix 14), and the remaining demographic information. Prior to collecting the two blood pressure measurements, the PI had no knowledge of how participants would respond or perform on the study questionnaires because only demographic information had been collected at this point. This was to eliminate bias in the blood pressure measurements.

After collecting the blood pressure and demographic information, participants were then provided with the study documents and instructions for completing the other questionnaires, which included self-reported assessments of medication adherence to their high blood pressure therapy, spirituality, social support, and active coping. To minimize social desirability issues and for privacy, a closed drop-box was hung in each study station for the participants' completed questionnaires. For privacy reasons, the PI stepped away from the study station while each participant completed his or her questionnaires.

The PI assessed whether each participant needed assistance with reading and completing the surveys by asking, "Are you able to complete this survey on your own, or do you need me to help you complete it?". If the participant had vision impairment or literacy issues, the PI read each survey item aloud, solicited a response, marked the response, and then repeated it to ensure that it had been documented properly. The PI enacted this routine

only for participants with literacy issues or visual impairment. All other participants read, answered, and marked their responses independently for each of the survey measures and placed the completed documents in the drop-box. The PI documented when assistance was given, along with the reason, on those participants' demographic questionnaires.

At the end of the study visit, each participant was given a multipurpose, lightweight, recyclable tote bag and a pill box as tokens of appreciation. Copies of informational brochures from the NIA about cardiovascular health, hypertension, and the importance of medication adherence were available for the participants to take away in their tote bags. All study materials were removed daily from the senior center sites and taken to the Cecil G. Sheps Center at the University of North Carolina at Chapel Hill for entry into the secure study database. Hard-copy study files were secured in a locked file cabinet, in a secure private office at the center.

### **Data Collected and Variables**

To maximize the response rate, each study questionnaire was given and collected by the PI on the same day the patient was enrolled into the research study and all data were collected from these questionnaires. The study questionnaires were self-report surveys of participants' demographic background, spirituality, social support, active coping, and medication adherence. The PI collected information from the demographic questionnaire before asking the participant to complete the following questionnaires:

- 1) 8-item Morisky Medication Adherence Scale (MMAS-8) (Appendix 8);
- 2) Visual Analog Scale for Medication Adherence (VAS) (Appendix 9);
- 3) Tangible, Informational, Emotional Social Support Survey (Appendix 10);
- 4) Self-Ranking of Spirituality (Appendix 3);
- 5) Spiritual Health Locus of Control Scale (SHLCS) (Appendix 2);
- 6) John Henryism Active Coping Scale (JHAC12) (Appendix 4).

Table 4 lists the key variables, measures, and sources, along with their type or range for this study. Most measures are only briefly described here as they are revisited from Aim 1 and are in the appendices). The only measures not repeated from Aim 1 are the demographic questionnaire and the original validated TIES instrument (social support measure); in addition, a medication adherence measure specific to hypertension medications was used for greater reliability. A visual analog scale was also administered as a global measure of adherence to hypertension medications (for future research).

**Table 10. Variables Used in Aims 2 and 3**

Variable	Source <sup>a</sup>	Type/Range	Definition
<b>Dependent Variable</b>			
Medication Adherence	8-item MMAS (Morisky)	1 = High adherence 0 = Low adherence	Self-reported adherence to anti-hypertensive meds; scores range from 0 to 8. A score $\geq 6$ connoted high adherence and low adherence consisted of scores $< 6$ .
Blood Pressure	Demographic Questionnaire	Continuous	Average of two blood pressures taken at the time of consent (systolic and diastolic).
<b>Key Independent Variables</b>			
Self-ranking of spirituality ( <i>primary spiritual measure</i> )	Self-ranking of spirituality	1 = High Spirituality  0 = Low/No Spirituality	Sspiritual intensity: 1 item measure asking “To what extent do you consider yourself a spiritual/religious person?” Responses: 4 (very spiritual) to 1 (not spiritual at all). Scores of moderately to very spiritual constituted high spirituality.
Active Spiritual Health Locus of Control ( <i>secondary spiritual measure</i> )	SHLCS	1 = High Active 0 = Low Active	Active spiritual health locus of control beliefs. Involves idea that God empowers one to take care of self; both God and self take a responsibility in health. Responses: 4 (Strongly Agree) to 1 (Strongly Disagree). Scores $\geq 28$ connoted as high active SHLC.
Social Support	TIES (validated version)	1 = High Support 0 = Low Support	How often participant had support s/he needed. Support suggested as necessary in cardiovascular disease and prevention. Responses: 0 (none of the time) to 2 (most or all of the time). Scores $\geq 15$ connoted high social support. Score of 15 separated those with support at least some of the time from those with support none of the time.
Active Coping	JHAC12	1 = High Active Coping 0 = Low Active Coping	A person’s behavioral predisposition to actively cope with difficult psychosocial stressors. Scores at the study sample’s median (score $\geq 48$ ) connote high active.
<b>Control Variables</b>			
Gender	Demographic Questionnaire	1 = Male 0 = Female	
Race/ethnicity		1 = Black 0 = White	
Age		Continuous	
Education		Categorical	
Difficulty obtaining meds due to cost?		1= Yes 0 =No	Participants were asked if they have had difficulty obtaining a prescription medication in the past 3 months due to cost.
Income		Categorical	

<sup>a</sup>Source acronyms: **MMAS** (Morisky Medication Adherence Scale 8-item); **SHLCS** (Spiritual Health Locus of Control Scale); **TIES** (Tangible, Informational, Emotional, Social Support Scale); **JHAC12** (John Henryism Active Coping Scale)



## Measures Administered and Definition of Variables

The specifics of the following measures can be found in the Methods section of Aim 1; the instruments are located in the appendices.

- ***Demographic Questionnaire and Blood Pressure Measurement.*** Age, race/ethnicity, gender, marital status, education, and income were obtained for each participant, along with whether participants had a hypertension diagnosis, used anti-hypertensive medication, lived independently in the community, and had difficulty obtaining medications due to cost during the previous three months were recorded on the demographic questionnaire (Appendix 7). Two blood pressure measurements were recorded for each participant in Section II of the questionnaire. The PI also recorded whether the participant needed assistance completing the self-report questionnaires and the reason for assistance. Age, race, and gender were considered a priori as potential control variables. The other characteristics were collected for descriptive purposes.

***Age:*** Continuous variable indicating participant's age in years at the time of consent.

***Race/ethnicity:*** Two-category variable indicating the best description of the participant's racial background (i.e., Black or White). Participants also reported ethnicity status by indicating whether they were of Hispanic or Latino origin or ancestry.

***Gender:*** Two-category variable indicating male or female.

***Education:*** Seven-category variable indicating highest grade completed with minimum of never attended/only kindergarten and maximum of postgraduate.

Variable was trichotomized as "less than high school," "high school graduate," and "college or more."

**Income:** Five-category variable indicating household income for previous 12 months with minimum of less than \$10,000 and maximum of \$35,000 or more. Variable was dichotomized as “less than \$35,000” and “35,000 and more.”

**Difficulty obtaining meds due to cost:** Two-category variable (Yes/No) measuring whether there was a time in the previous 3 months that the individual needed prescription medication but could not purchase it due to cost.

#### **Outcome Variable: Adherence**

- **8-item Morisky Medication Adherence Scale (MMAS-8):** Medication adherence (dependent variable) was assessed using the 8-item Morisky Medication Adherence Scale (Appendix 8). This self-reported adherence scale was developed from the 4-item Morisky instrument used in Aim 1 (the pilot study) and supplemented with additional items to better capture barriers to adherence behavior.<sup>307</sup> The new scale was determined to have higher reliability than the 4-item scale ( $\alpha = 0.83$  vs.  $\alpha = 0.61$ ) after its original validation in a sample of 1367 hypertensive patients; it was chosen in lieu of the 4-item scale used in Aim 1 because of its better reliability and because it is a disease-specific measure of adherence. Prior research has significantly associated the MMAS-8 with antihypertensive drug pharmacy refill adherence in seniors (concordance of 75% or higher).<sup>308</sup> In addition, the MMAS has been significantly associated with blood pressure control in patients with hypertension ( $p < 0.05$ ).<sup>307</sup> MMAS-8 scores, which range from 0 to 8, and has previously been dichotomized into two levels of adherence: high (score =  $\geq 6$ ) and low (score =  $< 6$ )<sup>307,309</sup> (D.E. Morisky, personal communication, March 7, 2011). In a study<sup>307</sup> that examined the validity of this instrument with the same cut-offs, the sensitivity of the measure identifying low versus high adherers was estimated to be 93% and the specificity was 53%.

- For the present study, the MMAS-8 was chosen over the 4-item scale because it is more reliable and was designed to facilitate the identification of barriers to and behaviors associated with adherence to antihypertensive medication.<sup>307</sup> Although the sample size for the current study was based on effect estimates from the 4-item measure used in the pilot study, it was considered reasonable to believe that because the MMAS-8 is a more precise and reliable measure, the adherence scores would have less error variance. Thus, the observed effect sizes of the spiritual variables on adherence in the present study were expected to be no smaller than the effects observed in the pilot study. Rather, they were expected to be larger; even though switching from the generic to the disease-specific measure would limit the generalizability of results to other chronic diseases.<sup>21</sup>
- **Medication adherence:** The self-report adherence measure (8-item MMAS), asked about medication-taking behavior specific to anti-hypertensive medication(s); its scores range from 0 to 8. The adherence outcome variable was dichotomized to low (MMAS-8 score < 6) and high adherence (MMAS-8 score  $\geq$  6).
- **Visual Analog Scale of Medication Adherence (VAS):** This measure was included only as a secondary measure of adherence, for the purposes of future analysis. The VAS is a single item that asks, "On a scale of 0% to 100%, which of the following percentages best reflects your compliance with your high blood pressure medicine over the past 4 weeks?". Subjects were instructed to indicate their adherence percentage on a horizontal line anchored by 0% and 100%, demarcated at every tenth percentile. This self-reported measure has been shown to be reliable and valid where it has been correlated with pill counts, pharmacy claims, and other electronic measures of adherence.<sup>310-314</sup>

## **Independent Variables**

### **Key Independent Variable: Self-Ranking of Spirituality**

***Self-ranking of spirituality:*** As in Aim 1 (the pilot study), this variable was dichotomized indicating overall self-ranking of spirituality (i.e., spiritual intensity). Participants were asked to indicate their spirituality according to one item: “To what extent do you consider yourself to be a spiritual/religious person?”. Responses ranged from 4 (very spiritual/religious) to 1 (not spiritual/religious at all). Participants who indicated that they were moderately to very spiritual/religious were dichotomized to the high spiritual group and those who considered themselves slightly or not at all spiritual/religious were placed in the low spiritual group. The one-item self-ranking of spirituality was administered along with a newly developed survey (Appendix 3).

### **Secondary Spiritual Variable: Active Spiritual Health Locus of Control**

***The Spiritual Health Locus of Control Scale (SHLCS):*** As in the pilot study, active spiritual health locus of control was assessed using 11 items on the SHLCS (Appendix 2). Responses range from 4 (strongly agree) to 1 (strongly disagree).

***Active SHLC:*** Dichotomous variable indicating high and low active spiritual health locus of control (SHLC). The total active SHLC score was the sum of values assigned to the responses of the 11 items. Total scores for active spiritual dimension were conservatively dichotomized at 28 points, which represents a scale split separating between those who disagreed or strongly disagreed to a majority of the 11 items and those who agreed or strongly agreed. Scores < 28 were categorized as low active SHLC and  $\geq 28$  above were high (Appendix 2). This score was the same as the cut-off score in the pilot study.

## Psychosocial Independent Variables

***Tangible, Informational and Emotional Social Support Survey (TIES)***: Differently than was administered in the Aim 1 pilot study, the original validated version of the TIES survey (Appendix 10) was administered to assess social support in aims 2 and 3. In Aim 1, the pilot study, this measure was shortened to a 7-item survey of questions specific to support access and medication-taking for descriptive purposes and to assess administration feasibility. Because the adapted version was not validated and the 16-item scale was found to be an acceptable time burden for study participants, the entire 16-item TIES instrument was used with no alterations. The TIES measure was developed to measure the types of social support that are necessary in cardiovascular disease prevention and management; responses range from 0 (none of the time) to 2 (all or most of the time), with higher scores indicating more support. Its validation and description can be found in the Methods section of Aim 1.

***Social Support***: The total social support score was the sum of the responses to the items on the TIES questionnaire. Total scores were dichotomized at a cut-off score of 15, which separated participants who indicated that they had support at least some of the time from those who had support none of the time to a majority of the scale's items. Scores of < 15 were categorized as low social support and  $\geq 15$  were categorized as high social support. The TIES instrument is a fairly new measure and the developers have previously dichotomized the high and low groups at a median split.<sup>281</sup> However, it was believed that a cut-off score of 15 was more meaningful and relevant, from a clinical perspective, for examining the proportion of older adults who had overall higher support from those who had lower support for the domains assessed.

***John Henryism Active Coping Scale (JHAC12):*** As in the pilot study, active coping was assessed using the 12-item John Henryism Active Coping scale (Appendix 4).

***Active Coping:*** The total active coping score was the sum of the values assigned to the responses for the 12 items. In keeping with the methodology proposed by developers and other researchers who have used this measure,<sup>260,271,272,276</sup> scores were dichotomized at the sample's median (score=48) to categorize respondents into high and low active coping groups. Scores at and above the sample median were categorized as high active coping and scores below the median were categorized as low active coping.

## **Aim 2 Analysis**

**Aim 2:** To examine the relationship between spirituality and self-reported medication adherence among community-dwelling older adults with hypertension.

### ***Hypothesis 2:***

- Older adults who report high spirituality versus those who report low spirituality are more likely to report being adherent to their anti-hypertensive medication(s).
- Older adults with high active spiritual health locus of control (SHLC) beliefs versus those with low active SHLC are more likely to report being adherent to their anti-hypertensive medication(s).

## **Overview**

Prior to analyses, all data were entered into the study database using Microsoft Access and cleaned for missing or nonsensical values. Next, data were converted to STATA 11 (StataCorp LP, 2009) for analysis, which was done in three stages. First, descriptive statistics were calculated for all variables and descriptive analysis was performed to describe participant, adherence, and spiritual characteristics in detail. Second, bivariate relationships to the medication adherence and spiritual variables were examined. Third,

multivariate logistic regression models were used to examine how each spiritual variable related to patient reports of adherence to anti-hypertensive medications, after controlling for the psychosocial and demographic variables.

### **Descriptive Data and Bivariate Analysis**

Descriptive statistics were calculated for the entire study sample of 170 community-dwelling older adults. These included age, gender, marital status, education, income, length of time with hypertension, difficulty purchasing prescriptions due to cost, average blood pressure, active coping, and social support. Frequencies and percentages were used to describe categorical and dichotomous variables (i.e., gender, race, marital status, education, income). Means and standard deviations were used to describe continuous and counted variables (i.e., participant age, length of time with hypertension, average blood pressure, active coping, and social support). Distributions for the adherence and spiritual characteristics were also examined, and frequencies, percentages, means, and standard deviations of participant characteristics were calculated by race. Bivariate relationships were examined for all variables using chi-square statistics for categorical variables and *t*-tests for continuous variables. Fisher's exact test was used for cell frequencies of  $\leq 5$ . Participant characteristics were examined by high and low self-reported adherence, high and low self-ranking of spirituality, and high and low active SHLC.

### **Logistic Regression Analysis**

For Aim 2, separate logistic regressions were conducted to assess the bivariate and multivariate relationships between the spiritual variables and self-reported medication adherence. The outcome variable was self-reported medication adherence measured by the 8-item MMAS.<sup>307</sup> Self-ranking of spirituality, the primary independent variable, was measured by one item ("To what extent do you consider yourself a spiritual/religious person?"). Active SHLC, the second spiritual variable, was assessed using the SHLCS. The

independent spiritual variables and the adherence outcome variable were all dichotomized for analysis. Separate multivariate logistic regression models were used to examine how self-ranking of spirituality and active SHLC related to self-reported medication adherence, after adjusting for the psychosocial and demographic variables. For all analyses, the alpha level was 0.05 and analyses were performed with STATA 11 (StataCorp LP, 2009).

Selection of the control variables used for the multivariate logistic regression was driven by several factors (the conceptual model, the bivariate analysis, and the relevance of variables mentioned in the literature to medication adherence). As in the conceptual model, social support and active coping were accounted for in the regression analysis because they are attributes/benefits of spirituality that are thought to facilitate health behaviors.<sup>26,119,221,224,315,316</sup> As in the literature, age, race, and gender were found to be the stronger correlates of adherence in the older population than the other participant characteristics that were collected for the present study.<sup>19,21,82,103,290-294</sup> Although these demographic characteristics were not significant in the pilot study, patients who reported being adherent to their medications were slightly older, female, and White.

Initially, the variable “could not purchase prescription medication due to cost” was intended to be a control variable; however, this turned out to be the case for relatively few participants (N = 7). Moreover, this question was not specific to antihypertensive medications. The challenges posed to multivariate modeling were therefore considered sufficient to exclude this variable from the regression analysis.

Statistical power was taken into account because the conservative sample size (N = 170) would only permit a few variables other than race to be included in the logistic regression analysis. Using the 10:1 event-to-variable ratio and assuming that 35-40% of the participants would report low adherence, logistic regression analysis would allow for approximately five to six variables for reliable estimates and model fit.<sup>317,318</sup> None of the



participant characteristics that were excluded from the multivariate logistic regressions were significantly related to either the adherence outcome variable or the independent spiritual variables in bivariate analysis. After these considerations, it was determined that social support, active coping, age, race, and gender would be the control variables used in the logistic regression models when examining the relationships of the spiritual variables to self-reported adherence.

### **Aim 2a Analysis: Secondary Aim**

**Aim 2a: To examine the relationships among spirituality, social support, active coping, and self-reported medication adherence in community-dwelling older adults with hypertension.**

- Spirituality is positively associated with self-reported medication adherence, and this association is mediated through social support and active coping.

### **Overview**

To address the secondary aim, separate logistic regression models were performed to examine the relationships between spirituality, social support, and adherence, as well as the relationships between spirituality, active coping, and adherence. As depicted in the conceptual model, it was thought that spirituality would affect adherence through its known attributes of social support and active coping. To examine whether social support and active coping were mediators in the relationship between spirituality and self-reported adherence for the subjects of the present study, an informal evaluation and the Sobel Test (a formal statistical method used to test for mediation) were conducted. The alpha level for all analyses was 0.05. The informal evaluation was performed with STATA 11 (StataCorp LP, 2009). For the formal statistical mediation analysis, given the dichotomous nature of the variables, standardized coefficients and standardized errors were calculated for each variable using an Excel (Microsoft Office, 2010) spreadsheet. The standardized values were

then entered into an interactive calculator tool developed by Preacher and Leonardelli to conduct the Sobel Test.<sup>319</sup>

## **Mediation Analysis**

### **Informal Evaluation**

A secondary aim of the present study was to explore whether social support and active coping serve as mediators for the relationship between spirituality and self-reported adherence. Mediators are defined as variables that account for all or part of the relationship between a predictor and an outcome variable.<sup>320-322</sup> Before mediation analyses can be attempted, a certain pattern of relationships must exist.<sup>321-323</sup> Generally speaking, mediation can be said to occur when the

- (1) Independent variable (IV) significantly affects the mediator variable(s) (MV);
- (2) IV significantly affects the dependent variable (DV) in the absence of the mediator;
- (3) Mediator(s) has a significant unique effect on the DV; and
- (4) The effect of the IV on the DV shrinks upon the addition of the mediator(s).

