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Back massage: Long term effects and dosage determination for persons with pre-hypertension and hypertension

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Back Massage: Long Term Effects and Dosage Determination for Persons With Pre-Hypertension and Hypertension

By

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Dedication

This dissertation is dedicated to my husband, Ronald Olney, who has been my best friend and a constant source of encouragement for more than 28 years. It is also dedicated to our children, Hannah and Elizabeth; they are the world's best cheering squad a mom could ever desire. It is my wish to always be an inspiration to them. Lastly, this dissertation is dedicated to my parents, Paul and Alice Neppel. Two statements (among their many sage words of wisdom) were of significant inspiration for me as a child. I believe these often repeated words laid the foundation for me to become a researcher: "because" and "you can do anything you choose to do", the former statement being the most unsatisfactory answer to my question of "why" and the latter statement instilling in me the confidence to go forth.

Acknowledgements

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for Persons With Pre-Hypertension and Hypertension

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ABSTRACT

Significance: Complementary and alternative therapies (CAM) are widely used however the efficacy of many CAM therapies for specific diseases has yet to be verified. Massage therapy, specifically back massage, used to assist in the management of elevated blood pressure is one such unverified therapy. A pilot study completed in 2002 resulted in significant changes in blood pressure using a repeated application of the 10 minute back massage. **Research Aims:** This study, evolving from a psychophysiology framework, aimed to determine the long term efficacy of a back massage treatment and possible dosage needed to effectively assist in the management of elevated blood pressure. **Primary Research Hypotheses:** After adjusting for covariates:

A. Systolic blood pressure (SBP) and or diastolic blood pressure (DBP) would decrease significantly over time using a back massage treatment in subjects with pre-hypertension or controlled hypertension.

B. There would be a significant difference in the SBP (and or DBP) changes over time using 10 applications of back massage versus five applications of back massage in the subjects with pre-hypertension and controlled hypertension.

Methods: *A priori* power analysis determined the three groups by four time points (repeated measures) design required a sample of 45 participants. The sample of men and women, 18-75 years of age, were recruited from a university setting. Outcome Variables: Systolic Blood Pressure, Diastolic Blood Pressure

Potential Covariates: Age, BMI, Medications, Years of Hypertension, Salivary cortisol, and State and Trait Personality Indicators (anger, anxiety, depression). Intervention: Group 1: Ten 10-minute back massages given three times a week for 3.5 weeks. Group 2: Five 10-minute back massages given three times a week for 1.5 weeks. Control (group 3): Ten 10-minute relaxation sessions using learned techniques for 3.5 weeks.

Findings: For participants with elevated body mass index ($\geq$27.85) in the 10-massage group, systolic and diastolic blood pressure changed significantly over time. The dosage analysis did not clearly reveal the direction of the trends, therefore further exploration is warranted.

Chapter One

Introduction

Massage has long been thought to have an effect on blood pressure levels (e. g. Longworth, 1982; Hernandez-Rief, Field, Krasnegor et al., 2000; Moyer, Rounds & Hannum, 2004). However, specific effects of massage on blood pressure levels remain controversial due to the scarcity of rigorous randomized clinical trials (Moyer et al., 2004). Recently an organized effort by the scientific community has emerged to understand the efficacy of massage. In 2004, Moyer et al. published a meta-analysis of 37 experimental clinical trials of massage therapy. This work calculated the effect sizes for nine dependent variables; five studies measured systolic and diastolic blood pressures as dependent variables. The meta-analysis results provided scientific evidence and a better understanding of the efficacy of massage in the management of blood pressure. Further the meta-analysis identified specific questions in need of exploration regarding the effects of massage.

The intent of this study was to explore specifically identified areas in question regarding the efficacy of massage effects on blood pressure. An in-depth review of literature about massage and blood pressure, along with the findings from the PI's pilot study (Olney, 2005), guided the proposal for this study. This study sought to determine the long-term effects of back massage

and to compare two dosages of back massage on persons with elevated blood pressure. Further, this study examined a specific physiological mechanism, baroreceptor response, which could possibly assist in the understanding of the effects of back massage on blood pressure.

Background

Massage therapy, in particular, therapeutic back massage, has long been of interest to nursing. Historically, back massage has been an integral part of nursing care, usually administered when preparing the patient for nighttime sleep. As the American health care system has changed, the workload of the hospital staff nurse intensified and back massage fell from the working vernacular of nursing care (Meintz, 1995). By the 1990's, complementary and alternative medicine became embedded in healthcare, reinvigorating interest in massage therapy and back massage. Currently, back massage, along with other forms of massage are now considered complementary therapies. Under the auspices of complementary therapy, back massage is commonly referred to as therapeutic back massage.

Elevated blood pressure is a serious health problem throughout the world. Unmitigated elevated blood pressure, be it pre-hypertension or hypertension often results in dire health consequences. Hypertension is a major contributor to cardiovascular disease, the primary cause of death in the United States (American Heart Association, 2006). Researchers, internationally, have historically identified multiple causes of hypertension, yet with more than 90% of cases of hypertension, causation remains elusive (Kaplan, 2002). Scientists

have studied and verified many phenomena that add to the understanding of the development of hypertension. One often addressed phenomenon for elevation of blood pressure is unrelenting stress.

Psychophysiology, the study of how psychological factors influence physiology, resulting in health or illness, provided a conceptual framework for this study. Psychophysiology considers the influence of stress on homeostasis, adaptation and allostasis to help explain the relationships between man and his internal and external environment.

Stress has long been recognized as a contributing factor to the development of elevated blood pressure (Benson, 2000). Movement from a Cartesian approach toward a holistic model of psychophysiology has allowed scientists to begin to explain the integrative interactivity of the human element within one's endogenous environment. Specifically, environmental chronic physical (external) stressors such as obesity, nicotine, and caffeine are known to contribute to the genesis of hypertension. Perceived stress (internal) is also recognized a as contributory factor in transitory and chronic hypertension. These external and internal stressors influence the autonomic nervous system, hormonal-endocrine system and the immune system (Segerstrom & Miller, 2004). The result is that blood pressure changes in response to the arousal or lack of arousal (Figure 1). The psychophysiology theory is developed further in Chapter two.

The relationship between stressors and their effects on blood pressure has been well studied by the scientific community. The knowledge gained

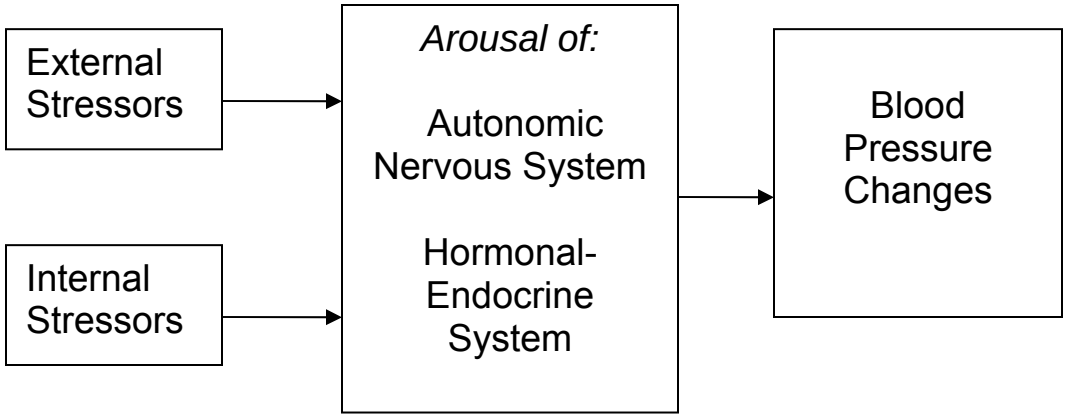

Figure 1: Psychophysiology and Blood Pressure Model

regarding stress and blood pressure has lead to the development of interventions to reduce the external and internal stressors. Stress-relieving methods such as controlled breathing, yoga, progressive muscle relaxation and transcendental meditation have been advocated as forms of non-pharmacological methods useful in decreasing blood pressure (Benson, Beary & Carol, 1974; Grossman, Grossman, Schein, Zimlichman, & Gavish, 2001; Jacobson, 1939). The recent public interest in non-drug stress-relieving practices demonstrates the need to determine their efficacy for preventing and assisting in the management of hypertension.

Significance of the Study

Complementary and alternative medicine was defined nearly 15 years ago as “interventions neither taught widely in medical schools nor generally available in US hospitals” (Eisenberg, Kessler, Foster, Norlock, Calkins, and Delbanco,

1993, page 246). The interest in complementary and alternative therapies, including massage therapy, has evolved rapidly. Reports of the usage of complementary and alternative therapies among Americans has varied from 28.9% (Ni, Simile, and Hardy, 2002) to 62% (Barnes, Powell-Griner, McFann, & Nahin, 2004) of the population. In a recent study measuring trends of complementary and alternative therapy use over the past 50 years by adults in the United States, researchers found the use of massage therapy experienced rapid growth in the 1980's and 1990's (Kessler, Davis, Foster et al., 2001). Tindle, Davis, Phillips, and Eisenberg (2005) further evaluated the trends of complementary and alternative therapies between 1997 and 2002 and found the trend in massage has stayed approximately the same as previous years. Barnes, Powell-Griner, McFann, and Nahin (2004), in a search for types of complementary and alternative therapies usage among American adults, agreed with Kessler et al. (2001) that massage therapy was used by approximately five percent of the population for many purposes. Yeh, Davis and Phillips (2006) reported that 36% of patients with cardiovascular disease use complementary and alternative therapies. Further, 5% specifically use complementary and alternative therapies to treat their hypertension.

Massage is used for a multitude of purposes including muscle relaxation, circulatory stimulation, myofascial release, and lymphatic drainage. Back massage is one type of massage used by nurses even though the efficacy of back massage is not well established. Therefore, research on back massage is important.

The media has led the general population to believe that massage can indeed influence their blood pressure trajectories (Prevention Magazine, 2006; Kurashova-Wine, 1999). Though there are some findings in the literature towards this end, the research is not rigorous enough to state that there are indeed any long-term effects. Therefore, long-term effects of therapeutic back massage are of relevant interest and rigorous studies are urgently needed to protect the public from possible harm. Further, the literature does not address the dosage needed to effect change. Is one back massage as effective as are several? There is little information available to advise a clinician for patient teaching. Another reason for further therapeutic back massage research is to clarify the underlying mechanism(s) influencing the changes in blood pressure with back massage. If indeed, there is a long-term effect of back massage on blood pressure, what mechanism(s) are involved?

Finally, offsetting the onset of hypertension has potential health care cost savings, including a delay in drug treatment intervention, a possible decrease in dosage needed, and the delay in overall health de-conditioning sequela that occurs with the onset of uncontrolled elevated blood pressure. This study evaluated a therapy that could easily be taught to family members for utilization, thus alleviating the need for costly massage therapy clinicians.

Purposes and Aims

The primary purpose of this study was to determine if therapeutic back massage could provide long-term effects to a person with elevated blood pressure. This study tested the findings of a pilot study in which an experimental

design compared back massage to relaxation (Olney, 2005). A second purpose of this study was to compare two dosages of therapeutic back massage on persons with elevated blood pressure. Finally, this study tested for changes in baroreceptor activity as a possible explanation of effects of therapeutic back massage.

The specific aims of this study were to:

1. Determine the difference in systolic blood pressure over time in a treatment versus control group of prehypertensive and hypertensive subjects.
2. Determine the difference in diastolic blood pressure over time in a treatment versus the control group of pre-hypertensive and hypertensive subjects.
3. Compare the systolic blood pressure changes over time of two dosages of back massage in pre-hypertensive and hypertensive subjects.
4. Compare the diastolic blood pressure changes over time of two dosages of back massage in pre-hypertensive and hypertensive subjects.
5. Determine the difference in lying versus sitting blood pressure change over time in the treatment versus control groups of pre-hypertensive and hypertensive subjects.

Research Hypotheses

The study tested the long-term effects and dosage of therapeutic back massage on persons with elevated blood pressure. Furthermore, the study aimed to examine a possible physiological mechanism, baroreceptor response, explaining part of the change which may occur with TBM. The following research hypotheses were tested:

1. After adjusting for covariates, systolic blood pressure will decrease significantly over time using back massage treatment in subjects with prehypertension and controlled hypertension.
2. After adjusting for covariates, diastolic blood pressure will decrease significantly over time using back massage treatment in subjects with prehypertension and controlled hypertension.
3. After adjusting for covariates, there will be a significant difference in systolic blood pressure changes using 10 applications of back massage versus five applications of back massage in subjects with prehypertension and controlled hypertension.
4. After adjusting for covariates, there will be a significant difference in diastolic blood pressure changes using 10 applications of back massage versus five applications of back massage in subjects with prehypertension and controlled hypertension.
5. There will be a significant change over time in reclining blood pressures compared to sitting blood pressures in the subjects with prehypertension

and controlled hypertension in the back massage treatment group of 10 applications when compared to the control group.

Chapter Summary

Chapter One presented a brief overview of what is known about the effects of massage on blood pressure and a statement of the purpose of this study to further understand that relationship. A short discussion about how the practice of the back rub with bedtime preparation has been lost only to have back rubs re-emerge under the auspices of complementary therapies. The seriousness of elevated blood pressure was briefly discussed. The psychoneuroimmunology theory provides a framework within which understanding of how elevated blood pressure develops and how a stress reduction method such as massage may assist in managing a healthy blood pressure level. The primary purpose of this study was presented: to test for long term effects of back massage. Further a second purpose was to test two dosages of massage for effects. Finally, the study tested for a mechanism, change baroreceptor function. The significance of the study discussed the increase in complementary therapy usage by the general population and the need to ensure that using massage for blood pressure management is indeed a safe practice. The financial impact of offsetting the onset of hypertension through the use of a complementary therapy such as massage was discussed. Finally the five study hypotheses were clearly stated.

Chapter Two

Review of the Literature

Chapter Two presents a review of the relevant literature regarding the state of the science on hypertension and massage therapy. A brief overview of blood pressure physiology is presented as well as the pathophysiology of hypertension. A full review of massage literature as it relates to this study follows. The framework for the study is discussed, clarifying the theoretical underpinnings for the study.

Initial computerized searches on Medline, Cochrane Database of Systematic Reviews, CINAHL and OVID-Full Text, using the headings of blood pressure, elevated blood pressure, hypertension, baro-receptors, or high blood pressure yielded more than 280,000 articles. Searches for massage literature under headings of massage, massage therapy, back massage, back rub, therapeutic massage, yielded more than 8,000 articles. In Pub Med alone, combining search terms using the Boolean “AND”, for example, massage AND blood pressure, yielded a much-reduced result of 413 hits. Limiting the articles to the English language, adults and human studies further reduced the number of articles to 120. Perusal of the reference lists from recovered articles led to additional relevant research discovery. In addition, computer searches and

expert opinion were sought regarding the phenomenon of baroreceptors, relaxation response and their relationship with blood pressure maintenance.

Blood Pressure and Hypertension

Physiology of Blood Pressure

This discussion will review the definition and key components of blood pressure maintenance. Several specific mechanisms of blood pressure which are of particular interest in this study will also be discussed.

Blood pressure is the force exerted by blood against the arterial walls within the circulatory system (Sherwood, 2007). Although blood pressure is regulated by mean arterial pressure, we normally assess arterial blood pressure by measuring systolic and diastolic blood pressure. Specifically, systolic blood pressure is the maximum pressure within the arteries when the left ventricle of the heart is in systole (contracted) (Sherwood). Diastolic blood pressure occurs during ventricular relaxation and is the minimum measured pressure exerted against the arterial walls (Sherwood).

The physiology of blood pressure maintenance is complex. The circulatory system, the heart and blood vessels, is a closed system that serves to transport oxygen, nutrients, waste and hormones throughout the body. Mean arterial pressure within that closed system is regulated by two variables: cardiac output and total peripheral resistance. Cardiac output is a function of stroke volume and heart rate. Total peripheral resistance is determined by arteriolar radius and blood viscosity (Kaplan, 2002). There are many influences on cardiac output and peripheral resistance which in turn influence mean arterial pressure.

