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THE HYPERTENSION AND SELF IDENTITY THROUGH HO'OPONOPONO
STUDY IN HAWAII

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Dedication

This dissertation is hereby dedicated to Kahuna Lapa'au Morrnah Nalamaku Simeona and The Foundation of I, Inc. (Freedom of the Cosmos) whose relentless work and support have made this research possible.

Ka Maluhia O Ka "I"

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ABSTRACT

Problem: Hypertension (HTN) affects 50 million people in the USA and 1 billion people worldwide, and is the leading risk factor for heart disease and stroke. Among ethnic groups in Hawai'i the prevalence of HTN is increasing. HTN contributes to 1/3 deaths in Hawai'i, and persists despite standard medical therapy (SMT).

Aims: 1) To determine if *Self Identity through Ho'oponopono* used in combination with SMT is associated with improved HTN management in Asian, Hawai'ian, and Other Pacific Islander populations; and, 2) To provide pilot data to design a randomized clinical trial.

Design: A pretest, post-test longitudinal design.

Sample: The study enrolled 23 adults with HTN and without serious risk of complications or death. Participants were primarily of Asian, Hawai'ian and Other Pacific Islander descent.

Methods and Analysis: Participants completed the Spiritual Orientation Inventory and Supplemental Spiritual Questionnaire at the beginning and end of the study, and had up to 9 blood pressure measurements (BPMs). The spiritual questionnaires were analyzed by paired t-tests. The BPMs were analyzed using

generalized estimating equations treating the repeated BPMs as clustered within patients.

Findings: Systolic BPMs (SBPMs) and diastolic BPMs (DBPMs) had statistically significant mean differences comparing the pre- to the post-intervention phases. Mean drops occurred in SBPMs and DBPMs of 6.8 ($p < 0.03$) and 3.51 ($p < 0.006$) mm Hg, respectively. In the first 30 days post-intervention SBPMs and DBPMs dropped 7.8 ($p < 0.01$) and 4.16 ($p < 0.01$) mm Hg, and in the second 30 days they dropped 11.86 ($p < 0.009$) and 5.44 ($p < 0.003$) mm Hg. On the day of the intervention SBPMs and DBPMs increased by 6.35 ($p < 0.03$) and 4.37 ($p < 0.001$) units, respectively. With the post-measurement from the intervention day excluded, the overall declines in SBPMs and DBPMs were estimated as 9.57 ($p < 0.006$) and 4.77 ($p < 0.002$) mm Hg.

Conclusions & Recommendations: In an Asian, Hawai'ian, and Other Pacific Islander population with HTN, *Self Identity through Ho'oponopono* demonstrated a statistically significant reduction of mean SBPMs and DBPMs for up to two months and may be an effective, adjunctive lifestyle modification. These findings merit further testing in a powered RCT.

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CHAPTER 1: INTRODUCTION

This chapter provides the theoretical basis for research on the integration of a spiritual intervention, *Self Identity through Ho'oponopono*, into the medical regimen of patients with hypertension who are of Asian, Hawai'ian, and Other Pacific Islander¹ descent in Hawai'i. It includes the objective, research questions, problem, purpose, significance, and definitions of terms for this study.

Objective

The objective of this study is to determine if *Self Identity through Ho'oponopono* combined with standard medical therapy is associated with improved hypertension management (reduced blood pressure) in comparison to standard medical therapy used alone on those with hypertension (HTN) in Asian, Hawai'ian, and Other Pacific Islander populations.

Research Questions

Two research questions create the foundation for this research: 1) Is there a significant difference between Asian, Hawai'ian, and Other Pacific Islander participants' pretest and post-test blood pressure (BP) measurements when *Self Identity through Ho'oponopono* is included as therapy in addition to standard

¹When referring to these populations throughout the main text of this dissertation, "Asian, Hawai'ian, and Other Pacific Islander" will be written in full; however, in tables, due to space constraints, the acronym AHOPi will be used.

medical therapy for HTN? 2) Is there a significant difference in Asian, Hawai'ian, and Other Pacific Islander participants' pretest and post-test spirituality scores regarding their sense of meaning and fulfillment of purpose in life, well-being, forgiveness, inner peace, and love when *Self Identity through Ho'oponopono* is included as therapy in addition to standard medical therapy for HTN?

Problem

HTN or high blood pressure affects approximately 50 million Americans and 1 billion people worldwide and is the leading risk factor for heart disease and stroke (USDHHS, 2003; USDHHS, 2000). HTN persists despite standard medical therapy. The prevalence for this condition has steadily increased in both males and females among ethnic groups of Hawai'i and is a contributing factor in one out of three deaths in Hawai'i (Hawai'i DOH, 1997). According to the recent Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (2003), pre-hypertension (PHTN) increases the risk for HTN, resulting in normotensive persons at age 55 having a 90% lifetime risk for developing HTN (USDHHS, 2003). Additionally, the United States has accumulated a \$259 billion financial and social burden for costs related to HTN (JNC 6, 1997).

Purpose

The purpose of this research study is to determine if *Self Identity through Ho'oponopono* is associated with improved HTN management when *Self Identity through Ho'oponopono* is used in combination with standard medical therapy in the Asian, Hawai'ian, and Other Pacific Islander populations. Further, the research findings may serve to establish a basis for power to conduct a randomized clinical trial (RCT) in the target population.

Significance

Blood pressure reduction is emphasized as a major goal in *Healthy People Objectives 2010* (NHLBI 2002-2006). JNC 7 (2003) articulates that healthy lifestyle modifications are a critical component in reducing the blood pressure of people with the new classification of PHTN (see Table 1, page 5). No adequately effective therapy currently exists for controlling HTN, and approximately one-third of the people with hypertension are unaware that they have high blood pressure. The success of *Self Identity through Ho'oponopono* in conjunction with standard medical therapy in improving blood pressure control in the Asian, Hawai'ian, and Other Pacific Islander populations would legitimize a new culturally appropriate treatment in Hawai'i that reduces the leading risk factor for heart disease and stroke in the target population. The success of *Self Identity through Ho'oponopono* could then result in a decrease in hypertension-related deaths in Hawai'i and help to reduce the financial and social burden in the

US. Additionally, this intervention would offer the target population a means to an improved lifestyle where participants may experience a greater sense of spiritual well-being, meaning and fulfillment of purpose in life, forgiveness, inner peace, and love.

Definition of Terms

Self Identity through Ho'oponopono is a "step by step approach to achieving Peace, Balance, and a new meaning of life through an understanding of one's Self-Identity. It is a process 'to make right, to correct and to rectify errors' through repentance, forgiveness, and transmutation" (The Foundation of I, Inc. (Freedom of the Cosmos) [FOI], 1990, p.14). The purpose of *Self Identity through Ho'oponopono* is for an individual to discover his/her true Self or identity. Through the care of Self, participants experience a peaceful "letting go" process using Divine or universal energy to forgive and allow spiritual, mental, and physical healing. Taught in classes and trainings throughout the world, participants learn how to incorporate *Self Identity through Ho'oponopono* easily into everyday life (FOI).

A native Hawai'ian Kahuna Lapa'au Mornah Nalamaku Simeona, developed this simple yet profoundly effective process to identify the cause of problems to allow the healing process to begin. Mornah Simeona was honored and named as a "Living Treasure" of Hawai'i in 1983 by the Hongwanji Mission of Honolulu and the Hawai'i State Legislature for her work as a Kahuna Lapa'au

(medical doctor). As the founder of The Foundation of I, Inc. (Freedom of the Cosmos), Mornnah Simeona has taught and conducted numerous lectures, classes, and presentations around the world, including a lecture at the Peace Conference in Copenhagen, three classes at the United Nations, and classes at The University of Hawai'i at Mānoa. People from Hawai'i, the continental US, Europe, Ireland, and other countries have experienced spiritual, mental, physical, material, financial, and karmic healing by incorporating the process of *Self Identity through Ho'oponopono* into their lives (FOI, 2004; Freke, 1999). Mornnah Simeona and The Foundation of I, Inc. (Freedom of the Cosmos) summarizes the guiding philosophy of *Self Identity through Ho'oponopono*:

If we can accept that we are the sum total of all past thoughts, emotions, words, deeds and actions and that our present lives and choices are colored or shaded by this memory bank of the past, then we begin to see how a process of correcting or setting aright can change our lives, our families and our society (FOI, 1990, p. 5).

The essence of a class or training on *Self Identity through Ho'oponopono* was provided by Ihaleakala Hew Len, PhD, Chairman Emeritus of The Foundation of I, Inc. (Freedom of the Cosmos), as an outline in a personal communication and is described in Figure 1 (Chapter 3: Methods).

Blood Pressure Classification: Table 1 outlines the blood pressure classification used for this research study, which is adopted from JNC 7 (2003).

Table 1. Blood Pressure Classification

BP Classification	SBP (mmHg)	DBP (mmHg)	Comments per JNC 7
Normal	<120	and <80	Persons normotensive at age 55, have a 90% chance of developing HTN. Risk of cardiovascular disease (CVD) beginning at 115/75 mmHg doubles every increment of 20/10 mmHg
Pre-hypertension	120-139	or 80-89	Requires health-promoting lifestyle modification to prevent CVD
Stage 1 HTN	140-159	or 90-99	Most will require thiazide-type diuretics
Stage 2 HTN	≥160	≥100	Most individuals will require 2 or more anti-hypertensive medications

(USDHHS, NHLBI, NIH - JNC 7, 2003)

SBP is the systolic blood pressure measured in millimeters of mercury (mmHg)

and DBP is the diastolic blood pressure measured in the same manner.

CHAPTER 2: LITERATURE REVIEW

The purpose of this chapter is to review the literature regarding *spirituality* in relation to *health* outcomes and offer a conceptual orientation for this study. This chapter discusses how spirituality through conceptual analysis and various experimental interventions as observed in research studies impacts health outcomes. Little information is available regarding the impact of spiritual interventions on the outcomes of HTN management in the Asian, Hawai'ian, and Other Pacific Islander populations in Hawai'i. Additionally, few studies have included spiritual interventions as part of lifestyle modifications to improve health outcomes; however, lifestyle modification is a clear objective in the *Healthy People 2010 Objectives* regarding the reduction of high blood pressure. Therefore, various health conditions not limited to HTN have been studied and are used as the basis for evaluating spirituality and health outcomes in this chapter.

The concept of spirituality is a topic of great interest to health practitioners in a variety of disciplines who are concerned with improving health outcomes. Why is spirituality important to nursing? Nursing has long relied on conceptions of spirituality, care of the whole person and mind/body/spirit connections, for the theoretical foundation of its disciplinary practice. Spirituality is significant because it is an all encompassing and total aspect of humanity; yet to date, accepted medical and nursing practices rarely include specific praxes relating to spirituality

in the health care of individuals. According to Kendrick & Robinson (2000), spirituality is integral in the health care of patients in order for healing to occur and thus achieve optimum health outcomes. The authors present spirituality as inclusive of all aspects of being human. It is the sum of all parts forming the human condition. Goldberg (1998) views the spirit as the vital life force motivating people and synthesizes spirituality and nursing care to generate the concept of connection. Macrae (1995) speaks of Nightingale's view of spirituality through one's inner connection with Divine Intelligence as being the most potent resource for healing known.

Studies affirm patients' desire to have spiritual issues addressed (Luskin, 2000). Ninety-one to 96% of the general population in America believes in God (Luskin); 96% believes spiritual well-being is important to health; and, 75%-77% of patients believe health practitioners should address spirituality (Anandarajah & Hight, 2001; Luskin; Matthews, et al., 1998). More than 75% of patients feel that health practitioners should discuss spiritual concerns, yet only 11% of practitioners actually address these concerns with patients. According to Anandarajah & Hight, this gap exists for several reasons: 1) practitioners' discomfort with their own sense of spirituality, 2) lack of education to conduct a spiritual assessment, and 3) lack of sufficient clinical time to perform a spiritual assessment.

The need for assessing patients' spiritual concerns and interests is addressed both in nursing literature (Dyson, Cobb & Forman, 1997; Oldnall,

1996) and medical literature (Anandarajah & Hight, 2001; Ironson et al., 2002). Baldacchino & Draper (2001) affirm the need to assess spirituality, which enhances meaning and purpose of life when illness strikes. They report spiritual coping strategies sustain the wholeness and integrity of people, particularly those requiring medical care.

Potential problems with integrating the concept of spirituality into health care and medical practice include the lack of consensus in the literature on the definition of this concept and the incongruence between existing conceptual definitions and measures. While there is some disagreement on whether spirituality and religiosity are interchangeable or surrogate terms, the general consensus is that spirituality is the more universal term which may subsume the concept of religiosity (or religiousness) (Burkhardt, 1989). In essence, a religious person may be spiritual, but a spiritual person need not be religious (Boudreaux, O'Hea & Chasuk, 2002; Coyle, 2002; Sulmasy, 1999). According to Boudreaux, O'Hea & Chasuk, the National Institute of Healthcare Research defines spirituality as "the feelings, thoughts, experiences, and behaviors that arise from a search for the sacred" (p. 440). Individuals who identify themselves as spiritual report a link to the divine, which empowers healing.

Another problem is measurement of the concept of spirituality. Like many intangibles, concepts such as love, peace, and joy may be difficult to measure directly even though we experience them daily. Finding meaning through proxy measures or some indirect form of measurement, such as self-report surveys,

questionnaires, and/or other instruments, may offer alternative methods to assess the reliability and validity of intangible attributes and concepts.

Other problems exist in clinical practice which inhibit the assessment of spirituality in relation to patient care such as practitioner failure to use assessment tools efficiently, lack of practitioners' education and understanding of how to perform a spiritual assessment, and lack of practitioners' assumption of responsibility to address spirituality (Anandarajah & Hight, 2001). Moreover, while there is an abundance of opinion literature regarding spirituality, few data based studies exist and even fewer data based studies focusing on specifically identified diseases, conditions, or ethnicities exist. There is a need to move from opinion to data based systematic analysis of this concept to determine its actual impact on health outcomes of all people.

If spirituality has a positive influence on the overall healing of individuals through a mind/body/spiritual connection and sustains the wholeness of individuals, and a significant number of patients advocate for incorporating spirituality into their individualized health care, then health care practitioners have a responsibility to consider how spirituality can affect health outcomes.

The purpose of this review is to analyze and describe the "state of science" related to spirituality through an integrative review of the literature and to generate a synthesized definition of the concept of spirituality as it applies to health outcomes. This review is organized according to the following categories of studies: spirituality and health outcomes, tools used to measure spirituality,

and common themes in definitions. Following the literature review, a synthesized definition of spirituality as it is used in this dissertation is provided, limitations of the current state of the science are discussed, and how this review and definition create the theoretical basis for this research study is articulated.

For clarification, *health* is defined in this review using the generally accepted definition provided by the World Health Organization (1946): “complete physical, mental, and social well-being, and not merely the absence of disease or injury.” *Health outcomes* are defined as “changes in health status (mortality and morbidity) which result from the provision of health (or other) services” (OECD, 1992).

This integrative review employed the use of the electronic database *Medline* for the years 1995 to 2003 and searched keywords “spirituality and health outcomes” and “concept of spirituality.” This period of time was chosen as a reasonable duration to review the literature since “spirituality” was entered into the *Medline* subject headings separate from religiosity in 2002. Thirty-six (36) articles from the first search and twenty-two (22) articles from the second search were retrieved in the English language. Additional, relevant data based articles identified through “snowballing” techniques were also included. Thirty-two data based articles involving human participants comprised the sample and were entered into the matrix data collection tool. A matrix tool was used to collect data from peer reviewed data based articles (n = 32) and to organize it into categories. It served as the structure for the synthesis of the findings in this review.

Analysis of the Literature

Literature on Spirituality

The articles in this literature review are organized according to the major categories generated in the analysis: 1.) general review (n = 7); 2.) concept analysis (n = 7); 3.) population-specific studies (n = 11); and, 4.) measurement tools (n = 7).

Review Articles: Seven general review articles address concept definitions, themes, and spiritual interventions and their results. The need to meet patients' spiritual needs and practitioners' influence on patients' behaviors and health outcomes are also discussed.

Emblen (1992) explored the nursing literature (1963-1989) looking for definitions of the concepts of religion and spirituality using library searches, bibliographic citations, and textbook references. Following Walker and Avant's (1995) procedures for concept analysis, six words appeared most often defining religion: system, beliefs, organized, person, worship, and practices; and, nine words appeared most often defining spirituality: personal, life, principle, animator, being, God, quality, relationship, and transcendent. Emblen concludes that spirituality is a broader term than religion and that clarification of the differences between spirituality and religiosity is needed.

Similarly, Greenstreet (1999) suggests spirituality is a broad concept encompassing religion but not equating religion. This author's objective was to define spirituality and spiritual needs, to determine which methods promoted

nursing students' awareness of such needs, and to learn how to encourage these students to develop skills and resources to help meet the spiritual needs of patients. This was done through a systematic review of the nursing literature through *CINAHL* CD-ROM and texts covering a 15-year time span and which are considered appropriate according to the author. The author highlights the following themes connected to spirituality: meaning and purpose of life, God, self, inter-connectedness, unconditional love, forgiveness (ability to live with ones flaws), hope, transcendental, well-being, joy, and freedom. Greenstreet posits that the search for meaning within life is fundamental to spirituality and that nurses need to consider their own spirituality prior to assessing patient needs. Greenstreet concludes that teaching methods need to be participatory and student-centered.

Mueller, Plevak & Rummans (2001) conducted a *Medline* search (1970-2000) and analyzed published studies, meta-analyses, systematic reviews, and subject reviews which examine the association between religious involvement and spirituality with health outcomes. Overall, spirituality is again identified as a broader term than religiosity, and many studies validate that spirituality correlates to improved health outcomes. The authors note that in nine of 13 clinical trials, religious and spiritual practices (prayer, meditation, and worship) decreased blood pressure. These practices led to positive emotions (hope, love, contentment, and forgiveness) and limited negative emotions, ultimately resulting in positive health outcomes. The authors note that spiritual needs may increase

during times of illness and that supporting the spirituality of patients may enhance clinicians' care of the patient.