The IV might influence the DV through several mechanisms, or it might have both direct and indirect effects. If the regression coefficient is largely reduced in the final criterion (step 4) but remains significant, partial mediation is believed to occur.<sup>321,322</sup> In other words, a portion of the IV is mediated by the MV(s) but other parts of the IV's effect are either direct or influenced by variables not included in the model for the present study. The above criteria are used to informally judge whether or not mediation is occurring,<sup>324</sup> but the Sobel Test is a statistically based way to formally test whether a mediator carries the influence of an IV to a DV.<sup>320,321,323</sup>

The first step of the informal evaluation was to determine whether the pattern of relationships for mediation was met between the variables. Using bivariate logistic regressions and the four criteria described above, social support and active coping were

examined in relation to the key independent variable (self-ranking of spirituality) and the dependent variable (self-reported medication adherence). When the four criteria were confirmed, the formal statistically based method for mediation was conducted.

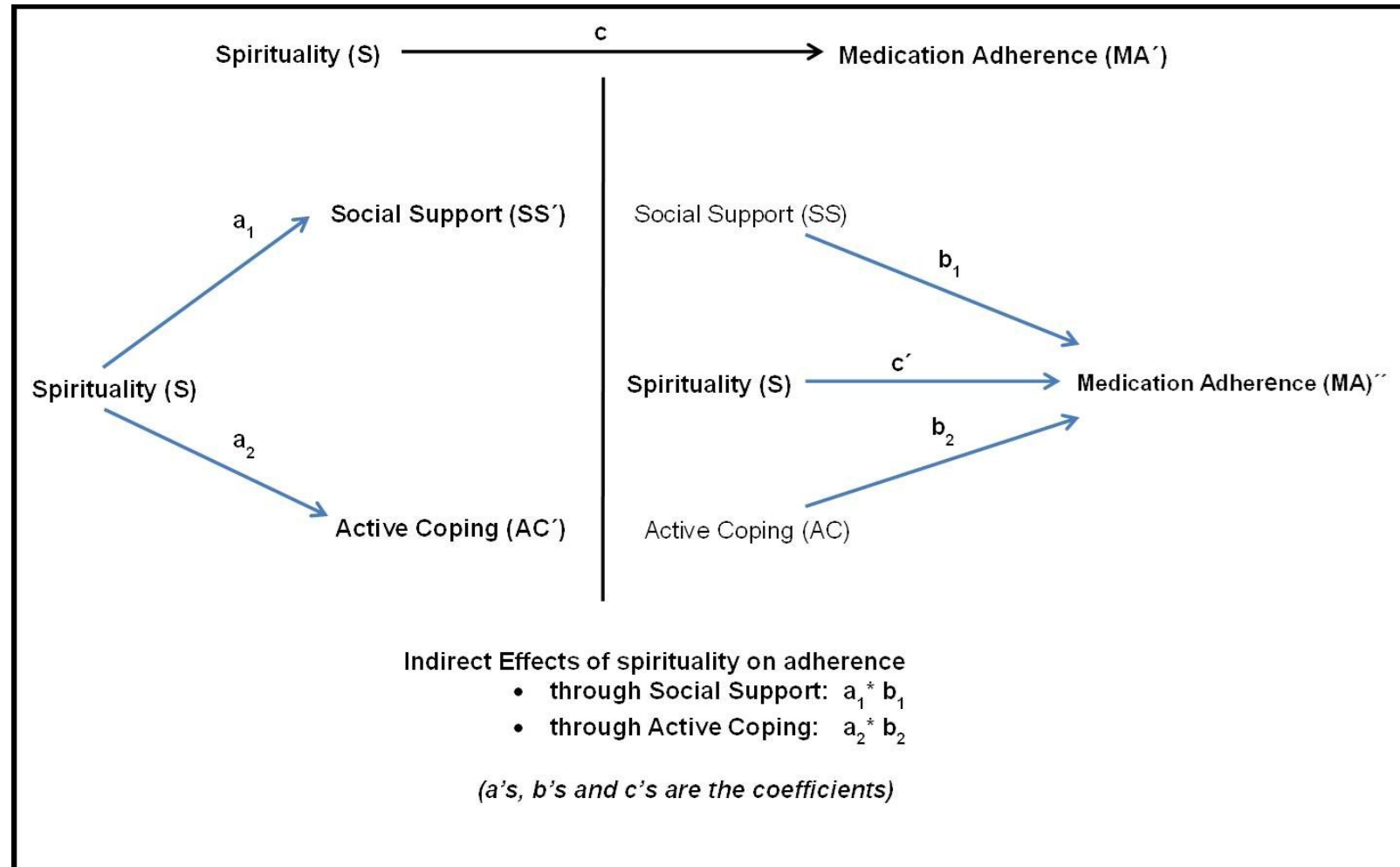
### **Sobel Test**

The Sobel Test for partial mediation was conducted to formally test whether social support and active coping are mediators in the relationship between spirituality and adherence.<sup>325</sup> The Sobel Test is a statistical evaluation of whether “the indirect effect of the independent variable on the dependent variable through the mediator variable is significant.”<sup>320,321,324,326</sup> When dichotomous variables are involved, the coefficients must be standardized prior to mediation analyses because the coefficients in the mediation analyses are placed on different scales.<sup>322,324,326-328</sup> For this reason, the coefficients of the variables have to be made comparable across the regression equations by standardizing them and their standard errors. This is accomplished by multiplying each coefficient by the standard deviation (SD) of the predictor variable in the equation and then dividing by the SD of the outcome variable. The standardized coefficients and standard errors can then be used to run the Sobel Test.<sup>322,324</sup>

After the pattern of relationships between the variables was confirmed, the coefficients and standard errors for the dichotomous variables were calculated and used to run the Sobel Test. For ease of calculation, the standardized coefficients and standardized errors were calculated for each variable using an Excel (Microsoft Office, 2010) spreadsheet. A diagram of the statistical mediation model is presented in Figure 3, and the main theoretical equation for the model and the equations used to standardize the coefficients for the predictor variables prior to statistical mediation analysis are presented in Table 11. Both the standardized coefficient values and their standard errors for the variable paths are needed to run the Sobel Test. The standardized standard errors are calculated

similarly to the standardized coefficients (Table 11). After calculating the standardized values for each variable, the values were then entered into an online, interactive calculator tool that was developed to conduct the Sobel Test using categorical variables.<sup>319,325</sup>

Figure 3. Diagram of Single-step Multiple Mediation Model



**Table 11. Standardizing Equations Used in the Sobel Test for Partial Mediation**

Model Equations		Equation Definition
$MA' = cS + e_1$		Direct effect of spirituality on medication adherence
$SS' = a_1S + e_2$		Direct effect of spirituality on social support
$AC' = a_2S + e_3$		Direct effect of spirituality on active coping
$MA'' = b_1SS + b_2AC + c'S + e_4$		Direct effects of spirituality and social support and active coping
Standardizing Equations for Coefficients		Standard Errors for Standardized Coefficients
$Std\ a_1 = a_1 * SD(S)/SD(SS')$		$SE(a_1) = SE(a_1) * SD(S)/SD(SS')$
$Std\ a_2 = a_2 * SD(S)/SD(AC')$		$SE(a_2) = SE(a_2) * SD(S)/SD(AC')$
$Std\ b_1 = b_1 * SD(SS)/SD(MA'')$		$SE(b_1) = SE(b_1) * SD(SS)/SD(MA'')$
$Std\ b_2 = b_2 * SD(AC)/SD(MA'')$		$SE(b_2) = SE(b_2) * SD(AC)/SD(MA'')$
$Std\ c = c * SD(S)/SD(MA')$		$SE(c) = SE(c) * SD(S)/SD(MA')$
$Std\ c' = c' * SD(S)/SD(MA'')$		$SE(c') = SE(c') * SD(S)/SD(MA'')$
Formula for Testing Two Mediators (SS and AC)		
$MA'' = b_1^2 VAR(SS) + b_2^2 VAR(AC) + 2b_1b_2cov(SS, AC) + 2b_1c'cov(S, SS) + 2b_2c'cov(S, AC) + c'^2VAR(S) + \pi^2/3$		

MA = medication adherence; S = spirituality; SS = social support; AC = active coping; Std = standardized coefficient; SD = standard deviation; SE = standard error; VAR = variance; cov = covariance

### **Aim 3 Analysis**

**Aim 3:** To examine the relationship between spirituality and blood pressure among community-dwelling, older adults with hypertension.

#### ***Hypothesis 3:***

- Older adults who report high spirituality will have lower systolic and diastolic blood pressures compared to older adults who report low spirituality.

To address this aim, the spiritual variables were examined in relation to systolic and diastolic blood pressure after adjusting for self-reported adherence, the psychosocial and demographic variables. Two blood pressure measurements were obtained from each participant at the time of consent. The average of the systolic and diastolic pressures was measured as continuous outcome variables in OLS regressions. The regressions were adjusted for adherence, the psychosocial and demographic variables. Self-reported adherence was a control variable because patient's adherence to antihypertensive therapy can effect systolic and diastolic blood pressure. It was of interest in this study to understand whether spirituality had an effect on blood pressure beyond whether a participant was adherent to their prescribed therapy. For all analyses in Aim 3, the alpha level was 0.05 and analyses were performed in STATA 11 (StataCorp LP, 2009).

## **Chapter 4**

### **RESULTS OF AIMS 2 & 3**

#### **Aim 2 Results**

##### **Overview**

The following sections include the results of the descriptive statistics, bivariate analyses, and multivariate logistic regression models predicting medication adherence for Aim 2, based upon the 170 hypertensive older adults who were recruited from four local Senior Community Centers and enrolled in the present study.

##### **Participant Characteristics**

Participant characteristics for the full sample of 170 community-dwelling older adults are presented in Table 12. The mean participant age was 75.1 (SD = 7.6); 61% were women; 45% identified as Black/African American; and none (0%) identified as Spanish or Hispanic. Most of the participants reported being either currently married (58, 34.1%) or widowed (57, 33.5%). At the time of enrollment, 21 (12.4%) participants reported a household income of less than \$10,000 in the previous 12 months. Only 29 (17.1%) reported having less than a high school education; 90 (52.9%) reported some college or more. The majority, 113 (66.5%), reported having had hypertension for at least 10 years, with a mean time of 14.6 years (SD = 11.0). Twelve (7.1%) reported that in the previous three months they could not purchase a prescribed medication due to cost; as a result of this inability, 7 (58.3%) went without their prescriptions. The mean systolic blood pressure



was 139.9 mmHg (SD = 19.1, ranging from 98 mmHg to 188 mmHg). The mean diastolic blood pressure was 74.2 mmHg (SD = 11.3, ranging from 45 mmHg to 95 mmHg).

The mean score on the active (JHAC12) was 47.5 (SD = 6.5); scores ranged from 31 to 60. The median score was 48 (95%, CI 46–50) and 6 participants scored at the median. When the scores were dichotomized at the sample's median per the scales guidelines, 90 (52.9%) participants were categorized as having high active coping. The median score for the current sample was slightly lower than was observed in the pilot study (i.e., score of 48 vs. 50, respectively). However, these scores are consistent and overlap with previous coping scores found in the literature with similar populations.<sup>260,271,272,276</sup> In addition, the cut-off score of 48 is believed to provide a meaningful difference between the high and low active coping groups as it separates those participants who responded positively (i.e., somewhat true=4 or completely true=5) to a majority of the measure's 12 items from those who responded negatively to a majority of the items.

Social support was assessed using the 16-item Tangible, Information, Emotional, Social Support Survey (TIES), a validated survey developed to measure dimensions of social support that are deemed necessary in cardiovascular disease and prevention. Question 16 ("If you smoke, is there someone to encourage you to quit smoking?") was dropped from the analysis because some participants responded that they did not smoke and therefore did not know how to respond to this item; they left it blank or put an X through it. However, other participants who stated that they did not smoke circled a response anyway and wrote their nonsmoking status in the margins of the instrument. Survey results indicated that only two respondents neither said nor wrote that they did not smoke but circled a response anyway. Because these inconsistencies were considered to have rendered the item unreliable, the social support analysis was based upon items 1 through 15 on the TIES instrument. (It should be noted that when this scale was originally validated, its

developers dropped this same smoking item from analysis because it did not significantly load on any of conceptual domains of social support<sup>261</sup> and that the developers attributed this problem to a dearth of smokers among their subjects.) Without the smoking item, the remaining 15 TIES items still had very good reliability for this study sample (Cronbach's  $\alpha$  0.92).

The mean social support score for the sample was 15.5 (SD = 7.6) in a range from 0 to 30. The median score was 14 (95%, CI 13–17) with five participants scoring at the median. The social support variable was dichotomized at a cut-off score of 15 (a scale split), which separated participants who responded to a majority of the items that they had support at least some of the time from those who responded to a majority of the items that they had support none of the time. Those with a score of  $< 15$  on this measure were categorized as having low social support. The social support groups were almost evenly distributed for this sample, where about half (84, 49.4%) were categorized as having high social support and the other half (86, 50.6%) had low social support.

Of the 170 participants who completed the study questionnaires, only 7 (4.1%) requested or required assistance with completion. Of these, one (14.3%) had literacy issues and six (85.7%) had vision impairment. All other participants completed the materials without assistance.

### **Characteristics by Race**

Because of the significance of racial identity in American society and because significant differences in adherence and hypertension outcomes by race have been reported in the literature (albeit these may be related to other factors), demographic characteristics were examined by race (Black versus White). Chi-square statistics were calculated for the cross-tabulation of race and the dichotomous or categorical variables; *t*-tests were conducted for race and the continuous variables. Characteristics that were found to

significantly differ by race were age, income, marital status, and active coping scores (Table 13). The Blacks in this study were significantly younger than the Whites ( $p < 0.01$ ), more likely to report a household income less than \$35,000 in the previous year ( $p < 0.05$ ), and also differed with respect to marital status ( $p < 0.05$ ). Significant differences were also found between Blacks and Whites in the active coping scores, where Blacks had a higher average JHAC12 score (48.9 vs. 46.4,  $p = 0.01$ ). No other characteristics differed significantly by race.

**Table 12. Participant Characteristics in Total Sample (N = 170).**

<b>Characteristics</b>	<b>No. (%) unless specified</b>
<b>Age</b> , mean (SD) <sup>a</sup> , range	75.1 ( $\pm$ 7.6), 65–93
<b>Women</b>	104 (61.2)
<b>Black</b>	76 (44.7)
<b>Marital Status</b>	
Never married	8 (4.7)
Married	58 (34.1)
Widowed	57 (33.5)
Divorced	43 (25.3)
Separated	4 (2.4)
<b>Education</b>	
Grades 1–8 (Elementary)	5 (2.9)
Grades 9–11 (Some high school)	24 (14.1)
Grades 12 or GED (HS grad)	51 (30.0)
College 1–3 yrs (Some college)	43 (25.3)
College 4 yrs (College graduate)	23 (13.5)
Postgraduate work	24 (14.1)
<b>Income</b>	
Less than \$10,000	21 (12.4)
\$10,000–\$34,999	89 (52.4)
\$35,000 or more	59 (34.7)
Don't know	1 (0.6)
<b>Length of time w/HTN</b> , mean(range)	14.6 (0.2–50)
< 10 years	57 (33.5)
10–20 years	80 (47.1)
> 20 years	33 (19.4)
<b>Could not purchase Rx b/c of cost</b>	12 (7.1)
Went without it	7 (58.3)
Someone else bought it	1 (8.3)
Other action	4 (33.3)
<b>Average Blood Pressure (mmHg)</b>	
Systolic (SD), range	139.9 ( $\pm$ 19.1), 98–188
Diastolic (SD), range	74.2 ( $\pm$ 11.3), 45–95
<b>Active Coping</b> , mean (SD), range	47.5 (+6.5), 31–60
Low active coping (< 48)	80 (47.1)
High active coping ( $\geq$ 48)	90 (52.9)
<b>Social Support</b> , mean (SD), range	15.5 (+7.6), 0–30
Low social support (< 15)	86 (50.6)
High social support ( $\geq$ 15)	84 (49.4)

<sup>a</sup>SD = standard deviation

**Table 13. Characteristics of Participants by Race<sup>a</sup> in Total Sample (N = 170)**

<b>Characteristics</b>	<b>Blacks (N = 76)</b>	<b>Whites (N = 94)</b>
	<b>No. of participants (%)</b>	<b>No. of participants (%)</b>
<b>Age</b> , mean (SD) <sup>b</sup> , range	73.1 ( $\pm$ 7.0), 65-90	76.7 ( $\pm$ 7.7), 65-93**
<b>Gender</b>		
Female	47 (61.8)	57 (60.6)
Male	29 (38.2)	37 (39.4)
<b>Marital status</b>		
Not Married	57 (75.0)	55 (58.5)*
Married	19 (25.0)	39 (41.5)
<b>Education</b>		
Less than HS grad	19 (25.0)	10 (10.6)
High school grad	21 (27.6)	30 (31.9)
College or more	36 (47.4)	54 (57.5)
<b>Income<sup>c</sup></b>		
Less than \$35,000	59 (77.6)	51 (54.8)**
\$35,000 or more	17 (22.4)	42 (45.2)
<b>HTN Years</b> , mean (SD), range	14.7 ( $\pm$ 10.5), 0.5-50	14.4 ( $\pm$ 11.3), 0.2-45
< 10 years	22 (29.0)	35 (37.2)
10-20 years	40 (52.6)	40 (42.6)
>20 years	14 (18.4)	19 (20.2)
<b>Not purchase Rx b/c of cost</b>	6 (7.9)	6 (6.4)
Went without it	4 (66.6)	3 (50.0)
Someone else bought it	1 (16.7)	0 (0.0)
Other action	1 (16.7)	3 (50.0)
<b>Avg. Blood Pressure (mmHg)</b>		
Systolic mean (SD), range	141.5 ( $\pm$ 19.1), 98-186	138.7 ( $\pm$ 19.2), 99-188
Diastolic mean (SD), range	75.3 ( $\pm$ 10.0), 50-95	73.3 ( $\pm$ 12.3), 46-95
<b>Active Coping</b> , mean (SD), range	48.9 ( $\pm$ 6.6), 31-60	46.4 ( $\pm$ 6.1), 34-59*
Low active coping (< 48)	25 (32.9)	55 (58.5)**
High active coping ( $\geq$ 48)	51 (67.1)	39 (41.5)
<b>Social Support</b> , mean (SD), range	15.5 ( $\pm$ 7.4), 0-29	15.5 ( $\pm$ 7.8), 1-30
Low social support (< 15)	38 (50.0)	48 (51.1)
High social support ( $\geq$ 15)	38 (50.0)	46 (48.9)

<sup>a</sup>Significance level of chi-square statistic for categorical variables and two-tailed t-test for continuous variables: \*p < 0.05, \*\*p < 0.01, \*\*\*p < 0.001

<sup>b</sup>SD = standard deviation

<sup>c</sup>Total is less than N = 170 due to missing data. Missing data n = 1.