Influences such as autonomic activity, skeletal muscle activity, myogenic activity of the arterioles, nitric oxide, endothelin, histamine, oxygen and carbon dioxide levels and hormones such as insulin, vasopressin and renin-angiotensin II are constant factors in blood pressure maintenance. Other factors such as acid-base balance, potassium levels, osmolarity, and adenosine and prostaglandin release also affect local arteriolar radius thereby affecting peripheral resistance (Sherwood, 2007). Blood pressure maintenance is complex when considering the multi-factorial influences.

Nearly every organ, including the heart, is stimulated by the sympathetic and parasympathetic branches of the autonomic nervous system. There are some exceptions, such as the blood vessels, sweat and salivary glands which are not stimulated by both branches. In the case of blood vessels, arteries and capillaries are stimulated by the sympathetic fibers only, causing vasoconstriction. For the most part, there is no parasympathetic innervation at the blood vessel site to counter the sympathetic norepinephrine stimulation (Sherwood, 2007). Thus, arteries can be stimulated to constrict but not stimulated to dilate by the sympathetic nervous system. Clarifying, it is the lack of sympathetic stimulation that contributes to the relaxation or dilation of arteries.

Baroreceptors, mechanisms within the autonomic nervous system, are of particular interest to this discussion about blood pressure maintenance. Baroreceptors, also known as mechanoreceptors, are pressure sensors located in the carotid sinus and the aortic arch and are sensitive to changes in mean arterial pressure. Baroreceptors are also sensitive to pulse pressure fluctuations.

Pulse pressure, the difference between systolic and diastolic pressures, can be altered by slight changes in systolic and diastolic pressures without changing the mean arterial pressure (Sherwood, 2007). When mean arterial pressure or pulse pressure changes, the baroreceptors sense the change. An example would be when a healthy supine person sits up. The action of sitting up initially lowers blood pressure (through gravity) thereby decreasing stroke volume and cardiac output. The sensed lower blood pressure causes the baroreceptors to fire at a slower rate, sending a message via the ninth and tenth afferent cranial nerves to the autonomic center in the brain (nucleus of the solitary tract) (Sherwood).

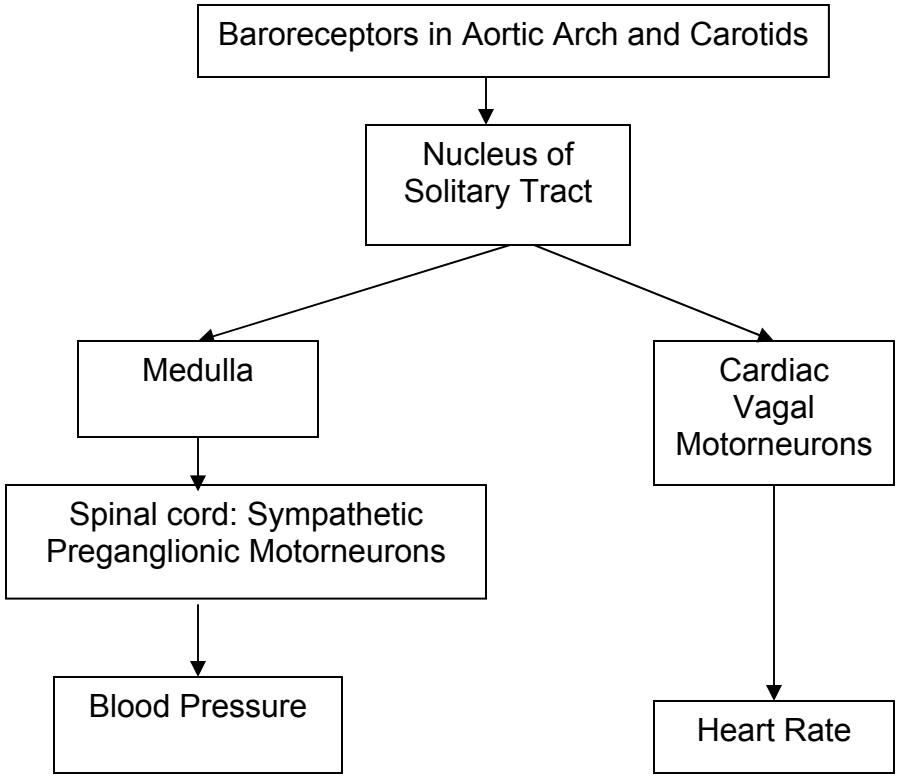

Figure 2: Baroreceptor Pathway

A responding sympathetic activity is initiated in an attempt to restore blood pressure to normal by increasing the cardiac output and constricting blood vessels (Figure 2), (Purves et al., 2001). Although debated whether baroreceptors play a role in long-term mean arterial pressure maintenance, the latest publications appear to support this theory (Thrasher, 2005).

There are other responses, or reflexes, besides the baroreceptor reflex that influence blood pressure maintenance. For instance volume receptors respond to salt and water balance, chemoreceptors sense oxygen or acid levels, the hypothalamus controls cutaneous arterioles for temperature maintenance, and cardiovascular responses are associated with exercise (Sherwood, 2007). One other response of interest is the cardiovascular response to emotions or certain behaviors, such as the "fight or flight" response, which is mediated through the cerebral cortex-hypothalamic pathway to the sympathetic nervous system (Izzo, 2000). This last response and its influence on blood pressure are of particular interest in this study and will be discussed further within the psychoneuroimmunology model.

Hypertension Pathophysiology

The statistics regarding hypertension are stunning and clarify the impact on our society. In 2003, approximately 65 million Americans, ages 20 years and older, had elevated blood pressure (American Heart Association, 2006). This infers that nearly one of every 3 adults has hypertension. Of those with the disease, approximately 63% are aware they have hypertension but only 29% have their blood pressure controlled at acceptable levels. Although awareness of

hypertension has improved over the past 10 years, the death rate due to elevated blood pressure has increased by almost 30%. In 2003, of those with hypertension, the overall death rate was 18%. Of all deaths in 2003, hypertension was either the primary cause or contributed to 12% of the deaths. Almost $64 billion is spent annually on direct and indirect cost due to hypertension (American Heart Association, 2006). Clearly the financial impact on our society is extreme.

Nearly 90% of hypertension cases are categorized as primary hypertension (American heart Association, 2006). Secondary hypertension, which has known renal, endocrine and neurogenic causes, comprises the remaining 10% of hypertension cases and will not be discussed.

Primary hypertension is of concern to health care providers because it alters normal function of the heart and blood vessels. With hypertension development, there is an abnormal increase in peripheral resistance and/or cardiac output thus increasing the heart workload and exposing blood vessels to excessive internal pressure (Kaplan, 2002). Unmitigated, chronic elevated blood pressure leads to target organ damage resulting in congestive heart failure, stroke, renal failure, and retinal damage. The majority of persons who experience their first heart attack, first stroke or have congestive heart failure have elevated blood pressure (American Heart Association, 2006).

The World Health Organization and the International Society of Hypertension have defined hypertension as a blood pressure measuring above 140/90 mmHg (World Health Organization, International Society of Hypertension

Writing Group, 2003; Chalmers, 1999.) The Seventh Report from the Joint National Committee on Prevention, detection, Evaluation and Treatment of High Blood Pressure (JNC7) amended the definition by adding an additional blood pressure classification called prehypertension for adults age 18 and older (Chobanian et. al., 2003). Prehypertension is defined as a systolic blood pressure of 120 -139 mmHg or higher and/or a diastolic blood pressure of 80 - 89 mmHg or higher (Table 1).

Table 1

JNC VII Classification of Blood Pressure

B/P Classification	Systolic (mmHg)		Diastolic (mmHg)
Normal	< 120	and	< 80
Prehypertensive	120-139	or	80-89
Stage 1 Hypertension	140-159	or	90-99
Stage 2 Hypertension	>160	or	> 100

A person whose blood pressure is in the prehypertensive category is at greater risk for developing hypertension than one whose blood pressure is normal (Vasan et al., 2001). Lifestyle modification is the treatment of choice for this classification (Chobanian et al., 2003) and includes recommendations of dietary changes such as a reduction in sodium and increase in calcium intake (Oparil, 2000), reduction in weight (Kaplan, 2002; McCowen, Chan, & Blackburn,

2000), cessation and avoidance of tobacco (Onken, White, Cooney et al., 2001), decrease in alcohol consumption (Cushman, 2000), increase in exercise (Herrera & Lowenthal, 2000), and stress reduction (Light, 2000). Results from stress reduction studies (Patel, 1997) have shown significant changes in blood pressure and support a strong argument for further research (Webb, 2002; Webb & Beckstead, 2002, Yucha, et. al., 2001). Massage therapy is one such stress reduction method researched for its impact on cardiovascular, immunological, and psychological outcomes (Groer, 1994; Ironson & Field, 1996; Moyer et al., 2004).

Any one or all of the highly interactive neural, hormonal, chemical, and mechanical systems may contribute to the development of high blood pressure (Kaplan, 2002). Further, these interactions are uniquely expressed and where the exact maladaptation occurs leading to the development of chronically elevated blood pressure is unique. Therefore using a reductionist approach to explain hypertension pathophysiology has historically proven difficult (Delgado & Weder, 2000).

Research has also identified contributory factors in the development of hypertension such as genetics, age, race/ethnicity, obesity, smoking, diet, lack of exercise, inflammation, salt sensitivity as well as psychological factors of anxiety, anger, hostility and depression (Charmandari, Kino, Souvatzoglou, & Chrousos, 2003; Chobanian et al., 2003; He & MacGregor, 2003; Li & Chen, 2005; Li, 2006; Rutledge & Hogan, 2002; & Yan et al., 2003).

Baroreceptors appear to have a role in hypertension. These mechanoreceptors “reset” their firing threshold to a higher level in the presence of chronically elevated blood pressure. When resetting occurs, a higher threshold is required to fire an action potential, allowing for a higher level of pressure against the vessel walls before the impulse signal is generated and responded to through the autonomic nervous system. Presently, there is great debate in the literature regarding the resetting of baroreceptors and hypertension (DiBona, 2004; Dickerson, 2004; Sleight, 2004; Thrasher, 2004). This dissertation study will not be resolving the debate, but does examine baroreflex sensitivity.

The association of psychological factors with hypertension has been studied for many years, although methodological issues have provided inconsistent findings (Rutledge & Hogan, 2002). For example, in their review of the literature relating anger and anxiety to essential hypertension, Spielberg and colleagues concluded that the evidence was controversial. It was clear that suppressed anger and hypertension had an association, but causation was not verified (Spielberger et al., 1991). A later review by Rutledge and Hogan (2002) assessed the associations between hypertension and psychological factors such as anger, anxiety and depression, arguing that the effect sizes of the 15 studies were not attributable to methodological characteristics. They concluded the effect sizes for the psychological variables of anger, anxiety and depression were significant. Scalco, Scalco, Azul and Lotufo (2005) reviewed the relationship between hypertension and depression. The evidence demonstrated a complex

relationship between depression and hypertension with suggestions that depression increases the risk of developing hypertension. Additionally, studies reviewed by Light (2001) clearly demonstrate the relationship between perceived stress and hypertension. This dissertation study measured psychological factors of anger, anxiety, and depression as covariates to the blood pressure outcome variables.

Persons initially diagnosed with pre-hypertension and hypertension should be advised to strictly adhere to lifestyle modifications such as weight reduction, following the Dietary Approaches to Stop Hypertension (DASH) diet and decreasing in dietary sodium consumption (Chobanian et al., 2003). Recommended modifications also included are increase in exercise, moderation of alcohol consumption, and cessation of smoking. Usual pharmacological treatments of hypertension include thiazide-type diuretics as an initial therapy alone, or in combination with one of the following classes of drugs: angiotensin converting enzyme inhibitors, angiotensin-receptor blockers, calcium channel blockers, or beta-blockers (Chobanian et al., 2003). Other medications are available to assist in gaining a desirable blood pressure level. The right combination of medication is often influenced by other disease processes the person may be experiencing (Chobanian et al., 2003).

Beyond the lifestyle modifications recommended by the Seventh Report of the Joint National Committee (Chobanian et al., 2003), some practitioners recommend non-pharmacological interventions to assist in the management of hypertension. Some of these interventions include biofeedback, relaxation

training, massage therapy, transcendental meditation, breathing exercises, cognitive therapy and herbal supplements (Light, 2001; Weil, 2007).

Massage

History of Massage

Massage has a long and rich history. Nearly every early culture in the world has recorded some form of manual manipulation of soft tissue. From the first known civilization, clay tablet writings dated 2100 BC, described rubbing and friction for a remedy of a diseased part (Benjamin, 2005). Ancient recordings of massage from China, Japan, India, Greece, Rome, and Turkey have provided the underlying foundation for modern massage practice (Salvo, 1999; Benjamin, 2005). The knowledge and use of massage, just as many other health practices, traveled with mankind as they traded and warred.

Hippocrates of Cos, (460-375 BC) the father of modern western medicine, and Galen, a Roman physician, promoted the use of rubbing and friction. The Greek's had gymnasiums, where their men exercised, and received massages regularly. The Roman's borrowed the Greek ideas to develop Roman baths, where massage, along with the bath, was utilized by both men and women (Benjamin, 2005).

During the Middle Ages, after the Roman Empire deteriorated, massage was mostly lost as a health practice, although there is some evidence that folk healers and mid-wives used massage. From that same period, the Arabic Empire offers writings from a physician/philosopher, Avicenna (980-1037 BC) who promoted the use of massage, exercise and bathing (Beck, 1999).

The modern western massage evolved in the 19th and 20th centuries. Pehr Henrik Ling (1776-1839) and Johann Mezger (1838-1909) are given credit for giving a scientific basis to massage. Ling, a Swedish fencing master and educator, believed that movement of the body was the key to good health. His writings on educational gymnastics influenced physical education in the western world. Ling's system of passive and active movements was used to treat medical conditions. The passive movements included shaking, pressing, stroking pinching, squeezing, kneading, clapping, vibrations and rolling (Benjamin, 2005). It was Mezger, a physician from Amsterdam who categorized the soft tissue movements (massage) into four categories, as we know them today: effleurage (stroking), petrissage (kneading), friction (rubbing), and tapotement (tapping).

The United States was introduced to Swedish massage techniques in the mid to late 19th century. It was through the practice and writings of people such as Drs. George and Charles Taylor, orthopedic practitioners, and Hartvig Nissen who published *Swedish Movement and Massage* in several medical journals, that medical practitioners in the United States became interested in the benefits of massage (Salvo, 1999). These renowned medical practitioners offered legitimate credence to massage health benefits. Massage was even more popularized in the late 19th century by John Kellogg (of Battle Creek, Michigan) who opened a natural healing resort which advocated healthy living through vegetarianism, sunshine, exercise, colonics, and massage.

Swedish massage held importance in health and healing early in the 20th century. Schools of massage taught students how to apply Swedish movement,

hydrotherapy, heat lamps, diathermy and colonic irrigation. After both World Wars I and II, massage therapists were employed for rehabilitation of soldiers with injuries. However, there was a decline in the use of massage as a treatment for illness (Goldstone, 2000). Post-war modern western medicine gave way to pharmaceuticals and new technology for disease treatment, leaving the hands-on therapies to specialties of physical therapy and rehabilitation. While at Harvard Medical School (1930-1950's), Mary McMillan, a renowned physical therapy educator wrote *Massage and Therapeutic Exercise.* This influential text touted massage and its benefits for physical therapists, which further separated medical practice from massage.

During the mid 20th century the reputation of massage was harmed when massage parlors became fronts for prostitution. It has taken the massage profession several decades of working with law enforcement and state legislatures to seriously prosecute prostitution fronts and resurrect their reputation as healthcare providers. Most states now have strict licensure through their health departments to maintain legitimate massage businesses. The profession has a very strict code of ethics, similar to nursing and medicine. Although the stigma of prostitution continues to linger most people today frequent massage professionals for stress reduction as well as deep tissue work with injuries.