Astin, Harness & Ernst (2000) conducted a systematic review of various forms of distance healing (a spiritual intervention) by searching *Medline*, *PsychLIT*, *EMBASE*, *CISCOM*, and *Cochrane Library* (from inception through 1999) and by contacting leading researchers in the distance healing field. Distance healing results in positive treatment effects in 13 of the 23 random, placebo-controlled trials (57%) which involved 2774 patients. Methodological limitations existed and results regarding the efficacy of the distance healing intervention are inconclusive in several of the studies they reviewed, suggesting a need for further study.

Several types of spiritual interventions were included in the review by Hawks, Hull, Thalman & Richins (1995). The authors identified a sample of 71 articles focusing on spiritual health and health outcomes by searching CD-ROM databases (*ERIC*, *Medline* and *PsychLIT*) and cumulative indexes of *Advances: The Journal of Mind-Body Health*. They state that interventions such as imagery, meditation, and group support may address one of the following spiritual health components: meaning and purpose in life; self-awareness; and the connection with others, the self, and the larger reality. Spiritual health may be associated with improved behavioral, emotional, and physical outcomes (reduced anxiety, improved mood states, enhanced immune function, and heart disease reversal).

The authors encourage health educators to develop and evaluate spiritual interventions for use in practice and comprehensive health programs.

Comparatively, Luskin (2000) in his review of the literature suggests practitioners pay closer attention to the religious and spiritual concerns and needs of patients. Luskin posits that health practitioners can have a positive influence on patient's behaviors and can facilitate health-enhancing spiritual or religious practices, such as meditation or expressions of forgiveness. Further, he identifies the importance of incorporating religious or spiritual dimensions into medical care through a randomized study where chaplain visits supported patients' health. An experimental group of open-heart patients with significant cardiac risk factors received usual medical care along with supplemental chaplain visits in contrast to patients in a control group who received usual medical care without the chaplain visits. Those patients with the supplemental chaplain visits required an average of two days less time in the hospital—for a savings of \$4200 per patient. Social connection, care, love, or sense of purpose in patients' lives can have protective effects on cardiovascular status (Luskin, 2000).

In contrast, Sloan & Bagiella (2002) offer little support for improved health from religious involvement. They state that 17% of 266 articles published in the year 2000 (*Medline* search) correlated health benefits with religious involvement. They also suggest many of these articles had significant methodological flaws or misrepresented findings. The authors conclude that there is little empirical

evidence that religious involvement in health care is associated with improved outcomes.

In summary, there is some agreement on the notion that spirituality is a broader term than religiosity and that spiritual interventions such as distance healing and/or factors such as social connection, meaning, care, love, sense of purpose in patients' lives, and self-awareness may be associated with improved behavioral, emotional, physical, and overall health outcomes. These health outcomes include reduced anxiety, improved mood states, enhanced immune function, and heart disease reversal.

Concept Analysis Articles: The following seven articles focus on a conceptual analysis of spirituality or the spiritual dimension. Dyson, Cobb & Forman (1997) in their review of nursing literature explore a working framework of spirituality consisting of the relationship between the self, others, and God. They address the themes of meaning, hope, relatedness/connectedness, beliefs/belief systems, and the expression of spirituality within the context of the framework. The authors contend that nursing must accept its responsibility to incorporate spirituality in the art and intuition of nursing. This framework offers practitioners and researchers a direction for further exploration of the incorporation of spirituality into the health care process.

Oldnall (1996) reviewed the nursing literature related to spirituality and holistic care prior to and including the years 1980-1994. He notes that nurses pay limited attention to spirituality in holistic care. He identified 14 of 26 nursing

theories which mention spirituality briefly using implicit language. Both Jean Watson and Betty Neuman, two nursing theorists, acknowledge spirituality in their work. Oldnall speaks of nurses advocating for holistic care provided through the biopsychosocial domains, but argues that spirituality is essential as a fourth domain. Little acknowledgment as to how spirituality impacts the individual may be due to a lack of understanding by nursing theorists, practitioners and educators. The author insists that nurses may enhance delivery of spiritual care to patients if nurses are provided enough guidance and education on spirituality.

Martsof & Mickley (1998) reviewed the nursing literature for the purpose of presenting modern nurse theorists' ideas on the concept of spirituality. These authors define spirituality in terms of one or more of the following attributes: meaning, value, transcendence, connecting, and becoming. They affirm that questions exist when researchers and practitioners address spirituality from a theoretical point of view in qualitative and quantitative research. The authors emphasize the existence of a reciprocal interaction worldview (spirituality as a dimension of the person interacting with other parts) and a simultaneous action world-view (spirituality focusing on inner experiences, feelings, etc.).

As a result of an encounter with a terminally-ill patient, Ross (1995) conducted a literature review on and investigation of the influence of the spiritual dimension on the patient's quality of life (health potential). She suggests the description of spiritual dimension includes meaning, purpose and fulfillment in life, the will to live, and belief and faith for an overall sense of health and well-

being. She posits a dual conceptualization of the spiritual dimension encompassing the vertical element (encompassing the transcendental relationship with a higher power, or one's value system), and the horizontal element (including one's relationship with self, others, and the environment). The author views delivering spiritual care as an essential responsibility for nurses.

Burkhardt's (1989) article serves to clarify the concept of spirituality. The author suggests that spirituality is the essence of an individual's human nature, and she describes it through the terms meaning, purpose and fulfillment in life, the will to live, and belief and faith for an overall sense of health and well-being. According to this position, through *unfolding mystery* one discovers meaning and purpose of life and experiences the mystery of life with a sense of peace, hope, comfort, and transcendence beyond the current reality and uncertainty. Through *harmonious interconnectedness* one may sense connection, joy, and meaning in all of life, nature, divinity, the universe or a higher power. This connection may involve self, love, service, forgiveness, reconciliation, and may be in a relationship with God or a Higher Being. Finally, through *inner strength*, the author suggests one may sense an inner awareness, joy, peace, and consciousness, thus attaining an inner core of vital principle and experience transcendence.

Matthews (2000) describes the role of spirituality among patients with arthritis in his analysis of *Medline* catalogued publications related to prayer and spirituality (D.A. Matthews, personal communication, January 21, 2004).

Matthews describes the case of a 58-year-old white woman with a disabling and long-standing history of rheumatoid arthritis. After a three-day intercessory prayer ministry retreat, the patient's self-reported fatigue and pain levels decreased 35% and her sense of well-being and functional level doubled. At the end of a one year post intervention period, the patient's functional level improved an additional 20%, fatigue decreased 48%, well-being increased 9%, pain significantly diminished, and medication dosages decreased. The author suggests that through developing a spiritually sensitive health practice, patient outcomes may improve.

McSherry & Draper's (1998) article describes spirituality as beyond the sphere of the human mind and suggests a universal approach in defining the spiritual dimension. The authors' view spirituality as being innate and fundamental to one's existence, impossible to separate from one's very nature.

In summary, spirituality is considered essential, fundamental to existence and associated with improved health outcomes. Spirituality in this section relates to meaning, hope, relatedness, connectedness, becoming, value, transcendence, purpose and fulfillment in life, the will to live, belief and faith in a sense of health and well-being.

Population-Specific Studies: This group of articles focuses on qualitative and quantitative studies investigating spirituality in various specific populations. Since there is an insufficient number of studies dealing with spirituality in relation

to a single health-related condition or disease (such as hypertension alone), an aggregation of outcomes for a variety of conditions is included in this section.

Pardini, Plante, Sherman & Stump's (2000) study explores the relationship among faith, spirituality, and mental health outcomes using multiple self-report questionnaires. Both spirituality and religiosity are associated with positive mental health outcomes in persons (n=236) recovering from alcoholism in the Alcoholics Anonymous group. Those participants rated themselves more spiritual than religious. A significant variance associated with hardiness is accounted for by religious faith; whereas, a significant variance associated with trait anxiety is accounted for by spirituality. Using hierarchical multiple regression, spirituality accounts for the added variance beyond that contributed by the religious faith measure. This pattern is also predictive of social support and optimistic life orientation.

Pendleton, Cavalli, Pargament & Nasr (2002) investigate how religiousness and spirituality affect the coping strategies of children with cystic fibrosis (CF) in a focused ethnography. This study consisted of semi-structured interviews with a convenience sample of 23 hospitalized children with CF. The results of this study assess both religiosity and spirituality as equally contributing factors. Religiousness and spirituality were associated with adaptive health outcomes in these hospitalized children. Eleven coping strategies emerged with six describing a direct relationship with God. The authors recommend further clarification of concepts and the development of valid and reliable

measurements. They advocate for prospective, longitudinal studies and testing of the role of these concepts in the provider-patient interaction (Pendleton, Cavalli, Pargament & Nasr, 2002).

Tatsumura, Maskarinec, Shumay & Kakai (2003) interviewed 143 cancer patients 2 to 3 years after diagnosis to identify religious and spiritual resources (RSR). The authors investigate what themes regarding RSR, complementary and alternative medicine (CAM), and conventional therapy were used by the patients, and the relationship among those resources and themes. The authors find that beliefs could affect issues of control, spiritual well-being, coping, depression, decision-making, and potential health outcomes in patients with cancer. Addressing these issues with patients is advocated.

An intervention study by Morris (2001) focusing on cardiovascular disease linked increased spirituality with improved health. Morris administered the Spiritual Orientation Inventory to 14 participants in Dr. Dean Ornish's earlier Lifestyle Heart Trial as a component of an experimental study. A significant difference in spirituality scores was noted between a control group (n= 6; mean=381) and the group practicing daily meditation (n=8; mean=474). Those with lower spiritual well-being scores showed the most progression of coronary obstruction and those with higher scores showed the most regression of coronary heart disease. Despite the limitations of this study (a small sample size of n=14 and a 10-year time lapse from the Lifestyle Heart Trial), the scores significantly correlate with the degree of reversal or progression of stenotic heart disease.

This study is novel in that it defines a relationship between spirituality and documented physical data. The authors recommend larger prospective studies which eliminate bias and test the relationship between spirituality and coronary heart disease.

Harris, et al. (1999) conducted a randomized, controlled, double-blind prospective parallel-group trial to determine if remote, intercessory prayer would reduce overall adverse events and length of stay of 990 consecutive patients newly admitted to a coronary care unit (CCU). The authors report lower CCU course scores for those patients receiving prayer. Using the Mid America Heart Institute CCU (MAHI-CCU) system of scoring, the authors find that supplementary, remote, intercessory prayer resulted in measurably improved health outcomes of critically ill patients. However, lengths of CCU stay were unaffected. The authors note that at least 50% of patients admitted to the MAHI hospital in Kansas City, Missouri stated that they were religious. A possible explanation offered by the authors for the lack of statistical differentiation between the two groups is that patients may have already been receiving intercessory or direct prayer from friends, family and others.

Pullen, Modrcin-Talbott, West & Muenchen (1999), in a descriptive study using a correlational design with a sample of 217 adolescents, investigate whether a relationship between alcohol and drug abuse and frequency of religious service attendance exist. This study sample is comprised of a clinical group from a mental health agency (n=77) and a non-clinical group from a church

whose members are assumed not to be receiving psychiatric care (n=140).

Alcohol and drug abuse decreased as attendance increased at religious services.

The authors note that adolescents as holistic beings have spiritual needs.

Spirituality must be included in the holistic treatment for adolescents to enhance recovery and decrease recidivism.

The following six population-specific studies include conceptual definitions of spirituality (Greasley, Chiu & Gartland, 2001; Råholm, 2002). The focus of a study by Friedemann, Mouch & Racey (2002) using a case study method for concept development shows how spiritual interventions can empower patients and how nurses caring for a terminally ill patient may address the patients' spiritual needs through self-exploration. The authors define spirituality as one's connection to God, nature, and people and the finding of meaning in those relationships. Through education, self-reflection, and practice, nurses can assist a dying patient to balance personal control with spirituality, regain emotional health, and refocus on self-acceptance and reconciliation with family.

Greasley, Chiu & Gartland (2001) investigate a series of nine focus groups (five to six members in each group) to obtain patients', caregivers', and nurses' views regarding spirituality, health, and spiritual care in mental health nursing. The groups defined spiritual care as providing one with a sense of meaning and purpose in life, with or without religious expression. Spirituality may be evidenced in quality of care and expressed through love, concern, kindness, well-being,

inner peace, hope, self-fulfillment, and compassion versus the more impersonal provisions of the “mechanics of nursing” in mental health nursing.

Similar themes are reported in a qualitative study of interpretative interactionism in which interviews with 10 men and women with advanced-stage HIV were conducted. Participants in this study identify differences between religion and spirituality (Hall, 1998). Hall finds meaning, purpose, peace, freedom from suffering, spiritual clarity, God or higher power, and spirituality create a valuable framework for life for the participants in this qualitative study. The findings demonstrate that patients experience spirituality through three themes: purpose in life emerging from stigmatization; opportunities for meaning arise from disease without a cure; and, after experiencing suffering, spirituality creates a valuable framework for life (Hall, 1998).

Råholm (2002) sampled 564 patients who underwent coronary bypass surgery using the grounded research methods and hermeneutics of Gadamer in an interpretative process to explain the relationship between spirituality and suffering. This study finds that spirituality becomes extremely important when one faces a life-threatening event. Spirituality can be described as finding meaning by gaining a new appreciation of life and health, discovering an inner strength perceived through love and faith, and an inner strength experienced through suffering and desire. The study concludes that caring involves wisdom beyond knowledge, and nurses have the ethical responsibility to respond to the spiritual needs of the patient.

Shirahama & Inoue (2001) conducted an ethnographic study through interviews, questionnaires, and participant observations. Ten (10) informants participated in the study aimed at learning how spirituality was defined by a Japanese farming community and how Japanese nurses provide care to patients. The authors find common expressions of spirituality to be faith, worship, prayer, hope, thanksgiving, and search for inner peace. For the subjects in this project, spiritual well-being (being content with life and living in harmony with nature/others) is expressed through thanking nature, helping the dying to experience peace and hope beyond death, ancestor worship, and caring for each other.

To summarize the findings of the population-specific studies, spirituality is important for an overall sense of improved health outcomes and spiritual well-being. Religiousness and spirituality are associated with adaptive health outcomes in hospitalized children. Spiritual interventions are reported to empower patients; connect them to God, nature, and people; and provide them with a sense of meaning and purpose in life. Spirituality may be evidenced through love, concern, kindness, well-being, inner peace, hope, self-fulfillment, meaning, purpose, freedom from suffering, and spiritual clarity.

Measurement Tool Articles in the literature also describes measures of spirituality, and results of these investigations are described below. The results of three studies, which assess both spirituality and religiousness, demonstrate varied benefits following interventions in the sample populations. Mokuau, et al.

(2001) used a modified Brief Multidimensional Measure of Religiousness/Spirituality (BMMRS) to evaluate the association of religiousness and spirituality in mental and physical health outcomes by administering a pre- and post-test to 15 Native Hawai'ian people. The subjects participated in a cultural intervention consisting of exercise, diet, and education. Internal consistency determined the reliability of the scale with the strongest subscales being in the domains of daily spiritual experiences, religious and spiritual coping, and religious support. The BMMRS subscale inter-correlations were low with wide variability suggesting inconsistent concurrent validity. However, correlations among 10 of the 17 subscales/single items ranged between moderate and high. These associations suggest measuring core religious and spiritual beliefs, values, and experiences in this Native Hawai'ian group. Despite its limitations (the small number and the nature of the sample), this study validates the need for future research (with modifications to the BMMRS for Native Hawai'ian participants).

The Ironson-Woods Spirituality/Religiousness Index (Ironson, et al. 2002) is an instrument used to measure both spirituality and religiosity. This investigation attempts to determine the reliability and validity of this instrument and to examine the association between spirituality and religiosity and health outcomes of people with HIV. Participants (n=279) were enrolled in this cross-sectional study: 79 long-term survivors (LTS) of AIDS and 200 HIV-positive comparison (COMP) group participants. The Index in this study demonstrates

significant correlations between longer survival, frequency of prayer, less distress, more hope, stronger social support, positive health behaviors, helping others, and lower cortisol levels. Two of four factors capturing spirituality (Sense of Peace and Compassionate View of Others) are identified in the Index. The LTS group scored significantly higher than the COMP group in these areas. Although there are limitations to this study, the authors conclude that both religiousness and spirituality are related to beneficial health outcomes in the lives of people with HIV.

Newlin, et al. (2003), in a cross-sectional pilot study, explores the relationship between spiritual well-being, emotional distress, blood pressure (BP), and HbA_{1c} values in a convenience sample of 22 Black women with diabetes mellitus (Type 2). Spiritual well-being (SWB) is assessed using the Spiritual Well-Being Scale (SWBS) with two subscales (existential well-being [EWB] and religious well-being [RWB]). This measure is based on the definition that "spiritual well-being is the affirmation of life in a relationship with God, self, community and environment that nurtures and celebrates wholeness" (Newlin, et al., p. 62). The Problem Areas in Diabetes Survey (PAID--a 20-item questionnaire) measured emotional distress. The scale resulting from the survey demonstrates significant internal consistency (Cronbach alpha = 0.93). The higher-scoring RWB group (n=11) had lower diastolic BPs than the lower-scoring RWB group (n=10; p = .005). Significant inverse correlations are identified between diastolic blood pressure (DBP) and total SWB (p = .02) and RWB

($p = 0.01$). Emotional distress had a positive relationship with SBP ($p = .03$).

No significant relationships were noted between SWB and glycemic control (HbA_{1c}) and emotional distress.