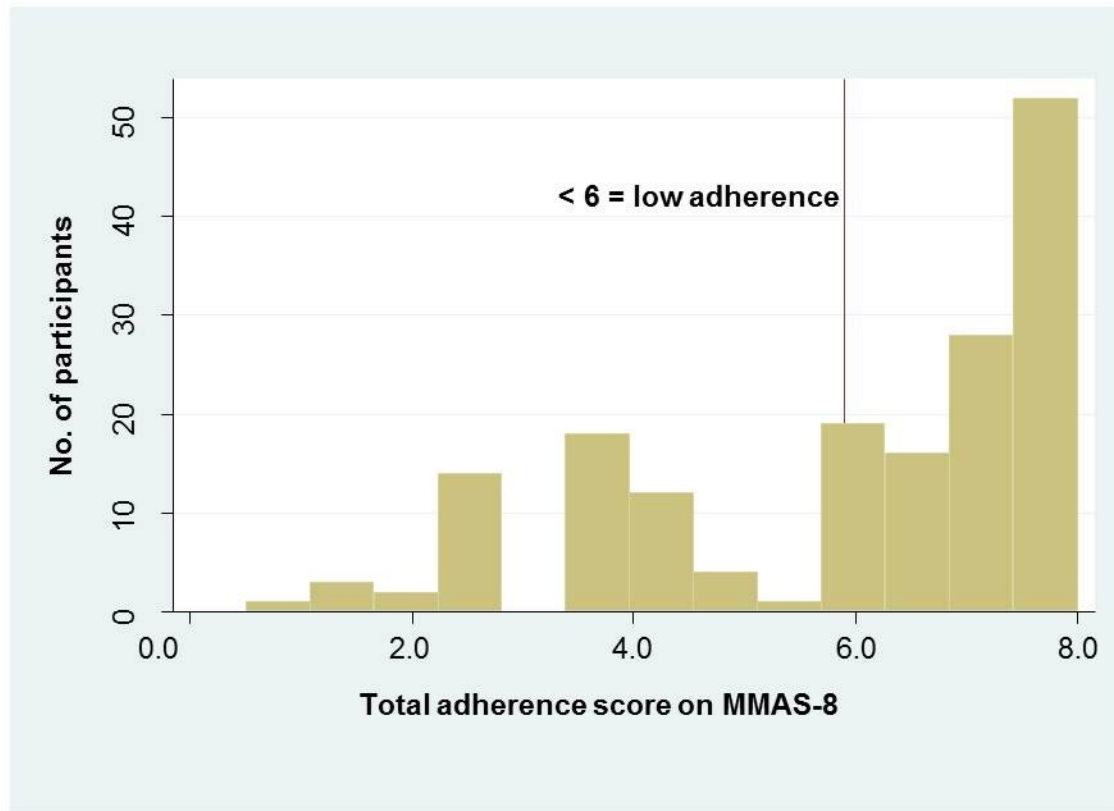
## **Adherence Characteristics**

### *Self-reported Adherence*

A histogram plot of the adherence scores is displayed in Figure 4. The mean score for the sample was 5.98 points with a median score of 6.75 points; scores ranged from 0.5 to 8. Sixty-five (38%) of the participants were categorized as having low adherence and 105 (62%) were categorized as having high adherence, which is similar to the distribution reported for the population in which the MMAS-8 was developed (32.1% low adherers); a population who also had hypertension.<sup>307</sup>

The distribution of participants who were categorized as adherent in the present study (62%) was higher than the distribution in the pilot study (44%). This result was expected because the measure used in the pilot study (4-item Morisky) was a generic measure of adherence that did not specify medication type. Also, because participants in the pilot study had been referred to a MTM service due to their medication complexity, the higher percentage of non-adherers in the pilot study may have been due to these patients reporting nonadherence to other chronic and/or acute medications. Using the MMAS-8 in the present study, however, provided an assessment of adherence to anti-hypertensive therapy only.

**Figure 4. Histogram of Self-Reported Medication Adherence Scores (N = 170).**



Adherence: Dichotomized	Frequency	Percent
Low adherence	65	38.24
High adherence	105	61.76
<b>Total</b>	<b>170</b>	<b>100.00</b>

## **Bivariate Results (Self-Reported Adherence)**

Table 14 shows the differences in demographic, hypertension, active coping, and social support characteristics by high and low self-reported adherence. Chi-square statistics were calculated for the cross-tabulation of high versus low self-reported adherence with the dichotomous or categorical variables. *T*-tests were conducted for high versus low adherence and the continuous variables. Of the demographic characteristics, only one had a statistically significant association with self-reported adherence. Adherence was found to differ significantly by gender: a higher percentage of female participants were more likely to report being adherent to their anti-hypertensive medication(s) than male participants (71% vs. 29%,  $p < 0.001$ ). No significant relationships were found between self-reported adherence and age, race, marital status, education, or income.

No differences were found in the length of time participants reported living with hypertension between those who reported high adherence to their anti-hypertensive medication(s) and those with low adherence. However, significant differences were observed for blood pressure measurements between the two groups. As expected, the average systolic blood pressure for the low adherence group was significantly higher than for the adherent group (151.9 mmHg vs. 132.5 mmHg,  $p < 0.001$ ). Similarly, the average diastolic blood pressure in the low adherence group was significantly higher than in the high adherent group (82.1 mmHg vs. 69.3 mmHg,  $p < 0.001$ ).

Differences were observed in both active coping and social support in the high and low adherence groups. Participants with high active coping were more likely to report high adherence to their anti-hypertensive medication(s) ( $p = 0.02$ ). Sixty percent of the participants who reported high adherence also had high active coping and 40% had high



adherence but low active coping. Similarly, participants with high social support were more likely to report high adherence ( $p < 0.001$ ); 61% had high adherence and high social support and 39% had high adherence but low social support.

**Table 14. Self-Reported Medication Adherence Characteristics by Other Demographic, Hypertension, Active Coping, and Social Support Characteristics (N = 170)**

Characteristics	Adherence <sup>a</sup>	
	High (N = 105) Frequency (%)	Low (N = 65) Frequency (%)
<b>Age, mean (SD)<sup>b</sup></b>	75.7 ( $\pm$ 7.3)	74.0 ( $\pm$ 8.0)
<b>Race</b>		
Black	43 (41.0)	33 (50.8)
White	62 (59.0)	32 (49.2)
<b>Gender</b>		
Male	30 (28.6)	36 (55.4)***
Female	75 (71.4)	29 (44.6)
<b>Marital status</b>		
Married	36 (34.3)	22 (33.8)
Not married	69 (65.7)	43 (66.2)
<b>Education</b>		
Less than high school grad	20 (19.1)	9 (13.8)
High school grad	36 (34.3)	15 (23.1)
College or more	49 (46.6)	41 (63.1)
<b>Income<sup>c</sup></b>		
Less than \$35,000	68 (65.4)	42 (64.6)
\$35,000 or more	36 (34.6)	23 (35.4)
<b>Length of time w/ HTN, mean (SD)</b>	15.3 ( $\pm$ 11.6)	13.3 ( $\pm$ 9.8)
< 10 years	33 (31.4)	24 (36.9)
10–20 years	48 (45.7)	32 (49.2)
>20 years	24 (22.9)	9 (13.9)
<b>Could not purchase Rx b/c of cost</b>		
Yes	9 (8.6)	3 (4.6)
No	96 (91.4)	62 (95.4)
<b>Average Blood Pressure (mmHg)</b>		
Systolic mean (SD)	132.5 ( $\pm$ 16.6)	151.9 ( $\pm$ 16.9)***
Diastolic mean (SD)	69.3 ( $\pm$ 10.5)	82.1 ( $\pm$ 7.6)***
<b>Active Coping score, mean (SD)</b>	48.8 ( $\pm$ 5.6)	45.5 ( $\pm$ 7.2)**
Low active coping (< 48)	42 (40.0)	38 (58.5)*
High active coping ( $\geq$ 48)	63 (60.0)	27 (41.5)
<b>Social Support score, mean (SD)</b>	17.6 ( $\pm$ 7.1)	12.0 ( $\pm$ 7.2)***
Low social support (< 15)	41 (39.1)	20 (30.8)***
High social support ( $\geq$ 15)	64 (60.9)	45 (69.2)

<sup>a</sup>Significance level of the chi-square statistic for categorical variables and two-tailed t-test for continuous variables: \*p < 0.05, \*\*p < 0.01, \*\*\*p < 0.001

<sup>b</sup>SD = standard deviation

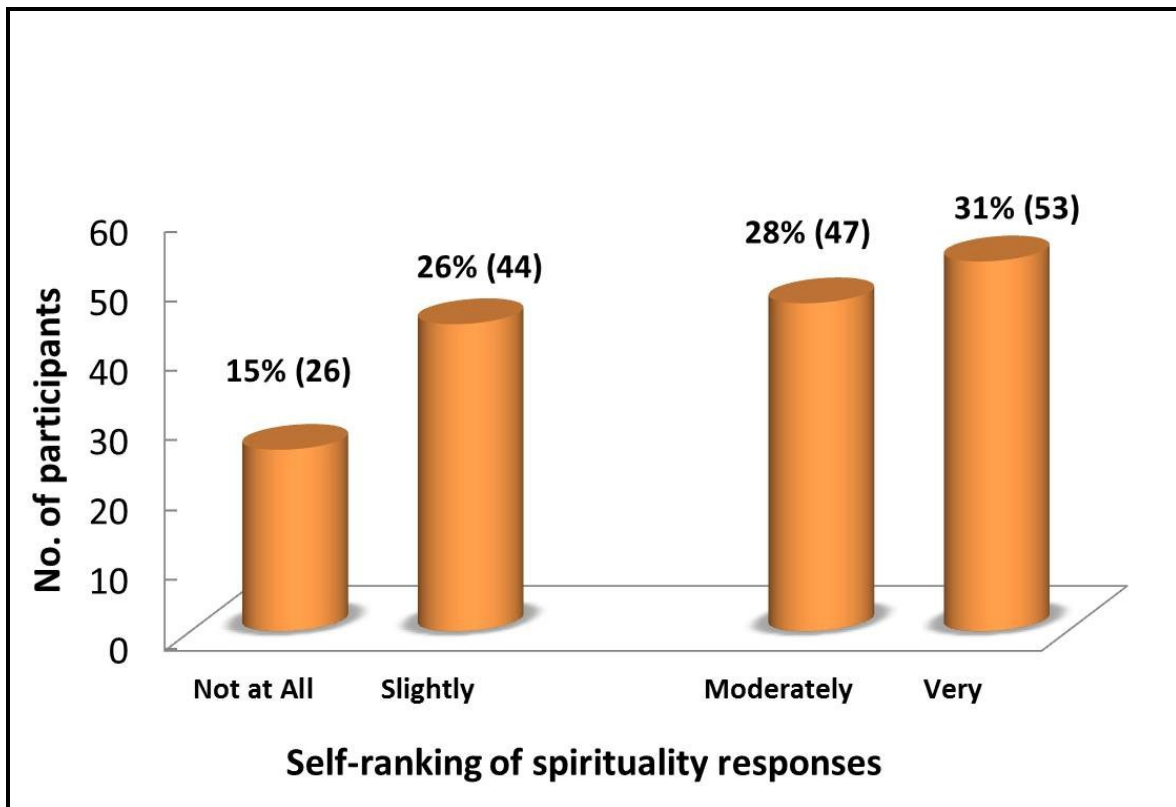
<sup>c</sup>Total number is less than N = 170 due to missing data. Missing data n = 1.

## **Spirituality Characteristics**

### *Self-ranking of spirituality*

Self-ranking of spirituality was the key independent variable in the present study. Participants responded to the question “To what extent do you consider yourself a spiritual/religious person?” (response distribution is shown in Figure 5). The spirituality variable was created by dichotomizing participants who reported moderately to very spiritual/religious (the high spiritual group) and participants who reported being slightly or not at all spiritual/religious (the low spiritual group). Most participants (84.7%) were at least slightly spiritual; 58.8% were moderately or very spiritual.

**Figure 5. Self-Ranking of Spirituality<sup>a</sup> Characteristics (N = 170)**



<sup>a</sup>Responses to the question "To what extent do you consider yourself a spiritual/religious person?"

Spirituality	Frequency	Percent
Low spiritual	70	41.18
High spiritual	100	58.82
<b>Total</b>	<b>170</b>	<b>100.00</b>

### **Bivariate Results (Self-Ranking of Spirituality)**

In the bivariate analysis shown in Table 15, a few notable differences appear between the high spiritual and low spiritual groups. The spirituality variable differed significantly by race, in that a higher percentage of Blacks than Whites were categorized as high spiritual (52% vs. 48%,  $p = 0.02$ ) and approximately 66% of the participants who reported low spirituality were White. Spirituality also differed significantly by gender, in that females were more likely than males to report being high spiritual (77% vs. 23%,  $p < 0.001$ ); approximately 65% of the males reported low spirituality. No differences were observed for marital status, education, or income characteristics. The spiritual groups did differ with respect to whether participants needed a prescription in the previous three months but could not afford to purchase it ( $p = 0.02$ ). Of the 12 participants who could not purchase medication they needed, 11 were characterized as high spiritual; only one was in the low spiritual group. It is important to note that this question on the demographic form was not specific to access to anti-hypertensive medications. Participants who responded affirmatively also indicated that the prescription they had gone without was not for their blood pressure.

Although no significant differences were observed between the high and low spiritual groups in the length of time participants had been diagnosed with hypertension, it is notable that blood pressures for the low spiritual group were significantly higher than for the high spiritual group ( $p < 0.001$ ). The average systolic blood pressure for the low spiritual group was 150.2 mmHg (SD=18.5). Similarly, the average diastolic blood pressure for the low spiritual group was significantly higher than for the high spiritual group (79.4 mmHg vs. 70.5 mmHg,  $p < 0.001$ ).

The spiritual groups differed with respect to active coping and social support. The high spiritual group had a higher active coping score on the JHAC12 measure than the low

spiritual group (49.5 vs. 44.8,  $p < 0.001$ ). Thus, a higher percentage of the high spiritual group had high active coping than low active coping (65% vs. 35%,  $p < 0.001$ ). Sixty-four percent of the low spiritual group was categorized as having low active coping. A similar significant trend ( $p < 0.001$ ) was observed with respect to social support: more participants who were categorized as having low social support were in the low spiritual group (73%) than participants who had low social support but were in the highly spiritual group (27%).

**Table 15. Self-Ranking of Spirituality Characteristics by Other Demographic, Hypertension, Active Coping, and Social Support Characteristics (N = 170)**

Characteristics	Spirituality <sup>a</sup>	
	High (N = 100) Frequency (%)	Low/Not at all (N = 70) Frequency (%)
<b>Age, mean (SD)<sup>b</sup></b>	75.3 ( $\pm$ 7.9)	75.3 ( $\pm$ 7.9)
<b>Race</b>		
Black	52 (52.0)	24 (34.3)*
White	48 (48.0)	46 (65.7)
<b>Gender</b>		
Male	23 (23.0)	43 (61.4)***
Female	77 (77.0)	27 (38.6)
<b>Marital status</b>		
Married	32 (32.0)	26 (37.1)
Not married	68 (68.0)	44 (62.9)
<b>Education</b>		
Less than high school grad	22 (22.0)	7 (10.0)
High school grad	26 (26.0)	25 (35.7)
College or more	52 (52.0)	38 (54.3)
<b>Income<sup>c</sup></b>		
Less than \$35,000	70 (70.7)	40 (57.1)
\$35,000 or more	29 (29.3)	30 (42.9)
<b>Length of time w/ HTN, mean (SD)</b>	14.9 ( $\pm$ 11.6)	14.0 ( $\pm$ 10.0)
< 10 years	33 (33.0)	24 (34.3)
10–20 years	47 (47.0)	33 (47.1)
>20 years	20 (20.0)	13 (18.6)
<b>Could not purchase Rx b/c of cost</b>		
Yes	11 (11.0)	1 (1.4)*
No	89 (89.0)	69 (98.6)
<b>Average Blood Pressure (mmHg)</b>		
Systolic mean (SD)	132.8 ( $\pm$ 16.2)	150.2 ( $\pm$ 18.5)***
Diastolic mean (SD)	70.5 ( $\pm$ 9.5)	79.4 ( $\pm$ 11.8)***
<b>Active Coping score, mean (SD)</b>	49.5 ( $\pm$ 5.7)	44.8 ( $\pm$ 6.5)***
Low active coping (< 48)	35 (35.0)	45 (64.3)***
High active coping ( $\geq$ 48)	65 (65.0)	25 (35.7)
<b>Social Support score, mean (SD)</b>	17.8 ( $\pm$ 7.3)	12.2 ( $\pm$ 7.0)***
Low social support (< 15)	35 (35.0)	51 (72.9)***
High social support ( $\geq$ 15)	65 (65.0)	19 (27.1)

<sup>a</sup>Significance level of the chi-square statistic for categorical variables and two-tailed t-test for continuous variables: \*p < 0.05, \*\*p < 0.01, \*\*\*p < 0.001

<sup>b</sup>SD = standard deviation

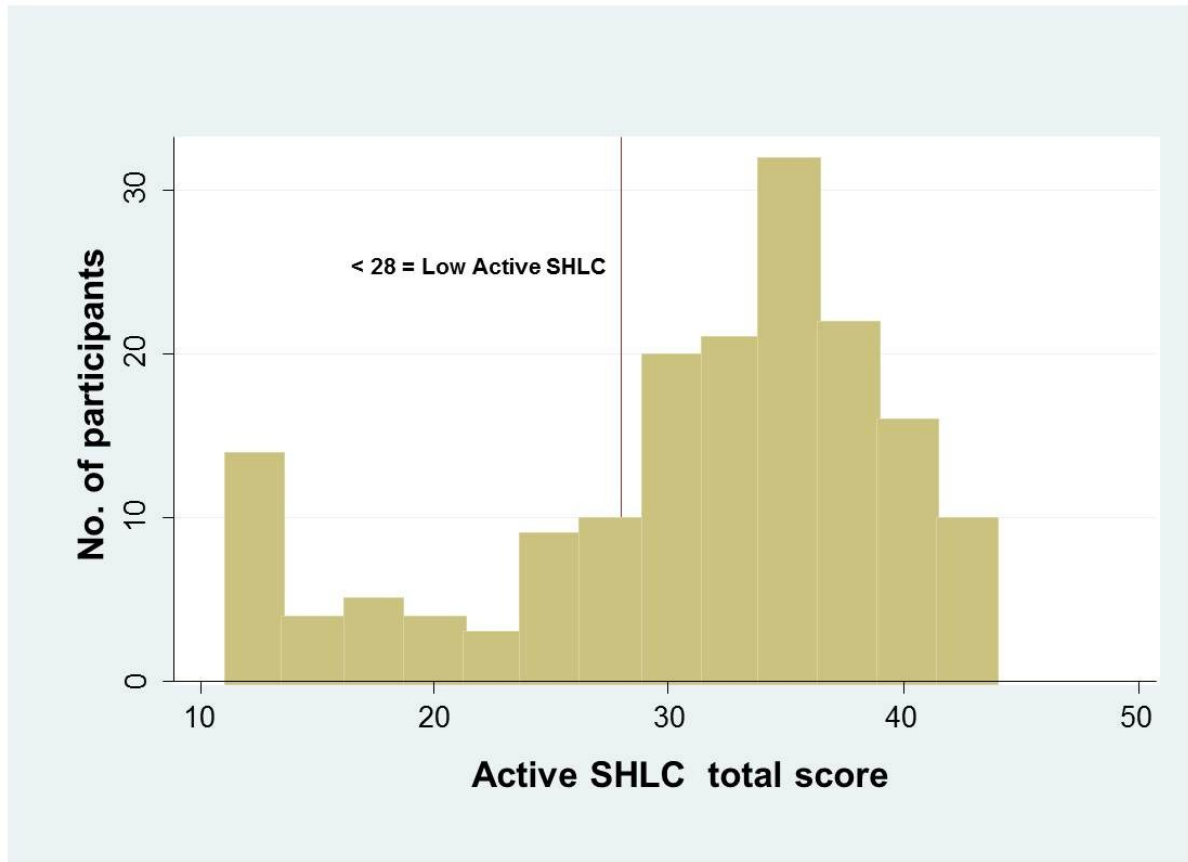
<sup>c</sup>Total number is less than N = 170 due to missing data. Missing data n = 1.