Massage therapy, was revitalized in the United States during the 1960-70's cultural revolution. A holistic model evolved, espousing the concepts of wellness and prevention. During the following 20 years the profession of

massage therapy gained acceptance. The American Massage Therapy Association Foundation was established in the early 1990's. A major mission of the American Massage Therapy Foundation has been to fund research and establish a data base for massage's efficacy. The University of Miami, College of Medicine, created the Touch Research Institute in the early 1990's with a goal to understand the role of touch in human health and development. The International Symposium on the Science of Touch will hold its third conference in 2008 with an effort to share the latest research and knowledge gained. The National Institutes of Health established an Office of Alternative Medicine in the early 1990's which in 1998 became the National Center for Complementary and Alternative Medicine. Millions of research dollars have been granted to the study of massage therapy's effectiveness through National Center for Complementary and Alternative Medicine.

The American Nurses Association acknowledges massage therapy as a sub-specialty for nursing. An active National Association of Nurse Massage Therapists organization has evolved from this recognition. The National Association of Nurse Massage Therapists promotes the use of touch with patients, the intention to heal and the use of current research findings (National Association of Nurse Massage Therapists, 2006). With this national support, entrepreneurial nurses have been able to own and manage private businesses with touch and massage being the holistic intervention used for healing (Mitzel-Wilkinson, 2000).

Types of Massage

Massage therapy treatments are marketed in many forms (Table 2). The

Table 2:

Types of Massage

Influence	Types/Names
Cultural influences	Ayuvedic (India)
	Lomi-LomiHawaii
	Tuina (Chinese)
	Swedish
Focused massage	Infant
	Sports
	Cranial- Sacral
	Lymphatic Drainage
	Myofascial
	Neuromuscular
Specific Developer	Rolfing, Feldenkrais, and Esalen

variation is due to the influence or focus during the development of that particular therapy. Some types of massage are combinations of several influences. Tappan suggests this availability for cross cultural sharing is due to the internet and access to international travel (Benjamin, 2005). Yet, each massage has a specific purpose that separates it from another form.

Benefits of Massage

A single good massage will leave a healthy person with a sense of well-being. Regular massage treatments are known to have many benefits (Beck,

1999). Table 3 is a listing of benefits often experienced with regular massage treatments, complied by expert and author Mark Beck (Beck, 1999).

Table 3

Benefits of Massage

Listed Benefits of Massage*
Relief of stress and tensions.
Mental and physical fatigue relief.
Pain in the shoulders, neck, and back is relieved.
Muscles and joints become suppler, soreness and stiffness are relieved.
Muscle soreness from overexertion is relieved.
Circulation is improved.
Digestion, assimilation and elimination improved.
Facial massage tomes the skin and softens fine lines.
Headache and eyestrain are often relieved.
Deep relaxation, relief of insomnia.
Muscular spasm relief.
Obesity and flabby muscles improved when combined with exercise and diet programs.
Pain in joints, sprains and poor circulation are relieved.
Increased circulation of nourishing blood to skin and other parts of the body to promote healing.
Mental strain reduced resulting in better productivity.
Mildly high blood pressure is temporarily reduced.
Renewed sense of confidence and control is experienced.
Constrictions and adhesions can be reduced and prevented as traumatized muscle tissue heals.
Joint mobility can be increased.

* Beck (1999) does not denote which of these listed benefits are scientifically based.

For critically ill persons there are some benefits with gentle massage such as improved mobility, help in controlling pain and discomfort, reduction in disorientation and confusion, reduction in isolation and fear, ease of emotional distress, and the development of a more positive attitude about condition. With all of these benefits listed, few are actually based upon scientific research. Most of these benefits are based upon observation of massage performed over the millenniums of massage practice.

The benefit of temporary reduction of mild high blood pressure along with several other listed benefits to include relief of stress, tension, mental strain, and increase in circulation and gain in a sense of relaxation are being addressed by a growing body of literature. This growing literature is building the psychophysiology framework for understanding the relationship between massage and blood pressure.

The purpose of the massage used in this study was to invoke relaxation by the use of a regularly applied back massage. Swedish massage uses five classic strokes of effleurage, petrissage, tapotement, friction and vibration. The effleurage stroke, when applied with moderate pressure, slowly and smoothly on the back, may stimulate the parasympathetic nervous system and evoke the relaxation response (Benjamin, 2005). Nurses are taught to use rhythmic effleurage strokes to provide comfort, relaxation, induce sleep, and reduce anxiety in the ill patient (Potter & Perry, 2001). Cambron, Dexheimer and Coe (2006) examined the six different types of massage. Interestingly, the researchers found that some baseline characteristics, i.e. younger age and taller

stature, were associated significantly with greater changes in systolic blood pressure. Although no significant relationships were found with gender, race, medication, or weight, there were trends of decreased pressure in males, heavier persons and Hispanics (Cambron, Dexheimer & Coe, 2006). Duration and pressure of the six different massage types were associated with change in blood pressure. Cambron and colleagues found that although not significant, Swedish massage had the greatest effect on blood pressure reduction (Cambron, Dexheimer & Coe, 2006). The authors noted that several therapy types increased blood pressure; therefore they encouraged the use of Swedish massage on persons with hypertension. In view of the review of literature, the specific technique used in this research project was Swedish massage which utilizes the effleurage stroke on the back.

Summarizing the Connection of Massage and Nursing

Massage has been used in nursing practice for years, particularly the back massage. Massage is recognized as part of nursing practice. A professional organization of nurses, active National Association of Nurse Massage Therapists promotes the use of massage. Holistic nursing, which embraces the practice of nursing through a bio-psycho-social-spiritual model, has energized and promoted the use of touch to heal (Dossey, Keegan & Guzzetta, 2000). Many of the research studies establishing the validity of massage have come from nursing, a number of them evolving from the holistic framework.

Review of Massage Literature

Massage literature is rich in many ways. There are hundreds of studies that have been completed. Some valuable information gleaned from these studies has help to validate the practice of massage. For example, research has validated that depression and anxiety are influenced by multiple doses of massage (Moyer, Rounds, & Hannum, 2004).

Outcomes from massage studies have influenced nursing practice. For example, research about massaging over boney prominences resulted in a change in nursing practice for prevention of pressure ulcers (Dyson, 1978; Buss, Halfens, & Abu-Saad, 1997). Prior to this research, nurses were encouraged to massage vigorously the boney prominences of a bedridden patient. Nursing presently espouses not to massage bony prominences, particularly if they are inflamed. The story is not finished, though, with yet another review of the literature recently published arguing there is not strong evidence either way regarding the massaging of bony prominences (Duimel-Peeters, Halfens, Berger, & Snoeckx, 2005). This is a good example demonstrating that even though there have been studies completed and the findings have changed practice, the findings may not necessarily be strong enough to confirm the practice.

Meta-Analysis and Systematic Reviews

Strength of evidence is very important when practice is being challenged. Meta-analysis and systematic reviews of experimental studies offer the strongest evidence in research (Burns & Grove, 2005). The literature search on massage yielded one meta-analysis of the effects of massage on nine dependent variables

(Moyer, Rounds, & Hannum, 2004). Moyer et al. (2004) analyzed five experimental studies that measured blood pressure. One of the five studies measured hypertensive participants (Hernandez-Reif et al., 2000), one measured patients undergoing cardiac catheterization (Okvat, et al., 2002) and the other three studies measured blood pressures of healthy participants (Delaney, et al., 2002; Mueller Hinze, 1988; & Wendler, 1999). The effect sizes (Hedge's *g*) for systolic and diastolic blood pressures were combined in this analysis, resulting in a medium effect ($g = 0.25$, $p < .05$). Hedge's *g* is essentially the same as a Cohen's *d*, except in the case of a very small sample size, as both are the within group pooled standard deviation (UCLA Department of Education, 2007)

A second meta-analysis specifically focused on the effects of the effleurage back massage on components of relaxation included calculation of systolic and diastolic blood pressures (Labyak & Metzger, 1997). Nine studies were examined, of which most were with-in group designs. Although the lack of randomization weakened the results, the authors found decreases in systolic and diastolic blood pressures with a significant gender effect. Specifically, blood pressure in female subjects rises during the first 3 to 5 minutes of the massage session, then blood pressure declines in the following 10 minute rest period. Contrasting, male subjects experience a decline in blood pressure during and 10 minutes following the massage (Labyak & Metzger, 1997).

Systematic reviews, the second highest level of evidence, have expanded what is known and not known about massage. PubMed lists over 600 reviews on massage. Many of the reviews focused on massage effects on neck pain, low

back pain, cancer pain, perineal care in the birthing mother, infant or neonatal care, nausea and vomiting, sports injuries, and lymphedema. These reviews, for the most part, did not discuss blood pressure changes due to massage. Some reviews did include blood pressure as a variable to measure and discuss. Richards and colleagues (2000) included 22 articles in their review of the effects of massage in acute and critical care patients (Richards, Gibson, & Overton-McCoy, 2000). The framework of the review was relaxation and sleep promotion. Nine of the 22 articles included systolic and diastolic blood pressure changes as variables reflecting level of relaxation. Seven of the 10 studies that reported physiological measures, showed that massage produced physiological relaxation. At least one or more of the physiological indicators (heart rate, blood pressure respiratory rate, EMG activity, cortisol level, skin temperature and galvanic skin response) had significant changes. This review (Richards et al., 2000) included all levels of inquiry; therefore the findings of the systematic review are not as strong as meta-analyses which include only randomized studies.

Two methodological critiques that evaluate massage research have been published (i.e. Cawley, 1997; Hobbs & Davies, 1998). Methodological variations acknowledged within these critiques included type of design, number of variables evaluated, number of treatments (massages given), length of massage, and timing of measurement. Further, samples varied greatly from very ill patients in critical care units to elderly in nursing homes to healthy nurses. The authors noted that sample size had been inconsistent. These critiques clearly stated a need for better research design, use of randomization and increase sample size.

Selected Research Studies

Twenty eight studies are presented in Table 4. All included studies measured blood pressure. Seventeen of the 28 studies used a control group and randomized participants to groups. These 17 studies offer higher level of evidence and are depicted by an "L= 1" in the last column. Within subject designs (not randomized) do not offer as much strength therefore are depicted by "L = 2".

The primary purpose of four of the studies was to measure the effects of massage on blood pressure (Aourell, Skoog, & Carleson, 2005; Combron, Dexheimer, & Coe, 2006; Hernandez-Reif et al., 2000; Olney, 2005). Two of the four studies evaluated participants with elevated blood pressure (Hernandez-Reif, 2000; Olney, 2005) while the other studies evaluated normotensive subjects.

The evidence regarding the effect of massage on blood pressure is murky in that there is little consistency among the studies regarding the number of applications of massage. The massage interventions vary from a single application (Bauer& Dracup, 1987; Cady & Jones, 1997; Corley, Ferriter, Zeh, & Gifford, 1995; Delaney, Leong, Watkins, & Brodie, 2002; Felhandler & Lisander, 1999; Goodfellow, 2003; Longworth, 1982; McNamara, Burnham, Smith, & Carroll, 2003; McRee, Noble, & Pasvogel, 2003; Okvat, Oz, Ting, & Namerow, 2002; Stevenson, 1994) to multiple applications such as Hernandez-Reif and colleagues (2000) study in which they applied a 30 minute body massage two

Table 4

Summary of Massage Studies in which Blood Pressure was Measured

Author (year) Journal	Purpose	Sample	Intervention	Measures	Outcomes Level of Evidence
Ahles, TA, Tope, DM, Pinkson, B, et al. (1999). *Journal of Pain and Symptom Management. 18(*3), 157-163.	To test the efficacy of massage therapy in reducing symptoms of physical and psychological distress with bone marrow transplant.	N = 34 (all bone marrow transplant) Massage = 16 Control = 18 Female = 26 Male = 8 Mean Age= 41 years	20 minutes of Swedish massage to face, scalp, shoulders, neck, spine, plus acupressure in upper *back*, shoulders neck and face. 11 pts received 8-9 massages three times per week, 5 pts received 4-7 massages. Control= standard care	Pre – Post*	Sig. DBP decrease in tx group L = 1
Aourell, M, Skoog, M, & Carleson, J (2005). *Complementary Therapies in Clinical Practice, 11*, 243-246.	To evaluate the effects on blood pressure in healthy young males.	N = 15 Single Group Males Median Age = 32 years.	30 minute massage to *back,* neck, and chest 2 times per week for 4 weeks 4 week washout period. 30 minute massage to legs, arms, and face 2 times per week for 4 weeks	Pre – Post*	Sig SBP decrease each tx. in first 4 wk period both grps. Sig SBP decrease 2nd period back neck chest massage. Sig. DBP decrease in tx. 1 to tx. 4 back neck and chest tx. L= 2

Author (year) Journal	Purpose	Sample	Intervention	Measures	Outcomes Level of Evidence
Barr, JS, & Taslitz, N (1970). *Physical Therapy, 50*(12), 1679-1691.	To test the influence of back massage on autonomic functions.	N =10 Single group Females Age range= 19 to 21 years.	20 minute *back* massage. Administered 3 times over several days	Pre- Post**	No Sig. changes in BP. L=2
Bauer, WC, & Dracup, KA (1987). *Focus on Critical Care, 14*(6), 42-46.	To determine the physiologic effects of back massage in patients with acute myocardial infarction.	N = 25 Single group Female = 7 Male =18 Mean Age = 55.6 years	6 minutes of *back* massage Administered once.	Pre- Post***	No Sig. changes in BP. L = 2
Beeken, JE, Parks, D, Cory, J, & Montopoli, G (1998). *Clinical Nursing Research, 7*(3), 309-317.	To determine the effectiveness of neuromuscular release massage therapy in five individuals with chronic obstructive lung disease.	N = 5 Single group Female = 1 Male = 4 Age range = 57-74 years	24 diaphragmatic release massage. Administered once a week for 24 weeks.	Pre- Post***	Sig. SBP decrease interaction L = 2
Bost, N & Wallis, N (2006). *Australian Journal of Advanced Nursing, 23*(4), 28-33.	To determine if massage therapy decreases physical and psychological indicators of stress in nurses.	N = 58 Massage = 30 Control = 28 Sex: not reported Median Age = 42 years	15 minute *back* massage Once a week for 5 weeks	Pre- Post	No Sig. changes in BP L = 1

Author (year) Journal	Purpose	Sample	Intervention	Measures	Outcomes Level of Evidence
Cady, SH & Jones, G E (1997). *Perceptual and Motor Skills, 84*, 157-158.	To determine if chair massage results in significant decrease in systolic and diastolic blood pressure.	N = 52 Single group Female = 12 Male = 40 Mean Age = 40 years	15 minute chair massage Administered once.	Pre- Post*	Sig. SBP & DBP decrease L = 2
Corley, MC, Ferriter, J, Zeh, J, & Gifford, C (1995). *Applied Nursing Research, 8*(1), 39-43.	To determine if the physiological and psychological responses are different between a 3-minute back rub and a 3-minute control period of undisturbed rest in the institutionalized elderly.	N = 19 Massage = 12 Control = 7 Female = 11 Male = 8 Mean Age= 78 years	3-minute *back* rub Administered once.	Pre-Post*	SIg. SBP in males vs. females in tx. group L = 1
Delaney, JP, Leong, KS, Watkins, A, & Brodie, D (2002). *Journal of Advanced Nursing, 37*(4), 364-371.	To investigate the effects of myofascial trigger-point massage therapy to the head, neck, and shoulder areas on cardiac autonomic tone and psychological outcomes.	N = 30 Massage = 15 Control = 15 Female = 16 Mean age = 31 Male = 14 Mean Age = 34	20 minutes of myofascial trigger point therapy. Controls sat for same period of time. Administered once.	Pre- Post*	Sig. SBP & DBP decrease in tx. group only. L = 1