Thus, all investigations integrating spirituality and religiousness report a positive association between these concepts and health outcomes. The next four studies measuring spirituality alone demonstrated positive health benefits. McBride, et al. (1998) investigates the relationship between patients' experience of health, pain, and intrinsic spirituality in a stratified, random sample of 442 patients in a family practice. The authors used the Index of Core Spiritual Experiences (INSPIRIT—a measure of intrinsic spirituality) and the Dartmouth Primary Care Cooperative Charts (COOP—a measure of overall health and pain) to assess if a relationship between health, pain, and intrinsic spirituality exists. The authors define intrinsic spirituality as “an intrinsic experience that goes beyond simply a belief in God or a higher power. Intrinsic spirituality is an internally focused perception or belief about God or a higher power that influences life's meaning and serves as a guide for living” (McBride, et al., p. 122). A significant correlation suggests there may be an association between intrinsic spirituality and the experience of health and pain. Those participants who claimed high or moderate levels of spirituality reported better overall health and less physical pain than those reporting low levels of spirituality. Based on these results, the authors advocate assessing spirituality in family practice settings.

Anandarajah & Hight (2001) reviewed the medical literature (*Medline* without time limitation) and attended various lectures, talks, and conferences, which addressed the subject of the relationship between spirituality and medicine (personal communication, May, 2004). They base their review on studies which suggest a positive correlation between spirituality or religious commitment and health outcomes. Questions on the HOPE tool designed from this study focus on H (sources of hope, meaning, comfort, strength, peace, love, and connection), O (organized religion), P (personal spirituality and practices) and E (effects on medical care and end-of-life issues). The brief HOPE assessment tool itself becomes a therapeutic intervention whereby practitioners offer their presence, understanding, acceptance, and compassion when assessing spirituality. By so doing, practitioners support aspects of spirituality such as connection, inner strength, comfort, love, and peace in relationship with self, others, nature, and the transcendent. No psychometrics on this tool are reported.

In their study, based on a review of the literature of major writers who address spirituality from a phenomenological approach and on a humanistic definition of the concept, Elkins, et al. (1988) discuss the Spiritual Orientation Inventory (SOI). Informal observations were conducted by professors and students at the graduate School of Education at Pepperdine University, California, USA, to address spirituality (without religious context) in relation to pathology, health, and psychotherapy. The authors' objective is to clearly define

the essence of spirituality and offer an assessment approach for spirituality that maintains sensitivity for those inclined toward religion.

Using qualitative methods and the SOI tool, five participants from various religious affiliations were interviewed. A definition emerged (see page number 33 in this chapter in *Definitions of Spirituality Revealed in the Literature* section of this paper). The operational form of this definition includes nine subscales: 1.) transcendent dimension (a natural extension of the conscious self into the unconscious or Greater Self); 2.) meaning and purpose in life; 3.) mission in life; 4.) sacredness of life; 5.) material values (appreciation of possessions); 6.) altruism (everyone is a part of the human commonality); 7.) idealism (committed to high ideals and positive potential in all of life); 8.) awareness of the tragic (as an enhancement of spiritual joy, appreciation, and value of life); and 9.) fruits of spirituality (effects of one's relationship to self, others, nature, life, and the Ultimate). A shorter 85-item "research form" of the SOI having an alpha range of .75-.95 on the nine scales is made available for future studies to assist clients with a legitimate, nonreligious approach to assessment of individuals in spiritual distress (Elkins, et al., 1988).

In a retrospective study of the concept of spirituality by Mathew, et al. (1996), 62 individuals from Alcoholics Anonymous (AA) and Narcotics Anonymous (NA) quantified materialism, spiritualism, and cognitive patterns before and after recovery from substance abuse. Participants completed the Mathew Materialism Spiritualism Scale (MMSS) and Cognitive Patterns

Questionnaire (CPQ). Sixty-one (61) control participants received the MMSS.

The authors find that measures in the spirituality scale and most subscales (God, religion, mysticism, spirits, character, psi) significantly increased for the recovering individual from pre- to post-recovery. Due to the retrospective nature of the study and possible bias in favor of spirituality, a future prospective study is suggested (Mathew et al., 1996).

In summary, a variety of measurement tools have been used to measure spirituality. Some have content validity, some defensible psychometrics.

Spirituality alone and in combination with religiosity factors relates to positive health outcomes in these investigations. However, measurement of the concept of spirituality is at an early stage of development. Moreover, inconsistency exists between the definitions of spirituality used to generate the measures. As can be seen from an analysis of the investigations reported above, recurrent themes defining spirituality appear in the articles contained in this literature review and may offer a foundation for clearly defining and measuring the concept of spirituality.

Summary of Categories: The majority of review articles and population-specific studies address the need for clarity in defining the concept of spirituality. A majority of the authors describe spirituality using many of the same terms. These articles and studies view spirituality as a broader term than religiosity, thus suggesting a need to test this concept independent of religiosity. They also show overall positive associations between improved health outcomes and the

incorporation of spirituality into health care. They encourage health practitioners, especially nurses, to assume responsibility for bringing this concept into each health care encounter. Many studies advocate the notion of self-inquiry by the health practitioner. Many authors suggest health education regarding spirituality in order to expand practitioner knowledge and educational curricula is needed to help meet the spiritual needs of practitioner, self, and patients. There are insufficient studies on specific (ethnic) populations with specific diseases, limiting generalizability in these populations. More studies are needed. Regarding the measurement tools articles, tools are promising but not readily available for large clinical trials. Several tools report varied health benefits and others demonstrate beneficial health outcomes. Additional testing of measurement tools is indicated by these findings.

Recurrent themes and attributes of spirituality as evidenced in this analysis include search for meaning and purpose in life, breath of life, self, connection, becoming, God, transcendence, and the Ultimate. As supported in the literature, awareness and incorporation of the dimension of spirituality into an individual's lifestyle or health care practice result in: the acquisition of knowledge, an increased sense of spirituality, inner peace, balance, hope, joy, comfort, forgiveness, and love. Improved health includes spiritual, social, mental, physical, and emotional benefits. These facets affect improved overall health, well-being, coping, physical functioning, and relationships, and result in decrease in pain,

anxiety, and depression. However, further research is needed to determine if these outcomes can be achieved.

Definitions of Spirituality Revealed in the Literature

Essentially, spirituality is considered private, natural, unstructured, and independent from formal institutions. Spirituality conveys a universal position. Religiosity is a public, man-made, formal, and socialized practice and is more concerned with beliefs and rituals (Burkhardt, 1989; Emblen, 1992). In this review, since the focus is on “spirituality,” the concept of “religiosity” or “religiousness” is not specifically analyzed. The following four definitions and themes relating specifically to *spirituality* are offered by several of the authors mentioned in this review:

Spiritus, meaning ‘breath of life,’ is a way of being and experiencingthrough awareness of a transcendent dimension and that is characterized by certain identifiable values in regard to self, others, nature, life and whatever one considers to be the Ultimate. (Elkins, et al., 1988, p.10);

The perceived spirit within each individual may be considered as the driving force that gives meaning to life for that individual and in so doing helps to create a set of values and beliefs that can influence the conduct of their lives. (Oldnall, 1996, p.140);

Unfolding mystery includes one's experience of dealing with mystery/uncertainty in life, discovering and struggling with the meaning and purpose of one's life, and can include a sense of transcendence. (Burkhardt, 1989, p. 72);

and,

Harmonious interconnectedness refers to a sense of relatedness to and connectedness with all of life or being in harmony with the universe. This includes a sense of harmony with self, love of self, and self-actualization; harmony with others, which involves love, service, and forgiveness or reconciliation; and generally includes a sense of relatedness to God or Higher Being. (Burkhardt, 1989, p. 72)

Proposed Definition of Spirituality

To provide a mechanism for the advancement of knowledge, a consistent definition of spirituality is essential to create a foundation for research and practice. Following a synthesis of the results of this review, for the purposes of this study, spirituality is defined as: *"that transcendent dimension of existence where the breath of life connects the self with a higher, divine power to experience meaning and fulfillment of purpose, well-being, forgiveness, inner peace, love and all aspects of life."* This or a similar definition is recommended as the basis for the evolution of measurement tools and the foundation for systematic investigations.

Limitations of Literature Review

Several limitations exist with this analysis of the literature. One is the paucity of comparable intervention studies available, likely due to the fact that this topic in healthcare is in an early developmental stage. A consistency in the literature is developing; however, investigations on how spirituality affects specific diseases (such as hypertension alone) or ethnic groups, is limited in numbers.

Conclusion of Literature Review

A definition of the concept of spirituality was generated from this review. This definition of spirituality is “that transcendent dimension of existence where the breath of life connects the self with a higher, divine power to experience meaning and fulfillment of purpose, well-being, forgiveness, inner peace, love and all aspects of life.” This systematically generated definition was operationalized and tested in this investigation in regards to the relationship between spirituality with *Self Identity through Ho’oponopono* and hypertension.

CHAPTER 3: METHODS

Chapter 3 delineates the methodology used to conduct The Hypertension and Self Identity through Ho'oponopono Study in Hawai'i. This chapter includes the methods and procedures for the research design; study sample; descriptions of the variables (conceptual and operational definitions), predictor and outcomes variables, measurement tools; procedures and recruitment; hypotheses; and, statistical and descriptive analysis.

Methods and Procedures

Research Design: The research design used in this study is a pre-test, post-test longitudinal design in which participants served as their own control. Participants with pre-hypertension (PHTN) or hypertension (HTN) were enrolled during the pre-test period (up to 45 days prior to the intervention class of *Self Identity through Ho'oponopono*). Throughout the study participants were allowed to continue standard medical therapy (SMT), including lifestyle modifications as recommended in JNC 7 (2003) (such as exercise, diet, weight reduction for those overweight or obese, and moderation of alcohol consumption) as well as anti-hypertensive medications prescribed by their health practitioners. The post-test interval lasted up to 60 days following the intervention.

Sample

Subjects: 23 participants were enrolled in the study.

Inclusion criteria: Participants were adults over 30 years of age, primarily from the Asian, Hawai'ian, and Other Pacific Islander population, with PHTN or HTN, and minimal changes in anti-hypertensive medications for at least 2 months prior to the start of the study. However, due to recruitment challenges, inclusion criteria were modified and expanded as long as the majority of criteria were met. All participants were residents of the local community or patients of the local health center where much of the recruitment was conducted. Some of the challenges during recruitment included potential participant's illness, travel issues and unavailability for scheduled intervention dates or BP appointment times.

Exclusion criteria: Persons who were pregnant, incarcerated, planning to relocate from Hawai'i, likely to have significant medication changes, or at increased risk for serious disease/death were excluded.

Description of Variables

Conceptual Definitions: The conceptual definitions (as defined in Chapter One) of spirituality, hypertension, and the intervention, *Self Identity through Ho'oponopono*, are described below:

1. The definition of *spirituality* used is one generated through the synthesis of the literature review: Spirituality is that transcendent dimension of existence where the breath of life connects the self with a higher, divine

power to experience meaning and fulfillment of purpose, well-being, forgiveness, inner peace, love, and all aspects of life.

2. The definition of *hypertension* used is based on the classification outlined in *The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC 7, 2003). Hypertension is defined as systolic blood pressure (SBP) of 120 mm Hg and higher or diastolic blood pressure (DBP) of 80 mm Hg or higher. Pre-hypertension, a SBP of 120-139 mm Hg or a DBP of 80-89 mm Hg, is included in the definition of HTN for this study.

3. *Self Identity through Ho'oponopono*, is a "step by step approach to achieving Peace, Balance, and a new meaning of life through an understanding of one's Self-I-dentity. It is a process 'to make right, to correct and to rectify errors' through repentance, forgiveness, and transmutation" (FOI, 1990, p.14).

Operational Definitions: The operational definitions of the tools used for the measurement of the outcome variables, 1.) direct blood pressure measurements, 2.) indirect measures of spirituality factors, as well as the description of the 3.) intervention (predictor) variable are described below:

1. *Blood pressure measurements* were obtained by one of two Welch Allyn Spot Vital Signs Monitor NIBP devices. These devices were newly purchased specifically for this research study. The BP accuracy of these devices meets or exceeds SP10-1992 AAMI standards for non-invasive

BP accuracy. The AAMI standard is ± 5 mm Hg M.E., 8 mm Hg S.D. (Welch Allyn, 2002).

2. *Spirituality measures* were evaluated by participant's self-report on the Spiritual Orientation Inventory (SOI) and Supplemental Spiritual Questionnaire (SSQ). SOI, an 85-item questionnaire, was chosen to assess spirituality factors since it has been used in previous studies of spiritual interventions and includes pertinent nonreligious questions related to the concept of spirituality. Each question asked participants to choose a value from a 7-point Likert scale (with 1 corresponding to intensely disagree and 7 corresponding to intensely agree). The SOI has not been normed as indicated by Dr. Elkins (personal communication, May, 2004). No psychometrics are available except for an alpha range of .75-.95 on nine scales used by the author; however, the SOI is used in studies to offer a valid, nonreligious approach to assess spiritual distress (Elkins, et al., 1988).

An additional Supplemental Spirituality Questionnaire without available psychometrics was developed by this author to incorporate those factors not specifically addressed in the Spiritual Orientation Inventory. This instrument included 15 questions and uses a 7-point Likert scale for responses so as to complement the SOI. However, departing from solely Likert scale responses, in the SSQ, the fifteenth question is a qualitative question ("Tell me how you feel about your own spirituality today?").

Together, the SOI and SSQ covered and subsumed the components of spirituality addressed in the definition of spirituality: meaning and fulfillment of purpose, well-being, forgiveness, inner peace, love and all aspects of life. Total scores were compared pre- and post-intervention for both questionnaires to note if a difference could be determined.

3. *Self Identity through Ho'oponopono* was the *study intervention*. It was offered through a one half-day training class. Participants chose their preferred date for attendance. Through the class, participants learned how this process relates to health and high blood pressure, and how to include the process of *Self Identity through Ho'oponopono* into their lifestyle. An outline describing the essence of the process is given in Figure 1.

Figure 1. Elements of Self Identity through Ho'oponopono

There are two basic elements that make up <i>Self Identity through Ho'oponopono</i> : I. <i>Identity</i> and II. <i>The Ho'oponopono process</i>	
<p>I. <i>Identity</i>: Identity and Mind are one and the same. Mind consists of four parts: A) Divine Creator, B) 'Aumakua, C) 'Uhane, and D) 'Unihipili</p> <p>A) Divine Creator:</p> <ol style="list-style-type: none"> 1) Functions: <ol style="list-style-type: none"> a. Creates Minds in its exact likeness, Void b. Converts memories, replaying problems to Void c. Inspires Mind with thoughts, words, and actions unique to it 2) Characteristics: <ol style="list-style-type: none"> a. Void b. Inspiration comes from the Void <p>B) 'Aumakua: (other names: Spirit; Super Conscious; Father)</p> <ol style="list-style-type: none"> 1) Functions: <ol style="list-style-type: none"> a. The connection to Divine Creator b. Represents the Divine Creator c. Has authority to modify cleansing petition by the 'Uhane and 'Unihipili to Divine Creator 2) Characteristics: <ol style="list-style-type: none"> a. Always free from memories replaying b. Responds naturally to situations without forethought <p>C) 'Uhane: (other names: Conscious mind; Intellect; Mother)</p> <ol style="list-style-type: none"> 1) Functions: <ol style="list-style-type: none"> a. Initiates cleansing b. Cares for the 'Unihipili c. Meditates to ask for directions from Divine Creator 2) Characteristics: <ol style="list-style-type: none"> a. Has the choice to clean or to stay engaged b. Important to be loving to the 'Unihipili <p>D) 'Unihipili: (other names: Subconscious; Physical; Child)</p> <ol style="list-style-type: none"> 1) Functions: <ol style="list-style-type: none"> a. Is the store house for memories b. Is where experience takes place as a function of memories replaying or inspirations. c. Operates physical body as memories replaying 2) Characteristics: <ol style="list-style-type: none"> a. No discretion <p>b. Moves according to memory or Inspiration</p>	<p>II. <i>Ho'oponopono</i>:</p> <p>A) Function:</p> <ol style="list-style-type: none"> 1) Ho'oponopono is a problem solving process of repentance, forgiveness, and transmutation of memories replaying problems in the subconscious of Mind <p>B) The Ho'oponopono process:</p> <ol style="list-style-type: none"> 1) Ho'oponopono consists of three parts: <ol style="list-style-type: none"> a. Repentance: Repentance - "I'm sorry" – is initiated by the 'Uhane b. Forgiveness: Forgiveness – "Please forgive me" – follows repentance by the 'Uhane c. Transmutation: Divine Creator transmutes memories replaying problems in the 'Unihipili to Void 2) Route of the Ho'oponopono: <ol style="list-style-type: none"> a. The repentance and forgiveness petition moves from the 'Uhane down to the 'Unihipili, from the 'Unihipili up to the 'Aumakua, and from the 'Aumakua up to the Divine Creator b. 'Uhane: Initiates the Ho'oponopono with repentance and forgiveness c. 'Unihipili: brings up memories to be transmuted by the Divine Creator d. 'Aumakua: reviews the petition that comes up from the 'Unihipili, makes modifications to the petition, and then sends it on to the Divine Creator e. Divine Creator: reviews petition, then responds with mana, transmuting energies; mana moves down to the 'Aumakua, then down to the 'Uhane, then down to the 'Unihipili, and begins the process of transmuting designated memories to Void <p>*When the Void occurs, the Divine Creator suffuses it with Inspiration at some point.</p>

(Hew Len, personal communication, May 12, 2005)

The above lists the major foci of *Self Identity through Ho'oponopono*, from which the intervention class related to health and hypertension was based.

Procedures

Power Calculations for Sample Size Estimation: The original calculation of 38 participants included a 10% attrition rate which allowed for oversampling and was the original estimated sample size for this study. These estimations are explained below and were calculated from 1) baseline blood pressure calculations determined through a randomized chart review completed at a health center in Hawai'i; and, 2) a literature search using keywords: *hypertension* and *exercise*.

Baseline Blood Pressure Calculation: For pre-test sample size estimation, a retrospective, randomized chart review, and a literature review were completed.