### **Active Spiritual Health Locus of Control (SHLC) Characteristics**

The secondary spiritual measure used in the present study was the active dimension of the Spiritual Health Locus of Control scale (SHLC). The measure, which consisted of 11 items, involved the notion that God (or some higher power) and self are involved in the health of individuals. Responses to the items were on a 4-point Likert-type scale that ranged from “strongly agree” to “strongly disagree.” The histogram plot in Figure 6 shows the distribution of the sample’s active SHLC scores. The mean score on the active SHLC scale was 30.9 points (median score = 33). This active SHLC variable was conservatively dichotomized at 28 points to separate those who disagreed or strongly disagreed with a majority of the 11 items from those who agreed or strongly agreed. Thirty-four (20.0%) of the participants were categorized as having low active SHLC beliefs and 136 (80.0%) with high active SHLC beliefs.



**Figure 6. Histogram of Active Spiritual Health Locus of Control (SHLC) scores (N = 170)**



Active SHLC	Frequency	Percent
Low active SHLC	34	20.00
High active SHLC	136	80.00
<b>Total</b>	<b>170</b>	<b>100.00</b>

### **Bivariate Results (Active SHLC)**

The active spiritual health locus of control (SHLC) variable significantly differed by race ( $p = 0.002$ ). Seventy-nine percent of White participants had low active SHLC compared to only 21% of Black participants. Active SHLC also significantly differed by gender, in that females were more likely than males to have high active SHLC (66% vs. 34%,  $p = 0.007$ ). The active SHLC groups did not differ with respect marital status, education, or income.

Similar to the trend observed for the primary spiritual variable (self-ranking of spirituality), participants in the high and low active SHLC groups did not differ with respect to the length of time they had been diagnosed with hypertension. They did however, differ in average blood pressures. The blood pressures measured for the low active SHLC group were significantly higher than for the high active SHLC group ( $p < 0.001$ ). The average systolic blood pressure for the low active SHLC group was 153.5 mmHg (SD = 20.8). Similarly, the average diastolic blood pressure for the low active SHLC group was significantly higher than for the high active SHLC spiritual group (82.7 mmHg vs. 72.1 mmHg,  $p < 0.001$ ).

Another similarity to the key spiritual variable was the difference between the SHLC groups with respect to both active coping and social support. A higher percentage of participants in the high active SHLC group were categorized as having high active coping than those in the low active coping group (60% vs. 30%,  $p = 0.001$ ). Seventy-four percent of the low active SHLC group was categorized as having low active coping. A similar significant trend ( $p < 0.001$ ) was observed with respect to social support: more participants who were categorized as having low social support were in the low active SHLC group (79%) than participants who had low social support but were in the high active SHLC group (43%).

**Table 16. Active Spiritual Health Locus of Control (SHLC) Characteristics by Other Demographic, Hypertension, Active Coping, and Social Support Characteristics (N = 170)**

Characteristics	Active SHLC <sup>a</sup>	
	High (N = 136) Frequency (%)	Low (N = 34) Frequency (%)
<b>Age, mean (SD)<sup>b</sup></b>	75.2 ( $\pm$ 7.6)	74.3 ( $\pm$ 7.8)
<b>Race</b>		
Black	69 (50.7)	7 (20.6)**
White	67 (49.3)	27 (79.4)
<b>Gender</b>		
Male	46 (33.8)	20 (58.8)**
Female	90 (66.2)	14 (41.2)
<b>Marital status</b>		
Married	44 (32.4)	14 (41.2)
Not married	92 (67.6)	20 (58.8)
<b>Education</b>		
Less than high school grad	27 (19.9)	2 (5.9)
High school grad	39 (28.6)	12 (35.3)
College or more	70 (51.5)	20 (58.8)
<b>Income<sup>c</sup></b>		
Less than \$35,000	92 (68.2)	18 (52.9)
\$35,000 or more	43 (31.8)	16 (47.1)
<b>Length of time w/ HTN, mean (SD)</b>	14.9 ( $\pm$ 11.4)	12.9 ( $\pm$ 9.0)
< 10 years	45 (33.1)	12 (35.3)
10–20 years	62 (45.6)	18 (52.9)
>20 years	29 (21.3)	4 (11.8)
<b>Could not purchase Rx b/c of cost</b>		
Yes	11 (8.1)	1 (2.9)
No	125 (91.9)	33 (97.1)
<b>Average Blood Pressure (mmHg)</b>		
Systolic mean (SD)	136.6 ( $\pm$ 17.2)	153.5 ( $\pm$ 20.8)***
Diastolic mean (SD)	72.1 ( $\pm$ 10.8)	82.7 ( $\pm$ 9.5)***
<b>Active Coping score, mean (SD)</b>	48.6 ( $\pm$ 5.8)	43.2 ( $\pm$ 7.1)***
Low active coping (< 48)	55 (40.4)	25 (73.5)**
High active coping ( $\geq$ 48)	81 (59.6)	9 (26.5)
<b>Social Support score, mean (SD)</b>	16.7 ( $\pm$ 7.4)	10.8 ( $\pm$ 7.0)***
Low social support (< 15)	59 (43.4)	27 (79.4)***
High social support ( $\geq$ 15)	77 (56.6)	7 (20.6)

<sup>a</sup>Significance level of the chi-square statistic for categorical variables and two-tailed t-test for continuous variables: \*p < 0.05, \*\*p < 0.01, \*\*\*p < 0.001.

<sup>b</sup>SD = standard deviation.

<sup>c</sup>Total number is less than N = 170 due to missing data. Missing data n = 1.

### **Correlation Matrix of Independent Variables Used in Analyses**

Table 17 presents the Pearson correlation coefficients and statistical significance of the independent variables used in the logistic regression analyses, which are described in the next section. These include the spiritual variables (self-ranking of spirituality and active SHLC), social support, active coping, age, race, and gender. Because the bivariate relationships between all the participant characteristics, spirituality, and self-reported adherence are presented above, this section focuses on the statistically significant interrelationships among the participant characteristics and spirituality variables used in the analyses.

The high spiritual participants were more likely to have a high active spiritual health locus of control (SHLC) than the low spiritual participants ( $r = 0.57, p < 0.001$ ). They were also more likely to have high social support ( $r = 0.37, p < 0.001$ ) and high active coping ( $r = 0.29, p < 0.001$ ) compared to the low spiritual group. The high spiritual participants were more likely to self-identify as Black ( $r = 0.18, p < 0.05$ ) than the low spiritual participants. Males were less likely to report being high spiritual ( $r = -0.39, p < 0.001$ ) than females. Participants with high active SHLC were more likely to have high social support ( $r = 0.29, p < 0.001$ ) and high active coping ( $r = 0.27, p < 0.001$ ) compared to participants with low active SHLC. In addition, the high active SHLC participants were more likely to self-identify as Black ( $r = 0.24, p < 0.01$ ) and less likely to be male ( $r = -0.21, p < 0.01$ ) compared to participants with low active SHLC.

Participants with high social support were more likely to have high active coping ( $r = 0.18, p < 0.001$ ) and were less likely to be male ( $r = -0.23, p < 0.01$ ) than participants with low social support. Participants with high active coping were more likely to be Black ( $r = 0.26, p < 0.001$ ) and less likely to be male ( $r = -0.24, p < 0.01$ ) compared to participants with

low active coping. Black participants were more likely to be younger compared to the White participants ( $r = -0.24, p < 0.01$ ).

Although statistically significant correlations were observed between the independent variables, the strength of these relationships were relatively weak to moderate. The largest correlation was between the two spiritual variables ( $r = 0.56, p < 0.001$ ), which was expected and the reason these spiritual domains were selected a priori to be examined in separate regression models. Nonetheless, the trends seem to support the proposed conceptualization of these constructs (i.e., that spirituality is positively related to social support and active coping).

<b>Table 17. Correlation Matrix Assessing Relationships Among Independent Variables Predicting Self-Reported Medication Adherence to Anti-Hypertensive(s)<sup>a</sup></b>							
	Spirituality	Active SHLC	Social support	Active coping	Age	Black	Male
Spirituality	1.00						
Active SHLC	0.56***	1.00					
Social support	0.37***	0.29***	1.00				
Active coping	0.29***	0.27***	0.18*	1.00			
Age	-0.03	0.05	-0.03	-0.09	1.00		
Black	0.18*	0.24**	0.01	0.26***	-0.24**	1.00	
Male	-0.39***	-0.20**	-0.23**	-0.24**	0.06	-0.01	1.00

<sup>a</sup>Based on two-tailed tests: \* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\* $p < 0.001$

### Checking for Multicollinearity of independent variables

To ensure that there were no multicollinearity issues with the independent variables used in the regression analyses, the variance inflation factor (VIF) and tolerance (1/VIF) values were examined. A variable with VIF values greater than 10, or a tolerance value lower than 0.1, may merit further investigation to rule out linear combinations of other independent variables. The VIF and tolerance (1/VIF) values for the explanatory variables that had been expected to predict adherence are shown in Table 18. These were not worrisome with respect to multicollinearity because the VIF values were all < 10 and the tolerance values were all > 0.1 (e.g., the variables were not redundant or were measuring the same thing).<sup>329-331</sup>

<b>Table 18. Variance Inflation Factor (VIF) and Tolerance (1/VIF) Values for Independent Variables Used in Regression Analyses Predicting Adherence.</b>		
<b>Variable</b>	<b>VIF</b>	<b>1/VIF</b>
Spirituality	1.77	0.563735
Active SHLC	1.58	0.632066
Male	1.23	0.813885
Black	1.20	0.831760
Social support	1.20	0.832975
Active coping	1.19	0.837600
Age	1.09	0.921459
<b>Mean VIF</b>	1.32	

## **Aim 2 Logistic Regression Results**

### **Overview**

In the next step of the analysis, separate logistic regressions were conducted to assess the bivariate and multivariate relationships between the spiritual variables and self-reported medication adherence while adjusting for social support, active coping, and the demographic variables (tables 19 and 20). Bivariate logistic models were examined for each of the spiritual variables and the other covariates in relation to self-reported adherence. The multivariate models were adjusted for the psychosocial (i.e., social support and active coping) and demographic variables (age, race and gender).

### **Effects of Self-ranking of Spirituality on Adherence**

Table 19 presents the bivariate and multivariate effects of self-ranking of spirituality on self-reported medication adherence. The models produced large estimates and wide confidence intervals, but significant positive relationships were observed between spirituality and adherence. A significant positive relationship was observed where participants reporting high spirituality had greater odds of reporting high adherence to their antihypertensive medication(s) compared to the low spiritual group (OR = 7.2; 95% CI 3.6–14.4). Social support and active coping were both positively and significantly related to self-reported adherence in bivariate analysis (95% CI 1.8-6.8 and 1.1–4.0, respectively) where participants with high social support and high active coping had greater odds of reporting high adherence than participants with low social support and low active coping. The only demographic variable significantly related to self-reported adherence in bivariate logistic analysis was gender: males had 70% lower odds of reporting adherence than females (OR = 0.3, 95% CI 0.2–0.6). Gender did not remain significant in the multivariate models, however.

The multivariate logistic model examined the effect of spirituality on self-reported adherence while adjusting for social support, active coping, and the demographic variables. Again, a significant positive relationship between spirituality and adherence was observed. The high spiritual group had greater odds of reporting high adherence to their blood pressure medications than the low spiritual group (OR = 6.2, 95% CI 2.7–14.5). The only other significant variable in the multivariate model was race. Blacks had 60% odds of reporting higher adherence than Whites when the other variables were held constant—a notable finding, considering that race was not a significant bivariate predictor of high adherence.

For further analysis, a logistic regression model was conducted to examine whether there was a significant interaction between the race and self-ranking of spirituality variables (not shown in table). Because race was significantly associated with spirituality in bivariate analysis, it was thought that an interaction might have been occurring between spirituality and race, which in turn affected the adherence outcome. Thus, an interaction term was created and entered in the regression model along with the other covariates to see if the combined effect of the spirituality and race variables was significant. The interaction was not significant (OR = 0.84, 95% CI 0.17 – 4.19) so the interaction term was dropped from the model for parsimony reasons. In addition, a regression model was conducted omitting the race variable and the odds ratio and confidence interval for the spirituality variable slightly decreased compared to the full model (OR = 6.2, 95% CI 2.6 – 14.5 vs. OR = 4.9, 95% CI 2.3 – 10.9). This result suggested that race may be functioning as a suppressor variable. In general, suppressor variables improve the prediction of a dependent variable.<sup>332,333</sup> When suppression occurs in regression analysis, an addition of a suppressor is frequently associated with a sizable increase in the regression coefficient of the suppressed predictor.<sup>332,334</sup> In this case, race may be suppressing some of the “outcome-irrelevant



variation or errors” in the spirituality variable, and improving or enhancing the overall predictive power of the model.<sup>333</sup>

To summarize the logistic regression results, self-reported high adherence seemed to be favorable for those who considered themselves more spiritual. This finding held true even after controlling for the effect of the psychosocial and demographic variables in the regression model. Therefore, there is support for the first hypothesis of Aim 2.

### **Effects of Active Spiritual Health Locus of Control on Adherence**

The secondary spiritual variable used in this study was the active spiritual health locus of control (SHLC) dimension, which involves the notion that God or a higher power gives individuals the strength to improve their health. The bivariate and multivariate effects of the active SHLC variable on self-reported medication adherence appear in Table 20. Similar to the key spiritual variable, the models examined produced large estimates and wide confidence intervals, but significant positive relationships were observed. In the bivariate model, active SHLC was significantly associated with self-reported adherence where those participants with high active SHLC had greater odds of reporting high adherence than participants with low active SHLC (OR = 6.7, 95% CI 2.86–15.54).

In multivariate regression, the psychosocial and demographic variables were adjusted for and active SHLC remained positively significant in relation to adherence (OR = 6.19, 95% CI 2.3–16.7). Active coping was not significant in the multivariate model, but social support remained significant (OR = 2.21, 95% CI 1.1–4.6), which suggests that participants’ perceptions of their social support positively affects their adherence beyond their SHLC beliefs and coping strategies. Gender was also significant in the multivariate model. Males had 55% lower odds of reporting adherence than females (OR = 0.45, 95% CI 0.21–0.95). Similar to the analysis with the key spiritual variable, race became significant in the multivariate model. Blacks’ odds of reporting high adherence were approximately 62%

lower than Whites' when the other variables were held constant (OR = 0.38, 95% CI 0.17–0.86). This finding was also notable because the same effect was observed with the self-ranking of spirituality variable wherein race was not a significant bivariate predictor of high adherence. Again, an interaction term was created and entered in the multivariate model to see if the combined effect of the active SHLC and race variables was significant (not shown in table). The results revealed that the interaction was not significant (OR = 3.6, 95% CI 0.37–34.86) and was therefore dropped. Also, as had happened with the key spiritual variable, the odds ratio for active SHLC in the full model decreased when the race variable was omitted (OR = 6.2, 95% CI 2.3–16.7 vs. OR = 4.3, 95% CI 1.7–10.8). Thus, suppressor effects may also be a possible explanation for this finding.<sup>332,335</sup>

To summarize the logistic regression results, self-reported high adherence also appears to be favorable for the second spiritual variable. Participants with high active SHLC beliefs had greater odds of reporting high adherence than those with low active SHLC, and this effect held true even after controlling for the psychosocial and demographics variables. These results support the secondary hypothesis for Aim 2.

**Table 19. Bivariate and Multivariate Effects of Spirituality on Self-Reported Medication Adherence in Hypertensive Older Adults (N = 170)**

Variable	Bivariate Models		Multivariate Model <sup>a</sup>	
Key Variable	OR [95% CI]	<i>p</i>	OR [95% CI]	<i>p</i>
<i>Spirituality</i>				
High	7.20 [3.60–14.39]	<b>&lt;0.001</b>	6.21 [2.66–14.52]	<b>&lt;0.001</b>
Low	Reference			
<b>Psychosocial Variables</b>				
<i>Social Support</i>				
High	3.51 [1.82–6.77]	<b>&lt;0.001</b>	1.91 [0.90–4.09]	0.09
Low	Reference			
<i>Active Coping</i>				
High	2.11 [1.13–3.96]	<b>0.02</b>	1.49 [0.68–3.30]	0.32
Low	Reference			
<b>Demographics</b>				
<i>Age</i>	1.03 [0.99–1.08]	0.14	1.03 [0.98–1.09]	0.19
<i>Black</i>	0.67 [0.36–1.25]	0.21	0.40 [0.17–0.92]	<b>0.03<sup>b,c</sup></b>
<i>Male</i>	0.32 [0.17–0.62]	<b>&lt;0.01</b>	0.67 [0.30–1.47]	0.31

<sup>a</sup>Multivariate Model: Adjusted for social support, active coping, age, race, and gender.

<sup>b</sup>An interaction term (race x spirituality) was entered in the multivariate model and was not significant (95% CI 0.2–4.2).

<sup>c</sup>When the race variable was omitted from the model, the odds ratio for the spirituality variable decreased (OR = 4.9, 95 CI 2.3–10.9).

**Table 20. Bivariate and Multivariate Effects of Active Spiritual Health Locus of Control (SHLC) on Self-Reported Medication Adherence in Hypertensive Older Adults (N = 170)**

Variable	Bivariate Models		Multivariate Model <sup>a</sup>	
Key Variable	OR [95% CI]	<i>p</i>	OR [95% CI]	<i>p</i>
<i>Active SHLC</i>				
High	6.67 [2.86–15.54]	<b>&lt;0.001</b>	6.19 [2.29–16.74]	<b>&lt;0.001</b>
Low	Reference			
<b>Psychosocial Variables</b>				
<i>Social Support</i>				
High	3.51 [1.82–6.77]	<b>&lt;0.001</b>	2.21 [1.06–4.60]	<b>0.03</b>
Low	Reference			
<i>Active Coping</i>				
High	2.11 [1.133.96]	<b>0.02</b>	1.58 [0.73–3.40]	0.25
Low	Reference			
<b>Demographics</b>				
<i>Age</i>	1.03 [0.99–1.08]	0.14	1.03 [0.98–1.08]	0.26
<i>Black</i>	0.67 [0.36–1.25]	0.21	0.38 [0.170.86]	<b>0.02<sup>b,c</sup></b>
<i>Male</i>	0.32 [0.17–0.62]	<b>&lt;0.01</b>	0.45 [0.21–0.95]	<b>0.04</b>

<sup>a</sup>Multivariate Model: Adjusted for social support, active coping, age, race, gender.

<sup>b</sup>An interaction term (race x active SHLC) was entered in the multivariate model and was not significant (95% CI 0.4–34.9).

<sup>c</sup>When the race variable was omitted from the model, the odds ratio for the active SHLC variable decreased (OR = 4.3, 95 CI 1.7–10.8).

## **Aim 2a: Mediation Analysis Results**

### **Overview**

For exploratory analysis, social support and active coping were examined as mediators in the relationship between spirituality and medication adherence. First, an informal evaluation was conducted to determine if the pattern of relationships between the variables (spirituality, social support, active coping, and adherence) existed for mediation, as described in the Methods section. Next, a formal statistical method (the Sobel Test) was conducted to determine whether social support and active coping significantly carried the influence of spirituality to medication adherence. Results from these evaluations are discussed below.