Author (year) Journal	Purpose	Sample	Intervention	Measures	Outcomes Level of Evidence
Dunn, C, Sleep, J, & Collett, D (1995). *Journal of Advanced Nursing*, 21, 34-40.	To determine the effectiveness of aromatherapy and massage used in the nursing care of patients in an ICU.	N = 122 Massage = 43 Aromatherapy = 41 Control = 38 Female = 53 Male = 69 Mean Age = 60 years	15-30 minutes Massage to *back* outer legs or scalp. Aromatherapy: same with essential oil of lavender. Control: 30+ min undisturbed rest. One to 3 treatments within 5 days.	Pre- Post*	No significant values. L=1
Fakouri, C, & Jones, P (1987). *Journal of Gerontological Nursing, 13*(2), 32-35.	To assess the effectiveness of the slow stroke back rub in promoting relaxation.	N = 18 Single group Female = 14 Male = 4 Mean Age 73.7 years.	3-minute slow stroke *back* massage applied at bed time. For 3 nights.	Pre- Post	Sig. SBP change each tx. Sig. DBP on third tx. only. L = 2
Felhandler, D & Lisander, B (1999). *Complementary Therapies in Medicine*, 7, 231-234.	To compare two non-invasive methods (with a control) to stimulate acu-points on the cardiovascular system	N = 24 Accupoint = 8 Stroking = 8 Control = 8	Pressure using dental tool on accupoints. Stroking along the meridians. Same amount of time for each group. One time application	Pre- Post*	Pressure: Sig. SBP & DBP decrease (compared to control) Stroking: Sig. DBP (compared to stroking). L =1

Author (year) Journal	Purpose	Sample	Intervention	Measures	Outcomes Level of Evidence
Ferrell-Torry, AT & Glick, OJ (1993). *Cancer Nursing, 16*(2), 93-101.	To examine the effects of therapeutic massage on pain perception anxiety, and relaxation levels of hospitalized patients with cancer pain.	N = 9 (day 1) N = 7 (day 2) Single group All men Mean Age = 56.6 years	30 min. massage of effleurage & petrissage to feet *back*, neck and shoulders plus 6 trigger points in upper middle and lower trapezium muscles. 2 consecutive nightly tx.	Pre-Post***	Day 1: Sig. SBP & DBP decrease @ T1 to T2 Day 2: Sig. SBP decrease @ T1 to T3 L = 2
Fraser, J. & Kerr, J. R. (1993). *Journal of Advanced Nursing,* 18, 238-245.	To measure the effects of back massage on anxiety and perceived relaxation levels of elderly.	N = 21 Massage=NR Control 1=NR Control 2=NR Females = 17 Males = 4 Mean Age = NR	Group 1: 5 minute *Back* massage and conversation. Group 2: Conversation only. Group 3: No intervention. Four consecutive days at bedtime.	Pre- Post**	Group 1: Within subject SBP & DBP decrease L = 1
Goodfellow, L. (2003). *Nursing Research, 52*(5), 318-328.	To determine back massage influence on psychosocial, physiologic and immune function of spouses of patients with cancer.	N = 42 Massage = 21 Control = 21 Females = NR Males = NR Mean Age = 52 years	20 minute therapeutic *back* massage Administered once	Pre- Post*	No sig. changes in BPs L = 1

Author (year) Journal	Purpose	Sample	Intervention	Measures	Outcomes Level of Evidence
Hayes, J & Cox, C (2000). *Complementary Therapies in Nursing & Midwifery, 6,* 9-13.	To describe research findings from a complementary therapy intervention designed to reduce anxiety in the critical care environment.	N = 25 Single group Female = 12 Male =13 Mean Age = 53.9 years	5 minute foot massage Mean number of foot massages = 2.7 (range 1-10 sessions)	Pre-Post**	Sig. MAP time effect from pre to during measurement. L = 2
Hernandez-Reif, Field, T, Krasnegor,J, Theakston,H, Hossain,Z & Burman, I (2000). *Journal of Bodywork and Movement Therapies, 4*(1), 31-38.	To assess massage therapy versus progressive muscle relaxation effects on adults with hypertension.	N = 30 adults: Massage = 15 Control = 15 Females = 21 Males = 9 Mean Age: 51.6 years	30 minute massage to head, neck arms torso, legs, and *back*, 2 times per week X 5 wks Control: 30 min progressive muscle relaxation 2 times per wk X 5 wks at home.	Sitting: Pre-Post* Reclining: Pre-Post*	No Sig. SBP changes. Sig. DBP decrease: Sitting: after first and last day tx. Reclining: first to last day pre tx. L = 1
Holland, B, & Pokorny (2001). *Rehabilitation Nursing, 26*(5), 182-186.	To determine the physiological and psychological effects of three consecutive days of SSBM on adult patients in a rehabilitation setting.	N = 24 adults Single Group Females = 21 Males = 3 Mean Age 71.8 years	3 minute *SSBM.* Three consecutive nights.	Pre- Post*	Sig. SBP & DBP decrease time effect L = 2

Author (year) Journal	Purpose	Sample	Intervention	Measures	Outcomes Level of Evidence
Longworth, JCD (1982). *Advances in Nursing Science, 4*(4), 44-61.	To examine the psycho-physiological effects of the slow-stroke back massage (SSBM) on normal individuals who were free of disease conditions that might influence the results.	N = 32 Single group All female Mean Age = 31.5 years	3 and 6 minutes of *SSBM.* Administered once.	Pre- Post**	Sig. SBP decrease in mean scores over time. No Sig. DBP changes. L = 2
McNamara, ME, Burnham, DC, Smith, C, & Carroll, DL (2003). *Alternative Therapies in Health and Medicine, 9*(1), 50-57.	To measure the effects of a 20 minute back massage on the physiological and psychological human responses in patients admitted for diagnostic cardiac catheterization	N = 46; Massage = 23 Control = 23 Female=12 Male=34 Mean Age = 64.9 years	20 minutes *back* massage. Administered once.	Pre- Post***	Sig. SBP & DBP decrease for within subjects main effect of time. Sig. SBP decrease between group. Sig. SBP decrease for time by group L= 1
Meek, SS (1993). *IMAGE: Journal of Nursing Scholarship, 25*(1), 17-21.	To examine the effects of SSBM on SBP, DBP HR and Skin temperature in hospice patients.	N = 30 Single Group Female =14 Male =16 Mean Age = 70.8 years.	3 minute *SSBM* 2 consecutive days	Pre- Post***	Sig. SBP & DBP decrease main effect due to time. Tx effect persisted for five min. L = 2

Author (year) Journal	Purpose	Sample	Intervention	Measures	Outcomes Level of Evidence
McRee, LD Noble, S, & Pasvogel(2003). *AORN Journal, 78*(3), 433-447.	Determine effects of preoperative massage and music therapy on pt's pre-op, intra-op and post-op experiences.	N = 52 Grp1 = 13 Grp2 = 13 Grp3 = 13 Control = 13 Female=33 Male=19 Mean age= 43 years.	Grp 1: 30 minute massage (neck, *back*, arms and lower limbs). Grp 2: 30 min. massage and music. Grp 3: 30 min piano music. Control: 30 min. sitting in waiting room. Administered once.	Pre-Post**	Sig. SBP decrease pre to intra-op Sig. DBP decrease intra-op to pre-op in massage and music Sig. DBP decrease intra-op to post-op in control L = 1.
Mok, E. & Woo, CP (2004). *Complementary Therapies in Nursing & Midwifery, 10*, 209-216.	To determine effects of SSBM on anxiety, BP HR pain perception immediately and three days after SSBM on stroke pts with shoulder pain.	N=102 Massage = 51 Control = 51 Female = 51 Male = 51 Mean age 73.2	10 minute *SSBM* at bedtime Administered for 7consecutive days	Pre-Post***	Sig. SBP & DBP decrease pre to post and post 2. L = 1
Okvat, HA, Oz, MC, Ting. W, & Namerow, P.B. (2002). *Alternative Therapies, 8*(3), 2002.	To determine feasibility and efficacy of massage for anxiety reduction in cardiac catheterization patients.	N = 78 Massage = 43 Control = 35 Female = 19 Male = 59 Mean age = 60.1 years	10 minute massage to hand, wrist , arm shoulder, *upper back*, scapular region and neck and scalp. Control: 10 minutes quiet time. Administered once.	Pre- Post**	No Sig. findings on any measures. L = 1

Author (year) Journal	Purpose	Sample	Intervention	Measures	Outcomes Level of Evidence
Olney, CM (2005). *Biological Research for Nursing, 7*(2), 98-105.	To determine feasibility and effectiveness of TBM on BP, HR and anxiety in hypertensive persons.	N = 14 Massage = 8 Control = 7 Female = 10 Male = 5 Mean Age = 54.5 years	10 ten minute back massages. Three times per week. Control: relaxation (same schedule) One therapist.	Pre- Post	Sig. SBP and DBP decrease (group by time) L = 1
Post-White, J, et al., (2003). *Integrative Cancer Therapies, 2*(4), 332-344.	To test the effects of Healing Touch (HT) and Massage Therapy (MT) or caring presence (P) vs control (own) to inducing relaxation or other cancer tx related symptoms.	N = 164 Massage = 63 Healing Touch= 56 Caring Pres. = 45 Female = 142 Male = 22 Mean age 54.7 years	45 minute sessions of massage, healing touch or caring presence Once per week for 4 weeks.	Pre-Post	Short term effects: MT & HT: Sig. SBP & DBP decrease. MT & HT vs P: Sig SBP decrease. L = 1
Stevenson, CJ (1994). *Complementary Therapies in Medicine, 2*, 27-35.	To assess the effects of aromatherapy foot massage, plain vegetable oil foot massage and verbal contact only vs control group in cardiac patients.	N = 100 Four groups Group sizes = NR Gender= NR Mean Age = NR	20 minute foot massage with: 1) plain foot massage 2) aroma therapy or 3) chatting or 4) no intervention Administered once.	Pre-Post ***	No Sig. BP changes. L = 1

Author (year) Journal	Purpose	Sample	Intervention	Measures	Outcomes Level of Evidence
Taylor, AG et al. (2003). *The Journal of Alternative and Complementary Medicine, 9*(1), 77-89.	To examine the effects on postoperative massage and vibration therapy on short-term post surgical pain, negative affect and physiologic stress reactivity.	N = 105 Massage = 35 Vibration = 35 Usual Care = 36 All female. Mean age = 56.2 years	45 minute Swedish massage to upper and lower body plus usual care; 20 minute vibration therapy plus usual care; Usual care (UC). Administered for 3 consecutive evenings	Pre-Post	No Sig. differences found. L = 1

N = sample size; Sig. = significant; BP = blood pressure; SBP= systolic blood pressure; DBP = diastolic blood pressure; tx. = treatment group; L = 1 is level of evidence: experimental with control group; L = 2 is level of evidence: with in group design; Pre-Post * = BP measurements taken before and after each treatment. Pre- Post ** = BP measurements before, during and after the treatment; Pre- Post *** = several BP measurements before and/ or after each treatment; NR = not reported; SSBM = Slow Stroke Back massage.

times a week for five weeks (Hernandez-Reif et al., 2000; see also Ahles, Tope, Pinkson et al., 1999; Aourell, Skoog & Carleson, 2005; Barr & Taslitz, 1970; Beeken, Parks, Cory, & Montopoli, 1998; Bost & Wallis, 2006; Dunn, Sleep & Collett, 1995; Fakouri & Jones, 1987; Ferrell-Torry & Glick, 1993; Fraser & Kerr, 1993; Hayes & Cox, 2000; Holland & Pokorny, 2001; Meek1993; Mok & Woo, 2004; Olney, 2005; Post-White, Kinney, Savik, Gau, Wilcox, & Lerner, 2003; Taylor, Galper, Taylor, Rice, Andersen, Irvin, Wang, & Harrell, 2003). Moyer and colleagues (2004) determined that single dose massage did elicit a moderate effect size for blood pressure (Moyer, Rounds & Hannum, 2004). They did not analyze multi dose effect on blood pressure.

Further, the variation in the length of massage application time, such as a 3-minute back massage (Holland & Pokorny, 2001) versus a 20-minute back massage (Goodfellow, 2003) has made it difficult to determine the most effective dosage. Moyer and colleagues (2004) reported in their meta-analysis that length of massage session did not reach statistical significance, but felt a higher powered study may prove differently. They encouraged further studies to include two levels of application time (Moyer, Rounds & Hannum, 2004).

Another issue of differentiation among the research is the type of massage applied. Some researchers utilized the slow stroke back massage which is a systematic effleurage applied to the back. The predominant massage utilized effleurage to the back and sometimes other parts of the body. When the effleurage is combined with other therapies, for instance acupressure point,

vibration, foot massage and or aromatherapy, determination of which stroke is effective becomes problematic.

The relationship of massage and psychological factors has been studied, particularly depression, anxiety, and anger which are known to also be associated with hypertension (Bost & Wallis, 2006; Field et al., 1996; Field, Quintino, Henteleff, Wells-Keife, & Delvecchio-Feinberg,1997; Groer et al., 1994; Hernadez-Reif, Dieter, Field, Swedlow, & Diego, 1998; Hernandez-Reif, Field , Ironson, Beutler, & Vera, 2005; Ironson et al., 1996; McRee, Noble & Pasvogel, 2003; Mok & Woo, 2004; Olney, 2005; Post-White et al., 2003; Rexilius, Mundt, Megel, & Agrawal, 2002; Shulman & Jones, 1996; Smith, Kemp, Hemphill & Vojir, 2002) . Depression, anxiety and anger have been shown to change significantly with application of massage. A meta-analysis (Moyer, Rounds & Hannum, 2004) found significant effects of massage on factors state anxiety, trait anxiety and depression (Hedge's) g = .37, g = .75 and g = .62, $p < .01$, respectively.

Neuroendocrine measures of the physiological stress response have been shown to be affected by massage therapy. Specifically, cortisol, a common measure of the hypothalamic pituitary adrenal axis, is often measured in massage studies. Cortisol is known to increase with perceived stress. Massage therapy research has mixed results regarding its effect on cortisol levels. In the Moyer, Rounds, and Hannum (2004) meta-analysis, massage did not produce a significant mean effect size in cortisol. Field and colleagues argue that cortisol

decreases on average 31% in reviewed studies using massage therapy (Field, Hernandez-Reif, Diego, Schanberg a & Kuhn, 2005).

Theoretical Framework

Psychophysiology provides the framework for this research. In this study, the goal was to determine characteristics (long-term effects and dosage) of the relationship between a known stress reduction therapy (massage) and a state of health (hypertension). In the review of literature, evidence was presented demonstrating the associations between psychological factors (anxiety, depression and anger), neuroendocrine function (cortisol), and health (levels of blood pressure) (Light, 2001; Lovello, 2005; Rutledge & Hogan, 2002). Figure 3 depicts this relationship.