1. For the chart review, BP measurements were analyzed for 14 patients diagnosed with PHTN or HTN. The charts provided information regarding the eligibility criteria for this research study (i.e., history of HTN, age, Asian, Hawai'ian, and Other Pacific Islander descent); however, no identifying data were recorded, except for age, gender, ethnicity, and weight. The charts were obtained from a local health care facility in Hawai'i (following IRB approval) and were used to estimate the BP variability of participants in the target population. Three retrospective and successive BP measurements were gathered from the chart

review within a one-year period. These three BP measurements were analyzed to estimate the required sample size.

2. The required sample size was also estimated from a literature review. The primary estimate was derived from a study investigating the effect of exercise training on BPs in two groups of women, Caucasians and African-American women (Santa-Clara, Szymanski & Fernall, 2003). The SBP in these groups ($n = 33$ Caucasian women and $n = 27$ African-American women) was unchanged, yet there was a statistically significant difference ($p < 0.05$) in DBP. The following delineates how the sample size was calculated in this example. The difference in the pre-test DBP mean (84 mm Hg) from post-test DBP mean (80 mm Hg) was 4 units of mm Hg for the DBP ($4 / 80 =$ a 5% change).

Accordingly, for the current study on HTN, to detect a 4 mm Hg difference would require a sample size of 34 participants, plus 10% attrition, for a total of 38 participants. In addition, the following is a summary of four articles in which patients with hypertension were evaluated through various designs. The medical literature was searched using keywords: *hypertension* and *exercise*.

Cooper, Moore, McKenna & Riddock (2000), in a RCT with a moderate intensity exercise program, observed a larger difference from baseline in SBP than DBP in a 6-week follow-up test with 2 groups (intervention $n = 47$ and control $n = 39$) The intervention group had a greater difference in SBP.

Tsai et al. (2002) divided 23 mildly hypertensive patients into a no exercise group and a moderate-intensity exercise group. There was a statistically

significant difference from baseline at 4 weeks, 8 weeks, and 12 weeks for the exercise group, showing a 13% drop or 18 mm Hg difference in SBP in the exercise (n = 12) group ($p < 0.001$). There was no statistically significant difference in DBP at 4 or 8 weeks, but at 12 weeks a 10% (10 mmHg) decrease for the DBP ($p < 0.05$), was detected.

Nakamura, et al. (1992) investigated aerobic exercise and its effect on antihypertensive efficacy on 20 patients who completed eight weeks of cycle ergometer training. BPs at baseline were measured at three stages (rest, warm-up, and anaerobic threshold) and decreased significantly after eight weeks of exercise therapy ($p < 0.01$).

Ohkubo, et al. (2001) investigated the home BP monitoring effects of exercise with 39 older adults who were randomly allocated either to 25 weeks of exercise or to a control group. Compared to a baseline means of SBP of 134.2 mmHg for home BP values (with a standard error {SE} of 2.4 mmHg), the post-intervention first period reported BP readings of 127.5 mmHg (SE of 2.3 mmHg). The post-intervention second period reported BP readings of 118.0 mmHg (SE 2.3 mmHg). The maximum difference occurred at 14-15 weeks, a SBP of 122.1 mmHg (SE 2.2 mmHg).

Thus, the average n of exercise/intervention groups was approximately 25 participants. It was considered feasible that similar differences in BPs would be detected in the present research study. Based on this published data, in order to detect a 5-10 mmHg difference in BPs, the sample size for the proposed pre-

test/post-test longitudinal design study was originally calculated at 38 participants (accounting for a 10% attrition rate), which is greater than that required for a conservatively adequate sample size. Since recruitment challenges precluded the ability to recruit 38 participants, this study actually enrolled 23 participants.

Recruitment: Potential Asian, Hawai'ian, and Other Pacific Islander participants with elevated blood pressures or an established diagnosis of PHTN (SBP <120 -139 or DBP \leq 80 - 89 mmHg) or HTN (SBP 140 -159 or DBP 90 - 99 mmHg or higher) were invited to join the study. A Revised Flier (Appendix A) and Introduction and Recruitment Information Handout (Appendix B) were available to potential participants at various Waimānalo, Hawai'i, health care facilities and at other community facilities. Methods of recruitment included announcements at public meetings, website list serves, word of mouth communication, provider referrals, booth set-ups, and telephone calls. Community presentations were conducted at senior centers, health fairs, churches, shopping malls, dental offices, pharmacies, and in a variety of other settings.

The recruitment process continued until 23 participants consented and were fully recruited. At recruitment time, those interested in enrolling were pre-screened using the initial Research Contact Record (Appendix C). If all or a majority of inclusion criteria was met, the participant could be enrolled.

Informed Consent: Informed Consents (Appendix D) and the Application for New Approval of a Study Involving Human Subjects (Appendix E) with

Institutional Review Board (IRB) approvals (Appendix F) were obtained to ensure ethical respect and the protection of all the participants in this study. Participants were informed of the study objective (to attempt to reduce BP) and plans for the study design both verbally and in writing via the Informed Consent form. Each participant was provided a copy of the Informed Consent form for their own records.

Implementation: Upon enrollment, participants completed the Initial Questionnaire of Participant's Demographics (Appendix G) which included a demographic profile, health history, and questionnaires addressing spirituality components (the Spiritual Orientation Inventory and Supplemental Spirituality Questionnaire are explained more fully in the Measurement Tools section of this chapter). Participants were also provided with instruction on using Participant's Diary of Changes (Appendix H) so that any unusual changes in BP or symptoms might be monitored. This form would be managed both qualitatively and manually.

Enrolled participants were instructed to meet at designated locations and facilities in the town of Waimānalo, or a nearby town when necessary, during the course of the study for sequential BP measurements. Times and dates for obtaining BP measurements were mutually-arranged. Sometimes participants arrived at a pre-designated time and were serviced on a first come, first serve basis. Three BP measurements were taken at each visit. Upon arrival for measurements, participants were instructed to sit quietly for about 5 minutes,

with feet on floor, and arm supported at heart level according to the JNC 7 guidelines (2003) for obtaining accurate BP measurements. An appropriate sized cuff (bladder encircling the individual's arm about 80%) was used for each participant. JNC 7 requires at least two measurements to be completed to ensure accuracy. For this study, three BPs were consistently measured at each visit, taken on one specified arm for the majority of readings.

Participants were also instructed to attend the actual intervention class at a local conference meeting room on the dates the intervention class was being offered. Three options for the *Self Identity through Ho'oponopono* class sessions were provided to participants at the time of sign-up. The participants registered for a one-half day session, which was provided at no cost to participants.

Participants received contact telephone numbers for the research team to facilitate scheduling and communications and were kept informed as to changes in location by phone, e-mail, or fax. Participants were assured they would receive the results of the study following the completion of data analysis.

Timetable: The following time frame guided this study. IRB approval was provided in June, 2004. Funds from the Clinical Research Center (CRC) were approved in October, 2004, and funds were set up in the account managed by the CRC in December, 2004. The retrospective chart review was completed in January, 2005. Advertisement, Recruitment, and Enrollment began during January and February, 2005, and the intervention and post-test analysis were conducted between March and May, 2005, as outlined in Table 2 below:

Table 2. Time Frame (4 months with optional analysis of 8 months)

	2005	
Activity	Time	Month/Year
Initial Retrospective Chart Review, Advertisement/Enrollment	2 months	January - February
Orientation & Pre-test Measurements & Questionnaires - Month 1	1 month	February - March
Pre-test measurements & Self Identity through Ho'oponopono Study Intervention	1 month	March
Post-Intervention measurements	1 month	March - April
Post-Intervention measurements & questionnaires	1 month	April - May
Analysis	concurrent with data acquisition	March - May
Final Data Synthesis	1 month	May, 2005
Report Writing	1 month	May, 2005
<u>Optional</u> longitudinal analysis (4 months post study)	1 month	July, 2005
<u>Optional</u> longitudinal analysis (6 months post study)	1 month	September, 2005

The implementation of this four-month plan was successful.

Analysis

Analytic Procedures: This study was calculated and powered at 80% with an alpha of 0.05. Procedures analyzed in this section included four areas: 1.) Repeated measures for BPs; 2.) Pre- and post-test spirituality scores including a qualitative review of one question from the SSQ; 3.) A Demographic profile including a qualitative review of Participant's Diary of Changes; and 4.) Retrospective, randomized chart review. Areas 1 – 3 constituted the main analytic procedures for this study and area 4 included pre-planning analysis.

Pre-planning analysis involved:

1. Analysis for BP measurements (used the SAS Program using Genmod Procedure, which treated the repeated blood pressure measurements as clustered within participants): Analysis included up to nine repeated BP measures. Four pre-post comparisons were made:

- a. Pre-test BP measurements were compared to measurements taken over the two months post-intervention period;
- b. Final (post) BPs completed on the intervention day were compared to pre-test measurements independently;
- c. BPs taken during each post-test month were compared independently to the measurements completed in the pre-test month, excluding those taken on the actual intervention day; and,
- d. Lastly, during post-intervention months, BPs taken in both the first and second months of this period were compared to the measurements completed in the pre-test month.

2. The Spiritual Orientation Inventory and the Supplemental Spirituality Questionnaire (which, in addition to the identical pre-test questionnaires, were completed by participants within the last week of the study) were analyzed using paired *t*-tests for comparing pre- and post-test spirituality scores. The paired *t*-tests were chosen since the differences in pre- and post-test scores met the requirement of being normally distributed. A qualitative analysis of question #15

of the Supplemental Spirituality Questionnaire to assess for common themes was done manually for pre- and post-test responses.

3. Descriptive statistics showing frequencies and percentages were used to analyze participants' demographics. Categories included: age, gender, ethnicity, health history profile, and a self-reported spirituality-related profile. A review of Participant's Diary of Changes was qualitatively evaluated for common themes correlating to unusual changes in BPs chronologically and is included in the demographic analysis section.

4. The data from the randomized chart review were analyzed using ANOVA statistical method which estimates the variability in BP measurements across time and is specific for the Hawai'ian, Asian and Other Pacific Islander population.

Hypotheses

Predictor (Intervention) Variable: The following Table 3 illustrates the hypothesis for the predictor variable, measurement level, and analysis:

Table 3. Predictor Variable (Intervention)

HYPOTHESIS	PREDICTOR VARIABLE(S)	MEASUREMENT LEVELS	ANALYSIS
<i>Self Identity through Ho'oponopono</i> is associated with improved BP management.	<i>Self Identity through Ho'oponopono</i>	Dichotomous Categorical	repeated measures regression

The hypothesis for the predictor variable states that the intervention, *Self Identity through Ho'oponopono*, is associated with improved BP management. Through

regression analysis using repeated measures, results were expected to report if the null hypothesis could be rejected.

Outcomes Variables: The outcome variables applicable in answering the two questions driving this research are described here, first for BP measurements and second for spirituality scores. The hypotheses are listed first, followed by the associated research questions:

1. For BP - There will be a reduction in mean blood pressures post-test compared to pre-test measurements. The first question seeks to find a difference in pre- and post-test BPs for the sample population. The hypothesis can be illustrated as:

$$H_0 1) BP_{pre} = BP_{post} = 0$$

$$H_a 1) BP_{pre} \neq BP_{post} \neq 0$$

2. For spirituality scores - There will be a significant difference in participants' self-reported scores of spirituality. The second question asks if there is a significant difference in pre- and post-test spirituality scores for the sample population when *Self Identity through Ho'oponopono* is included as therapy in addition to standard medical therapy for HTN. The specific components of spirituality included within the conceptual definition of spirituality and subsumed within the questionnaires were: participant's sense of meaning and fulfillment of purpose in life, well-being, forgiveness, inner peace, and love. The hypothesis can be illustrated as:

$$H_0 \text{ Spirituality scores pre-test} = \text{Spirituality scores post-test}$$

H_a Spirituality scores pre-test ≠ Spirituality scores post-test

These outcomes are included in the following Table 4:

Table 4. Outcome Variables

HYPOTHESES	OUTCOME VARIABLES	MEASUREMENT LEVELS	ANALYSIS
1. There will be a reduction in mean BPs post-test compared to pre-test measurements	BP measurements	Continuous	repeated measures regression
2. There will be a significant difference in participants' self-reported scores of spirituality	A. Spiritual Orientation Inventory	ordinal	paired <i>t</i> -test
3. There will be a significant difference in participants' self-reported scores of spirituality	B. Supplemental Spirituality Questionnaire	ordinal	paired <i>t</i> -test

No further analysis was done at this time. Since the questions posed by this study were answered, there was no need to conduct *ad hoc* analysis for this study.

NB.: A regression to the mean for pre-test BP measurements was considered for the analysis. Since none was found, analysis could proceed for BP measurements. A slope fit through the pre-test period for spirituality scores showing normal probability (except for a small increase), so analysis for this study could proceed reliably as outlined in the methods section.

Quality Control and Data Management

To reduce systematic and random error, BP measurements were completed using the high quality digital Welch Allyn Spots Vital Signs. JNC 7 requires at least two BPs for a reading, this study consistently took three

measurements for a reading. Blinding of investigators and research assistants—although optimally desirable for this study—was not possible since insufficient resources were available to hire the technical support for blinding in this study.

To minimize random error and to assure a low Type I error rate, this study employed a reasonable sample size and precision, judged from the p value and consistency of results from previous studies. After collecting data and storing it in a locked drawer, it was entered into an appropriate data management database. All data and study information has been de-identified and no information identifying any of the participants will be published. The data was converted into Excel tables and imported into the SAS Program for analysis.

Ethical Considerations

All efforts to minimize risks in relation to the principle of beneficence were accorded the participants. There were no invasive measures utilized and vulnerable populations (children, prisoners, pregnant women, persons with impaired mental capacity) were not part of this study. All benefits and burdens of this study were distributed fairly to the target population and analyses and results will be available to all participants. Small tokens of appreciation were provided for research participants, distributed at registration into the study and in the final month of the study for minimal compensation and travel expenses (averaged at a total of \$35.00 for each participant for the entire study time).

CHAPTER 4: RESULTS

Chapter 4 summarizes the results of this research study and incorporates tables and figures of results. Guided by the research questions, this chapter describes the sample population; pre-test and post-test mean blood pressure differences; pre-test and post-test mean differences of the spirituality questionnaires' scores; graphic illustrations; and pertinent results of the qualitative questions. The findings discussed in this chapter will serve to facilitate the discussion of the implications of these outcomes which will be addressed in Chapter 5.

Sample in this Study

At least 200 people were informed of and invited to join this study. Thirty-three respondents joined; however, ten withdrew prior to intervention and were not included in the study. Twenty-three respondents, primarily of the Asian, Hawai'ian, and Other Pacific Islander population, joined and became part of the study. One of the 23 participants participated up through the fifth post-intervention blood pressure measurement. Since post-spirituality questionnaires were not completed by two participants (including the subject just mentioned), the pre-test scores for these participants were excluded. The remaining 21 of 23 participants completed both pre-test and post-test measurements of blood pressures and spirituality questionnaires. Except for this adjustment to the

spirituality questionnaires' results, all other results presented here reflect this sample population of 23 participants as indicated.

Description of Sample: Demographics

Table 5 outlines the demographics of age, gender, and ethnicity in the sample population. .

Table 5. Participants' Demographics*

DEMOGRAPHICS	RANGE/YEARS	FREQUENCY (%)
Age	34 - 49	4 (17%)
	50 - 64	10 (44%)
	65 +	9 (39%)
Gender	Female	16 (70%)
	Male	7 (30%)
Ethnicity	Hawai'ian/Part-Hawai'ian	15 (65%)
	Asian	5 (22%)
	Caucasian	2 (9%)
	Other*	1 (4%)

*Other = missing value.

Of the 23 participants in this study all of whom must have met the majority of inclusion criteria, female participants composed 70% of the sample population. Ages of both females and males ranged from 34 to over 65 years of age, with the majority (83%) being 50 years and older. More than half of all participants identified themselves as Hawai'ian or Part-Hawai'ian, 22% as Asian, 9% as Caucasian, and 4% as Other. Anyone identifying her/himself as any part Hawai'ian was considered to be of Hawai'ian ethnicity. Thereafter, anyone identifying her/himself as any part Asian or Filipino was considered to be part of

the Asian ethnicity. Responses to selected questions regarding HTN risk factors (smoking, exercise, alcohol consumption, family history, prescriptions) follow:

Table 6. Participants' Health Information

HEALTH-RELATED QUESTION	ANSWERS POSSIBLE	FREQUENCY (%)	NUMBER OF RESPONSES (%)
1. Do you smoke?	Yes	1 (4%)	23/23 (100%)
	No	22 (96%)	
2. Are you currently exercising?	Yes	11 (50%)	22/23 (96%)
	No	11 (50%)	
3. Do you engage in regular aerobic physical activity for 30 minutes/day most days of the week?	Yes	6 (26%)	23/23 (100%)
	No	17 (74%)	
4. Do you limit alcohol consumption to no more than 1 oz (30 ml) of ethanol/day if male, and ½ oz. (15 ml) if female?	Yes	19 (86%)	22/23 (96%)
	No	3 (14%)	
5. Do you consume low-fat foods?	Yes	15 (65%)	23/23 (100%)
	No	8 (35%)	
6. Do you have a family history of high blood pressure?	Yes	21 (95%)	22/23 (96%)
	No	1 (4%)	
7. Are you taking prescription medication for HTN?	Yes	17 (74%)	23 (100%)
	No	6 (26%)	
8. Are you actively involved in caring for your health?	Yes	20 (87%)	23/23 (100%)
	No	3 (23%)	
9. Would you like to be more involved in your health care treatments?	Yes	21 (91%)	23/23 (100%)
	No	2 (9%)	

NB- Some missing values change the percentages for actual numbers of participants responding

Out of 23 participants responding to the question on smoking, 22 of 23 (96%) reported they do not smoke. Almost all participants, 21 of 22 (95%) have a family history of HTN, and three-quarters take anti-hypertensive medications. About half of all individuals in this study partake in some form of exercise; however, only one-quarter exercise aerobically. Eighty-seven percent of the 23 participants reported they are actively involved in their health care; yet, 91% of all would like to be even more involved. Most participants consume low-fat foods (65%), and a large majority (86%) limit alcoholic beverage consumption. All participants replied to the question inquiring about the number of medications they are prescribed for hypertension, and 17 of 23 participants (74%) indicated they take medications for HTN.