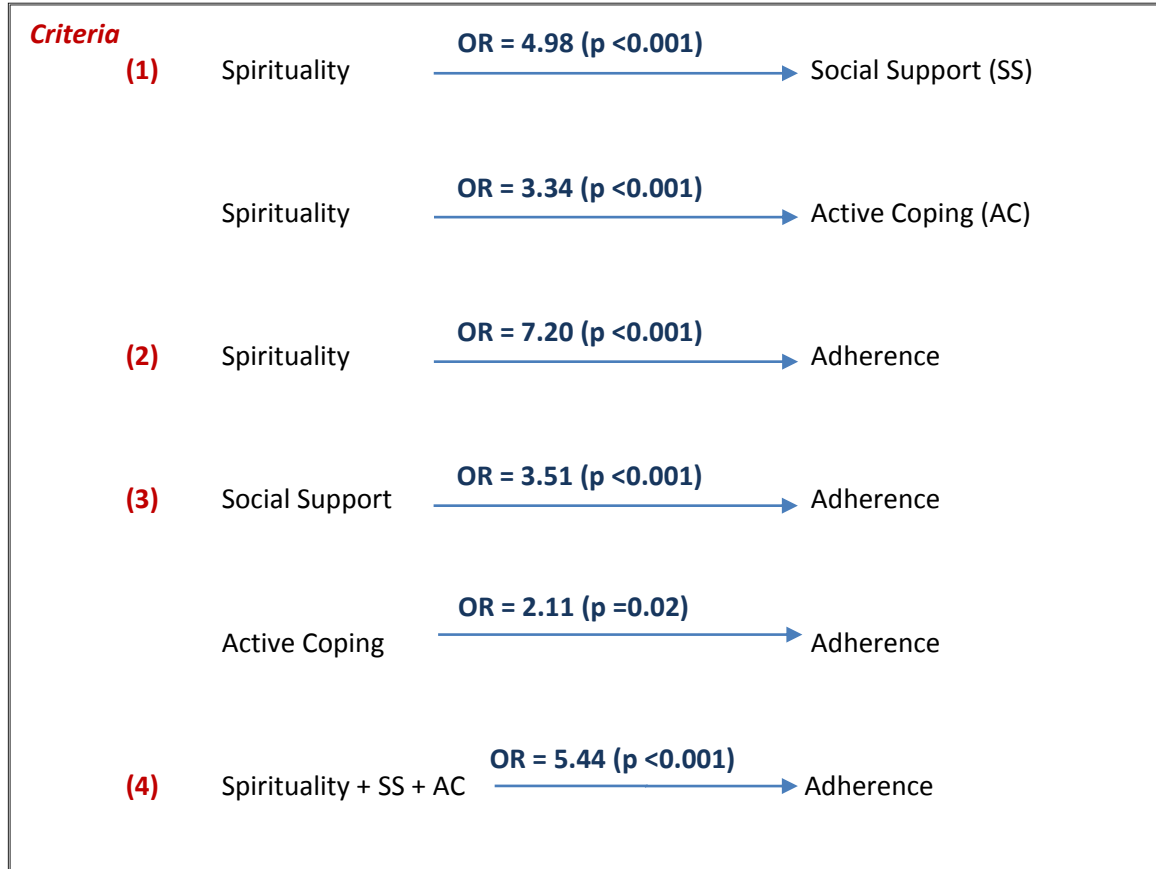
### **Analysis of Social Support and Active Coping as Mediators of Self-ranking of Spirituality**

#### **Informal evaluation**

Using bivariate logistic regressions and the four criteria described in the Methods section, social support and active coping were examined in relation to the key independent variable (self-ranking of spirituality) and the adherence outcome (Figure 7). The independent effects of spirituality on the two potential mediators were examined first; both regressions revealed significant effects in that spirituality was significantly related to social support and active coping (95% CI 2.6–9.7 and 1.8–6.3). Thus, the first criterion was satisfied in that the IV significantly affected the mediator(s). As revealed in the bivariate analysis, spirituality was significantly related to self-reported medication adherence (95% CI 3.6–14.4), which satisfied the second criterion in that the IV significantly affected the DV in the absence of the mediator. Next, the potential mediators were examined for unique effects on medication adherence: both social support and active coping had significant effects on the outcome (95% CI 1.8–6.8 and 1.1–4.0), which satisfied the third criterion. Finally, when social support

and active coping were added to the logistic regression model that examined the effect of spirituality on adherence, the effect of spirituality decreased from an odds ratio of 7.2 to 5.4 but remained significant (95% CI 2.5–11.4); this satisfied the fourth criterion in that the effect of the IV on the DV shrank upon the addition of the mediator(s). In spite of this shrinkage the effect remained significant, however, which suggests that full mediation was not demonstrated although results from the informal evaluation indicate that the social support and active coping variables may function as partial mediators in the relationship between spirituality and adherence. A formal statistical test was conducted to further examine this assumption.

**Figure 7. Informal Test of Social Support and Active Coping as Mediators**



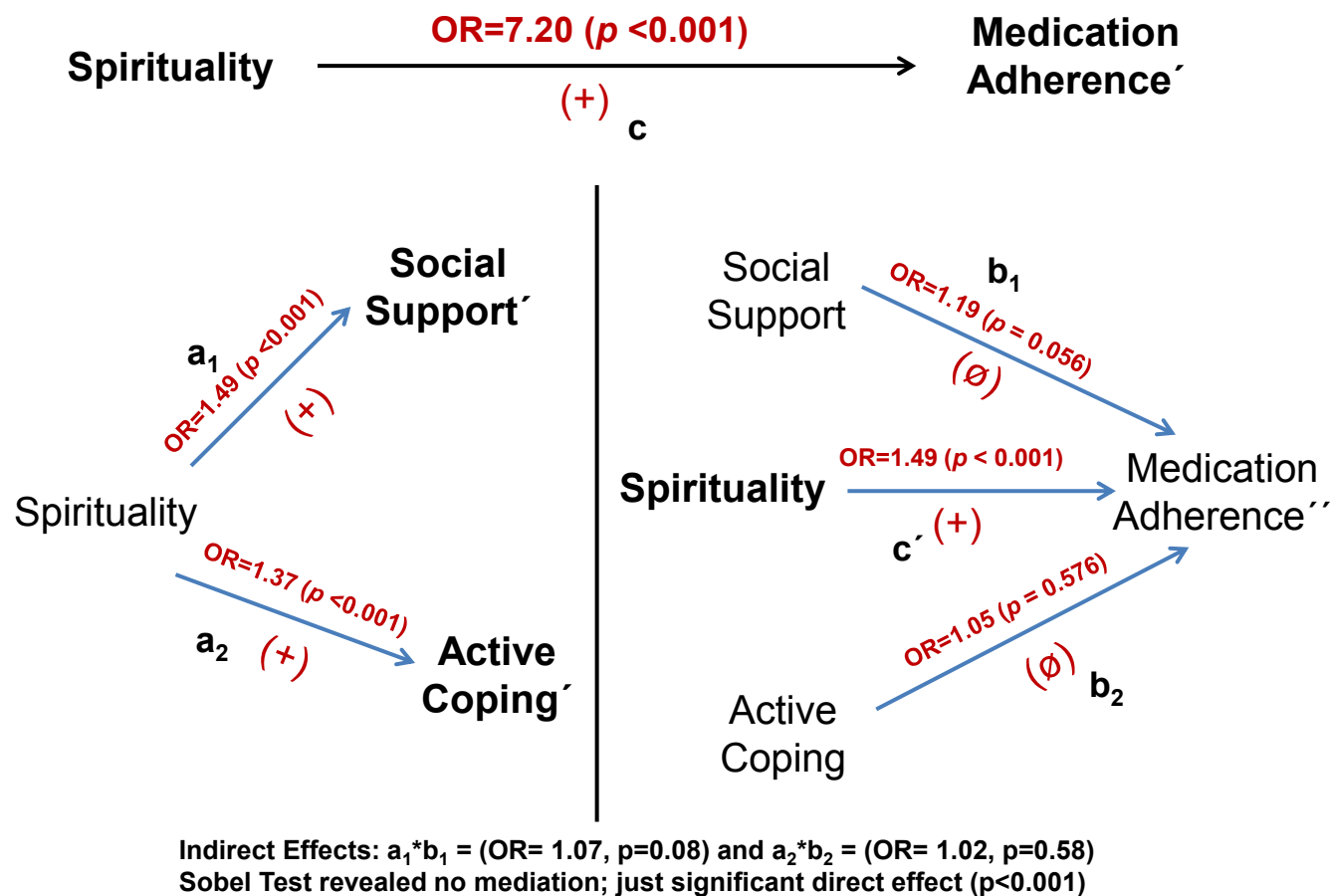
### **Formal Statistical Evaluation: Sobel Test**

The Sobel Test was used to formally test whether social support and active coping functioned as partial mediators between spirituality and self-reported medication adherence. (As discussed in the Methods section, the coefficients in mediation analyses end up being in different scales when the outcome variables are dichotomous in a logistic regression; therefore, the coefficients and standard errors of the variables must be standardized prior to conducting the Sobel Test for mediation.) For this analysis, both the mediator and outcome variables were dichotomous, which required standardization of the coefficients and standard errors of the variables involved. The calculations were performed using the equations in the Methods section.

After the standardized coefficients and errors were calculated, the values were used to run the Sobel Test for mediation analysis (Figure 8). Results showed that neither social support nor active coping mediated the relationship between spirituality and adherence; moreover, the Sobel Test showed only a significant direct effect of spirituality on self-reported adherence (OR = 1.49,  $p < 0.001$ ). That is, the indirect paths of spirituality to adherence were not significant. In the logistic regression models that examined social support as a mediator of the relationship between spirituality and adherence, the estimate for the indirect effect ( $a_1 * b_1$ ) was OR = 1.07 ( $p = 0.08$ ), which suggests that the association between spirituality and adherence is not mediated by social support. The same pattern emerged with active coping, where the logistic regression models produced an odds ratio estimate for the indirect effect ( $a_2 * b_2$ ) of 1.02 ( $p = 0.58$ ). Therefore, the present study does not show the relationship between spirituality and adherence to be mediated by social support or active coping.



Figure 8. Model of Sobel Test of Mediation



It must be noted that the present study was not specifically powered to examine the mediation effects of social support and active coping; and the analysis was conducted for exploratory purposes. Therefore, the results of the mediation analysis should be interpreted with caution because a larger sample might have produced different results. Although the informal evaluation of mediation posed social support and active coping as partial mediating variables between spirituality and medication adherence, the Sobel Test of partial mediation revealed no significant indirect effects. Instead, only significant direct effects were observed between spirituality and medication adherence, which suggests that spirituality influences adherence when controlling for social support and active coping.

### **Aim 3 Results**

#### **Overview**

The purpose of Aim 3 was to examine the relationship between spirituality and blood pressure among community-dwelling, older adults with hypertension. Linear regression models were conducted to assess the bivariate and multivariate relationships between the spiritual variables and blood pressure. Average systolic and diastolic blood pressures were the outcome variables and were measured continuously using OLS regression methods. Self-ranking of spirituality and active SHLC beliefs were the independent variables of interest. The spirituality, adherence and blood pressure characteristics of the study sample have previously been discussed. Thus, this section focuses on the linear regression results predicting blood pressure.

#### **OLS Regression Results**

Table 21 presents the bivariate and multivariate effects of self-ranking of spirituality on systolic and diastolic blood pressures. In both the bivariate and multivariate models, participants who reported being more spiritual had significantly lower blood pressures than participants in the low spiritual group. As mentioned previously (Table 15), the average

blood pressures were significantly different between the participants who reported being more spiritual than those in the low spiritual group (132.8 vs. 150.2 mmHg systolic and 70.5 vs. 79.4 mmHg diastolic, respectively). In the adjusted regression model (Table 21), the average systolic blood pressure was 12 points lower for the high spiritual group than the low spiritual group (95% CI -18.40, -6.04). Age and self-reported adherence were the only other covariates that remained significant in the adjusted model. On average, the systolic blood pressure of participants who reported high adherence was 14 points lower than participants who reported low adherence ( $\beta = -14.24$ ; 95% CI -20.04, -8.43). Participants' systolic blood pressure reduced slightly as their age increased. Diastolic blood pressure was approximately 4 points lower for those who reported being more spiritual and was also slightly lower with increasing age and for participants who reported high adherence. The adjusted models explain about 34% of the variance in systolic blood pressure and 37% of the variance in diastolic blood pressure.

Similar to the aforementioned analyses, active SHLC was examined in relation to systolic and diastolic blood pressures (Table 22). In both the bivariate and multivariate models, participants who reported high active SHLC beliefs had significantly lower blood pressures compared to participants with low active SHLC. In the adjusted regression model (Table 22), systolic blood pressure was, on average, 11 points lower for the high spiritual group versus the low spiritual group (95% CI -18.16, -3.85). Consistent with the primary spiritual variable, age and self-reported adherence also remained statistically significant in the adjusted model for the systolic and diastolic outcomes. For this analysis, the adjusted models explain about 31% of the variance in systolic blood pressure and 38% of the variance in diastolic blood pressure.

To summarize the linear regression results, both systolic and diastolic blood pressure seemed to be favorable for those who considered themselves more spiritual and

for those with active SHLC beliefs. These findings held true even after adjusting for the effects of adherence, the psychosocial and demographic variables in the models. Results indicate that there is support for the hypothesis of Aim 3, in that, older adults who report high spirituality are more likely to have lower blood pressure compared to those who report low spirituality. As in previous analyses, the confidence intervals around the estimates were large and imprecise making it difficult to determine a precise magnitude of the effect of the spiritual variables on blood pressure. The wide confidence intervals are likely due to the study's modest sample size and the variability in the participants' blood pressures.

**Table 21. Bivariate and Multivariate Effects of Self-ranking of Spirituality on Systolic and Diastolic Blood Pressure in Hypertensive Older Adults (N = 170)**

Variable	Systolic				Diastolic			
	Bivariate		Multivariate <sup>a</sup>		Bivariate		Multivariate <sup>a</sup>	
Key Variable	b [95% CI]	p	b [95% CI]	p	b [95% CI]	p	b [95% CI]	p
<i>Spirituality</i>								
High	-17.44 [-22.71, -12.16]	<b>&lt;0.001</b>	-12.22 [-18.40, -6.04]	<b>&lt;0.001</b>	-8.84 [-12.07, -5.61]	<b>&lt;0.001</b>	-3.73 [0.07, 0.48]	<b>0.04</b>
Low	Reference							
<b>Adherence</b>								
High	-19.42 [-24.62, -14.22]	<b>&lt;0.001</b>	-14.24 [-20.04, -8.43]	<b>&lt;0.001</b>	-12.85 [-15.81, -9.90]	<b>&lt;0.001</b>	-9.87 [-13.2, -6.52]	<b>&lt;0.001</b>
Low	Reference							
<b>Psychosocial Variables</b>								
<i>Social Support</i>								
High	-9.03 [-14.68, -3.38]	<b>&lt;0.01</b>	-0.77 [-6.07, 4.53]	0.78	-5.28 [-8.63, -1.94]	<b>&lt;0.01</b>	-0.85 [-3.91, 2.21]	0.58
Low	Reference							
<i>Active Coping</i>								
High	-5.22 [-10.99, 0.55]	0.08	-0.37 [-5.65, 4.91]	0.89	-2.97 [-6.39, 0.45]	0.09	-0.21 [-3.25, 2.84]	0.89
Low	Reference							
<b>Demographics</b>								
Age	0.18 [-0.20, 0.56]	0.36	0.34 [0.01, 0.67]	<b>0.04</b>	-0.35 [-0.57, -0.13]	<b>&lt;0.01</b>	-0.28 [-0.48, -0.09]	<b>&lt;0.01</b>
Black	2.75 [-3.08, 8.59]	0.35	4.87 [-0.44, 10.18]	0.07	1.93 [-1.53, 5.38]	0.27	0.69 [-2.37, 3.76]	0.65
Male	7.14 [1.27, 13.00]	<b>0.02</b>	-1.98 [-7.48, 3.53]	0.48	5.62 [2.19, 9.05]	<b>&lt;0.01</b>	1.54 [-1.64, 4.72]	0.34
<b>R<sup>2</sup></b>			0.34				0.37	

<sup>a</sup>Multivariate Model: Adjusted for adherence, social support, active coping, age, race, and gender.

**Table 22. Bivariate and Multivariate Effects of Active Spiritual Health Locus of Control on Systolic and Diastolic Blood Pressure in Hypertensive Older Adults (N = 170)**

Variable	Systolic				Diastolic			
	Bivariate		Multivariate <sup>a</sup>		Bivariate		Multivariate <sup>a</sup>	
Key Variable	b [95% CI]	p	b [95% CI]	p	b [95% CI]	p	b [95% CI]	p
<i>Active SHLC</i>								
High	-16.91[-23.71, -10.11]	<b>&lt;0.001</b>	-11.01 [-18.16, -3.85]	<b>&lt;0.01</b>	-10.67 [-14.66, -6.68]	<b>&lt;0.001</b>	-5.65 [-9.67,-1.64]	<b>&lt;0.01</b>
Low	Reference							
<b>Adherence</b>								
High	-19.42 [-24.62, -14.22]	<b>&lt;0.001</b>	-15.64 [-21.43, -9.85]	<b>&lt;0.001</b>	-12.85 [-15.81, -9.90]	<b>&lt;0.001</b>	-9.75 [-13.0, -6.50]	<b>&lt;0.001</b>
Low	Reference							
<b>Psychosocial Variables</b>								
<i>Social Support</i>								
High	-9.03 [-14.68, -3.38]	<b>&lt;0.01</b>	-1.76 [-7.09, 3.57]	0.52	-5.28 [-8.63, -1.94]	<b>&lt;0.01</b>	-0.84 [-3.83, 2.15]	0.58
Low	Reference							
<i>Active Coping</i>								
High	-5.22 [-10.99, 0.55]	0.08	-0.54 [-5.92, 4.84]	0.84	-2.97 [-6.39, 0.45]	0.09	-0.06 [-3.08, 2.96]	0.97
Low	Reference							
<b>Demographics</b>								
Age	0.18 [-0.20, 0.56]	0.36	0.39 [0.05, 0.73]	<b>0.02</b>	-0. [-0.57, -0.13]	<b>&lt;0.01</b>	-0.26 [-0.45, -0.07]	<b>&lt;0.01</b>
Black	2.75 [-3.08, 8.59]	0.35	5.02 [-0.48, 10.52]	0.07	1.93 [-1.53, 5.38]	0.27	1.23 [-1.86, 4.31]	0.43
Male	7.14 [1.27, 13.00]	<b>0.02</b>	0.26 [-5.16, 5.69]	0.92	5.62 [2.19, 9.05]	<b>&lt;0.01</b>	2.10 [-0.94, 5.14]	0.18
<b>R<sup>2</sup></b>			0.31				0.38	

Multivariate Model: Adjusted for adherence, social support, active coping, age, race, and gender.

## **Chapter 5**

### **DISCUSSION**

Although the spirituality and health literature has emphasized the positive relationship between some spiritual characteristics and various health domains, to our knowledge the present study is one of the first quantitative studies to examine the effects of spirituality on antihypertensive medication adherence and blood pressure in community-dwelling older adults with hypertension. As such, it contributes to both the adherence and the spirituality and health literature. Because the conclusions of Aim 1 (the pilot study) have been previously discussed, the following sections summarize the prominent findings from the main study (aims 2 and 3), possible explanations for the findings, the limitations and strengths of the study, and possible directions for future research.