The intervention of massage has a relationship with blood pressure, as discussed in the review of literature. Because of the integrated relationship between the environmental, psychological and physiological factors within hypertension, each must be measured when blood pressure is measured. Blood pressure is, in essence, evaluated in the presence of the psychophysiologic status. In other words, the internal and external factors are covariates to the blood pressure at the moment it is measured. It is only in this context, evaluating blood pressure in the presence of the covariates, that the influence of back massage can be understood. No one piece exists in isolation of the other. Further, this very simplified model, Figure 3, does not intend to exemplify the intricately complex full model of massage, blood pressure and psychophysiology. Lovallo (2005) has built numerous elaborate models to depict the psychological

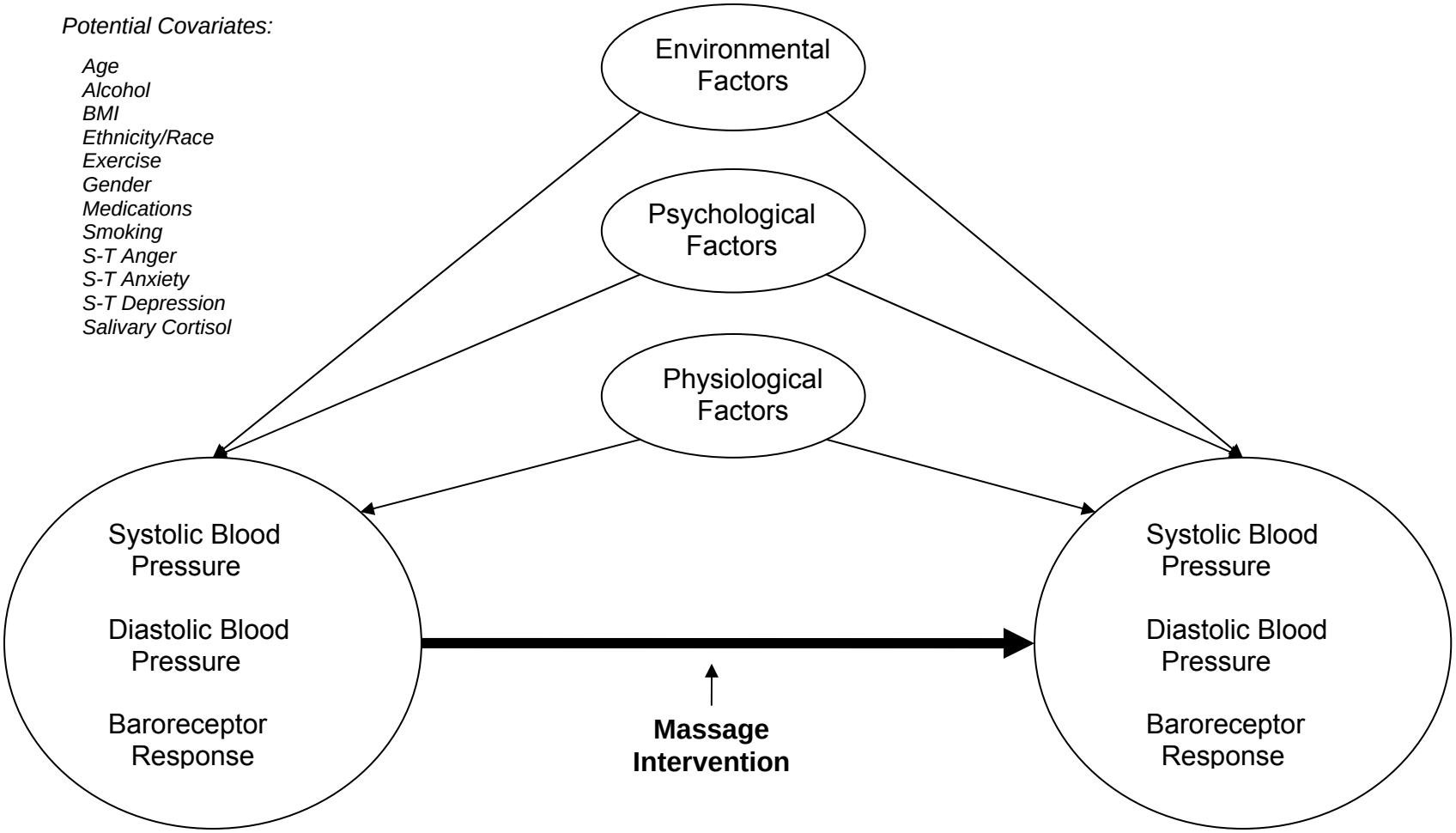

Figure 3: Model of Massage Influence on Blood Pressure within the Psychophysiology Framework

and neuroendocrine relationship with health status. Figure 3 is intended to demonstrate that massage is known to have an influence on blood pressure as it exists within the model of psychophysiology. The environmental, psychological, and physiological factors shown in this model are operationalized by the potential covariates: age, alcohol, body mass index (BMI), ethnicity/ race, exercise, gender, medications, smoking, anxiety, anger, depression, and salivary cortisol and are not exclusive of other influences that may be included in a full psychophysiology model.

Chapter Summary

Chapter Two has reviewed the physiology of blood pressure and the pathophysiology of hypertension conveying the complexity and the seriousness of the disease process. The history of massage was discussed developing a background of why effleurage stroke is the type of massage recommended for eliciting the relaxation response. The review of massage literature clarified the troubling lack of consistency in massage research thus far, specifically the lack of systematic approach to type of massage, length of massage, and number of dosages needed to elicit particular responses. The psychophysiology framework has provided a solid theoretical basis upon which to explore the effects of massage on persons with hypertension. This framework is a holistic model in which the relationship of the covariates in the model can be explored.

Chapter Three

Method

Chapter three presents the methodology used in this study. Included are: the study design, setting, sample, sampling method, instrumentation, procedure and data analysis plan.

Study design

The study was a 3 x 4 experimental design. Participants were randomized to one of three groups. Treatment 1 received 10 back massages, treatment 2 received 5 back massages and the control group received ten sessions using self-selected relaxation. Four measurement time points included pre-intervention, 48-72 hours post-intervention, at week eight of the study (2 weeks post intervention for the 10-Massage group and Control group / 4 weeks post intervention for the 5-Massage group) and at week ten of the study. The study design attempted to blind the researcher to the data by having a research assistant do data collection.

Setting

The research study took place at a large metropolitan university. A suite provided by the College of Nursing had two rooms, the first being a sitting area where participants were able to sit in comfortable chairs with a water fountain providing a continuous, relaxing soft sound and magazines to page through while

waiting. The second room contained a table at which the participant sat to complete written instruments, a comfortable adjustable chair in which the participant sat to have blood pressures taken, and the massage table upon which the participant lie to receive the massage or to do relaxation. The room was divided by a folding screen behind which the massage table was positioned, offering participants a sense of privacy while gaining the horizontal position onto the massage table. The rooms, painted in a soft butter color, were approximately 12 x 20 feet, providing adequate space. The air temperature in the rooms averaged 72 degrees Fahrenheit. Soft relaxing music played continuously throughout the day from a stereo in the second room. See Appendix 1 for a list of the musical CDs used in this study.

Participants were granted permission by the university parking and transportation department to park in the parking lot adjacent to the College of Nursing during the period of data gathering. The entire data collection took 235 days beginning April 7, 2006 and ending November 28, 2006.

Sample

An *a priori* power analysis, based on the researcher's pilot study, (Olney, 2005) suggested that a sample size of seven per group for diastolic pressure ($\alpha = .05$, $\beta = .80$, effect size 1.56) or sample size of three per group for systolic pressure ($\alpha = .05$, $\beta = .80$, effect size 2.25) was needed to detect a difference. With no other literature suggesting significant findings using such a small sample, the researcher consulted experienced researchers to gain a better estimate for sample size needed in this study. In a phone conversation with expert massage

researcher, Dr. Maria Hernandez-Reif of the Touch Research Institute, University of Miami, Miami, FL, advised that smaller samples are appropriate with massage because the effect sizes on outcome variables tend to be large. Therefore, it was determined that 15 subjects per group would be adequate to detect a significant change in systolic or diastolic blood pressure. The researcher proposed to recruit 18 subjects per group to allow for attrition due to dismissals and drop out. Therefore, the goal was to recruit and enroll 54 participants.

Recruitment

Given that nearly one in three adults has hypertension (American Heart Association, 2006), the researcher determined the local university population would be adequate from which to pull a sample of hypertensive participants. Therefore a convenience sample was recruited from the University of South Florida faculty, staff, students and associates, which has a total population of approximately 50,000 with >43,000 students (University of South Florida, 2005), and >7,000 faculty and staff, (University of South Florida, 2004). Therefore, an estimated 16,000 hypertensive persons, not considering age variance, were available to be recruited from the university campus. Recruitment began with a mass mailing of an approved recruitment flyer via the University of South Florida Health Sciences Center's e-mail system (Appendix 2). A hard copy of the flyer was also posted on approved bulletin boards through out the Health Science Center's campus. Due to the nature of the study, a rolling enrollment had to occur; therefore the internet flyer was posted on average every 3 weeks to recruit more participants. After several months of posting throughout the Health

Sciences, recruitment numbers began to decline. Therefore, the flyer was also posted on other campus e-mail lists and hard copies were posted on approved boards throughout the university campus. All flyers were removed from the boards when recruitment was completed.

Over the eight months of recruitment, 220 people contacted the researcher via either phone or e-mail to inquire about the study. Each interested person was screened by the researcher for inclusion into the study. Sixty-three of the 220 (28.6%) consented into the study. Table 5 lists the reasons for the 157 inquirers to not join the study.

Table 5

Reasons Interested Persons did not Join Study

Reason	Number of people (%)
Did not return researcher's return call or e-mail	46 (20.9%)
Too far to drive	28 (12.7%)
Schedule would not allow time required	26 (11.8%)
Recently changed medications	18 (8.2%)
Inquired for another person	11 (5.0%)
No reason	11 (5.0%)
Family Crisis	9 (4.1%)
Insulin Dependent Diabetes Melitus	3 (1.4%)
BP not elevated	3 (1.4%)
Accident or Illness	2 (1%)
On weight loss program	2 (1%)
Money not offered	2 (1%)
Total	157 (71.4%)

Sampling Method

The researcher initially screened each person in a phone conversation for inclusion criteria, described the study, and burden to the potential subject. The inclusion and exclusion criteria based upon literature review. Inclusion criteria included: 1) Between ages 18 to 75 years of age, 2) Diagnosis of pre-hypertension as defined by the JNC VII or controlled hypertension as defined by participant's health care provider, 3) Persons with diagnosis of hypertension had to be under the care of a primary health care provider and have no changes in medications in the past 6 months, 4) Be able to speak, read, understand, and write English at the seventh grade level, 5) Must be available for ten weeks. Exclusion criteria included: 1) Less than 18 years or over 75 years, 2) Persons with uncontrolled hypertension as defined by systolic blood consistently > 140 mmHg, 3) Persons with hypertension not under the care of a primary care provider, 4) Persons with recent (past 6 months) changes in antihypertensive medications including dosage changes, 5) Non-English speaking, reading and writing persons, 6) Persons with inflammation or open sore or rash on the back, shoulders and or neck areas, acute infections, advanced osteoporosis, aneurysm, hematoma or edema of the area being massaged, diabetes, active treatment of cancer, experiencing extreme fatigue, intoxication, psychosis, frailty or any other process that deemed contraindicated by their personal health care provider, 7) Persons with insulin dependent diabetes, 8) Pregnant women beyond the second month, due to discomfort of lying on abdomen during the massage, 9) Unable to commit to entire length of

study, and 10) Persons with history of thoracotomy. This last criteria was added after an adverse event (See Appendix 3 for letter from Institution Review Board).

Of the 220 inquiries, 63 interested persons met the study criteria. A 30 minute appointment was arranged for the participant to complete the initial paper work, meet the researcher, and have the study explained again to ensure the participant understood the commitment.

Protection of Human Subjects

The initial paper work included the approved University of South Florida Human Subjects Institutional Review Board consent form (Appendix 4), the approved University of South Florida Research Authorization for Use and Disclosure of Protected Health Information form (Appendix 5), and a Subject Information form (Appendix 6) . If the participant was older than 65 years of age, a Mini-Mental State Exam was administered (Appendix 7). Once the researcher was assured the participant was committed to the study, that they understood the commitment and the consent and health information protection form was signed, a schedule was arranged with the participant for the entire study.

Randomization

Fourteen of the consented 63 participants dropped from the study prior to randomization. The reasons for leaving the study are listed in Table 6. Randomization to group occurred on the fifth visit to the research lab (see procedure). At the study's completion, there were 42 participants who had

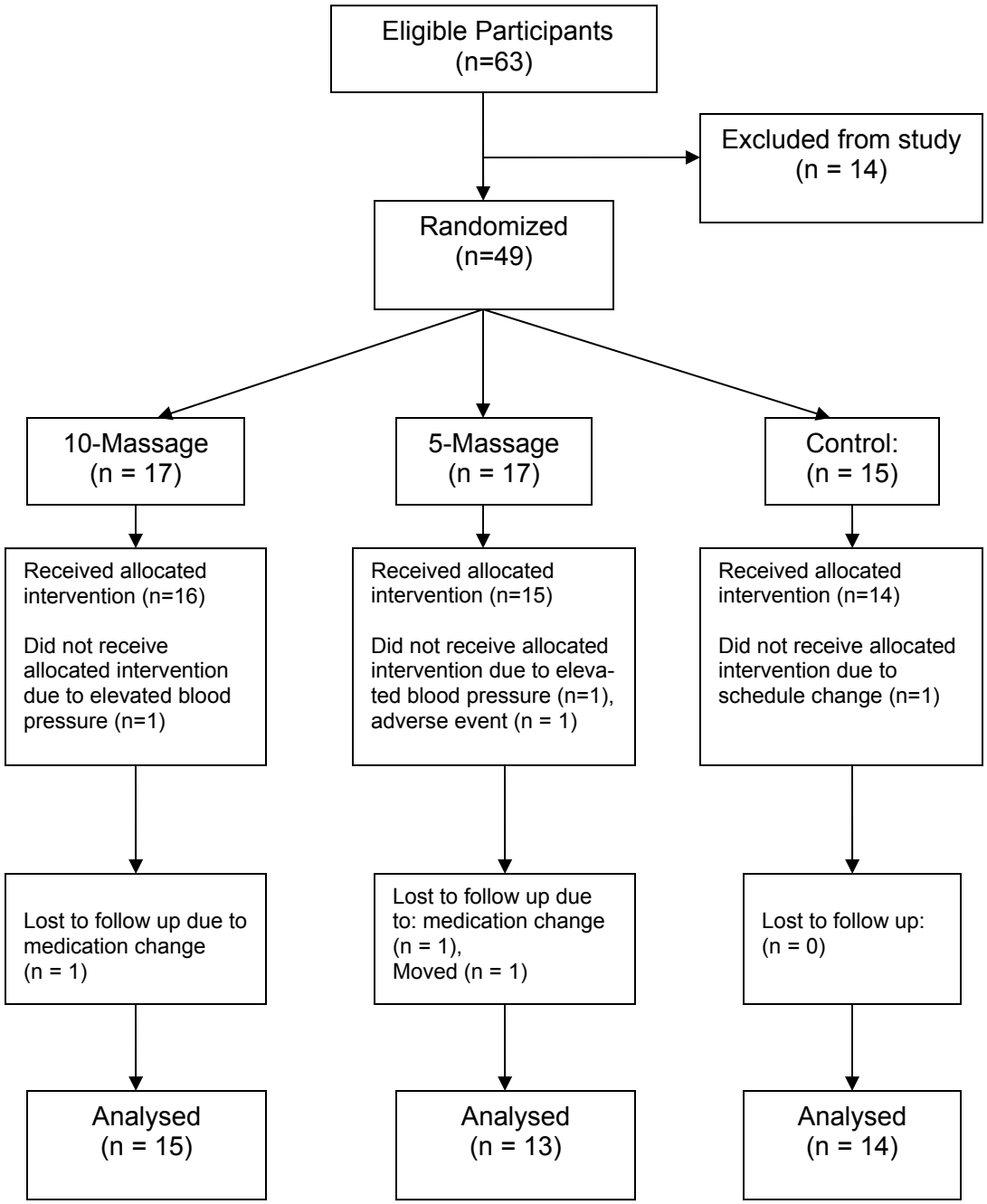

Figure 4: Participant Eligibility and Attrition

Table 6

Reasons Consented Participants Dropped out of Study

Reason	Number
Scheduling conflicts with work or family	7
Change in BP medication	2
Blood pressure too high*	2
Blood pressure too low	1
Refusal to comply with protocol	1
No reason	1
Total	14

* Referred to primary physician.

completed all 4 times points in this study. Figure 4 depicts the break out of how the sample of 42 participants occurred.

Instrumentation

The main outcome variables in this study were systolic and diastolic blood pressure. Unlike most stress intervention studies, this study measured several stress related variables as covariates as opposed to outcome variables to test the theoretical structure of this design. For example within the psychophysiology theory, it is known that blood pressure changes are possibly due to perceived stress. Understanding the levels of stress that the participant was experiencing at the time of each measurement helps with the interpretation of the blood pressure level. Levels of stress are measured many ways in science. This researcher chose to measure stress biologically and psychologically using salivary cortisol, and anxiety, depression, and anger, respectively. Table 7 lists and discusses the instruments used to measure the outcome variables and the covariates.