Regarding participants' views of themselves and their sense of spirituality as it relates to health care, Table 7 profiles the key questions asked and respective responses:

Table 7. Participants' Spirituality-Related Profile

SPIRITUALITY-RELATED QUESTION	RESPONSE	FREQUENCY
1. Do you consider yourself spiritual?	Yes	19 (86%)
	No	3 (14%)
2. Please rate your level of spirituality:	Not at all	0
	About average	18 (76%)
	Totally	5 (22%)
3. Do you sense spirituality is important to your health?	Yes	22 (100%)
	No	0

When asked to rate their spirituality as either “not at all,” “about average,” or “totally,” most (76%) participants consider themselves to be “about average” spiritually; however, all (100%) view spirituality as important to health care.

In summary, for these 23 participants who joined the study, this analysis presents a profile of participants being generally at or over 50 years of age, mostly non-smokers, female, and of Hawai’ian/Part-Hawai’ian, followed by Asian descent. Half of the respondents get some form of physical exercise, most limit alcohol intake and consume low-fat foods. The majority take anti-hypertensive agents, consider themselves to be active participants in their health care, and want to be even more involved with their health care. Most participants consider themselves to be spiritual, with about one-quarter of the sample population viewing themselves as totally spiritual and three-quarters viewing themselves as average. All participants (100%) consider spirituality important to health.

Research Question #1

Is there a significant difference between Asian, Hawaiian, and Other Pacific Islander participants’ pre-test and post-test BPMs when *Self Identity through Ho’oponopono* is included as therapy in addition to standard medical therapy for HTN?

In this section, the results of participants' BP measurements are discussed. Repeated measure methods were used to analyze the pre-test and post-test BP measurements.

Blood Pressure Measurements (BPMs)

Preplanning - Chart Review Results: The chart review data were analyzed by ANOVA to determine variability in BPMs across time. The standard deviation (SD) within person was 6.52 mm Hg, which was the number used to calculate the estimated sample size. The variability between individuals was about three times greater (20.97 mm Hg). The within variance is smaller than the between variance for this sample population.

The variability was similar to that reported in other published studies and reflects the expected variation for this geographic area. Thus, the requirements for sample size needed to power this investigation, especially in light of the proposed repeated measures analysis, were met.

Actual Study: The mean BP differences from pre- to post-test are summarized in Table 8 with Confidence Intervals (C.I.) at 95%. BP mean differences were analyzed over intervals designated as: 1) intervention day, 2) first month post-test interval, 3) second month post-test interval, 4) both first and second month post-test interval combined, and 5) all post-test measurements including post measurement on the intervention day. The results of this analysis

follow with units of measurements of systolic blood pressures (SBPs) and diastolic blood pressures (DBPs) given, respectively:

Table 8. Post-Test Intervals of Mean SBP & DBP Analysis Using Regression Methods with Repeated Measures

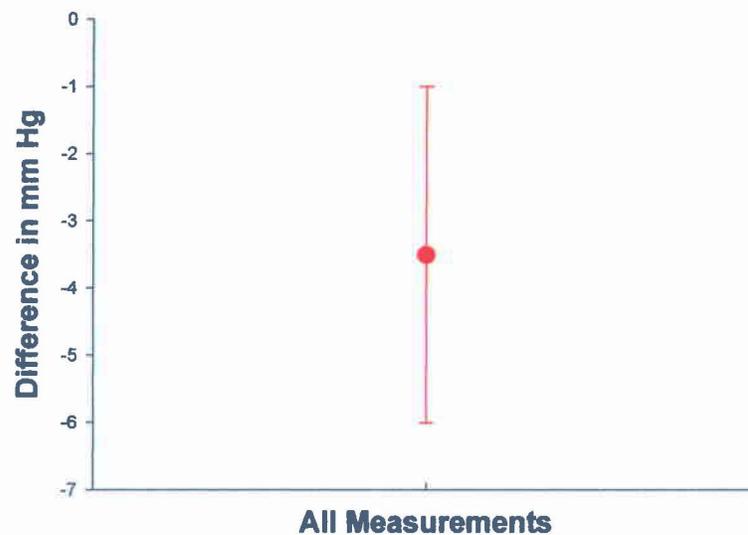
<u>POST-TEST INTERVAL</u>	<u>MEAN SBP ESTIMATE (95% C.I.)</u>	<u>P VALUE</u>	<u>MEAN DBP ESTIMATE (95% C.I.)</u>	<u>P VALUE</u>
Intervention Day	6.35 (0.80, 11.90)	<0.03	4.37 (2.05, 6.69)	<0.001
First Month Post-Test	-7.83 (-13.86, -1.80)	0.011	-4.16 (-7.42, -0.90)	0.013
Second Month Post-Test	-11.86 (-20.77, -2.96)	<0.009	-5.44(-9.03, -1.85)	0.003
First & Second Months Post-Test	-9.57 (-16.40, -2.74)	<0.006	-4.76 (-7.78, -1.74)	0.002
All Post-Test Measurements*	-6.81 (-12.86, -0.76)	<0.03	-3.51 (-6.02, -0.99)	<0.01

*All post measurements include only post BPMs on intervention day and all other BPMs post-intervention.

On the intervention date, the mean systolic blood pressures (SBPs) and diastolic blood pressures (DBPs) increased 6.35 and 4.37 units (mm Hg) ($p < 0.03$; $p < 0.001$), respectively, and achieved statistical significance. The first month post-test, SBP and DBP decreased -7.83 and -4.16 units (mm Hg) ($p = 0.011$; $p = 0.013$); the second month post-test, SBP and DBP decreased -11.86 and -5.44 units (mm Hg) ($p < 0.009$; $p = 0.003$); for the first and second months post-test combined, SBP and DBP decreased -9.57 and -4.76 units (mm Hg) ($p < 0.006$; $p = 0.002$); and over the entire post-test period, intervention measurements of SBP and DBP decreased -6.81 and -3.51 units (mm Hg) ($p < 0.03$; $p < 0.01$).

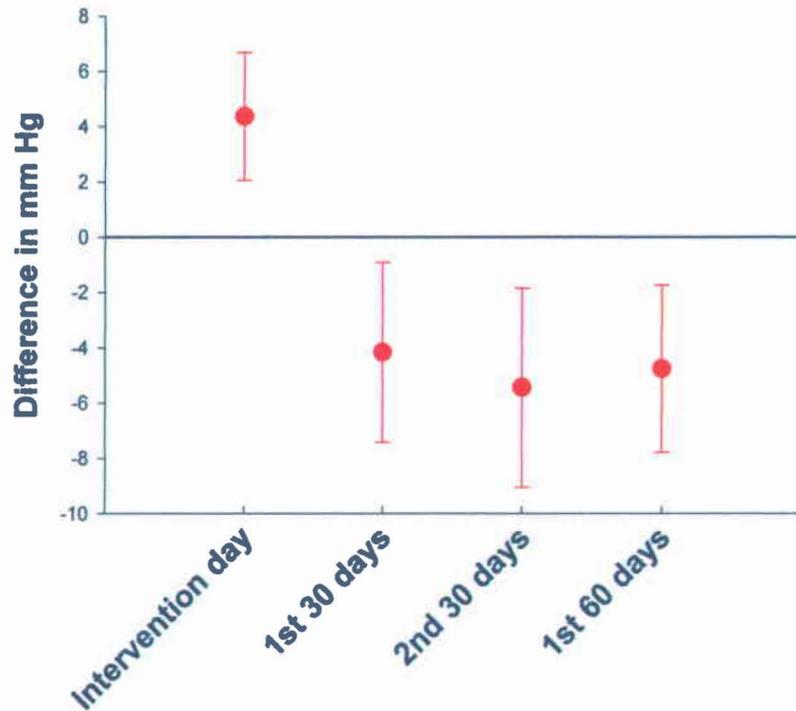
Figure 2 below graphically describes all DBPM differences for all post-test measurement differences in mm Hg. Here the mean DBP estimate is -3.51 with confidence intervals of 06.02 to 0.99 :

Figure 2. Post-test differences in all DBPMs



The mean difference for all post-test measurements (-6.81) can then be further divided into specific time periods. There are depicted in Figure 3 below. The mean and the confidence intervals show each time interval on the x axis and the differences in BP as measured by mm Hg is on the y axis.

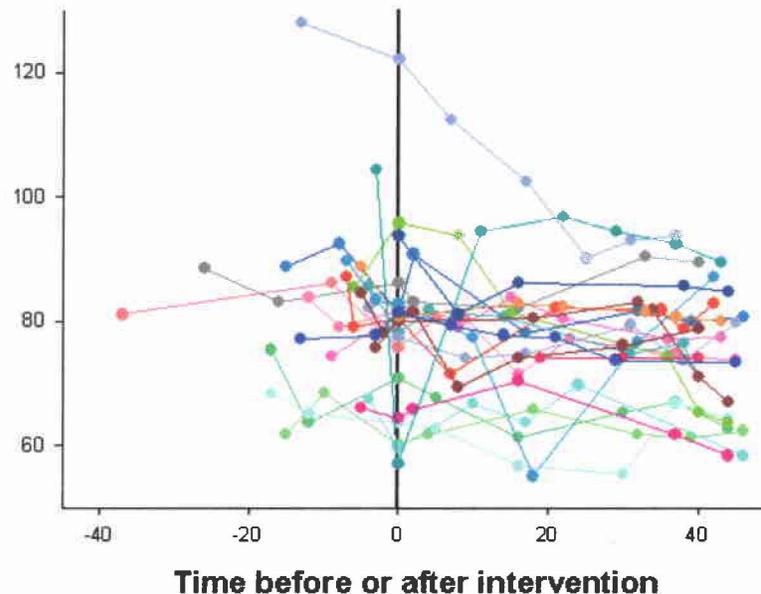
Figure 3. Post-test differences in DBPM post-test intervals



This figure demonstrates the improvement of DBPMs in all post-intervention intervals, with the exception of the intervention day. Mean DBP estimates with confidence intervals are highlighted in Table 8. The potential reasons for the increase on the intervention day and subsequent decreases thereafter is discussed in Chapter 5.

Figure 4 provides a graph of DBP measurements for all participants.

Figure 4. Graph with DBPs for all Participants (Pre to Post)



This graph of the DBPMs for all participants depicts the actual trend of those measurements for this study. The diastolic number (in mm Hg) is on the y axis. The time before and after the intervention is listed in days below on the x axis. Zero is the intervention day.

A regression toward the mean was checked by estimating slope using pre-test measurements. A linear regression (straight line) was fit through the pre-test points. No significant decrease in DBPs was found and the slope was not statistically significant in showing a regression toward the mean. If anything, a slight increase was evident for the mean of pre-test DBPMs for all participants.

Hypothesis testing: For the predictor variable, the hypothesis states that *Self Identity through Ho'oponopono* is associated with improved BP

management. Through use of regression methods with repeated measures for the BPMs of the 23 participants in this study and achieving statistical significance, it can be stated that the research hypothesis for the predictor variable may be true and that the null hypothesis was rejected.

Summary: For this research study of 23 participants, with the exception of BPs taken on the actual intervention day when mean BP differences increased with significance, measurements significantly decreased for both SBP and DBP. The mean differences for post-intervention intervals of the first month, second month, first and second months combined, and for the total of all post BP measurements shows a decrease in mean BP.

Research Question #2

The following results of the scores for the spiritual questionnaires applies to the second question of this study:

2) Is there a significant difference in Asian, Hawaiian, and Other Pacific Islander participants' pre-test and post-test spirituality scores regarding their sense of meaning and fulfillment of purpose in life, well-being, forgiveness, inner peace, and love when *Self Identity through Ho'oponopono* is included as therapy in addition to standard medical therapy for HTN?

The specific components of spirituality are those subsumed within the operationalized definition of spirituality used in this study.

Table 9 outlines the pre-test and post-test analyses of 21 participants' self-report responses to the 1.) Spiritual Orientation Inventory (SOI), and the 2.) Supplemental Spirituality Questionnaire (SSQ). Mean scores for pre-test SOI and SSQ are indicated:

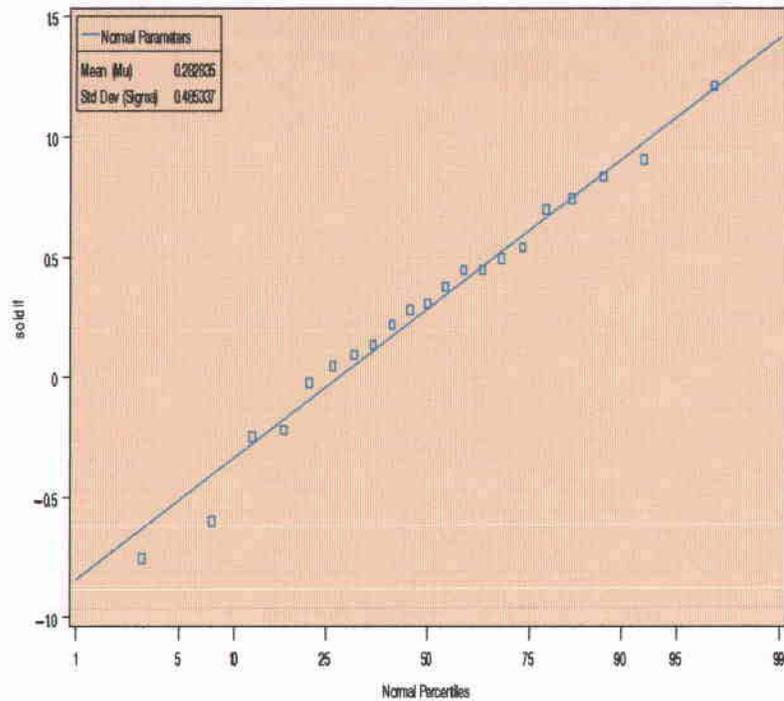
Table 9. t-test Mean Differences for SOI and SSQ

	MEAN DIFFERENCE	C.I.	P VALUE	MEAN PRE-SCORES	NO. OF PARTICIPANTS
SOI	0.28	0.06, 0.51	<0.02	5.42 + 0.81 SD	21
SSQ	0.31	0.09, 0.53	<0.01	5.67 + 1.23 SD	21

The mean difference using the paired *t*-test is approximately 0.3 units for both questionnaires. This shows a statistically significant mean increase for all post-test scores of the SOI and SSQ of approximately 0.3 units on the Likert scale as compared to pre-test scores ($p < 0.02$ and $p < 0.01$, respectively).

The pre-test and post-test analyses for these questionnaires is depicted in the normal probability graph (Figure 5), which shows that differences were approximately normally distributed for the SOI.

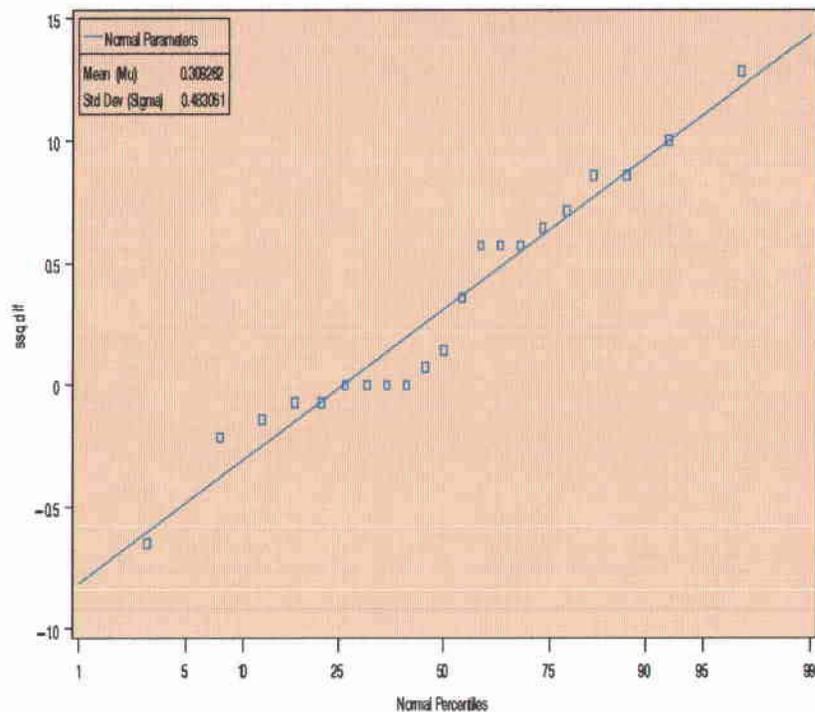
Figure 5 . SOI Probability Graph



Using the *t* test for 21/23 responses to the questionnaires, this graph illustrates a statistically significant mean difference of 0.28 (95% CI = 0.06, 0.50) with a probability value of $p = 0.02$ for the SOI.