#### **Summary of Findings**

##### **Spirituality and Medication Adherence (Aim 2)**

This study was informed by a conceptual model (Figure 1) that suggests three dimensions of spirituality (i.e., faith in a transcendent force, relationship with God and others, and transformation and consolation) which may directly and indirectly affect adherence behavior and may also be useful in decreasing blood pressure and maintaining control.<sup>26</sup> Because this model has never been tested, nor have the indirect pathways which mediate the relations of spirituality to medication adherence been empirically evaluated, this dissertation provides important contributions to the literature. This exploratory study examined self-ranking of spirituality and active SHLC beliefs in relation to self-reported

medication adherence. These two spiritual measures represent the three dimensions of spirituality in the conceptual model.

Supporting the hypothesis for Aim 2, the logistic regression models indicated that both self-ranking of spirituality and active SHLC beliefs are significantly and positively related to self-reported medication adherence. The positive relationships held true even after adjusting for the psychosocial (social support and active coping) and demographic variables (age, race, and gender) in multivariate analyses. These results are supportive of earlier studies that evaluated the associations between spiritual characteristics and other positive health behaviors (e.g., diet, exercise, lower alcohol/smoking prevalence).<sup>34,121,122,130,336,337</sup> Furthermore, these results support previous qualitative studies in which informants indicated that their spirituality is a positive resource for coping with and managing their chronic illness.<sup>43,59-61,338</sup>

Most of the previous quantitative studies have examined only one, concrete measure of spirituality, religious service attendance, without considering the broader aspects of spirituality. Most importantly, these previous studies did not evaluate spirituality in relation to medication adherence, which is a crucial health behavior for chronic disease maintenance and longevity. The majority of past qualitative studies, moreover, were conducted in overwhelmingly homogeneous racial minority populations, which limits the generalizability of their findings. Therefore, the current study supplied new information that contributes to the literature on the role of spirituality in adherence behavior in a racially diverse sample of older adults.

### **Possible Explanations of Findings**

The cross-sectional design of the present study limits its ability to definitively unravel the mechanisms by which spirituality affects adherence behavior beyond the associations observed. However, by building on the insights of previous researchers—and taking into



account the key strengths of the present study (i.e., diverse hypertensive sample, use of different measures of spirituality) when viewed in the context of the extant literature, some possible reasons for the findings can be provided. The most descriptive studies to date reside in the HIV and cancer literature, where researchers report that higher spirituality predicts adherence to antiretroviral therapy<sup>33,269,339,340</sup> and that patients often become spiritual after diagnosis, rely on their spirituality for coping, and try to deal with the challenges of their illnesses both purposefully and positively.<sup>240,301,341</sup> It is believed that the nature of these diseases (HIV and cancer) may influence why and how these patients incorporate their spirituality in disease management.<sup>339,342</sup>

The stressors and challenges of hypertension, a disease even more prevalent in the United States than HIV or cancer, may also catalyze patients to rely on their spirituality for meaning of their illness and disease management—responses that have been particularly noted in qualitative studies involving older Black women.<sup>59,151,343</sup> Informants have articulated that they use their faith in God and spiritual practices (e.g., meditation, prayer, scripture reading) to specifically guide their self-care management, including taking their medications.<sup>43,59,158,159,343</sup> Our findings suggest that spirituality may function as a positive resource for White older adults as well. The older adult population, regardless of race, is known to regard spirituality as not only a significant personal experience involving intimate relationship with a transcendent, divine force,<sup>344</sup> but also as a source of guidance about how to behave in the context of life events, including health crises.<sup>344-347</sup> Some reports have specifically found that spirituality offers support, enhances self-empowerment, and provides strength for individuals to cope with chronic illness.<sup>39,59,348,349</sup> These effects may be at play in our study, in that supportive guidance and the power to cope are inherent to participants' spiritual identity and beliefs. As seen in the bivariate analyses, both spiritual variables were

positively associated with social support and active coping as well as with adherence behavior.

For some patients, spirituality is a source for transformation (i.e., personal growth) and consolation, which in turn provide strength to proactively cope with chronic illness.<sup>39,342,350</sup> These effects have been documented in cancer,<sup>351</sup> HIV/AIDS,<sup>339</sup> and in the management of diabetes<sup>159</sup> as well as hypertension.<sup>151</sup> In the present study, elements of the participants' spiritual alignment or faith may have enabled them to come to terms with their hypertension and also provided them with the strength and self-empowerment to take control of their situation by adhering to their medication. These effects have been observed in previous studies of older adults.<sup>59,338,346</sup>

Because of the common perception that patients (especially minorities and older adults) who are highly spiritual/religious tend to relinquish control or adopt a passive orientation toward their health,<sup>352,353</sup> the spiritual variable of active SHLC was specifically chosen for the current study.<sup>263,279,280</sup> As hypothesized, participants with high active SHLC reported better adherence than those with low active SHLC, perhaps because the former group considers health maintenance to be a partnership with God in which they must fulfill certain responsibilities (e.g., take their medications). Evidence for this effect has been found in qualitative studies in which informants viewed management of their hypertension as a collaborative relationship between God and an individual<sup>59,151</sup> and in studies in which active SHLC beliefs were positively associated with health-promoting behaviors and inversely related to health risk behaviors.<sup>160,279,283,299</sup> However, findings from these studies and others like them are limited as they have mostly involved examining these factors in minority women. Because of the lack of cross-racial and studies involving men, future research should examine the similarities and differences of spirituality in relation to adherence by race and gender.

### **Mediation Analysis: Social Support & Active Coping (Aim 2a)**

Aim 2a addressed the indirect pathways by which spirituality may be linked to self-reported adherence behavior, with social support and active coping as putative mediators. The expectation was that the benefits of spirituality would provide increased social support and active coping, which function as resources to overcome barriers associated with medication adherence.<sup>26</sup> Contrary to the conceptual model, however, neither of the psychosocial variables (social support and active coping) were found to be significant mediators in the relationship between spirituality and self-reported adherence. Although the present study did not produce evidence in support of Hypothesis 2a, this may be because the study was under-powered for mediational analysis. Another possible explanation for the insignificant results may be the lack of data on study participants' level of self-efficacy. Increased self-efficacy has been linked to spiritual practices and beliefs across different populations;<sup>43,111,136,354</sup> in fact, some researchers have noted that the relational aspect of spirituality may increase one's capability or self-efficacy to manage different health situations and decrease the barriers to health-promoting activities.<sup>26,345,352</sup> Although self-efficacy was not measured in the present study, it may have some bearing on how social support and active coping functioned in this sample of older adults. In addition, other mediating and/or moderating relationships may have been operating between the spirituality and adherence variables that were not measured in the present study.

The literature contains insufficient evidence to show how social support functions as a mediator between spirituality and other health domains and behaviors. Some researchers report significant mediational effects<sup>226,355-358</sup> whereas others have found marginal or no effect.<sup>194,359-362</sup> Although associations between spirituality and active (or positive adaptive) coping have been found,<sup>39,224,229,358,363</sup> and active coping has been linked to improved medication adherence,<sup>244,283,316,364</sup> knowledge of whether active coping mediates the

relationship between spirituality and adherence behavior has been speculative.<sup>26,167,194,352</sup>

Due to this lack of evidence and the limitations of the current study's findings, further investigation of social support and active coping as mediators in this relationship is warranted.

### **Spirituality and Blood Pressure (Aim 3)**

The objective of Aim 3 was to examine the relationship between the spiritual variables and blood pressure. As with the results of Aim 2, spirituality was significantly and positively related to blood pressure. These findings support Hypothesis 3 (i.e., that spirituality has positive effects on blood pressure). In adjusted analysis, participants who reported high spirituality were found to have lower systolic and diastolic blood pressures than participants with low spirituality. This trend was also supported in the analysis with the second spiritual variable; those with high active SHLC had significantly lower systolic and diastolic blood pressures. While these findings support previous reports that aspects of spirituality positively impacts blood pressure and hypertension,<sup>34,37,39,53,174,186,365-368</sup> this study is one of the first to control for medication adherence, which is a major predictor of blood pressure control in hypertension. Past studies have focused mainly on the relationship between religious involvement and blood pressure but have not considered the older adult population, in which individualized aspects of spirituality (as opposed to organized religious expression) have been shown to positively influence health.

Overall, findings from this study strongly indicate that spirituality has positive influences on blood pressure in older adults with hypertension, beyond their adherence to anti-hypertensive therapy. These results may have been influenced by over- or underreporting of spiritual magnitude, active SHLC, or adherence behavior by study participants. Although modest overreporting of spirituality/religiosity is likely,<sup>39</sup> the operationalization of the spiritual variables in this study should have separated the more

spiritual from the less spiritual individuals. Because the current study did not adjust for other behavioral (e.g., diet, exercise, alcohol consumption) and psychological (e.g., stress, anxiety) factors that may affect blood pressure, further investigation is warranted of how spirituality impacts blood pressure (e.g., through behavioral and psychological mechanisms) in hypertensive patients.

## **Limitations**

Several limitations must be recognized when interpreting the results of the present study. First, its results may not be generalizable to other chronic diseases, younger adults, or populations outside the geographical region of central North Carolina. Similarly, older adults who visit senior centers may differ from older adults who do not go to such social gathering places in terms of their resources and/or other salient characteristics that may influence adherence behavior and health. Therefore, the results of this project may not be generalizable to older adults outside of those who visit senior centers.

Second, the cross-sectional design of the present study did not permit determinations of causal relationships among the variables. This design is considered appropriate, however, given that (1) little other examination of the relationship between spirituality and adherence has been made, especially in community-dwelling older adults with hypertension; and (2) a deeper understanding (i.e., the mechanism) itself was examined. For these reasons, the study results should be considered exploratory. Given that the full range of potential variables were beyond the scope of the present study, it is possible that unobserved heterogeneity or unmeasured confounding affected the findings (as there may be other mediating variables that affect the relationships between spirituality, adherence behavior, and blood pressure). In addition, the current study may have been heavily biased toward the Christian faith due to its population and the geographical region in which it was conducted. Different faiths and belief systems (e.g., Christian Science,

Judaism, Islam, Hinduism, Buddhism) may have inherent factors that affect medication-taking behavior and blood pressure quite differently.

Other factors that may influence medication adherence that were not incorporated into the present study include: (1) health literacy, (2) number of health conditions, (3) the number of medications prescribed, and (4) the extent to which participants were burdened by the number of hypertension medications prescribed to them. These factors, which have been associated with adherence outcomes, could have been mediating variables in the relationships observed in this study.<sup>64,82,103,106,369</sup> However, the absence of these factors is not assumed to have skewed the results because the logistic regressions in the present study were adjusted for some predictors known to be correlated with spirituality and blood pressure (i.e., age, race, gender, social support, active coping).

This study relied on participant reports of hypertension diagnosis without access to medical charts or physician diagnosis for confirmation; in addition, one of its primary instruments, the MMAS-8, measures hypertensive medication adherence by relying on participants' memories and self-assessments. Given that some older adults may not remember or know which medications they are prescribed or take for their hypertension, adherence may have been over- or underreported. In addition, some older adults may over-report adherence for reasons of social desirability or to please their health care providers. To reduce the possibility that these factors would function as limitations, the present study was conducted outside of clinic or hospital settings. Although there is evidence in the literature that self-reported adherence measures such as the MMAS-8 have moderate to high concordance with pharmacy refill records and electronic monitoring devices,<sup>370-372</sup> including additional and more objective measures of adherence would be ideal. The MMAS-8 was used because it is a disease-specific adherence measure, was originally validated in hypertensive older adults, and has been shown to have high concordance with pharmacy

refill records.<sup>307,308</sup> Nevertheless, the possibility of bias in participants' ability to accurately and truthfully report their adherence behavior must be acknowledged.

Another consideration for the current study has to deal with the measurement of the active coping variable used in analysis. The JHAC12 was used to assess this construct, and following the developers methodology of scoring, a median split was used to categorize participants into the high and low active coping groups. There are a couple of issues that must be recognized with the use of this categorization scheme. First, dichotomization of the participants' continuous active coping scores (ranging from 12 to 60), may have resulted in a loss of power and residual confounding.<sup>202</sup> Also, it is unclear whether using the median split score is an optimal and meaningful cutpoint with regards to the assessment of the active coping concept. Finally, using the median split as a cutpoint limits the ability to compare active coping scores across different studies because the median score will most likely be different for different sample populations.

In a sensitivity analysis of the current study data, when comparing active coping as a continuous measure versus as a dichotomized median split measure, the results did not change with regards to the significance, magnitude and the study's conclusions. However, it is best-practice that researchers not dichotomize continuous data unless it clearly makes meaningful sense to do so, and in particular, dichotomization should not be applied to explanatory variables in regression models.<sup>200,202</sup> It is suggested that dichotomization of a continuous variable only be when the distribution of the the variable of interest is highly skewed or its relation with another variable is nonlinear.<sup>200</sup> Although the developers suggest that JHAC12 scores are expected to be skewed with scores on the higher end, they provide no firm justification for the scoring scheme that they have used. Moreover, the median scores for the populations have varied, making it difficult to compare active coping across studies. Thus, further investigation into the proper cutpoint for this active coping measure is

warranted, or it is probably more appropriate to measure this concept as a continuous variable. Future analysis will provide more insight into the scoring scheme of this measure.

Finally, although the results of the present study revealed positive and significant relationships among the spirituality, adherence and blood pressure constructs, the confidence intervals around these estimates were quite large. Therefore, it is difficult to make precise estimates for the magnitude of the associations found. A larger sample size is required for more precise estimates of spirituality's effect on adherence behavior and blood pressure.

### **Strengths**

The present study addresses a persistent gap in the adherence literature and sets the stage for identifying potential mediators and mechanisms by which spirituality may affect adherence behavior in hypertensive patients. It advances the adherence and medical literature as its findings provide evidence that spirituality may be an important factor that has been largely overlooked, but should be considered for some hypertensive patients (i.e., for those who identify as spiritual). Findings from this study also illuminate that patients who have low or no spiritual alignment may be at risk for nonadherence and higher blood pressure. Thus, this study has presented another construct that should be considered in understanding predictors of medication adherence and health outcomes.

As one of the first studies to examine spirituality and medication adherence in a community-dwelling, hypertensive older adult population, the present study extends the design of the majority of past studies, which have focused mostly on terminally ill or hospital inpatients in the terminal stages of illnesses such as cancer and HIV. Although whether the latter group(s) rely upon their spirituality in the same ways and for the same reasons as hypertensive patients remains unknown, it is reasonable to assume that the findings of the



present study are linked to different types of bias, or influences from hypertension itself, on the participants' perspectives or spiritual intensity.

Another strength of the present study is that it broadly defined and measured spirituality, whereas past studies almost routinely narrowed the definition and measurement of spirituality to frequency of religious service attendance or to religiosity (i.e., outward expressions of faith).<sup>167,338,349,373</sup> Because the present study's use of a broad measure of spirituality was more inclusive, it may have more accurately captured participants who identify as spiritual; clearly, the active SHLC measure captured some religious aspects (e.g., the use of the term "God" or "Lord" in some question items) that are relevant to the study's population and geographical location. Although two different domains of spirituality were examined, both were significantly and positively associated with adherence and blood pressure; these associations provide affirmation that the relationships of the variables are valid.

Several other components of the present study contribute to its robustness as well. These include its systematic and careful planning, which involved a pilot study (Aim 1) of the spiritual measures that are relevant to older adults. In addition, a power analysis of an appropriate and sufficient sample size for exploring the possible relationship between spirituality and adherence was conducted—an ideal method that is not available or feasible for many researchers. The fact that this was a multi-center study conducted in a diverse sample of older adults was also advantageous in that the study sample was heterogeneous by race/ethnicity (more than 40% Black/African American). This mix was impressive, given the difficulty of recruiting and enrolling Blacks into research studies, especially in the South. The enrollment of a fairly even distribution of both racial identifications was also advantageous because Blacks have been shown to have poorer adherence and blood pressure control than Whites.

## **Implications for Future Research and Practice**

The findings of the present study may serve as a useful starting point for the design of future studies on additional domains of spirituality in relation to hypertension self-care management and outcomes. Future research should examine these domains across and within other populations. Such studies would provide necessary insight into whether the concepts are consistent across different cultures, in different geographical regions, and among different racial/ethnic backgrounds, spiritual faiths, and age groups. To extend the present study in these ways will be clinically important because hypertension is just not an older adults' disease, nor can its presence be classified as homogeneous in terms of location, ethnicity, and so forth. Hypertension affects all ages, diverse communities and a large proportion of the population in the United States.<sup>374</sup>

Clearly, the variables of interest must be examined in larger and more diverse samples. Although the logistic regression results of the present study revealed significantly strong associations between spirituality, self-reported adherence, and blood pressure, the confidence intervals around the estimates were large and imprecise. Therefore, a precise calculation of the magnitude of the effect of spirituality on these outcomes cannot be made; the large estimates may merely be a function of the modest sample size. A larger sample, as well as use of additional and more objective measures of adherence (e.g., pharmacy refills) may generate more precise results.<sup>26,167,194,352</sup> Use of additional and more objective measures of medication adherence will help to minimize the influence of cognitive functionality within the sample and to confirm accuracy of self-reported adherence behavior.

Next, because the use of a cross-sectional study design in the present study provides evidence for an association between the spiritual variables and the outcomes, a prospective study design would permit the assessment of adherence behavior and blood pressure over time and improve the ability to make causal inferences among the variables.

Due to the current findings and inconsistent reports in the literature, future research should attempt to further examine the mechanisms by which spirituality affect health behavior and health outcomes. In particular, social support and active coping should be further examined as mediators in the relationship between spirituality and medication adherence. Future studies should also attempt to identify other important mediators of spirituality and adherence and the impact of these variables on cardiovascular outcomes. Such mechanisms and factors may include: (1) subjects' level of spiritual engagement; (2) subjects' spiritual practices, beliefs, or faiths; (3) subjects' levels of self-efficacy and strength; and (4) the effect of spiritual variables upon other determinants of subjects' medication adherence (e.g., spiritual concordance with health providers). Such research would help resolve certain unknowns that have been consistently noted in the literature, which would subsequently help researchers and clinicians better develop appropriate adherence and hypertension interventions.

That spirituality may assist in healthy lifestyle behaviors and in improving health outcomes, such as decreasing blood pressure,<sup>190,349</sup> is evidenced in the literature and supported by the current findings. However, how health care professionals can use this information to help improve adherence behavior and hypertension outcomes will remain unclear until the research needs mentioned above are addressed. Nevertheless, health care providers should increase their sensitivity to patients' spiritual orientation, understand the prevalent beliefs (or lack thereof) in the communities they serve, and refer patients to chaplains or ministers when appropriate (e.g., when patients have spiritual struggle that conflicts with disease management).<sup>25,375</sup> These approaches are important for patient-centered and culturally appropriate care.

Of course it would be grossly inappropriate to prescribe or try to change a patient's spirituality; however, the attributes and benefits of spirituality in patients' lives are subjects

that researchers and clinicians should actively consider in order to help inform the development of interventions that are appropriate and effective for individuals who do not identify as spiritual. For example, activities that may or may not be necessarily spiritual in nature have been shown to positively impact health; these include meditation (or mindfulness techniques), acts of compassion, and participation in strong social support networks.<sup>376,377</sup> Capitalizing on these activities may cultivate adherence behavior and ameliorate outcomes in older adults who are at high risk for nonadherence but lack spiritual alignment. From a public health standpoint, researchers may explore the use of faith-based organizations and community support groups as platforms for health education about hypertension and the importance of medication adherence.