Each participant was measured at four time points during the study: pre-randomization (week two), post intervention (week four for the 5-massage group, week six for the 10-massage group and control), at week eight and week ten (Appendix 12). Written instructions in preparation to the data gathering sessions were provided to the participants. The instructions asked that the participant not

Table 7

Variables Measured and Instruments used to Measure each Variable

Variable	**Instrumentation**
Systolic Blood Pressure	Dinamap Pro Care 400 automated oscillometric monitor with digital screen and printout.
Diastolic Blood Pressure	Dinamap Pro Care 400 automated oscillometric monitor with digital screen and printout.
Heart rate	Dinamap Pro Care 400 automated oscillometric monitor with digital screen and printout.
Baroreceptor Response	Dinamap Pro Care 400 automated oscillometric monitor digital screen and printout.
Salivary Cortisol	DRG Diagnostics Cortisol ELISA, DRG International, Inc. USA
Anxiety	Spielberger's revised State-Trait Personality Inventory
Depression	Spielberger's revised State-Trait Personality Inventory
Anger	Spielberger's revised State-Trait Personality Inventory
Expectations	Subjective Rating Scale
Touch Perception	Subject Touch Perception Scale (Semantic Rating Scale)
Rapport with Therapist	Subject Perceived Rapport Scale (Semantic Rating Scale)
Age Alcohol BMI Ethnicity/Race Exercise Gender Medications Smoking	Subject Information form: Self reported.

eat or drink at least one hour prior to the measurements. The routine for data gathering went as follows: saliva sample (5-minutes), five blood pressures of three sitting, one lying and one just after sitting up (~ 17 minutes) and State-Trait Personality Inventory (~ 8 minutes). The routine was strictly followed for all cases except one in which the measurement routine was reversed due to participant having only fasted for 45 minutes prior to coming in for data gathering session.

Blood Pressure

This study used a Dinamap Pro Care oscillometric monitor, donated by General Electric Medical Systems Information Technologies to measure blood pressure. Blood pressure has traditionally been measured by auscultatory methods using a mercury sphygmomanometer (Pickering et al., 2005). Other methods, such as the oscillometric monitor, are becoming more common and have several advantages over the mercury method (Pickering et al., 2005). One detriment to using a oscillometric monitor is that the algorithms used to measure blood pressure vary from one monitor to the next. To avoid this problem in the study, the same monitor was used throughout the study. The Dinamap Pro Care 400 automated oscillometric monitor is a highly respected and commonly used instrument within health care systems (GE Healthcare, 2007). The instrument used in this study was calibrated and tested repeatedly for reliability to measure blood pressure accurately. The instrument was tested for function and safety prior to the study's use by General Electric technicians. During this study the researcher tested the instrument against a manual sphygmomanometer on a

regular basis to ensure the Dinamap Pro Care 400 continued to measure accurately.

Correct blood pressure cuff size is very important for accurate blood pressure measurement (Pickering et al., 2005). Each participant had their non-dominant arm measured by the researcher to determine correct cuff size prior to the first blood pressure measurement according to the American Heart Association Guidelines for cuff sizes. Three systolic and diastolic blood pressures were measured and averaged at each of the four time points.

The Dinamap Pro Care 400 monitor was also used to record the heart rate during each blood pressure measurement. The monitor stored the recordings and provided a paper print out of those blood pressure and heart rate recordings at the end of each participant's visits.

To determine baroreceptor response, blood pressures sitting and lying are compared. Therefore the appropriate instrument to measure this variable was the Dinamap Pro Care 400.

Salivary Cortisol

Salivary cortisol was used as a physiological marker of perceived stress (Smyth et. al., 1998). Salivary cortisol kits obtained from DRG Diagnostics Cortisol ELISA, DRG International, Inc. USA were used by the researcher. Dr. Maureen Groer, University of South Florida, College of Nursing, provided the lab, freezer space, and guidance in correct laboratory methodology.

State Trait Personality Inventory

The revised State Trait Personality Inventory (STPI) is an 80-item inventory comprised of eight 10-item scales (Spielberger et al., no date). The scales measure emotional states and personality traits of anxiety, anger, depression and curiosity. This self report questionnaire is arranged so that the 40 state items are listed on the front of a single page and the 40 trait items listed on the back of that page (Appendix 8).

The psychometrics of the STPI were reported in the *Preliminary Manual for the State Trait Personality Inventory* by Charles C. Spielberger and colleagues, unpublished, unless otherwise indicated (Appendix 9: correspondence with Dr Spielberger about the manual). The 10-items for state and trait anxiety were selected as the best items from the 20-item parent scales, the State and Trait Anxiety Inventory (form Y), correlating .95 or higher with college students. Alpha coefficients based on working adults were: $\geq$ .88 for trait anxiety and $\geq$ .91 for state anxiety (Spielberger et al., unpublished).

The state and trait anger scales are the same as the original State-Trait Anger Expression Inventory (STAXI). Correlations with original State and Trait Anger Inventory based on 198 Navy personnel and over 200 college students were high ($r > .94$). The anger alpha coefficients for working adults were: trait anger .88 or higher and for state anger .93 or higher (Spielberger et al., unpublished).

The internal consistency (alpha coefficients) for state and trait depression scales (and subscales) were .93 or higher for university students (81 males and 170 females) (Spielberger, Ritterband, Reheiser & Brunner, 2003). Further, there is good concurrent validity (r =.72 to .85) with the Beck Depression Inventory (BDI), Center for Epidemiological Studies-Depression scale (CES-D) and the Zung Depression Rating Scale (ZDRS) for the trait depression scales (Spielberger, Ritterband, Reheiser & Brunner, 2003). .

Expectations Rating Scale

The Expectations Rating Scale was developed by the researcher. This subjective scale asked the participants a dichotomous question: "Do you expect the massage therapy (or relaxation) to lower your blood pressure?" The purpose of this question was to provide insight regarding the influence of the participant's expectation on the outcome variables.

Touch Perception Scale

The Subject Touch Perception Scale (Appendix 10) was developed by the researcher. This semantic scale asked the participant to respond to their perception of the back massage and it was anticipated that this scale would provide insight regarding the influence of touch perception on the outcome variables. This scale was administered to only those participants that received a massage intervention and only at the second measurement session.

Perceived Rapport Scale

The Subject Perceived Rapport Scale (Appendix 11) was developed by the researcher. This semantic scale asked participants who received a massage

intervention to respond to their perception of the relationship with the massage therapist. This scale was administered at the second measurement session only. It was anticipated that this scale would provide insight regarding the influence of perceived rapport on the outcome variables.

Subject Information form

The Subject Information form is a self report form developed by the researcher. The body mass index (BMI) used in this study was calculated from the reported height and weight (705 X weight / height^2).

Procedure

The participant's first visit was a data gathering session taking a total of 30 minutes time. Consent, Protection of Health Information, and demographics information was obtained from the participant. A detailed schedule for meeting times was agreed upon by the participant and the researcher. The planned schedule asked the participant to come for visits three times per week, on a Monday, Wednesday, Friday schedule, for 30 minutes each (See Appendix 12). The purpose of the second, third and fourth meetings, was to acclimate the participant to having their blood pressure measured in that environment. During these three visits every participant was taught methods of relaxation to include controlled breathing, progressive muscle relaxation, and imagery. Every participant was instructed to use these methods through out the study whenever blood pressure measurement was occurring. Baseline data was gathered during the fifth visit including saliva for cortisol, three blood pressures and the State Trait Personality Inventory. After baseline data was completed, the subject was

randomized to one of three groups by drawing an assignment from a canister. The canister had equal numbers of folded slips of paper with a designated group assignment to: *Treatment 1* (10-Massage group), *Treatment 2* (5-Massage group) or *Control*. The specified group procedure was then explained to the participant. The sixth through fifteenth visits for the 10-Massage and Control groups and the sixth through tenth visits for the 5-Massage group was the intervention period. During the 30-minute intervention visit the participant first sat quietly for 3-5 minutes, utilizing the learned methods of relaxation. Once the participant indicated he or she felt relaxed, one measurement of blood pressure was obtained. Then the individual treatment procedure was instituted.

The Massage Therapist

For fidelity purposes, this study utilized one massage therapist. The researcher is a nationally certified, state licensed massage therapist. The researcher developed the back massage based on professional experience, the empirical evidence and advice from a former massage instructor, Maggie Kelly, Licensed Massage Therapist. Former clients offered feedback during the development phase of the back massage, allowing refinement to the pressure used and the speed of the strokes.

Massage Routine

The massage routine used a sequence of three types of strokes for the duration of the 10-minute back massage. Using both hands the therapist applied long effleurage strokes that started from the base of the neck, along both sides of the spine, to the base of the sacrum, then returning to the neck base by a smooth

pulling stroke to the lateral sides of the back. The hands of the therapist never lost contact with the subject's back. This effleurage stroke was rhythmic and repeated three times. The second stroke, also repeated three times, was a circular stroke starting at the base of the occipital bone, at ear level. The stroke was moved along the lateral neck and over the upper shoulders (deltoids) and returned to the ear area. The third stroke, repeated three times, again started at the base of the neck, circling the perimeter of the scapula. Each set of three strokes took approximately five seconds to complete. The sequence was repeated for the full 10-minute application.

10-Massage Group and 5-Massage Group Procedure

The therapist stepped out of the room while the subject disrobed (behind a screen) from the waist up and then lay prone on a cleanly draped massage table with her/his face resting on the face support extension. The researcher re-entered the room only after the participant indicated she/he was prepared. A towel was tucked into the participant's waist band to protect the clothing and a pillow placed under the lower leg and ankle to support the feet. A rhythmic 10-minute back massage was administered using a non-allergenic massage lotion. The back was dried with a clean towel. Before leaving the room, the therapist reminded the participant to sit at the edge of the table and breathe for several breaths prior to getting off the massage table to redress. The therapist left the room and returned once the participant indicated she/he was dressed and sitting in the chair. The participant sat quietly for 2-5 minutes allowing the researcher to

assess any adverse effects of the massage such as dizziness, and then a second blood pressure and heart rate was measured.

Control Group Procedure

The control group participants experienced the same procedure as the treatment group participants except they did not receive a massage. The control participants were directed to use the learned relaxation techniques for the 10 minutes as they lie supine on the massage table. They were offered pillows for support under the head and knees and a blanket for warmth.

Post Intervention Procedures

Three post-intervention visits took place in this study. For the 10-Massage and Control group participants the first post measurement was the sixteenth visit (~week 6). For the 5-Massage group participants, the first post measurement was eleventh visit (~week 4). The third and fourth post measurements occurred during the eighth and tenth week after their enrollment (Appendix 12).

Data Management

Security

All data was gathered on paper and filed in the respective participant's file. The files were maintained in a locked cabinet at the study site throughout the duration of the study. During the analysis phase the files were maintained in a locked cabinet in the researcher's office. The data were loaded into an EXCEL file using only coded identification numbers. A password was needed to access the data file.

Data Analysis Plan

The data were analyzed using the SPSS Graduate Pack 11.5. Alpha was set at .05, protecting against a Type I error. Prior to analysis, all data were examined for accuracy in data entry, missing values, and whether assumptions of each analysis were met. Basic analysis of variance was used to determine differences in the mean group demographic characteristics.

Hypotheses 1 through 4 required adjustment of covariates prior to the analysis comparing changes in group means over time. The MANOVA procedure provided insight and adjustments needed to meet the assumptions of analysis of covariance (ANCOVA). An analysis of covariance tested for mean group changes over time in systolic and diastolic blood pressure. Follow up orthogonal analysis was planned for the expected interactions.

Hypothesis 5 was concerned with the change in baro-receptor function. This hypothesis stated that the change in the lying blood pressure group mean compared to the sitting blood pressure group mean would be significantly different for the participants who received 10 massages than the control group. This hypothesis was analyzed using an ANOVA procedure.

Chapter Summary

Chapter 3 described the method used in this study. The process of sample selection was described, including protection of their human rights and their personal information. A figure (Figure 4) of participant eligibility depicted the number of interested individuals and how, once completely randomized into the study, the attrition rate prolonged the recruitment time period. The instruments to

measure each variable were fully described. The procedure for each group was different therefore full discloser was included in this report. Data security throughout the study was ensured. The analysis plan for each hypothesis was discussed and the results will be fully disclosed in Chapter four.

Chapter Four

Overview of Findings

The purpose of this study was to evaluate the long term effects and dosage of back massage for persons with hypertension or pre-hypertension. This randomized clinical trial tested five hypotheses addressing the effectiveness of back massage. The first two hypotheses were related to the long term effects of back massage. The third and fourth hypotheses compared dosage of back massage. The fifthl hypothesis addressed a possible causal physiological mechanism for change in blood pressure using back massage. Each participant was measured for all variables at four time points during the study: pre-randomization (week two), post intervention (week four for the 5-massage group, week six for the 10-massage group), at week eight, and week ten (Appendix 12). The probability of making a Type I error was set at $p<.05$ for all the analyses.

Analytical Strategy

Unlike many stress intervention studies that measure biological and psychological variables as outcome variables, this study was designed to evaluate blood pressure changes within the context of the psychological and biological status of the participant at each measurement session. Therefore, this study used analysis of variance (ANOVA) and analysis of covariance (ANCOVA) to determine the effects of massage on blood pressure. The assumptions of ANOVA and ANCOVA were assessed for violations. If violations to the

assumptions were found, the necessary adjustments were made. The purpose for using covariates in the analysis was to decrease error variance and increase power. Further, each covariate was analyzed for its relationship to the dependent variables prior to adding to the model. Significant correlations regarding covariate to dependent variable and group by time interactions and patterns helped determine support for each hypothesis.

Preliminary Analyses

Sample

The sample consisted of 42 participants (26 females, 16 males). The sample had a 67% completion rate for the study (see Figure 4). The data set from these 42 participants' self-reported characteristics had no missing data (Table 8). The age range was 26 to 70 years with a mean age of 48.67 (SD = 12.1) years. The racial and ethnic make up of the sample was mostly white (86 %). African Americans made up 9 % of the total and Asians and Unknown/ Other categories each made up 2% to the sample. The three groups were compared to determine if there were significant differences among them on specific variables. The only significant difference found among the three groups was body mass index (BMI), a weight-height ratio (weight(kg) / [height (meter)]^2): (F [2, 39] = 3.38, $p<.045$) (Table 8). Antihypertensive and diuretic medication usage (Table 9) did not differ between the three groups. Nearly half (53%) of the participants in the 10-Massage group were on medications, and nearly two thirds (64%) of the

Table 8

Characteristics of Groups

Group Characteristic	10-Massage (n = 15)	5-Massage (n = 13)	Control (n = 14)	Total Group (n = 42)	Significance P-value (.05)
Gender					X^2 (2) = 2.108, p =.349
Female	9 (60%)	10 (77%)	7 (50%)	26 (62%)	
Male	6 (40%)	3 (23%)	7 (50%)	16 (38%)	
Age*	48 (13.95)	50.15 (10.60)	48.00 (12.06)	48.67 (12.1)	F = .136, p = .873
Race/Ethnicity					X^2 (8) = 7.877, p =.446
African-American	2(13%)	2 (15%)	0	4 (9%)	
Asian	0	0	1 (7%)	1 (2%)	
Caucasian	11(73%)	11 (85%)	11 (79%)	33 (86%)	
Hispanic	1 (7%)	0	2 (14%)	3 (7%)	
Other	1 (7%)	0	0	1 (2%)	

Table 8
(continued)

Group	10-Massage (n = 15)	5-Massage (n = 13)	Control (n = 14)	Total Group (n = 42)	Significance P-value (.05)
Body Mass Index (kg/m^2)* Self-reported.	27.85 (3.67)	30.33 (7.68)	34.22 (8.01)	30.74 (7.03)	F = 3.35, p = .045
Smoker (Yes or No)	1 (7%)	2 (15%)	1 (7%)	4 (9.5%)	X^2 (2) = .752, p =.686
Drinks Alcohol (Yes or No)	10 (67%)	8 (62%)	6 (43%)	24 (57%)	X^2 (2) = 1.83, p =.402
Exercise (Mean Minutes per day)*	31 (24.78)	22 (20.40)	18 (23.51)	23.65 (23.44)	F = 1.29, p = .286
Hypertension (Mean years diagnosed)*	2.9 (3.73)	9.5 (11.26)	6.4 (6.41)	6.10 (7.89)	F = 2.65, p =.083
Takes at least one medication for Hypertension	8 (53%)	11 (85%)	10 (71%)	29 (69%)	X^2 (2) = 3.244, p =.197

* Mean (Standard Deviation).

Control group were on medications. See Appendix 13 for all medications used by study participants.