Likewise, the probability graph (Figure 6), shows that differences were approximately normally distributed for the SSQ as well:

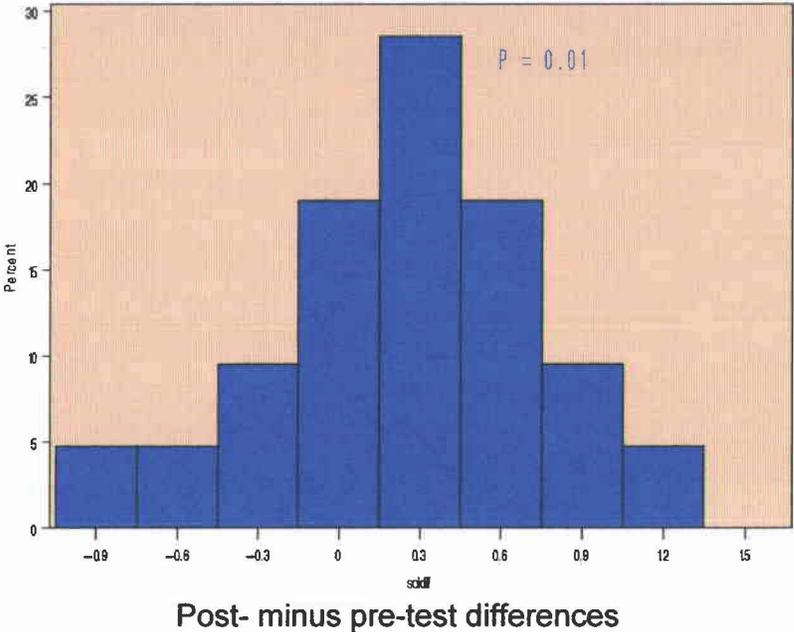
Figure 6. SSQ Probability Graph



Using the t test for the same 21 responses to these questionnaires, this graph illustrates a statistically significant mean difference in responses pre-and post-test of 0.31 (95% CI = 0.09, 0.53) with a p value of $p < 0.01$ for the SSQ.

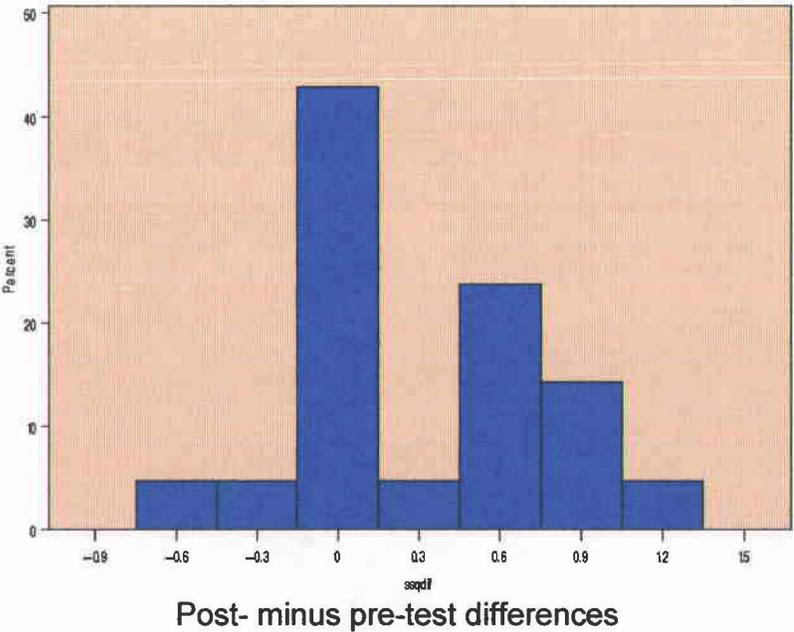
Subsequent distributions of differences in both SOI and SSQ pre- and post-test scores are shown in Figure 7 and Figure 8, respectively. The SOI is represented first.

Figure 7. SOI Distribution of differences



Here, the peak difference in scores is a 0.3 unit difference (increase) post-test versus pre-test. The SSQ distribution of differences follows:

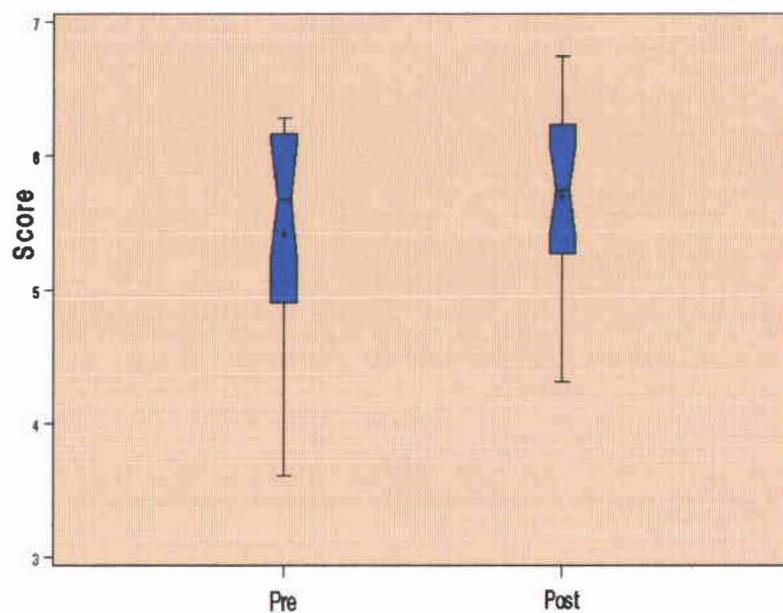
Figure 8. SSQ Distribution of differences



In this distribution graph, differences of 0.3 are depicted to the right of zero as well.

The following two figures depict box plots showing the pre- and post- SOI distributions:

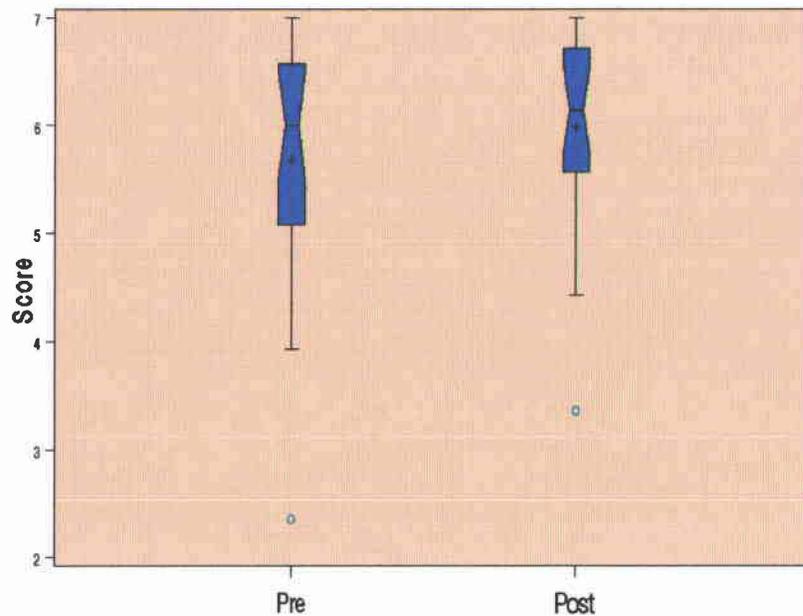
Figure 9. SOI Box Plot with pre- and post-distributions



This box plots diagram depicts the mean of scores (lines at indents) for the SOI approaching the median (+ sign on each box) in the post-test scores of all individuals. The extreme range and interquartile range decreased from pre- to post-scores.

The following figure depicts the box plots of the pre- and post- SSQ distributions:

Figure 10. SSQ Box Plot with pre- and post-distributions



Like the SOI, the mean scores for the SSQ also approach the median post-test and extreme and interquartile ranges decreased post-test as compared to pre-test ranges.

Qualitative Question Responses

SSQ Question #15: For the SSQ, the 15th question asked participants to state in their own words how they felt about their spirituality at the time they completed both pretest and post-test. For the pre-test, 11 responses were affirmative or positive which indicated the participants were pleased or interested in spirituality; 5 responses indicated the participants believed in God or a higher power; 3 responses indicated participants were unsure about how they felt

spiritually on that given day; no responses were clearly negative or denied the importance of spirituality or presence of a higher being; and two replies were considered to be neutral or non-committal responses. Actual examples (as quoted entirely or in part) are included in Table 10:

Table 10. Examples of Qualitative Responses - Pre-test SSQ Themes

	<u>INDICATED BELIEF IN GOD OR HIGHER POWER</u>	<u>UNSURE OF OWN SPIRITUALITY</u>	<u>AFFIRMATIVE AWARENESS</u>	<u>NON- COMMITTAL</u>
No.	5	3	11	2
E.g.	To know that there is a higher power other than myself and all I need to do is release and "let live".	I am somewhat in agreement with my spirituality	I feel happy everyday that I wake up	will bring in writing on next visit
	I believe in the Lord above. Whenever I'm in trouble I always ask for help. The problem is I believe and I ask for help only when I feel in trouble.	I do not seem to have the time to seek spiritual healing. I have always wanted to....	It is quite interesting. It has taught me how to be focused, balanced, and in touch with life itself	I feel the same every day
	I believe in God.		I feel at peace almost always...	
			I know that spirituality exists. I've had a near death (out of body) experience	

Examples of positive responses (in brief) include: great, happy, high, comfortably evolving, and I feel the same every day. Words used to express thoughts regarding spirituality include: fulfilled, "let live," great, happy, comfortably evolving, and feel at peace. Statements about spirituality in relation to this question include:

- 1.) I feel okay about it but I am not sure about my own spirituality today.

- 2.) I feel happy.
- 3.) It's growing.
- 4.) I am very well pleased with my overall being.
- 5.) ...spirituality plays a big part in my life at home.....

Overall, most participants showed an interest, an awareness, and an appreciation for the concept of spirituality in the pre-test SSQ. Table 11 outlines responses and themes from the post-test SSQ, identifying 12 positive responses, six believing in a higher power, and one with some uncertainty (part of the response unsure; part believes in God). No apparent non-committal responses were noted. Some examples are included.

Table 11. Examples of Qualitative Responses - Post-test SSQ Themes

	<u>INDICATED BELIEF IN GOD OR HIGHER POWER</u>	<u>UNSURE OF OWN SPIRITUALITY</u>	<u>AFFIRMATIVE AWARENESS</u>	<u>NON- COMMITTAL</u>
No.	6	1	12	0
E.g.	I'm ok with my concept of a higher power.....sometimes it carries me.	I wish I was more spiritual. Then I would know how to face the world and my problems better. (Part of answer believes in God)	I am (on) a spiritual high. I forgive people all the time....	
	God has given me a second chance at life.		Spirituality is an inconstant experience-mixed in with human consciousness of daily life.	
	in spirituality god shows me (the) power he has...	I feel my spirituality growing	
	Feeling good about myself and being with my higher power....		I feel I have the where-with-all to experience my life as sacred.	

Words used in response to this question include: very good, good, very much fulfilled, being forgiven, at peace, keep moving on, growing, happy, ever evolving, so blessed, inconstant experience, thank you, and I will overcome.

Statements about spirituality in relation to the question asked include:

- 1.) If God is for us, who can be against us! Slow down, enjoy life!
- 2.) I have adopted an attitude that is less anxious, more calm.
- 3.) My destiny is to be here and make a difference.
- 4.) Spiritually, I believe there is a plan for each of us in this life that we must fulfill.
- 5.) Today I feel very much fulfilled.

Participants' Diary of Changes: The Participants' Diary of Changes showed some changes in some participants medications (anti-hypertensives and others were included for some participants), diet, supplements, exercise, and lifestyle (such as travel). For instance, one participant traveled to Las Vegas, lost some money to gambling, shared his concern, and his BP was elevated the next week. Another participant's blood pressures were dropping to unsafe levels. This participant was advised to consult with participant's health care practitioner, who decreased participant's medications in half. The following week the same participant's BP was back to a more normal level.

Overall, thorough record-keeping for most participants was not evident. Most participants claimed no changes. Of those who included changes, the question is whether or not the participants documented the changes. Although

the diaries described a variety of examples such as lifestyle, travel and medication changes, the information gathered from this form is not precise.

Summary

Overall, differences in BPMs were statistically significant in all 23 participants from the Asian, Hawai'ian and Other Pacific Islander populations in this study sample during all post-intervention intervals (with the exception of BPs taken on the intervention day itself), which resulted in a decrease in mean differences for both SBP and DBP. Mean differences in scores for the SOI and SSQ were statistically significant showing an increase post-test as compared to pre-test scores. The null hypotheses for these two qualitative sections of the research study are rejected. A positive change in BPMs and self-reported spirituality scores for this sample population correlates to an affirmative answer to the two research questions. In addition, recurring themes in the responses to the spirituality-related question indicates a belief in a higher power and an affirmative awareness of spirituality and predominate the pre- and post-test responses.

CHAPTER 5: DISCUSSION, FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS

Chapter 5 explores the findings of this research study in relation to the current state of the science. Research questions, limitations, conclusions, and implications and recommendations for future research and practice are presented. This author's thoughts on the findings and possibilities of why results occurred are included.

This is the first study to my knowledge investigating the effects of *Self Identity through Ho'oponopono* with regard to hypertension; thus, research studies in this area are lacking. The literature review in Chapter 2 addresses spirituality and health outcomes and offers a basis for the importance of incorporating spirituality into health care. The literature referenced in Chapter 3 addresses HTN and lifestyle modifications such as exercise. In addition, lifestyle modifications for persons with HTN are recommended by JNC 7 and are included as SMT for many persons with HTN. The current research study indicates that including the spiritual intervention *Self Identity through Ho'oponopono* as a lifestyle modification has positive effects on BP improvement and self-reported scores on spirituality questionnaires for this group of 23 participants with HTN in Hawai'i.

Findings

- BP measurements decreased and improved following the intervention, with the exception of those taken on the intervention day itself.
- Quantitative and qualitative measures indicated that spirituality was increased following the *Self Identity through Ho'oponopono* intervention.

Thus, the null hypotheses for BPMs and spirituality questionnaires are rejected. These findings show that both research questions are answered affirmatively; there is a significant difference in BPMs and scores of spirituality among those primarily of Asian, Hawai'ian, and Other Pacific Islander ethnicities when *Self Identity through Ho'oponopono* is included as therapy in addition to standard medical therapy for HTN.

Limitations

Some reasons for possible limitations affecting the scope and interpretation of the findings of this investigation include:

- No blinding occurred. The placebo effect is considered a possibility when there is no blinding involved.
- The intervention was conducted by one instructor: Replicability is a concern when an intervention is implemented by a single entity.

- There was no separate comparison group offering participants another class or alternative program (such as exercise, meditation, etc.) which might create a threat to validity.
- Conditions outside the study (such as medication adjustments or additions, rigorous exercise programs, etc.) may have occurred during the study; yet, not recorded by participants.
- Environmental variables affecting human behavior were not monitored.
- The intervals at which BPMs were taken were irregularly spaced. Testing BPMs on the same days of the weeks would offer increased consistency for interpreting results.
- This sample population might have been more open to the concept of a spiritual approach to health care initially, so the participants' mean scores for spirituality may have already been higher than the general population.
- The tools used for scoring levels of spirituality lack extensive testing in ethnic populations.

Recommendations to address each limitation

Blinding with this study design was not possible since participants served as their own controls; however, with a larger two or three group study population which includes separate comparison groups, results could consider the placebo

effect and blinding of participants and observer in each of the groups. In the current investigation, observer bias (such as the unconscious or conscious tendency to misread BPs as suggested by Hulley, et al. [2001]) was eliminated by way of accurate, high quality digital BP devices.

Replicability can be verified by reproducing another study in several ways: a) exactly, b) approximately, c) concurrently or d) through systematic extension (Burns & Grove, 1997). If the findings hold up in an approximate replication with the same instructor with small changes, they can be considered consistent and credible. Consistency can also be determined through multiple concurrent replications of a study, conducted in different geographic locations (Burns & Grove, 1997) (Chapter 5). Other possible ways to establish consistency include having various instructors teach the class of *Self Identity through Ho'oponopono* and analyze and compare findings against this study.

Conducting another study similar to this one would confirm internal and external validity by determining if the results achieved were from the intervention alone rather than another variable (internal), or if they were generalizable to other populations (external) beyond the sample population. Moreover, further education of participants regarding form completion might facilitate accurate and prompt recording efforts and result in consistently valid responses of participants and outcomes of the forms. A column addressing environmental factors might be Included.

Conditions existing outside the study affecting results, such as medication changes, are factors which must be addressed in any study, yet are less of a concern with this study since there was only one group. Without a comparison group, no other group can be considered to have an advantage or disadvantage due to environmental factors. One way in which environmental factors can be more tightly controlled in such a study would be to take each participant's BPM on the same day each week. This process would increase accuracy for testing intervals and offer consistency for intervals within persons.

The recruitment for this study sample may have resulted in a selection threat of internal validity since those who joined might be considered different from those who did not join—for example, the participants may be viewed as more spiritually inclined. This phenomena was similarly considered in the study by Harris, et al. (1999) with regard to prayer. The results conjectured that some of the patients in the study may have been receiving prayer already and the results were questioned for lack of statistical significance. This phenomena is more of a concern with randomization of a comparison group with the study group, but should be addressed when considering which participants are willing to join the study.

The tools for this study regarding spirituality were selected because the study purpose focused on spirituality and spiritual interventions, not religiosity or religious concepts. The focal point of the SOI and the SSQ met that criteria and was consistent to that extent. Continued testing of the tools is essential to note

reliability and validity measures of the tools. BPMs were completed by using high standard devices, so it is believed that BPMs were as accurate as currently possibly. Thus, BPMs are believed to be reliable and valid.

Discussion

The one variable that all participants had in common throughout this study was that they all attended the intervention class of *Self Identity through Ho'oponopono*. Some participants were not taking prescribed medications (and refused to do so despite recommendations from their health practitioners), most were in their sixth decade of life or more, some were not exercising, most had a family history of HTN, most did not smoke or drink alcohol in excess, and all believed spirituality is an important aspect of health care. It is possible that their "belief" that a spiritual intervention could be helpful could be an influencing factor in their overall improvement. It is also possible that some people practiced what they learned from the class more than others. Moreover, some participants might have adjusted their lives consciously or unconsciously through exercise, diet, meditation, prescribed medications, etc. What is essential to recognize is that whatever the participants received as a 'take-home message' from the class, that message resulted in significant findings overall for this small yet statistically significant sample size.