## **Conclusion**

The literature emphasizes the importance of spirituality in overall health and some behaviors of chronically ill persons; however, spirituality has been largely overlooked in the study of medication adherence. The present study addresses a pertinent gap in the literature regarding the association between spirituality and medication adherence in hypertensive older adults. It is one of the first studies to examine spirituality, adherence and blood pressure outcomes from a conceptual framework and to explore the mechanism from both psychosocial and cultural contexts. Study results indicate that spirituality is significantly and positively associated with both medication adherence and significantly related to lower blood pressure. The discovery of these associations provides direction for future studies that will aid in understanding how health professionals can use this information to provide culturally sensitive and patient-centered care that will improve medication adherence and cardiovascular outcomes.

## **APPENDICES**

Appendix 1. Duke University Religion Index (DUREL) used in Aim 1

Appendix 2. Spiritual Health Locus of Control Scale (SHLCS)

Appendix 3. Self-ranking of Spirituality

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Appendix 9. Visual Analog Scale for Medication Adherence

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Appendix 12. Referral List Form

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Appendix 14. Blood Pressure Measurement Protocol

## Appendix 1. Duke University Religion Index (DUREL); used in Aim 1

Subject #: \_\_\_\_\_

Date of Visit: \_\_\_\_\_

**Directions:** Please answer the following questions about your religious beliefs and/or involvement. Please indicate your answer by circling one number.

(1) How often do you attend church or other religious meetings?

1. More than once/wk
2. Once a week
3. A few times a month
4. A few times a year
5. Once a year or less
6. Never

(2) How often do you spend time in private religious activities, such as prayer, meditation or Bible study?

1. More than once a day
2. Daily
3. Two or more times/week
4. Once a week
5. A few times a month
6. Rarely or never

***The following section contains 3 statements about religious belief or experience. Please mark the extent to which each statement is true or not true for you.***

(3) In my life, I experience the presence of the Divine (i.e., God).

1. Definitely true of me
2. Tends to be true
3. Unsure
4. Tends *not* to be true
5. Definitely *not* true

(4) My religious beliefs are what really lie behind my whole approach to life.

1. Definitely true of me
2. Tends to be true
3. Unsure
4. Tends *not* to be true
5. Definitely *not* true

(5) I try hard to carry my religion over into all other dealings in life.

1. Definitely true of me
2. Tends to be true
3. Unsure
4. Tends *not* to be true
5. Definitely *not* true

Koenig HG, Meador K, Parkerson G. Religion Index for Psychiatric Research: A 5-item Measure for Use in Health Outcome Studies. American Journal of Psychiatry 1997; 154:885-886

## Appendix 2. Spiritual Health Locus of Control Scale (SHLCS)

Subject #: \_\_\_\_\_

Date of Visit \_\_\_\_\_

### SHLCS

Please think about the following statements regarding your spiritual beliefs and your health in general. The following questions use the word “God” which refers to whatever form of higher power you believe in. For each statement, circle the one number (1, 2, 3, 4) that comes closest to how much you *agree with* that statement.

**\*\*\*There are no right or wrong answers to your responses. We just want to know your opinions to these statements\*\*\***

1.	Through my faith in God, I can stay healthy.	<b>4</b> Strongly Agree	<b>3</b> Agree	<b>2</b> Disagree	<b>1</b> Strongly Disagree
2.	If I lead a good spiritual life, I will stay healthy.	<b>4</b> Strongly Agree	<b>3</b> Agree	<b>2</b> Disagree	<b>1</b> Strongly Disagree
3.	If I stay healthy, it's because I am right with God.	<b>4</b> Strongly Agree	<b>3</b> Agree	<b>2</b> Disagree	<b>1</b> Strongly Disagree
4.	Living the way the Lord says I'm supposed to live means I have to take care of myself.	<b>4</b> Strongly Agree	<b>3</b> Agree	<b>2</b> Disagree	<b>1</b> Strongly Disagree
5.	Even though I trust God will take care of me, I still need to take care of myself.	<b>4</b> Strongly Agree	<b>3</b> Agree	<b>2</b> Disagree	<b>1</b> Strongly Disagree
6.	God gives me the strength to take care of myself.	<b>4</b> Strongly Agree	<b>3</b> Agree	<b>2</b> Disagree	<b>1</b> Strongly Disagree
7.	I rely on God to keep me in good health.	<b>4</b> Strongly Agree	<b>3</b> Agree	<b>2</b> Disagree	<b>1</b> Strongly Disagree
8.	God works through doctors to heal us.	<b>4</b> Strongly Agree	<b>3</b> Agree	<b>2</b> Disagree	<b>1</b> Strongly Disagree
9.	Prayer is the most important thing I do to stay healthy.	<b>4</b> Strongly Agree	<b>3</b> Agree	<b>2</b> Disagree	<b>1</b> Strongly Disagree
10.	If I stay well, it is because of the grace of the good Lord.	<b>4</b> Strongly Agree	<b>3</b> Agree	<b>2</b> Disagree	<b>1</b> Strongly Disagree
11.	It's ok not to seek medical attention because I feel that God will heal me.	<b>4</b> Strongly Agree	<b>3</b> Agree	<b>2</b> Disagree	<b>1</b> Strongly Disagree
12.	There is no point in taking care of myself when it's all up to God anyway.	<b>4</b> Strongly Agree	<b>3</b> Agree	<b>2</b> Disagree	<b>1</b> Strongly Disagree
13.	God and I share responsibility for my health.	<b>4</b> Strongly Agree	<b>3</b> Agree	<b>2</b> Disagree	<b>1</b> Strongly Disagree



## Self-ranking of Spirituality and SMAS

Please think about the following statements regarding your spiritual/religious beliefs and how you take your medications. The following questions use the word “God” which refers to whatever form of higher power you believe in. For each statement, circle the one number (1, 2, 3, 4) that comes closest to how much you *agree with* that statement.

**\*\*\*There are no right or wrong answers to your responses. We just want to know your opinions to these statements\*\*\***

### Self-Ranking of Spirituality

To what extent do you consider yourself a spiritual/religious person?

☐<sub>4</sub> Very spiritual/religious    ☐<sub>3</sub> Moderately spiritual/religious    ☐<sub>2</sub> Slightly spiritual/religious    ☐<sub>1</sub> Not at all

### SMAS

1. God works through health providers (doctors, nurses, pharmacists) to keep me in good health.	4 Strongly Agree	3 Agree	2 Disagree	1 Strongly Disagree
2. My spiritual/religious beliefs influence the way I take my medications.	4 Strongly Agree	3 Agree	2 Disagree	1 Strongly Disagree
3. I have faith that God is healing me through my medications.	4 Strongly Agree	3 Agree	2 Disagree	1 Strongly Disagree
4. God wants me to take my medications the way my doctor prescribed them for me.	4 Strongly Agree	3 Agree	2 Disagree	1 Strongly Disagree
5. I can get better without taking medications, by relying on my spiritual/religious beliefs.	4 Strongly Agree	3 Agree	2 Disagree	1 Strongly Disagree
6. I use my spiritual beliefs as a guide for how to take my medications.	4 Strongly Agree	3 Agree	2 Disagree	1 Strongly Disagree
7. I have faith that taking medications is part of God's plan to heal me.	4 Strongly Agree	3 Agree	2 Disagree	1 Strongly Disagree
8. I consult with (or pray to) God on whether or not I should take my medications.	4 Strongly Agree	3 Agree	2 Disagree	1 Strongly Disagree
9. My spiritual/religious beliefs help me to take my medications like I am supposed to.	4 Strongly Agree	3 Agree	2 Disagree	1 Strongly Disagree
10. I would stop taking my medications if God revealed to me to trust in Him, only.	4 Strongly Agree	3 Agree	2 Disagree	1 Strongly Disagree
11. Sometimes I feel better by just praying, rather than taking my medications.	4 Strongly Agree	3 Agree	2 Disagree	1 Strongly Disagree
12. If I take medications, it means that I am not relying on God to heal me.	4 Strongly Agree	3 Agree	2 Disagree	1 Strongly Disagree

## Appendix 4. John Henryism Active Coping Scale (JHAC12)

### JHAC12

We would like to ask you some questions about how you see yourself right now, today, as a man/woman living and doing things in the real world. Please read each statement and then circle the one number that comes closest to how TRUE or FALSE each statement is for you, personally. For each statement, circle only one number (1, 2, 3, 4 or 5).

**\*\*\*There are no right or wrong answers to your responses about these statements\*\*\***

	1	2	3	4	5
1. I've always felt that I could make of my life pretty much what I wanted to make of it.	Completely False	Somewhat False	Don't Know	Somewhat True	Completely True
2. Once I make up my mind to do something, I stay with it until the job is completely done.	Completely False	Somewhat False	Don't Know	Somewhat True	Completely True
3. I like doing things that other people thought could not be done.	Completely False	Somewhat False	Don't Know	Somewhat True	Completely True
4. When things don't go the way I want them to, that just makes me work even harder.	Completely False	Somewhat False	Don't Know	Somewhat True	Completely True
5. Sometimes I feel that if anything is going to be done right, I have to do it myself.	Completely False	Somewhat False	Don't Know	Somewhat True	Completely True
6. It's not always easy, but I manage to find a way to do the things I really need to get done.	Completely False	Somewhat False	Don't Know	Somewhat True	Completely True
7. Very seldom have I been disappointed by the results of my hard work.	Completely False	Somewhat False	Don't Know	Somewhat True	Completely True
8. I feel that I am the kind of individual who stands up for what he/she believes in, regardless of the consequences.	Completely False	Somewhat False	Don't Know	Somewhat True	Completely True
9. In the past, even when things got really tough, I never lost sight of my goals.	Completely False	Somewhat False	Don't Know	Somewhat True	Completely True
10. It's important for me to be able to do things the way I want to do them rather than the way other people want me to do them.	Completely False	Somewhat False	Don't Know	Somewhat True	Completely True
11. I don't let my personal feelings get in the way of doing a job.	Completely False	Somewhat False	Don't Know	Somewhat True	Completely True
12. Hard work has really helped me to get ahead in life.	Completely False	Somewhat False	Don't Know	Somewhat True	Completely True

James S.A., Strogatz D.S., Wing S.B., Ramsey D.L. Socioeconomic Status, John Henryism, and Hypertension in Blacks and Whites. American Journal of Epidemiology, 1987, vol. 126, pp. 664-673

## **Appendix 5. Tangible, Informational and Emotional Social Support (adapted TIES)**

Please think about the following questions regarding the support you have with your health and taking your medications. For each question, circle the one number (2, 1, or 0) that comes closest to how often you have the support you need.

### **HOW OFTEN IS THERE....**

- |   |  |   |   |
|---|--|---|---|
| 1. Someone to encourage you to take your medications?   | <b>2</b><br><b>All or Most</b><br><b>of the time</b> | <b>1</b><br><b>Some of</b><br><b>the time</b> | <b>0</b><br><b>None of</b><br><b>the time</b> |
| 2. Someone available to help you get access to your medications (getting your prescriptions filled)?  | <b>2</b><br><b>All or Most</b><br><b>of the time</b> | <b>1</b><br><b>Some of</b><br><b>the time</b> | <b>0</b><br><b>None of</b><br><b>the time</b> |
| 3. Someone available to actually take you or go with you to the hospital/doctor when you are sick?    | <b>2</b><br><b>All or Most</b><br><b>of the time</b> | <b>1</b><br><b>Some of</b><br><b>the time</b> | <b>0</b><br><b>None of</b><br><b>the time</b> |
| 4. Someone who could discuss your condition or health concerns with your doctor?                      | <b>2</b><br><b>All or Most</b><br><b>of the time</b> | <b>1</b><br><b>Some of</b><br><b>the time</b> | <b>0</b><br><b>None of</b><br><b>the time</b> |
| 5. Someone who could visit you or check up on you while you are in the hospital or at home?           | <b>2</b><br><b>All or Most</b><br><b>of the time</b> | <b>1</b><br><b>Some of</b><br><b>the time</b> | <b>0</b><br><b>None of</b><br><b>the time</b> |
| 6. Someone (other than your doctor) you could turn to for general advice regarding your health?       | <b>2</b><br><b>All or Most</b><br><b>of the time</b> | <b>1</b><br><b>Some of</b><br><b>the time</b> | <b>0</b><br><b>None of</b><br><b>the time</b> |
| 7. Someone (other than your doctor) you could turn to for general advice regarding your medications?* | <b>2</b><br><b>All or Most</b><br><b>of the time</b> | <b>1</b><br><b>Some of</b><br><b>the time</b> | <b>0</b><br><b>None of</b><br><b>the time</b> |

Adapted from: Boutin-Foster C; Alexander J. Development and Validation of the Tangible, Informational, and Emotional Social Support Survey. Journal of Cardiopulmonary Rehabilitation 2006; 26:307-313.

### Appendix 6. Morisky Compliance Assessment Scale (4-item)

Subject #: \_\_\_\_\_

Visit: Baseline

3 months

6 months

Date of Visit: \_\_\_\_\_

#### MORISKY INSTRUMENT

#### SELF-REPORT MEASURE OF ADHERENCE

Interviewer: I am going to ask you four questions.

Think about how you have taken your medications during the past 4 weeks.

	Yes	No
1. Did you ever forget to take your medicines?		
2. Are you careless at times about taking your medicines?		
3. When you feel better, did you sometimes stop taking your medicines?		
4. Sometimes if you felt worse when you took your medicines, did you stop taking them?		

Scoring: A response of "Yes" is equal to 0 and a response of "No" is equal to 1.

Range: 0-4

Total Score: \_\_\_\_\_

## Appendix 7. Demographic Questionnaire

Subject #: \_\_\_\_\_

Date of Visit: \_\_\_\_\_

Study site: \_\_\_\_\_

### Section I.

1. Age

2. Date of Birth (e.g., 01/01/1920)

3. Has your doctor (or other health provider) ever told you that you have high blood pressure (or hypertension)?

☐ Yes

☐ No

If yes, how long have you had high blood pressure? \_\_\_\_\_

4. Do you take a high blood pressure medicine(s)?

☐ Yes

☐ No

5. Do you live independently in the community (not in an assisted living or long term care facility)?

☐ Yes

☐ No

6. Race

☐ Black/African American

☐ White

☐ Other (specify)

\_\_\_\_\_

7. Ethnicity

☐ Hispanic or Latino

☐ Not Hispanic or Latino

8. Gender

☐ Female

☐ Male

9. Marital Status

☐ Never married

☐ Married

☐ Widowed

☐ Divorced

☐ Separated

10. What is the highest grade or year of school you completed?

☐ Never attended school or only attended kindergarten

☐ Grades 1 through 8 (Elementary)

☐ Grades 9 through 11 (Some high school)

☐ Grade 12 or GED (High school graduate)

☐ College 1 year to 3 years (Some college or tech.I school)

☐ College 4 years (College graduate)

☐ Postgraduate work

☐ Refused to answer

Subject #: \_\_\_\_\_ Date of Visit: \_\_\_\_\_ Study site: \_\_\_\_\_

11. "Was there a time in the past 3 months when you needed prescription medication but could not purchase it due to cost?"

☐ Yes ☐ No ☐ Don't know/Not sure

If "Yes," what did you do? ☐ Went without it ☐ Someone else bought it for me? ☐ Other \_\_\_\_\_

12. Without talking about exact dollars, how would you describe your household's financial situation right now?

Would you say that....

- ☐ After paying the bills, you still have enough money for special things that you want.
- ☐ You have enough money to pay the bills, but little spare money to buy extra or special things.
- ☐ You have money to pay the bills, but only because you have to cut back on things.
- ☐ You are having difficulty paying the bills, no matter what you do.
- ☐ Don't know
- ☐ Refused

13. Can you tell me if your household income was more or less than \$10,000 in the past 12 months?

- ☐ Less than \$10,000 (Go to Section II)
- ☐ \$10,000 or more
- ☐ Don't know
- ☐ Refused

14. Can you tell me if your household income was more or less than \$35,000 in the past 12 months?

- ☐ Less than \$35,000
- ☐ \$35,000 or more
- ☐ Don't know
- ☐ Refused

Subject #: \_\_\_\_\_ Date of Visit: \_\_\_\_\_ Study site: \_\_\_\_\_

Section II.

***Blood Pressure Measurement***

**First digital blood pressure**

SBP / DBP

Time: \_\_\_\_\_ / \_\_\_\_\_ mmHg

***\*\*Wait at least 5 minutes seated \*\****

**Second digital blood pressure**

SBP / DBP

Time: \_\_\_\_\_ / \_\_\_\_\_ mmHg

***\*Ask participant if s/he will need assistance with completing the remaining study surveys \*\****

Did participant request or require assistance with completing study surveys (i.e., reading each survey item)?

☐ Yes ☐ No

If yes, what was the reason for assistance (e.g., literacy, vision): ☐ Literacy ☐ Vision Impairment  
☐ Do not know ☐ Other (specify) \_\_\_\_\_



## Appendix 8. Morisky Medication Adherence Scale (MMAS 8-item)<sup>®</sup>

Subject #: \_\_\_\_\_

Date of Visit: \_\_\_\_\_

<b>You indicated that you are taking medication for your 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.</b>		
<b>(Please circle the correct number)</b>		
1. Do you sometimes forget to take your high blood pressure pills?	<b>No=1</b>	<b>Yes=0</b>
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 medicine?	<b>No=1</b>	<b>Yes=0</b>
3. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?	<b>No=1</b>	<b>Yes=0</b>
4. When you travel or leave home, do you sometimes forget to bring along your high blood pressure medication?	<b>No=1</b>	<b>Yes=0</b>
5. Did you take your high blood pressure medicine yesterday?	<b>No=1</b>	<b>Yes=0</b>
6. When you feel like your high blood pressure is under control, do you sometimes stop taking your medicine?	<b>No=1</b>	<b>Yes=0</b>
7. Taking medication every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your high blood pressure treatment plan?	<b>No=1</b>	<b>Yes=0</b>

8. How often do you have difficulty remembering to take all your medications?

**(Please circle the correct number)**

Never/Rarely.....	4
Once in a while.....	3
Sometimes.....	2
Usually.....	1
All the time .....	0

Use of the <sup>®</sup>Morisky Medication Adherence Scale (MMAS-8) is protected by US copyright laws. Permission for use is required. A license agreement is available from: Donald E. Morisky, ScD, ScM, MSPH, Professor, Department of Community Health Sciences, UCLA School of Public Health, 650 Charles E. Young Drive South, Los Angeles, CA 90095-1772. E-mail: [dmorisky@ucla.edu](mailto:dmorisky@ucla.edu); Phone: (310) 825-8508

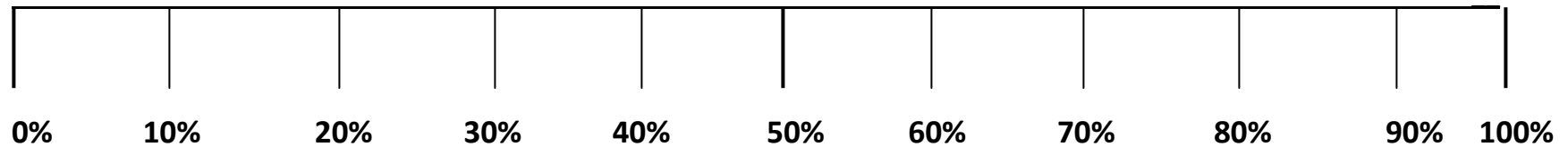
## Appendix 9. Visual Analog Scale for Medication Adherence

Subject #: \_\_\_\_\_

Date of Visit: \_\_\_\_\_

### Instructions to participant:

On a scale of 0% to 100%, which of the following percentages best reflects your compliance with your high blood pressure medicine over the past 4 weeks?