Table 9

Antihypertensive Medications Used by Study Participants

Medication	10-Massage Group # (% of group)	5-Massage Group # (% of group)	Control # (% of group)	Total # (% of total sample)
ACE Inhibitors	3 (20%)	3 (23%)	2 (14%)	8 (19%)
Angiotensin II Receptor Blockers	3 (20%)	3 (23%)	2 (14%)	8 (19%)
Beta Blockers	0	3 (23%)	2 (14%)	5 (12%)
Calcium Channel Blockers	1 (6%)	0	2 (14%)	3 (7%)
Diuretics	4(27%)	4 (31%)	5 (36%)	14 (33%)
# of Participants on HBP meds [# on 2 meds]	11 [3] (53%)	13 [2] (85%)	13 [3] (71%)	37 [8] (69%)

The psychological variables were measured to reflect the level of perceived stress at the time of each measurement session. The State Trait Personality Inventory (Spielberger et al., unpublished) was used to measure three psychological variables that are related to hypertension: anxiety, anger and depression. The reliabilities for the inventories in this study were strong (i. e. State inventory = .88 and trait inventory = .94).

The means and standard deviations for state anxiety, anger and depression are reported in Table 10. The means and standard deviations for trait anxiety, anger and depression are reported in Table 11. There were no between-group differences on any of these psychological measures at any of the time points.

Table 10

Means (Standard Deviations) and Significance of State Anxiety, Anger and Depression

Variable*	10-Massage Group	5-Massage Group	Control	TOTAL	Significance
Pre State Anxiety	15.53 (5.69)	13.23 (2.89)	15.36 (4.88)	14.76 (4.71)	F(2,39) = 1.002, *p* = .376
Post State Anxiety	15.80 (6.96)	14.85 (7.05)	14.07 (6.44)	14.93 (6.69)	F(2,39) = 0.234, *p* = .793
Post 1 State Anxiety	15.27 (4.45)	17.38 (8.17)	15.43 (8.12)	15.98 (6.94)	F(2,39) = 0.378, *p* = .688
Post 2 State Anxiety	16.40 (6.67)	14.00 (6.10)	14.64 (5.58)	15.07 (6.09)	F(2,39) = 0.581, *p* = .564
Pre State Anger	12.40 (5.29)	10.38 (0.96)	11.29 (2.20)	11.40 (3.47)	F(2,39) = 1.197, *p* = .313
Post State Anger	11.47 (3.91)	12.92 (8.04)	11.00 (2.72)	11.76 (2.72)	F(2,39) = 0.485, *p* = .620
Post 1 State Anger	10.73 (1.28)	13.08 (5.65)	11.93 (5.36)	11.86 (4.46)	F(2,39) = 0.960, *p* = .392
Post 2 State Anger	11.60 (4.36)	10.31 (0.86)	11.00 (1.84)	11.00 (2.84)	F(2,39) = 0.712, *p* = .497
Pre State Depression	13.20 (2.91)	12.31 (1.70)	15.64 (5.49)	13.74 (3.91)	F(2,39) = 2.928, *p* = .065
Post State Depression	16.47 (5.58)	15.08 (4.72)	15.86 (7.89)	15.83 (6.10)	F(2,39) = 0.174, *p* = .841
Post 1 State Depression	14.67 (3.50)	16.31 (6.26)	16.50 (7.50)	15.79 (5.85)	F(2,39) = 0.418, *p* = .661
Post 2 State Depression	15.67 (5.12)	16.38 (6.46)	16.29 (7.45)	16.10 (6.23)	F(2,39) = 0.053 *p* = .948

*Pre = measurement at week 2
Post = measurement at week 4 if in 5-Massage group or at week 6 if in 10-Massage group or Control
Post 1= measurement at week 8
Post 2 = measurement at week 10

Table 11

Means (Standard Deviations) and Significance of Trait Anxiety, Anger and Depression

Variable*	10-Massage Group	5-Massage Group	Control	TOTAL	Significance
Pre Trait Anxiety	18.53 (5.42)	16.85 (5.51)	18.50 (5.13)	18.00 (5.28)	$F(2,39) = 0.438$, $p = .649$
Post Trait Anxiety	17.80 (4.90)	15.69 (5.20)	17.43 (6.16)	17.02 (5.39)	$F(2,39) = 0.581$, $p = .564$
Post 1 Trait Anxiety	17.67 (4.97)	16.54 (4.98)	17.64 (6.34)	17.31 (5.36)	$F(2,39) = 0.187$, $p = .830$
Post 2 Trait Anxiety	17.87 (5.28)	17.23 (5.97)	17.64 (6.33)	17.60 (5.72)	$F(2,39) = 0.042$, $p = .959$
Pre Trait Anger	18.40 (5.54)	18.31 (5.09)	16.57 (3.78)	17.76 (4.83)	$F(2,39) = 0.628$, $p = .539$
Post Trait Anger	17.27 (4.42)	16.31 (3.33)	16.21 (3.47)	16.62 (3.74)	$F(2,39) = 0.342$, $p = .713$
Post 1 Trait Anger	17.27 (4.18)	16.77 (4.83)	15.64 (4.11)	16.57 (4.32)	$F(2,39) = 0.519$, $p = .599$
Post 2 Trait Anger	16.93 (4.33)	16.23 (5.09)	15.57 (4.24)	16.26 (4.47)	$F(2,39) = 0.325$, $p = .724$
Pre Trait Depression	16.73 (5.09)	15.62 (4.79)	17.64 (5.42)	16.69 (5.05)	$F(2,39) = 0.531$, $p = .592$
Post Trait Depression	17.07 (5.43)	15.23 (5.05)	17.93 (7.11)	16.79 (5.90)	$F(2,39) = 0.721$, $p = .493$
Post 1 Trait Depression	16.60 (5.12)	15.62 (5.30)	16.57 (6.70)	16.29 (5.62)	$F(2,39) = 0.128$, $p = .880$
Post 2 Trait Depression	17.87 (5.72)	16.54 (7.13)	17.43 (8.00)	17.31 (6.83)	$F(2,39) = 0.129$, $p = .879$

*Pre = measurement at week 2
Post = measurement at week 4 if in 5-Massage group or at week 6 if in 10-Massage group or Control
Post 1= measurement at week 8
Post 2 = measurement at week 10

The cortisol means and standards deviations and ANOVA results are reported in Table 12. There were no group differences at any of the four time points.

Table 12

Cortisol Means (Standard Deviations) and Significance

Variable*	10-Massage Group	5-Massage Group	Control	TOTAL	Significance
Pre Cortisol	12.54 (8.38)	14.14 (7.18)	10.65 (4.79)	12.45 (6.99)	F(2,38) = 0.804, *p* = .455
Post Cortisol	15.37 (5.92)	16.33 (7.11)	14.64 (6.46)	15.44 (6.36)	F(2,38) = 0.223, *p* = .801
Post1 Cortisol	14.35 (6.81)	15.47 (7.42)	12.83 (7.09)	14.22 (7.00)	F(2,38) = 0.455, *p* = .638
Post2 Cortisol	13.44 (7.70)	14.73 (6.60)	11.28 (6.38)	13.16 (6.93)	F(2,38) = 0.817, *p* = .450

*Pre = measurement at week 2
Post = measurement at week 4 if in 5-Massage group or
at week 6 if in 10-Massage group or Control
Post 1= measurement at week 8
Post 2 = measurement at week 10

The expectation question, a dichotomous variable, asked if the participant believed if the massage (or relaxation, if in the control group) would help lower their blood pressure. Over 86% of the participants in the 10-Massage group and 93% of participants in the 5-Massage group responded to the expectation question in the affirmative. Approximately 76% of the Control group believed the relaxation would decrease their blood pressure. The groups did not differ X^2 (4) = 4.616, p = .329.

The Subject Touch Perception Scale is a 6-item semantic differential scale developed by the researcher used to gain a sense of what the participant may be experiencing when receiving the back massage. The groups were similar in their responses to these items. Findings are reported in Table 13. The reliability of this scale was poor (alpha = -.045).

Table 13

The Subject Touch Perception Scale Means (Standard Deviation)

Item	10-Massage Group (n = 15)	5-Massage Group (n = 13)
Soothing / Irritating	1.13 (.352)	1.08 (.277)
Unpleasant/ Pleasant*	1.07 (.258)	1.15 (.376)
Pressure	2.53 (.640)	2.69 (.480)
Rough/ Smooth*	1.20 (.414)	1.38 (.870)
Rhythmic/ Jerky	1.13 (.516)	1.00 (.000)
Relaxing/ Tensing	1.27 (.594)	1.08 (.277)

* indicates items that were reverse scored.

The Subject Perceived Rapport Scale is a 10-item Semantic Differential scale developed by the researcher used to gain a sense of the participant's perceived relationship with the massage therapist/researcher. Findings are reported in Table 14. The reliability of this scale was good (alpha = .83).

The means and standard deviations of the dependent variables of systolic blood pressure and diastolic blood pressure are reported in Table 15. There were no significant differences between groups at any time points of the study.

Table 14

Subject Perceived Rapport Scale Means (Standard Deviation)

Item	10-Massage Group (n = 15)	5-Massage Group (n = 13)
Comfortable/ Uncomfortable	1.20 (.561)	1.00 (.000)
Distrustful/ Trustful *	1.27 (1.03)	1.00 (.000)
Less Anxious/ More Anxious	1.27 (.594)	1.31 (.630)
Calm/Annoyed	1.20 (.561)	1.00 (.000)
Worse/ Better*	1.33 (.617)	1.23 (.599)
Physically Tense/ Physically Relaxed/ *	1.53 (.915)	1.08 (.277)
Willing to share feelings/ Unwilling to share feelings	1.40 (.737)	1.15 (.555)
Unsafe/ Safe *	1.00 (.000)	1.00 (.000)
Respected/ Ignored	1.13 (.516)	1.00 (.000)
Unpleasant/ Pleasant *	1.13 (.516)	1.08 (.277)

* indicates items that were reverse scored

Assumptions

Missing data

All data concerning participant characteristics, and considered for use as covariates, were complete. All other variables that were considered potential covariates in the analysis were assessed for missing data.

Missing data were present on several items in the State Trait Personality Inventory (STPI). The State Trait Personality Inventory consists of 80 items to which the participant responds. Each item was responded to four times during the study. Of the 13,440 (80 items/ inventory x 4 times x 42 participants)

Table 15

Demographics of Dependent Variable Means (Standard Deviations)

Variable	10-MassageGroup (n = 15)	5-Massage Group (n = 13)	Control (n = 14)
Pre Systolic	121.04 (11.32)	118.95 (12.49)	124.19 (10.53)
Post Systolic	119.38 (17.97)	120.79 (13.91)	119.83 (9.35)
Post Systolic1	119.76 (13.09)	122.38 (14.80)	119.43 (8.12)
Post Systolic2	120.73 (15.06)	115.82 (12.80)	118.31 (11.22)
Pre Diastolic	76.91 (7.18)	75.87 (5.59)	75.69 (10.86)
Post Diastolic	76.73 (10.81)	76.51 (6.27)	72.64 (9.41)
Post Diastolic1	77.58 (8.97)	76.82 (8.46)	76.14 (7.18)
Post Diastolic2	76.69 (10.60)	75.31 (7.34)	76.62 (9.07)

*Pre = measurement at week 2
Post = measurement at week 4 if in 5-Massage group or at week 6 if in 10-Massage group or Control
Post 1= measurement at week 8
Post 2 = measurement at week 10
Note: The groups did not differ; all p values were > .05

possible responses in the State Trait Personality Inventory, 10 participants failed to respond to 17 items. The provided instructions for managing missing data were followed for all missing data (Spielberger, unpublished). Briefly, a prorated score was computed by determining a mean score for the subscale from which the item was missing. The value was then multiplied by 10 and rounded to the next highest whole number.

Heart rate data were missing on two participants in the control group at pre-measurement. Three heart rate post-measurements were missing on one participant. These cases were dropped in any analyses that involved heart rates. Salivary cortisol was measured at the four established time points. One case in the control group had missing data at each of the four time points. The case was dropped from any analyses that involved cortisol as a covariate.

There were no missing data from the Subject Touch Perception Scale and the Subject Perceived Rapport Scale data set. The Expectations question, which asked for a "yes" or "no" response, had one missing case in each of the massage groups. These cases were left out of any subsequent analyses. There were no missing data on the dependent variables, systolic and diastolic blood pressures.

Normality and Outliers

There was significant positive skewness in the potential covariates of anxiety, anger, and depression. Figures 5, 6 and 7 depict the means with standard deviations of state anxiety, anger and depression, respectively.

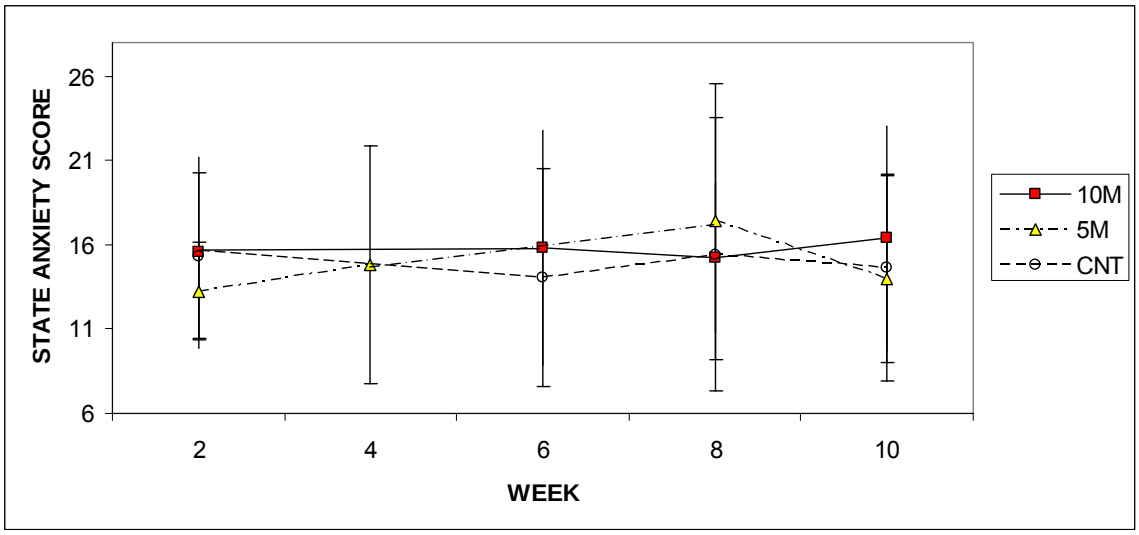

Figure 5: State Anxiety Means and Standard Deviation Bars

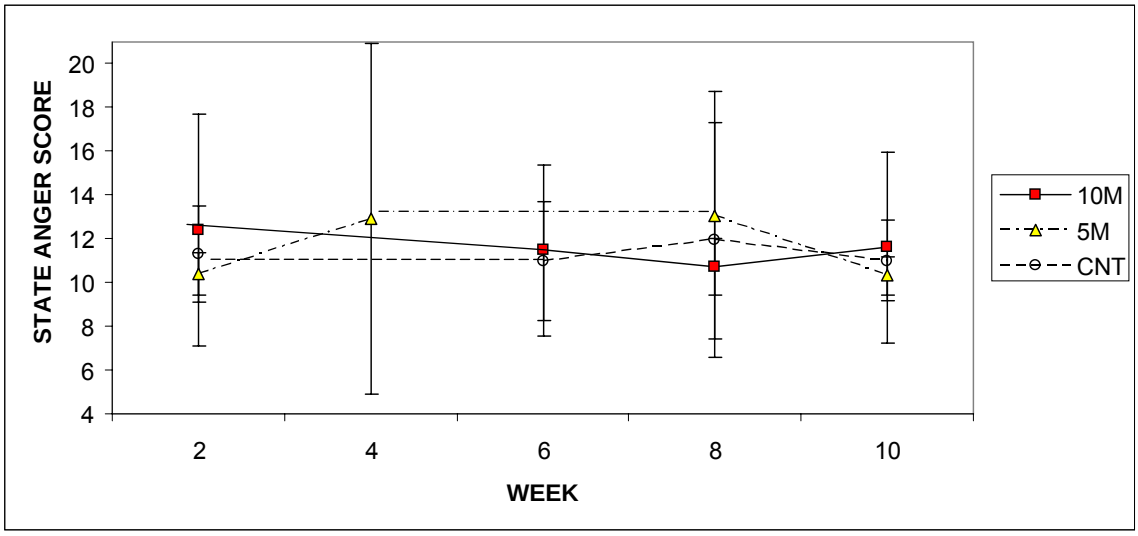

Figure 6: State Anger Means and Standard Deviation Bars

Appendix 14 shows a similar depiction of the means with standard deviation bars for trait anxiety, anger and depression. Of particular interest, preliminary analysis resulted in no difference (effect sizes did not change, error did not decrease) using both the skewed data and the transformed data. Therefore for ease of interpretation, the un-transformed data of anxiety, anger and depression were used in the analysis.