With regard to the increase in BPMs during the intervention itself, it is possible that this might of occurred as a result of attending the class itself and

learning about an approach new to most participants and referred to as a spiritual intervention, some extraneous variable unique to each participant and unaccounted for, or a combination of these or other factors. In this class participants are shown how to look at themselves to identify what the problem causing the HTN is. In the following first month post-intervention, it is conjectured that participants became more comfortable with this approach and the intervention process became easier to integrate into their lives. In the subsequent month, BPs decreased to a greater degree and it is conjectured that BPs were responding to the impact of the intervention itself since this was the unique and commonality of all participants. Another larger study and longer in duration would allow these hypotheses to be accepted or rejected.

Members of the U.S. Preventive Services Task Force (2003) indicate that non-pharmacological therapies (reducing dietary sodium intake, potassium supplements, increased physical activity, limiting alcohol consumption, etc.) show some association in reducing blood pressure, but the impact of this on cardiovascular outcomes is unknown. This study shows significance for the *Self Identity through Ho'oponopono* intervention and will allow a basis to look further at specific cardiovascular outcomes or other human conditions or diseases. Reducing BP in the USA will help decrease the risk for heart disease and stroke, and has the potential to reduce the financial burden in the US.

With regard to the sample size, the initial calculation of 38 participants, which included 10% attrition, may have been overpowered. Statistical

significance was achieved with a smaller sample, suggesting that the repeated measurements built into the initial design provided the added power and made the sample size of 23 participants adequate. This study was assuming about a 4 mm Hg difference from initial sample size calculations and achieved at least that much of a difference as designed.

The magnitude of effect of the intervention was at least comparable to published intervention studies on exercise for the treatment of hypertension for both diastolic and systolic BP measurements, such as those described in Chapter 3. Cooper, Moore, McKenna & Riddoch (2000) noted a reduction in both SBP and DBP of -2.8 mm Hg and -1.9 mm Hg in the exercise group after 6 weeks, but an insignificant net difference between exercise and control group for a moderate intensity exercise program. The magnitude of effect for the study completed by Cooper, et al. was not significant. A spiritual intervention program such as *Self Identity through Ho'oponopono* might be an intervention especially important for reducing BP for those persons unable to engage in exercise greater than moderate intensity.

Self Identity through Ho'oponopono is a low-cost, non-invasive, first-time used and culturally-sensitive intervention which effectively helped improve BPs for participants of the sample population using SMT for management of HTN. It has validated what other people have conjectured but never tested. Dr. Hew Len describes numerous health outcomes of people who have used the process of *Self Identity through Ho'oponopono* and believes the method as proposed in

this study may revolutionize the health care industry by changing the way it looks at health problems. Anyone can use the process. It is for patients, health care providers, and anyone interested in getting to the cause of any problem.

As Morrnah Nalamaku Simeona asserts, this intervention is a profoundly effective process to identify the cause of problems and then to allow the healing process to begin. It is an approach which allows the individual to identify who she/he is and to release the memories replaying problems in the subconscious of Mind through repentance, forgiveness and transmutation (Figure 1, Chapter 3). Morrnah recommends this process for health care practitioners as well (Simeona, 1992).

Conclusions

The intervention, *Self Identity through Ho'oponopono*, merits further testing and should be considered as an intervention in a larger randomized clinical trial. Consideration should be given for referring people with HTN to a class on *Self Identity through Ho'oponopono*. This intervention was demonstrated to be an effective therapy for HTN management and it appears to improve person's sense of spirituality.

Recommendations

The following recommendations are made regarding the findings of this research study:

1. Formalize a large RCT to test the efficacy of *Self Identity through Ho'oponopono* for HTN management. Replicate this study with additional instructors.
2. Consider a comparison group employing an alternate class or program randomizing participants into either comparison or intervention group and include blinding of observers and participants wherever possible.
3. Consider extending the post-intervention period with a second class of the intervention part way through the full post-intervention period of at least four to six months in a similarly or alternately designed study.
4. Continue to develop user-friendly data management forms for participants' use so as to correlate factors and modifications in their lives with their BP monitoring.
5. Continue to evaluate the psychometrics of spiritual measures.
6. Measure BPs on set days of the weeks at evenly-spaced intervals each month.
7. Consideration should be given to referring people with HTN to a class on *Self Identity through Ho'oponopono* because it has demonstrated effective results for lowering BP, is non-invasive and poses no risk to people.

Based on the literature as it exists, a generated conceptual definition of spirituality has been operationalized and empirically tested in this study where persons with HTN have achieved improved health outcomes. This study developed an empirically tested design for the inclusion of *Self Identity through*

Ho'oponopono as a spiritual intervention to improve the health outcomes of persons with HTN. HTN is an extremely costly health problem and leading risk factor for heart disease and stroke. It is a health disparity in a number of disadvantaged ethnic populations. Such populations may be amenable to spiritual interventions, especially those that are culturally appropriate. Introducing an intervention that improves health outcomes by lowering blood pressure for those with HTN, that lends to decreasing the financial burden of the US, that potentially reduces the number of prescriptions needed for management of HTN, and enables people to have an overall sense of well-being and improved health, deserves our attention from the health care disciplines.

In comparison to the large financial burden of health costs and pharmaceuticals required to manage patients with HTN over their lifetime without success, this intervention is a low cost, non-invasive, low risk way to introduce it into health care and improve the quality of life for people. This intervention is culturally tailored to Pacific peoples, and without physiologic or social risks. This suggests the need to consider its prompt inclusion into therapeutic programs for these persons and to test it in diverse populations, reinforcing the need to further explore this in a powered RCT.

Appendix A

Revised Flier

Do you have

HIGH BLOOD PRESSURE ?

**The University of Hawaii at Manoa
Honolulu, Hawai`i**

**Invites you to join a research program which may
help lower your blood pressure**

***The Hypertension and Self Identity through Ho`oponopono
Study in Hawai`i***

Place:

Waimanalo, Hawai`i

Time: 8 AM to 11 AM

Days: Mondays, Tuesdays, Wednesdays and Saturdays

Call for further information:

or

Edna K. Kretzer, PhDc, APRN - 808-734-0395 or 808-590-9444

Appendix B

RECRUITMENT INFORMATION HANDOUT

Electronic Mail, Flier, Announcements

I am a doctoral student at the University of Hawai`i at Mānoa, Honolulu, Hawai`i. I also am a family nurse practitioner and nursing instructor at the University of Hawai`i at Manoa. In partial fulfillment of the doctoral requirements, I plan to conduct a study regarding a spiritual intervention for people with PHTN and Stage 1 HTN. The purpose of this study is to look at the effects spirituality may have on improving your health. This will be done by including a spiritual intervention, *Self Identity through Ho'oponopono* (SITH), into your health care and lifestyle. It is a two-day workshop. The purpose of the study is to learn if the spiritual intervention SITH may help lower your blood pressure. You should not change your medications for this study unless your health practitioner advises.

Your participation in this study would be greatly appreciated and will require an initial sign-up meeting, completing several forms and questionnaires. Completion of an initial questionnaire asking about your demographics, a spiritual tool questionnaire, some research-pertinent questions and a consent form at the time of sign-up will be requested. You will have your blood pressure measurements taken. The total initial time is expected to be approximately 1 hour. Instructions will be provided.

Over three months' time (90 days), we will collect these measurements 9 times. Some visits may take less time. At the end of the first month, the SITH

intervention will be offered. It is a two-day workshop (9 AM to 2 PM each day which includes BP measurements). It will be offered free of charge to you for participating in this program at a convenient location on Oahu. Three sets of measurements and questionnaires will be required prior to the training. One set will be completed the afternoon of the workshop. Following the SITH intervention, we will continue collecting your measurements for two months to complete the study and one more spiritual tool questionnaire at the end. An additional meeting time may be requested four and six months after the completion of the study, depending on results achieved.

If you have any change in medications, treatments or health care we ask that you inform us by contacting the Principal Investigator (PI.) It is important that confidentiality of participants and information during the course of the study will be honored.

Thank you very much for your willingness to participate in this program. This gives us all an opportunity to learn how spirituality can influence health outcomes of patients with hypertension in Hawai'i.

Sincerely,

Edna K. Kretzer, MS, APRN-Rx
POB 4327
Kailua-Kona, HI 96745
808-322-6161

Appendix C

RESEARCH CONTACT RECORD

Name _____ Phone: _____

Alternate Phone Contacts: Mobile phone: _____

Family member: _____

Friend: _____

Date of First Contact: _____

Recruited by: _____ Date: _____

Meets Inclusion Criteria	Yes	No
Age: 35 or above		
Asian, Hawaiian or Other Pacific Islander		
Has diagnosis of Pre-hypertension or well-controlled Hypertension Stage I		
Has had minimal changes in anti-hypertensive medications for at least 2 months prior to start of study		
Is not pregnant		
Is not at increased risk of serious disease or death		
Is not planning to relocate from Oahu in the next 9 months		

Consent on file: Yes No Code No. _____

Appendix D

INFORMED CONSENT

A. Title of the Research Project. The Hypertension and Self Identity through Ho'oponopono Study in Hawai'i (The HTN & SITH Study HI).

B. Investigators.

Principal Investigator: Edna K. Kretzer, MS, APRN, PhDc
University of Hawai'i at Manoa
P.O. Box 4327
Kailua-Kona, Hawai'i 96745
808-322-6161 phone, 808-324-7316 fax

C. Purpose of the Research Project. This study involves a research study of people with hypertension in Hawai'i. The people it includes are Asians, Hawaiians and other Pacific Islander (AHOPI) Populations. The purpose of this study is to determine if high blood pressure improves when *Self Identity through Ho'oponopono* (SITH) is included as part of my care and medical management along with usual medical treatments I am already receiving from my health practitioner. It also is to determine if I gain a greater sense of spirituality or sense of meaning and fulfillment of purpose, well-being, forgiveness, inner peace and love in my life. Blood pressures and spirituality factors will be measured during the study.

D. Procedures. I have received an oral and a written explanation of this study and I understand that as a participant in this study the following things will happen:

1. Pre-study Screening.

Potential participants will be pre-screened with the Research Contact Form. This will establish if I currently have a diagnosis of pre-hypertension or hypertension stage 1 and if you meet the eligibility criteria. Pre-hypertension means my systolic blood pressure (BP) is <120 -139 or my diastolic blood pressure (BP) is \leq 80 - 89 mmHg. Stage 1 hypertension means my systolic BP is 140 -159 or my diastolic BP is 90 - 99 mmHg. I must be 35 years or older, of the Asian, Hawaiian or Other Pacific Islander populations. I must not have had changes in BP medications for at least 2 months prior to beginning the study. I must not be pregnant or planning to be pregnant during the study. I must not be imprisoned or at increased risk for serious disease or death. I do not plan to move from Oahu in the next 9 months. At the end of this pre-screening, I may or may not be asked to participate.

Participants will complete a demographic questionnaire with a brief medical history. I will also complete a Spiritual Orientation Inventory and a brief additional questionnaire on spirituality at the time of registration/recruitment. Information will be offered regarding the study aims to attempt to reduce blood pressure and about the design of the study. Forms will be available with information regarding the plans of the study and questions will be answered at the time of sign-up. The date for the spiritual intervention, SITH Plus workshop, will be provided at the time of sign-up or as soon

thereafter as is possible. I may register for the intervention, SITH Plus, at this time and it will be offered free of charge to me.

If I identify myself as part of the Asian, Hawaiian and other Pacific Islander population and have a diagnosis of pre-hypertension or mild hypertension and I fit the criteria, I will be permitted to sign-up for this study. If I choose to enter the study at recruitment time, I will have an opportunity to complete the above questionnaires (demographic information, personal medical history and spirituality factors). Then I will have my blood pressure monitored with a high quality automatic BP device and the average of three blood pressures at each time period will be calculated. All measurements are non-invasive and require just a few minutes of my time. The first and last meeting will take about 1 hour. In-between visits may be about 15 minutes and will be conducted at the Waimanalo Health Center or a nearby location.

I understand that confidentiality of this study is requested and I will not discuss the project until it is over. Blood pressures will be taken at Time Period 1 through Time Period 9 (a total of approximately 90 days) for this study to establish my blood pressure measurements. Spirituality factors will be measured with the Spiritual Inventory Orientation and Supplemental Spirituality Questionnaire at Times 1 and 9. Times 10 and 11 are optional for all measurements (BP and spirituality factors).

2. What participants will do during the study. I am requested to continue with my standard medical therapy as I have been doing. I will not change my routine with medications, dietary supplements, diet, lifestyle modifications, etc. as a result of participating in this study. I will keep a diary for at least three months from the date of recruitment into the study until the completion of the research, noting changes that I feel or my health practitioner recommends. A diary schedule will be provided to me today.

One month after the start of the study, I will be given the opportunity to have the spiritual intervention, SITH Plus, available to me in my community at Waimanalo Health Center. I will be asked to attend a 2-day workshop to learn a simple process to help lower my blood pressure. I may contact the Principal Investigator (PI), Edna K. Kretzer, APRN, a family nurse practitioner, who will be doing most of the monitoring and measuring of blood pressures, questionnaires, etc. If I have any questions, I may contact her or her research assistant at the numbers provided.

Visit Timeline for Measurements and Intervention

<u>Visit</u>	<u>1</u>	<u>2</u>	<u>3</u>		<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>		<u>10</u>	<u>11</u>
	Month No. 1				Month No. 2			Month No. 3				Four months	Six months
				Intervention SITH (time 3 & 4 inclusive pre and post SITH)								post-study (optional)	post-study (optional)

BP	X	X	X		X	X	X	X	X	X		X	X
SV	X									X		X	X
Day	1	10	30		32	40	60	70	80	90			

***SV = Spirituality variables**

3. Foreseeable risks or discomforts. There are no known adverse effects or risks caused by SITH. It is a non-invasive process of healing. Should I encounter any blood pressure symptoms such as high or low BPs, dizziness, chest pain, palpitations, shortness of breath, I will contact my health care practitioner as usual or call 911 and go to the nearest emergency room if the situation becomes emergent. I will do what I would normally do for my normal health care needs while being part of this research study. It is not expected that I will encounter any foreseeable risks or discomforts, but if I do, I will contact my health practitioner promptly or go the nearest emergency room if needed. I will also contact the PI as indicated above and record any concerns in the diary provided. If you have any concerns about the study procedure, please notify the PI promptly at the number below.

4. Benefits to be expected from the research. Although I may not notice a direct benefit, I will be offered the SITH Plus training free of charge approximately one month after the study begins. I will be having my blood pressure monitored nine times throughout the study, including today's measurement. I may experience a change in blood pressure and may experience a change in well-being, meaning and purpose in life, forgiveness, peace and love.

I may be aiding present day knowledge of whether a spiritual intervention will help lower blood pressure and the risks associated with high blood pressure, such as heart attacks and strokes. It may help lower blood pressures, reduce the amount of medication taken and save costs. The results of this study have the potential for advancing knowledge for high blood pressure and for ways people will feel better physically, mentally and spiritually. I am willing to contribute to these findings by participating in this study on spirituality and health outcomes related to high blood pressure.

E. Confidentiality. A list of participants in the study will be maintained by the PI. A separate list of coded names will be made available to The Foundation of I, Inc. (Freedom of the Cosmos) for registration for the scheduled SITH Plus training. No information identifying me will be released to the public.

I understand that all information collected about me as a participant in this study will remain strictly confidential to the extent allowable by the law. I understand that results from this study may be published or shared with other interested parties such as other physicians, research institutions and/or federal authorities, but I will not be personally identified. My records may be examined by personnel from the University of Hawaii Committee on Human Subjects, a research protection oversight board.

F. Compensation for Injury. I understand that the principal investigator (PI) and the University of Hawai'i does not provide research participants with compensation or medical treatment in the event that the participant is injured as a result of participation in

the research project. All medical and health care expenses are my responsibility as a research participant. I understand that if I am injured in the course of this research period, I alone may be responsible for the costs of treating my injuries.

G. Voluntary Participation Statement. I understand that my participation in this study is completely voluntary, and that I may refuse to participate or discontinue participation at any time without any penalty.

H. If I Have Questions. I understand that any questions I have about the research study and/or specific procedures should be directed to Edna K. Kretzer, POB 4327, Kailua-Kona, HI, telephone: 808-322-6161 or cell phone: 808-937-2438 or e-mail: Kikikipa@hawaii.rr.com. In the event of injury I should contact my health practitioner promptly and notify Edna K. Kretzer, POB 4327, Kailua-Kona, HI, telephone: 808-322-6161 or cell phone: 808-937-2438 or e-mail: Kikikipa@hawaii.rr.com. Any other questions that I have regarding my rights as a research participant should be directed to the UH-Committee on Human Studies, 2540 Maile Way, Spalding Hall, Honolulu, Hawai'i 96822, 808-956-5007, e-mail: uhirb@hawaii.edu.

My signature below indicates that I have read and that I understand the procedures described above and give my informed and voluntary consent to participate in this study. I understand that I will receive a signed copy of this consent form. Signature of Subject (or Subject's legally authorized representative)

_____ Date Signed: _____

Phone: _____

Copy to Participant: _____

Appendix E

CHS 04/04

CHS

Application for New Approval of a Study Involving Human Subjects

University of Hawai'i, Committee on Human Studies (CHS)
 Spalding Hall 253, 2540 Maile Way, Honolulu, Hawai'i 96822
 Telephone: (808) 956-5007

Date: 5.15.04PI (name & title): Edna K. Kretzer Email: Kikikipa@hawaii.rr.com Phone: 808-322-6161Department: UHM SONDH & JABSOM
 Faculty or Staff Student - name of supervising professor: Rosanne C. Harrigan,
Ed.D.
Training in Human Subject Protection: When, where, & what? June 16, 2003 NIH Online

Project Title: The Hypertension and Self Identity through Ho'oponopono Study in Hawai'i (The HTN & SITH Study in HI)

Proposed Sponsoring Agency: University of Hawai'i at Manoa SONDH & JABSOM Start
 Date: Aug. 2004

Complete Agency address: 2528 McCarthy Mall, Honolulu, HI 96822

1. Summarize your proposed research. Outline objectives and methods.

The **objective** of this study is to determine if Self Identity through Ho'oponopono (SITH) used in addition to standard medical therapy (SMT) is associated with improved hypertension management (reduced blood pressure {BP}) in comparison to SMT used alone in the Asian, Hawaiian and other Pacific Islander (AHOPI) populations with hypertension (HTN). The purpose of this research study is to determine if SITH is associated with improved hypertension management when SITH is used in combination with SMT in the AHOPI population. Further, it is to establish a basis for power needed to conduct a randomized clinical trial for reducing hypertension-related risks & health disparities in the target population.