164



Have taken none of the recommended doses over the past 4 weeks



Have taken about half the recommended doses over the past 4 weeks



Have taken all of the recommended doses over the past 4 weeks

## **Appendix 10. Tangible, Informational and Emotional Social Support Survey**

**Subject #:** \_\_\_\_\_

**Date of Visit:** \_\_\_\_\_

**Please think about the following questions regarding the support you have with your health and taking your medications. For each question, circle the one number (2, 1, or 0) that comes closest to how often you have the support you need.**

**\*\*\*There are no right or wrong answers. We just want to know your opinion to these questions.**

## HOW OFTEN IS THERE....

1. Someone to encourage you to follow a healthy diet?	2 All or Most of the time	1 Some of the time	0 None of the time
2. Someone available to help you to prepare healthy meals?	2 All or Most of the time	1 Some of the time	0 None of the time
3. Someone to encourage you to take your medications?	2 All or Most of the time	1 Some of the time	0 None of the time
4. Someone available to help you get access to your medications (getting your prescriptions filled)?	2 All or Most of the time	1 Some of the time	0 None of the time
5. Someone available to actually take you or go with you to the hospital/doctor when you are sick?	2 All or Most of the time	1 Some of the time	0 None of the time
6. Someone to encourage you to exercise?	2 All or Most of the time	1 Some of the time	0 None of the time
7. Someone who could participate in exercise with you?	2 All or Most of the time	1 Some of the time	0 None of the time
8. Someone who could discuss your condition or health concerns with your doctor?	2 All or Most of the time	1 Some of the time	0 None of the time
9. Someone you can talk to about important things in your life?	2 All or Most of the time	1 Some of the time	0 None of the time
10. Someone who could visit you or check up on you while you are in the hospital or at home?	2 All or Most of the time	1 Some of the time	0 None of the time
11. Someone who makes you laugh?	2 All or Most of the time	1 Some of the time	0 None of the time
12. Someone you can go out with just for fun (like going to the movies)?	2 All or Most of the time	1 Some of the time	0 None of the time
13. Someone who could make sure you get enough rest and relaxation?	2 All or Most of the time	1 Some of the time	0 None of the time
14. Someone to encourage you, tell you "things will be okay," or reassure you?	2 All or Most of the time	1 Some of the time	0 None of the time
15. Someone (other than your doctor) you could turn to for general advice regarding your health (eating, dieting, exercise, medications)?	2 All or Most of the time	1 Some of the time	0 None of the time
16. If you smoke, is there someone to encourage you to quit smoking?	2 All or Most of the time	1 Some of the time	0 None of the time



**High Blood Pressure?**

**Taking MEDICINE  
to treat it?**



We want to learn about your experiences with taking your high blood pressure medication.

**Are you  $\geq 65$  years old?  
Do you have High Blood Pressure?  
Do you take medicine to treat it?**

If so, you may be eligible to participate in a study to help researchers from the UNC Eshelman School of Pharmacy understand what is important to you when it comes to your health and taking your medicine.

If you are interested in learning more about this study, please contact:

**Amica Yon, PharmD  
919-843-8757 (office)  
336-577-6194 (cell)**

## Appendix 12. Referral List Form.

### Factors Influencing Medication-taking Behavior in Older Adults with Hypertension Study

#### REFERRAL FORM

If you would like to learn more about this study, your name and contact information will be forwarded to the researcher and she will contact you by phone. This information will not be shared for any other purpose. If you are interested in participating in this study, please keep in mind that you must meet the following eligibility criteria:

- Must self-identify as black or white
- 65 years of age or older
- On at least 1 high blood pressure medication
- Living independently (i.e., cannot reside in assisted living facility or nursing home)
- Be English-speaking

Patient Name	Contact Telephone Number
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2.	
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9.	
10.	

## Appendix 13. Telephone Script Used For Recruitment

### Script

1. Hello, may I please speak with Mr/Mrs\_\_\_\_\_. My name is \_\_\_\_\_ and I am a graduate student researcher with the UNC Eshelman School of Pharmacy. How are you today? Your name was forwarded to me by Mrs\_\_\_\_\_ at the \_\_\_\_\_ (*Senior Center*). You provided your name on a list at the center so that someone could follow up with you to describe the study we are conducting and invite your participation.
2. I am the principal investigator for this study and I am calling today to see if you are interested in learning more about our research study. My call today will take less than 10 minutes. Is this an O.K. time to talk?

*If not, see if individual is interested in setting aside a time to talk when it is more convenient for him/her.*

*If the individual is not interested, please thank them for their time.*

3. The purpose of this research study is to learn about different factors that older adults consider important when it comes to their medication-taking behavior and blood pressure control. We want to learn about your personal experiences with taking your high blood pressure medication, and understand your personal beliefs/attitudes, learn about the support you have, and how you cope with having to take your medicine and manage your high blood pressure. If you decide to be in this study your participation will only be for 1 day, and will take about 30 minutes to complete. You will be asked to come to your local senior center for this 30 minute visit at a time that is convenient for you. This can be a day that you have already planned to come to the center. At the study visit you will be interviewed by me (or the research assistant). During this visit, I (or the research assistant) will explain the study in more detail, obtain your consent and signature to participate and then ask you to complete a few questionnaires. For this study, we will also be checking blood pressure (similar to how you get your blood pressure checked at your doctor's office). So, the entire study process will take about 30 minutes and there will be no additional follow-up for this study. In appreciation for your time we will give you a multi-purpose tote bag, a medication pill box, and informational health brochures. Does this sound like something you would be interested in doing? Again, I will explain the study in much greater detail at the first visit.

*If not, please thank them for their time and end the call.*

4. Great! I really appreciate your interest and willingness in helping us. Before we schedule the study visit, would you be willing to answer a few questions to help me determine if you are eligible for this study?

*If yes, proceed; if no thank them for their time and end the call.*

5. Good. I will read off a list of questions. If your answer to any of them is *no*, wait until I am all done and tell me that when I am finished. I do not want you to answer each question, individually. Here are the questions:

Are 65 years or older?

Has your doctor ever told you that you have high blood pressure?

Do you take a medicine to help control your blood pressure?

Do you self-identify your race as being either black or white?

Do you live independently in the community (not in an assisted living or long-term care center)?

Would your response to any of these questions be “no?”

*(If person says yes, thank them for their time and that they are not eligible for the study. If they answer no, proceed)*

6. OK, let’s go ahead and schedule the study visit?

What day is best for you? \_\_\_\_\_

What time is best for you? \_\_\_\_\_

7. That is great. I will call you a day before your visit to remind you of this appointment time.



8. Do you have any questions for me at this time?
9. Thank you so much Mr./Mrs.\_\_\_\_\_. We look forward to meeting you soon. Here is our phone number in case you have to reschedule the appointment or in case you have any questions: 919-843-8757.
10. Have a nice day! And, again thank you for your time!

*If a message has to be left for potential subjects on telephone answering machines or with people other than the potential subject, leave the reason for the call and contact information to minimize the risk of breach of confidentiality. Follow the script as outlined below:*

11. *Voicemail/Answering Machine Script:*

“Greetings! This message is for Mr./Mrs.\_\_\_\_\_ (*potential subject’s name*). It is (*say the date*) at (*say the time*). My name is \_\_\_\_\_ (*name*) from the UNC Eshelman School of Pharmacy. I am calling in reference to the study that you requested to learn more about when you were at the \_\_\_\_\_ (*Senior Center Name*). I would like to briefly describe the study with you and see if you would be interested in participating. Please contact me, \_\_\_\_\_ (*say name again*) at 919-843-8757 if you are still interested in learning more about the study. I hope to hear from you soon. Thank you and have a wonderful day.”

12. *Leaving Message with People other than potential subject:*

“Hello, may I please speak with Mr/Mrs\_\_\_\_\_.”

*When notified that potential subject is unavailable, proceed with...*

“Ok. Is there a better time that I can contact him/her?” (*note day/time if given*) May I also please leave my contact information?

Great! My name is \_\_\_\_\_ from the UNC Eshelman School of Pharmacy. I am calling in reference to a study that Mr./Mrs.\_\_\_\_\_ (*potential subject’s name*) requested to learn more about. S/he can contact me at 919-843-8757 and I will describe the study to him/her. Again, my name is \_\_\_\_\_ and s/he can contact me at 919-843-8757. Thank you for your time and I hope you have a nice day.”

## **Appendix 14. Blood Pressure Measurement Protocol**

### **Blood Pressure Measurement Protocol**

Study personnel will be trained and certified to conduct BP measurements according to this study protocol.

Version: 7/22/2011

### ***Blood Pressure Overview***

Correct measurement of blood pressure (BP) is of importance in this study. It is essential that the procedures described for measuring BP be followed exactly. Precision is essential for valid comparisons of blood pressure between groups of people.

### ***Equipment Required***

OMRON® HEM-907XL digital automated non-invasive blood pressure monitor is used to obtain the outcome blood pressure reading.

### ***Cuffs***

Proper cuff size is essential for accurate BP measurement. OMRON® HEM-907XL is equipped with four different cuff sizes (small, medium, large and extra large), and each cuff is labeled with the arm circumference INDEX and has specific RANGE markings for proper fitting. The range markings are located on the inside of each cuff. The following corresponds to the arm circumference ranges and size for each cuff:

<u>Arm Circumference</u>	<u>Name of the Cuff (Size)</u>
(7" - 9") 17-22 cm	HEM-907-CS19 (Small)
(9" - 13") 22-32 cm	HEM-907-CR19 (Medium)
(13" - 17") 32-42 cm	HEM-907-CL19 (Large)
(17" - 20") 42-50 cm	HEM-907-CX19 (Extra Large)

### ***Preparation for Blood Pressure Measurement***

The setting in which BP readings are taken must be a quiet area. No other activity should be taking place there and temperature fluctuations are minimal. It is recommended that the room temperature be 65-75o F.

### ***Measurement Procedures***

BP will be measured 2 times for each participant during the study visit. It will take approximately 10 minutes to take the readings, including an initial five-minute rest period.

Once the participant has had the procedures explained and the equipment has been checked, BP measurement begins. The following steps must be followed precisely.

The right arm should always be used for the measurements. If the participant indicates that there is a medical reason for not having BP measured on his or her right arm (such as surgery, or if the right arm is missing), reverse chairs and proceed with the left arm. Write a note on the form where BP will be recorded indicating that the left arm has been used. If the participant seems particularly apprehensive about the procedure, delay wrapping the cuff until after the five-minute wait. Measure the arm circumference using the following procedure.

Have participant relax their arm. With the participant's arm relaxed at their side, measure the arm circumference at the midpoint using a measuring tape in metric units. The midpoint of the arm is measured from the acromion or bony extremity of the shoulder girdle to the olecranon or tip of elbow. Select the appropriate cuff size to use for BP measurement based on the arm circumference.

Have the participant put his/her right arm on the table with the palm of hand facing forward. The bend at the elbow (antecubital fossa) should be at heart level. Legs should be uncrossed and feet comfortably flat on the floor with back against the back of the chair. If necessary, place a book, footstool, or other flat object beneath the participant's feet so that they do not dangle.

Align the Artery Position Mark (ART.) on the cuff with the brachial artery. Wrap the cuff snugly using both hands and securely fasten it with the Velcro™ tape. At this time, the lower edge of the cuff must be placed 1/2" to 1" above the inner side of elbow joint. As a second measure of proper cuff size, make sure that the INDEX marking located on the cuff is positioned within the RANGE mark, once the cuff is wrapped on the participant.

- If the INDEX is positioned outside the RANGE, select the cuff suitable for the patient's arm circumference and wrap it again.
- Wrap the cuff so that you can insert only one finger between the cuff and arm.

Keep the level of the cuff at the same level as the heart during the measurement.

**Allow a five-minute wait before taking the BP.** Conversation should be limited during this period. However, a brief explanation of the procedure can be repeated, if necessary, and the next steps of the study process can be described.

After five minutes:

1. Turn on the power button of the monitor by pressing the ON/OFF Button.
2. Connect the cuff to the standard digital monitor.
3. Push the “Start” button to start the measurement.
  - Do not push the START Button without wrapping the cuff.
  - If you want to stop measurement, push the STOP Button. The cuff will rapidly deflate.
4. Record reading of Blood Pressure (systolic and diastolic). The measurement results are displayed by the top to numbers on the monitor.
5. Hit the “Clear” button to clear first reading.
6. Wait 30 seconds having participant raise arm for 5 seconds/ level for 25 seconds  
\*note – you may need to disconnect monitor from cuff when participant raises arm.
7. Allow for a rest period before second reading (~5 minutes)
8. Hit the “Start” Button for second reading.
9. Record the second reading of Blood Pressure.
10. Hit the “Clear” button to clear second reading.
11. Disconnect the cuff from the monitor.
12. Remove the cuff from the participant’s arm.
13. Push the ON/OFF (power) Button to turn off the power.
14. Wipe the cuff and monitor with a disinfectant wipe after use on every participant.

If for any reason, you are unable to get a valid reading of the blood pressure on the participant, ask permission from the participant to retry the BP measurements. Take off the cuff, rewrap it on the arm, and retake BP measurements.

If the participant expresses discomfort during BP measurement, push the STOP Button and the cuff will rapidly deflate. Ask the participant if s/he would like to continue with the assessment. If not, discontinue BP measurement and proceed with study questionnaires.

BP control is considered to be SBP <140mmHg and DBP <90 mmHg. If BP readings for a participant are concerning, for the participants safety the research personnel should instruct the participant to contact his/her physician to have further BP evaluation.

***BP safety levels based upon JNC7 & VA Hypertension Guidelines***

<b><i>BP Outcomes</i></b>	<b><i>Action</i></b>
<b><i>Symptomatic:</i></b>  High: Stroke symptoms, CHF, headache  Low: Dizziness, shortness of breath, chest pain	Study personnel instructs subject to contact MD as soon as possible w/in 24 hours  Study personnel asks subject would s/he like for personnel to call for medical assistance (911)
<b><i>Asymptomatic:</i></b>  <u>SBP &gt; 180 and/or DBP &gt;110*</u>	Study personnel tells subject to contact MD w/in 1 week and to check blood regularly (every 24 hrs) until MD is contacted.

*\* Mean of 2 Outcome Blood Pressure measurements at study visit*

### ***Equipment Maintenance and Safety***

The condition of the instrument for blood pressure measurement is too often ignored in common practice and should be a special responsibility of the principal investigator (PI), who understands the construction and function of the blood pressure equipment. The cleanliness and general working order of the cuffs and monitor display unit can usually be determined by simple inspection. Each week the principal investigator will inspect the OMRON® HEM-907XL blood pressure unit. Upon inspection, the air tubes for each cuff will be checked to assure that they are not clogged or cracked (free of leaks). In addition, the entire monitor unit and cuffs will be wiped with a soft, damp cloth diluted with disinfectant alcohol. Cleaning will be completed by wiping the monitor with a soft, dry cloth. If the BP monitor is not functioning properly, the PI will contact Omron Healthcare's Customer Service at 1-877-216-1336 and the monitor will be removed from service until issues are resolved.

### ***Training***

#### ***Introduction***

In order to standardize the previously described methods of the BP outcome measurement and to ensure that a high level of performance is attained, a training protocol has been developed. Before study personnel begin collecting standardized BP measurements, a training and certification of proper BP measurement will be provided for study personnel.

The principal investigator (Amica Yon, PharmD) will be the trainer. The training protocol will be presented at this time. Documentation of study personnel's training performance from the trainer includes the successful understanding of the equipment, ability to place manual cuff on patient, and correct ascertainment of BP measurement.

#### *Steps Needed for Certification*

1. Before starting the certification process, study personnel should read/review the outcome information outlined in the previous pages.
2. All study personnel taking BP measurements must receive training from the study trainer.
3. All study personnel must demonstrate proper technique for BP measurement using the OMRON<sup>®</sup> HEM-907XL digital blood pressure monitor.
4. Successful completion of the Checklist for Monitoring Form is the final step. All study personnel must be checked to ensure that they are following procedures correctly and utilizing proper measurement techniques. This is necessary and will be assessed prior to performing BP measurements on participants in this study. The trainer will use the Checklist for Monitoring Form to grade the study personnel while s/he follows the entire outcome protocol to obtain two BP readings on a non-study individual. When carried out without procedural errors, this record should be completed, signed, and maintained in a file within the office where other study materials are kept. Errors of procedure should be reviewed, discussed, and corrected until one completed determination is accomplished without error.

#### Study Forms Required for Certification Procedures

1. Outcome Checklist for Monitoring Form (see enclosed).
2. Outcome Certification Form (see enclosed).

### Checklist for Monitoring BP Outcome Form

Study personnel's name \_\_\_\_\_

Date Observed \_\_\_\_/\_\_\_\_/\_\_\_\_

Instructions: Check if procedure step is carried out correctly.

#### **Procedure**

1. \_\_\_\_ Check BP equipment
2. \_\_\_\_ Give participant explanation of BP procedures
3. \_\_\_\_ Measure arm for correct cuff size; choose correct size
4. \_\_\_\_ Mark brachial artery point
8. \_\_\_\_ Align the Artery Position Mark on cuff with brachial artery
9. \_\_\_\_ Wrap HEM-907XL BP cuff correctly
10. \_\_\_\_ Keep level of cuff at same level as the heart during measure
11. \_\_\_\_ Leave subject for 5 min. rest, instruct on posture
12. \_\_\_\_ Press start button
13. \_\_\_\_ Record first BP reading (SysBP/DiaBP)
14. \_\_\_\_ Clear the monitor of first reading
15. \_\_\_\_ Instruct participant to raise arm for 5 sec and allow rest period
16. \_\_\_\_ Begin steps for next reading; press start button
17. \_\_\_\_ Record second BP reading (SysBP/DiaBP)
18. \_\_\_\_ Clear monitor of second reading and remove cuff
19. \_\_\_\_ Wipe the cuff and monitor with disinfectant wipe

#### **Comments**

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Trainer: \_\_\_\_\_

Pass/Fail: \_\_\_\_\_



**BP Outcome Measure**

Certification Form

**Name:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Arm Circumference** \_\_\_\_ \_\_\_\_/cm

**Cuff Size**

1) Small (< 22 cm) \_\_\_\_\_

2) Medium (22 – 32 cm) \_\_\_\_\_

3) Large (32 - 42cm) \_\_\_\_\_

4) Extra Large (42 - 50cm) \_\_\_\_\_

*Blood Pressure Measurement \*\*Wait 5 minutes seated \*\**

First digital blood pressure

SBP / DBP

Time: \_\_\_\_\_ / \_\_\_\_\_ mmHg

**\*\*Raise arm for 5 seconds / level for 25 seconds\*\***

Second digital blood pressure *\*\*Wait 5 minutes seated \*\**

SBP / DBP

Time: \_\_\_\_\_ / \_\_\_\_\_ mmHg

**Pass/ Fail** \_\_\_\_\_

**Trainer Signature** \_\_\_\_\_

**Trainee Signature** \_\_\_\_\_

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