Methods: A. Design Cross-over/longitudinal design for pretest & post-test study. Participants will serve as their own control. Assignment to pretest group while receiving SMT for PHTN or HTN will begin 1 month prior to the intervention of SITH.

B. Subjects: Inclusion Criteria: Adults from the AHOPI population aged 35 years and older with PHTN or stable, well-controlled Stage 1 HTN with minimal changes in anti-hypertensive medications for at least 2 months prior to the start of the study will be invited to enroll in The HTN & SITH Study. PHTN is SBP \leq 120-139 or DBP 80-89 mmHg. Stage 1 HTN is SBP 140-159 or DBP 90-99 mmHg.

C. Exclusion Criteria: Persons with unstable BPs or who are pregnant, incarcerated, planning to relocate from Oahu, likely to have medication changes or are at increased risk for serious disease/death.

D. Variables: Predictor: *Self Identity through Ho'oponopono.*

E. Outcomes: 1) Reduction in BPs as measured by approved automatic digital BP devices from pretest means. 2) Improved self-report scores of participants' sense of well-being, meaning, fulfillment of purpose in life, forgiveness, inner peace and love variables.

F. Statistical Issues Objective: To determine if SITH is statistically significant as an effective, adjunctive therapy in the treatment of PHTN & HTN in the AHOPI population.

G. Hypotheses: 1. There will be a reduction in mean BPs and BP variability post-test compared to pretest measurements. 2. There will be a significant difference in participant's sense of meaning, fulfillment of purpose in life, forgiveness, inner peace and love post-test as compared with pretest.

H. Sample Size: \geq 38 participants from the AHOPI population. **G. Analysis:** Power: \geq 80%, alpha 0.05, repeated measures analyses and descriptive statistics. Oversampling will allow for 10% attrition.

2. Summarize all involvement of humans in this project (who, how many, age, sex, length of involvement, frequency, etc.) and the procedures they will be exposed to. Attach survey instrument, if applicable.

There are two aspects of this study: 1. A preliminary chart review; and 2. The cross-over design research study.

(1) A preliminary and retrospective random chart review of 10 participants of the AHOPI population, aged 35 years and older with pre-hypertension or well-controlled hypertension stage 1 will be completed. Information will require: age, gender, height, weight and three blood pressure measurements taken within a 6-12 month time frame. No identifying data will be collected or required or submitted for analysis or publication. This information is to establish BP variability for the sample population and will be used as a basis for this research study involving human participants.

(2) The actual cross-over designed research study follows:

Subjects: Inclusion Criteria: Adults from the AHOPI population aged 35 years and older with PHTN or stable, well-controlled Stage 1 HTN with minimal changes in anti-hypertensive medications for at least 2 months prior to the start of the study will be invited to enroll in The HTN & SITH Study. *Exclusion Criteria:* Persons with unstable blood pressures or who are pregnant, incarcerated, planning to relocate from Oahu within 9 months of the start of the study, likely to have medication changes or at increased risk for serious disease (such as terminally ill or hospice patients) or death will be excluded.

Participants will receive information regarding the study aims to attempt to reduce blood pressure and about the design of the study. Consent forms (Appendix D) will be available with information regarding the logistics of the study. Any questions will be answered at this time of sign-up. The date for the initial SITH Plus workshop will be provided to participants at the time of sign-up or as soon thereafter as is possible. They may register for the SITH Plus workshop at this time and it will be offered free of charge to respondents. This procedure will be repeated until at least 38 participants enter the study.

Those who identify themselves as part of the target population and with a diagnosis of Stage 1 HTN or PHTN and who fit the criteria will be permitted to sign-up for inclusion into this study. Participants who choose to enter the study at recruitment time, will complete questionnaires (demographic information, personal medical history and spirituality factors), will have their BPs monitored with a high quality automatic BP device (the average of 3 BPS at each time interval will be computed). Participants will complete spirituality questionnaires assessing outcome variables relating to the operational definition of spirituality. These questionnaires will be provided at the initial testing and the final testing. The

Spiritual Orientation Inventory (SOI—see Appendix F) by D. Elkins, PhD, has been chosen to be the instrument used in this study to assess spirituality factors since it offered the most pertinent questions related to the concept of spirituality and not religiosity as derived from the literature review on spirituality. The Supplemental Spirituality Questionnaire (Appendix G) is a second questionnaire which matches the concept of spirituality proposed in this study..

Measurements/Tools: Physical measurements (BP) will be taken at Time 1 and at each time interval through Time 9 (duration: 90 days) for this study to establish BP variability. Blood pressures will be evaluated at nine intervals using a high quality digital sphygmomanometer (blood pressure measuring device) obtained for the purpose of this study. Spirituality variables will be assessed through self-report questionnaire at Time 1 & 9. The SITH Plus training is the spiritual intervention which will be provided participants one month after the study begins. SITH Plus is a two-day workshop designed for participants to learn how to easily apply these healing tools to everyday life. By the individual's use of these tools, they may release the cause of their problems and begin to enjoy improved health, freedom, peace, balance and a new meaning of life as a result. *Self Identity through Ho'oponopono* (SITH) is modeled after the ancient

Hawaiian method of stress reduction and problem-solving known as Ho'oponopono (a process to right an error and to create balance). The purpose of SITH is to identify the internal cause of stress or problems (negative thoughts and memories) and to release or erase them spiritually, mentally and physically. SITH is an approach for the individual to discover one's Identity, to make right and heal any stressful relationship or situation through cleansing, releasing and transmutation. BP measurements will be assessed the morning of the first day of the training and at the end of the second day of the training. A total of nine BP measurements will be required of each participant, with an optional 10th and 11th time interval at 4 and 6 months after the initial study.

Participants will not be exposed to any harmful or invasive procedures.

Check whether any subject of your research will be selected from the following categories:

NONE...

- Minors Pregnant Women Mentally Disabled
- Abortuses Physically Disabled Prisoners Fetuses

3. Research involving humans often exposes the subjects to risks: For the purpose of this application, "risk" is defined as exposure of any person to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field or service.

a. Check all the risks to human subjects that apply to your project:

- Physical trauma or pain Deception Experimental diagnostic procedures
- Side effects of medications Contraction of disease Experimental treatment procedures*
- Contraction of disease Worsening of illness Loss of privacy
- Psychological pain Loss of legal rights Other – explain*

*The study is a spiritual experimental treatment with no known side effects and no known risks. Participants will be continuing with the normal and usual medical plan of care and adding SITH adjunctively as a spiritual intervention.

b. Check procedures that will be used to protect human participants from risks:

- M.D. or other appropriately trained individuals in attendance
- Sterile equipment
- Precautions in use of stressor or emotional material (explain below)
- When deception used, subjects fully informed as to nature of research at feasible time (explain below)
- Procedures to minimize changes in self-concept (explain below)
- Confidentiality of subjects maintained via code numbers and protected files
- Anonymity - no personally identifiable information collected
- Others—explain (PI is a Board Certified Family Nurse Practitioner in HI)

c. Has provision been made to assure that Human Subjects will be indemnified for expenses incurred as a direct or indirect result of participating in this research?

- Not applicable

No - The following language should appear and does in the written consent form: *I understand that if I am injured in the course of this research procedure, I alone may be responsible for the costs of treating my injuries.*

YES, explain:

d. Are there non-therapeutic tests that the research subjects may be required to pay for?

Not applicable

No

Yes - explain below. The following language should appear in the written consent form: *I understand that I may be responsible for the costs of procedures that are solely part of the research project.*

4. Describe mechanism for safety monitoring: How will you detect if greater harm is accruing to your subjects than you anticipated? What will you do if such increased risk is detected?

Participants will be advised if they have any symptoms, concerns, changes in medication, etc., regarding their health and blood pressure during this research study, they should communicate that information to us, mark it on their diary (Appendix J) and discuss these issues with their primary health practitioner. If they discuss their concern with us or we note dangerously elevated blood pressures or worrisome symptoms (such as palpitations, chest pain, shortness of breath, dizziness, disorientation), we would recommend that they be evaluated by their health practitioner or go directly to the local emergency room for further evaluation. All participants in this research study will be of emancipated adult age and will be able to make reasonable decisions for their health care. As a board certified family nurse practitioner I am prepared to make recommendations for participants who notify us or present with these symptoms and will document such as a licensed health practitioner within the State of Hawai'i. The first priority is to get the individual or individuals proper medical care. Then I will immediately discuss this with the program director, notify the IRB and determine if the research must be halted or stopped.

5. Briefly describe the benefits that will accrue to each human subject or to mankind in general, as a result of the individual's participation in this project, so that the committee can assess the risk benefit/ratio.

The potentially direct benefit to the individual participants is to statistically and significantly lower blood pressure, to improve blood pressure control, to reduce the number of medications necessary, to eliminate unnecessary medications and to live longer without suffering heart disease and strokes. This will also add a financial benefit for each participant through fewer costs for medications, office visits, hospitalizations, long-term and rehabilitative care and lost work time. Additionally, participants may gain a greater sense of spirituality to allow for improved well-being and peace allowing them an opportunity to improve their overall health--mentally, physically, emotionally and spiritually.

If SITH in conjunction with SMT improves BP control in the AHOPi population, it will offer an new culturally-appropriate treatment in HI and a method to reduce the leading risk factor for heart disease and stroke in the target population, reduce HTN-related deaths in HI, reduce the \$259 billion financial and social burden in USA & offer the target population an improved sense of spirituality (well-being, meaning, fulfillment of purpose in life, forgiveness, inner peace and love). As a non-invasive adjunctive treatment, mankind has much to gain in the way of physical, mental and spiritual healing and the reduction of financial and material resources for the USA and for people with hypertension, heart disease, stroke and potentially many other disease conditions.

6. **Participation must be voluntary: the participants cannot waive legal Rights, and must be able to withdraw at any time without prejudice.** Indicate how you will obtain informed consent:

Subject (or Parent/Guardian) reads complete consent form & signs ('written' form)

- Oral briefings by PI or project personnel, with simple consent form ('oral' form). Explain below the reason(s) why a written consent form is not used.
- Other- explain
7. Are there any other local IRB's reviewing this proposal? No Yes, Location: __

I affirm:

(i) that the attached drug sheet(s) submitted to CHS for this project have been checked and confirmed to be accurate and current. If changes in a CHS-approved drug sheet have been made to insure accuracy and currency these changes have been listed on the attached, and (ii) that the above and any attachments are a true and accurate statement of the proposed research and of any and all risks to human subjects.

Signed: _____ Date: _____
Principal Investigator

Signed: _____ Date: _____
Supervising Professor (required if PI is a student)
Date of Human Subject Protection Training: 6.16.03

Submit the ORIGINAL plus 12 copies of this form with the following attachments:

- Three (3) copies of proposal
 - Thirteen (13) copies of all consent forms
 - Thirteen (13) copies of any other information to be read or presented to the participants
 - Thirteen (13) copies of verbal information to be given if short form is used
 - Thirteen (13) copies of the survey instrument
- (Please consult with the CHS staff if providing the survey instrument is a problem.)

Appendix F

UNIVERSITY OF HAWAII

Committee on Human Studies

MEMORANDUM

June 25, 2004

TO: Edna K. Kretzer, MS, APRN
Principal Investigator
John A. Burns School of Medicine

FROM: William H. Dendle 
Executive Secretary

SUBJECT: CHS #13096- "The Hypertension and Self Identify Through Ho'oponopono Study in Hawaii "

Your project identified above was reviewed by the Chair of the Committee on Human Studies through Expedited Review procedures. The project qualifies for expedited review by CFR 46.110 and 21 CFR 56.110, Category (4) of the DHHS list of expedited review categories.

This project was approved on June 24, 2004 for one year. If in the active development of your project you intend to change the involvement of humans from plans indicated in the materials presented for review, prior approval must be received from the CHS before proceeding. If unanticipated problems arise involving the risks to subjects or others, report must be made promptly to the CHS, either to its Chairperson or to this office. This is required in order that (1) updating of protective measures for humans involved may be accomplished, and (2) prompt report to DHHS and FDA may be made by the University if required.

In accordance with the University policy, you are expected to maintain, as an essential part of your project records, all records pertaining to the involvement of humans in this project, including any summaries of information conveyed, data, complaints, correspondence, and any executed forms. These records must be retained for at least three years from the expiration/termination date of this study.

The CHS approval period for this project will expire on June 24, 2005. If your project continues beyond this date, you must submit a continuation application to the CHS at least four weeks prior to the expiration of this study.

We wish you success in this endeavor and are ready to assist you and your project personnel at any time.

Enclosed is your certification for this project.

Enclosure

**Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)**

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type <input checked="" type="checkbox"/> ORIGINAL <input type="checkbox"/> CONTINUATION <input type="checkbox"/> EXEMPTION	2. Type of Mechanism <input type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER: _____	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
4. Title of Application or Activity "The Hypertension and Self Identity Through Ho'oponopono Study in Hawaii"		5. Name of Principal Investigator, Program Director, Fellow, or Other Edna K. Kretzer, MS, APRN

6. Assurance Status of this Project (Respond to one of the following)

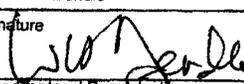
- This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance identification No. F-3526, the expiration date October 15, 2005 IRB Registration No. IORG0000169
- This Assurance, on file with (agency/dept) _____, covers this activity.
Assurance No. _____, the expiration date _____ IRB Registration/Identification No. _____ (if applicable)
- No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.
- Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph _____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

- This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: Full IRB Review on (date of IRB meeting) _____ or Expedited Review on June 24, 2004
 If less than one year approval, provide expiration date _____
- This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

CHS #13096

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.		10. Name and Address of Institution University of Hawaii at Manoa Office of the Chancellor 2444 Dole Street, Bachman Hall Honolulu, HI 96822	
11. Phone No. (with area code) (808) 956-5007	12. Fax No. (with area code) (808) 539-3954		
13. Email: dendle@hawaii.edu			
14. Name of Official William H. Dendle		15. Title Compliance Officer	
16. Signature 		17. Date June 25, 2004	

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Appendix G

INITIAL QUESTIONNAIRE OF PARTICIPANT'S DEMOGRAPHICS

Please answer the following questions. All safeguards to keep this information strictly confidential will be provided.

Name: _____ Age _____ Gender: Female _____ Male _____

Height _____ Weight _____

Island you reside on _____ How long in Hawai'i? _____ years _____ months

Do you plan to move away from Oahu within the next 9 months? Yes No

Do you require an interpreter? Yes No

Are you now or do you intend to be pregnant within the next 9 months? Yes No

Do you understand this study to be confidential until completion? Yes No

Ethnicity: Please check one:

Asian Indian

Cambodian

Filipino

Hmong

Japanese

Taiwanese

Malaysian

Vietnamese

Chinese

Indonesian

Laotian

Pakistani

Thai

Guamanian

Marshallese

Melanesian

Micronesian

Polynesian

Samoa

Hawaiian

Part-Hawaiian Other: _____

Questions on Spirituality: Please circle one:

Do you consider yourself spiritual?
Please rate your level of spirituality: Not at all About average Yes No
Totally

Are you willing to participate in a spiritual intervention study while continuing with your current management with your health practitioner? Yes No

Have you ever attended a *Self Identity through Ho'oponopono* training? Yes No

Questions on Health and Hypertension:

Are you aware that high blood pressure is the leading risk factor for heart disease and stroke which affects ~50 million Americans? Yes No

Are you aware that high blood pressure is considered to be 140 mmHg (systolic reading) over 90 mmHg (diastolic reading) according to The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure [JNC 7], 2003? Yes No

Do you have a family history of high blood pressure? Yes No

Have you been diagnosed with pre-hypertension? Yes No

Have you been diagnosed with high blood pressure (hypertension)? Yes No

Have you ever had a heart attack?	Yes	No
Have you ever had a stroke?	Yes	No
Have you ever had a mini-stroke?	Yes	No
Have you been diagnosed with Diabetes Mellitus?	Yes	No
Do you have other diagnoses?	Yes	No
Please write in what other diagnoses you have now:		

Do you ever experience symptoms related to your blood pressure? Please give examples of symptoms (such as headache, palpitations, shortness of breath, dizziness?)	Yes	No
--	-----	----

Are you actively involved in caring for your health?	Yes	No
Would you like to be more involved in your health care treatments?	Yes	No
Are you careful about what you eat as part of your management plan?	Yes	No
Do you add table salt to your diet?	Yes	No
Are you currently exercising?	Yes	No
Do you engage in regular aerobic physical activity for 30 minutes/day, most days of the week?	Yes	No
Is your weight as described above, higher or lower than normal?	Higher	Lower
Do you limit alcohol consumption to no more than 1 oz (30 ml) of ethanol/day if a male, and ½ oz (15 ml) if female?	Yes	No
Do you believe you get enough potassium a day?	Yes	No
Do you eat at least five fruits or vegetables each day?	Yes	No
Do you consume low-fat foods?	Yes	No
Do you smoke?	Yes	No
Do you take medications for your blood pressure?	Yes	No
How many medications do you take for your blood pressure?	<hr/>	
How many medications do you take for all health conditions?	<hr/>	
Do you know the names and dosage amounts?	Yes	No
Please write in the names of your blood pressure medications: _____		

Have you taken your blood pressure medications today?	Yes	No
Are you currently using complementary or alternative health practices?	Yes	No
Do you sense spirituality is important to your health?	Yes	No
BP Measurements Today: L / R Arm #1 _____ #2 _____ #3 _____		

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