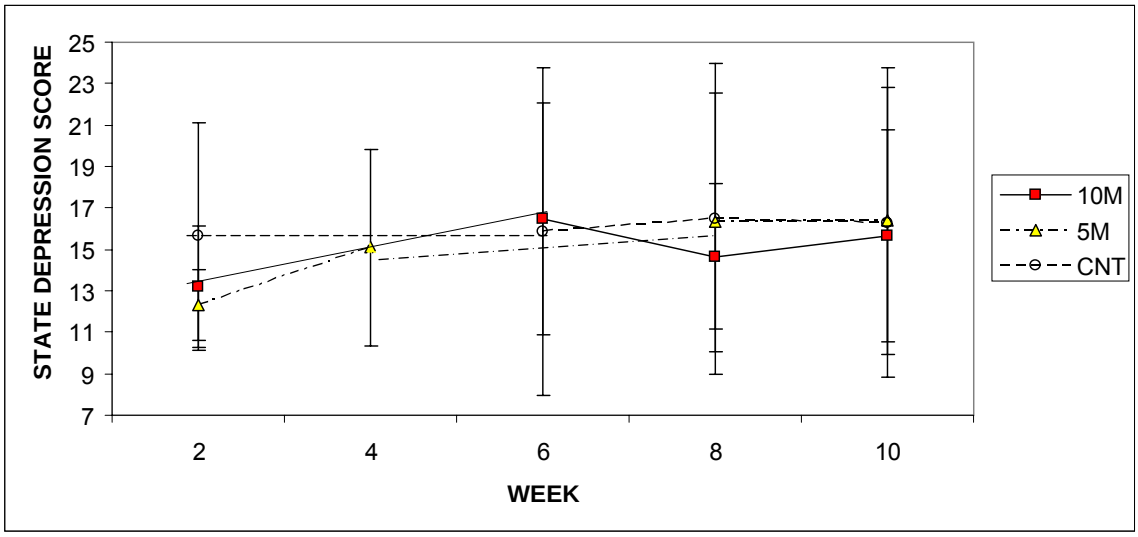

Figure 7: State Depression Means and Standard Deviation Bars

Cortisol data were normally distributed. Figure 7 depicts the means with standard deviation bars for the three groups over time.

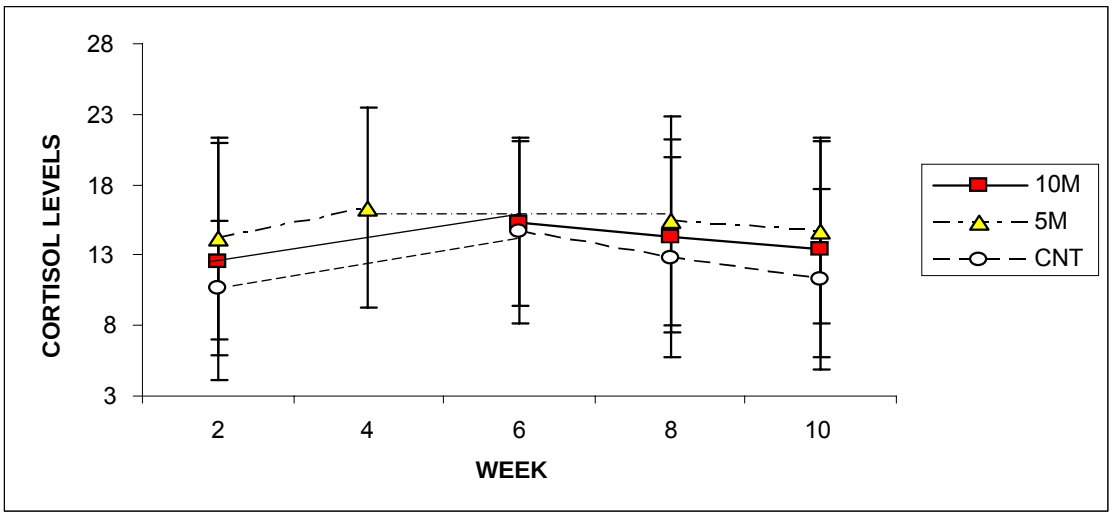

Figure 8: Group Means of Cortisol Levels over Time

Systolic blood pressure and diastolic blood pressure data were normally distributed. See Figures 8 and 9 for group means with standard deviation bars depicting the overlap of the distribution of systolic and diastolic blood pressures.

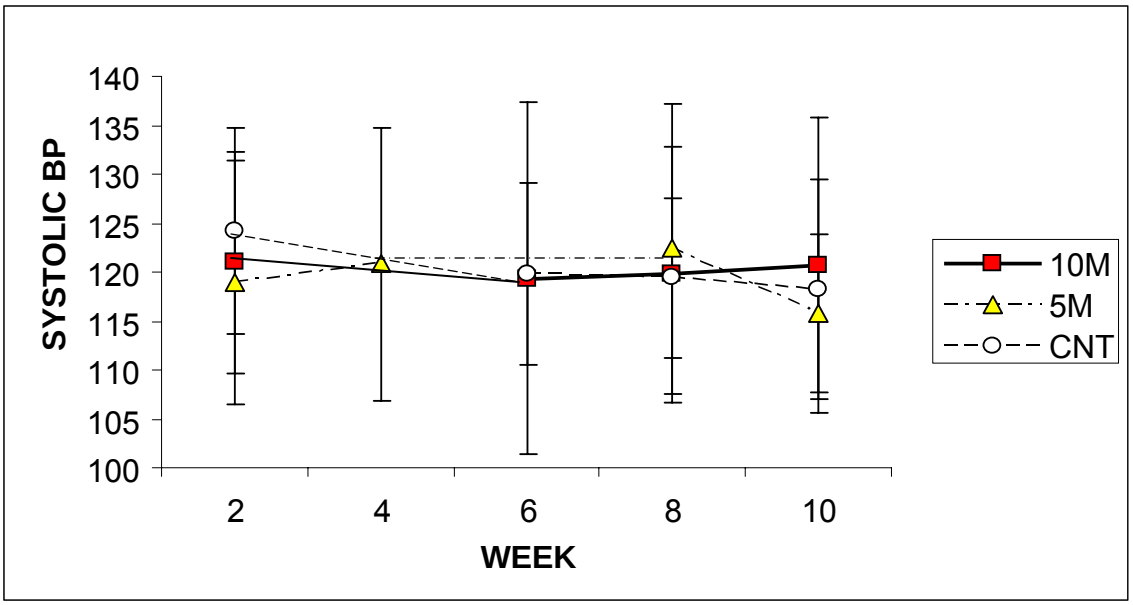

Figure 9 Group Means of Systolic Blood Pressures over Time

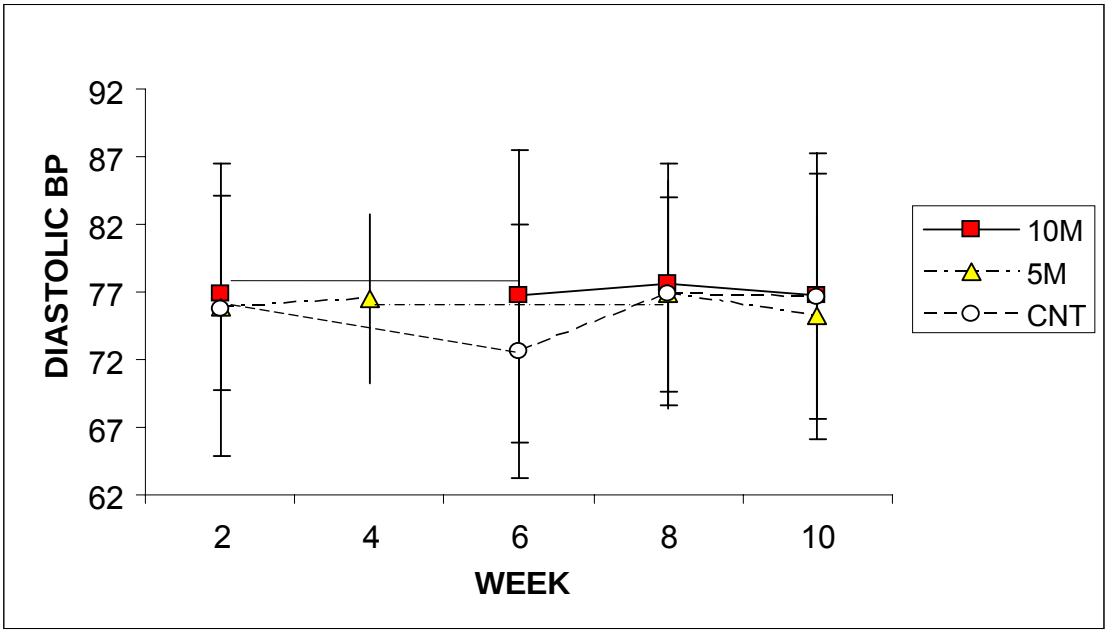

Figure 10 Group Means of Diastolic Blood Pressure over Time

The between group values did not differ at any of the four time points. Specifically, systolic blood pressure at week 2: $F(2, 39) = .721$, $p = .493$; systolic blood pressure at week 10: $F(2, 39) = .484$, $p = .620$; diastolic blood pressure at week 4 & 6: $F(2, 39) = .734$, $p = .487$.

Homogeneity of Variance

The dependent variables were homogeneous in their variances. Systolic blood pressure: Box's M = 28.59, F(20, 5295) = 1.213, p = .232; diastolic blood pressure: Box's M = 34.12, F = (20, 5295) = 1.448, p = .089.

Sphericity

The assumption of sphericity was tested on the dependent variables. The test for sphericity was found to be not significant, thus protecting from Type 1 error.

Homogeneity of Regression Slopes

One of the assumptions using ANCOVA is that there is homogeneity of the regression slopes i.e. the dependent variable-covariate slopes are the same for the three groups. All covariates were tested with both dependent variables for homogeneity of regression slopes. There was significant heterogeneity of regression slopes with the covariate BMI and the systolic blood pressure but not diastolic blood pressure. Table 16 depicts the significant relationship of BMI within the 10-Massage group, F (1, 36) = 5.14, p = .029. The BMI within the 5-Massage group and the BMI within the Control group appear to have flat slopes. All other covariates were tested with the dependent variables and appear to have homogeneity of regression slopes. This means that the covariate-dependent variable slopes are the same for the three groups.

Table 16

Heterogeneity of Variance of BMI and Systolic Blood Pressure

Source of Variance	SS	df	MS	F	P Value
Group	3107.0	2	1553.5	3.38	.045
TBMI within 10-Massage Group	2362.82	1	2362.82	5.14	.029
TBMI within 5-Massage Group	734.35	1	734.35	1.60	.214
TBMI within Control Group	33.31	1	33.31	.07	.789

Note: TBMI is the variable representing body mass index

Correlations

The framework of this study required that the relationship between the dependent variables and the covariates be assessed within the context of time. Therefore the correlation matrices (Appendix 15) were designed to evaluate relationships of dependent and covariates at each of the four measuring time points: pre-randomization (week 2) post-intervention (week 4 for the 5-Massage group or week 6 for the 10-Massage group and Control group), post 1-intervention (week 8) and post 2-intervention (week 10). The following discussion will point out interesting significant relationships at each time point.

Correlations at pre-randomization: pre-systolic and pre-diastolic blood pressures had significant negative correlations with antihypertensive medications ($r = -.438$ and $r = -.348$) respectively. This most likely indicates that the more medications are used, the lower the blood pressure. Antihypertensive medications had a positive correlation with number of years with hypertension

(r = .326) which can be interpreted as the more years diagnosed with hypertension, the more apt to be on medication. The negative relationship between medications and minutes per day of exercise (r = -.415) infer that the more one exercises the fewer medications one is on. The negative correlation between age and minutes per day of exercise (r = -.443) infers the older participants exercised fewer minutes per day. State anger was negatively correlated with age (r = -.319) and positively correlated with state anxiety (r = .703). State depression had positive relations with BMI (r = .354), state anxiety (r = .636) and state anger (r = .393). Trait anxiety related positively to BMI (r = .398), state anxiety (r = .504), state anger (r = .366) and state depression (r = .620). Trait anger was positively related to state anger (r = .362) and trait anxiety (r = .327). Trait depression was positively related to BMI (r = .407), state anxiety (r = .476) state anger(r = .390) state depression (r = .622) and trait anxiety (r = .872). Finally, the biological marker for perceived stress, cortisol, was positively related to trait depression.

The second measurements were done at week 4 for the 5-Massage group and week 6 for the 10-Massage group and the Control group. The correlations changed with any variables that were time sensitive. Systolic and diastolic blood pressures had negative correlations with antihypertensive medications (r = -.422 and r = -.391) respectively. Unlike the pre-randomization there was a positive correlation with systolic and diastolic blood pressures and state anxiety (r = .443 and r = .401) respectively. State anger was positively related to years on medication (r = .367) and state anxiety (r = .779). State depression

relationship at this second measure bore about the same positive relations as the pre-randomization with BMI (r = .374), state anxiety (r = .712) and state anger (r = .429), but not state depression. Trait anxiety compared to pre-randomization was similar with positive relations to BMI (r = .450), state anxiety (r = .420), and state depression (r = .661). Trait anger was positively related to state depression (r = .661).The biological marker for perceived stress is positively related to years on medication which is different from the pre randomization.

The third measurements were done at week 8. Systolic and diastolic blood pressures continued to have negative correlations with antihypertensive medications. State anxiety continued to be positively related to systolic and diastolic blood pressures. State anger had a positive relationship with at this measurement diastolic blood pressure (r = .347), which is different from the previous times. State anger and state anxiety continued to be positively related (r = .839). State depression related to BMI about the same as week 2/4 and related to positively to state anxiety (r = .849) and state anger (r = .833). Trait anxiety continued to be positively related to BMI. Trait anxiety also was positively correlated with all three state anxiety, anger and depression. Trait and state depression were positively related (r = .370). Trait depression had positive correlations with state anxiety(r = .417), state anger(r = .415), state depression (r = .681) and trait anxiety(r = .870) and trait depression(r = .347). There were no correlations with cortisol at week 8. This is interesting in view of the high correlations with depression and the other psychological markers.

The fourth measurements were completed at week 10 of the study. Systolic and diastolic blood pressures continued to be negatively related to the number of medications and positively related to state anxiety. Diastolic blood pressure showed a positive correlation with state anger (r = .406), similar to week eight. State anger and state anxiety continued to be positively related. State depression continued to be positively related to BMI, state anxiety and state anger. Trait anxiety was positively correlated to BMI (r = .46) as well as with state anxiety and state depression but not state anger. Trait anger was different from the previous measurements with positive correlations with BMI, state anxiety, state anger, state depression and trait anxiety. Trait depression correlations were similar to week 8 except there was no significant relationship with state anger. Cortisol had a positive correlation with state anxiety (r = .334) and depression (r = .315).

Between-group variances were assessed on the sample characteristics that were considered potential covariates. As noted earlier, body mass index was the only potential covariate that was found to be significantly different between the groups, rendering adjustment necessary.

Two covariates in particular came into focus as areas of concern. Antihypertensive medications relationship was of concern because of the strong relationship with blood pressures at each time point. Also BMI was of concern because of the great variance between groups. A variable was created to help evaluate the blood pressure change over time and the relationships of these two covariates. A new variable was created and represented the difference scores

between the first and the last blood pressure measurements. Correlations between the two covariates of concern (BMI and antihypertensive medications) and systolic and diastolic pressures change scores, by group, are shown in Tables 17, 18 and 19. In the 10-Massage group there are significant negative correlations between all BMI and the pressure change scores except one (Post 2 diastolic blood pressure – Pre-diastolic blood pressure). Antihypertensive medications did not have a significant correlation with any of the change scores in the 10-Massage group. In the 5-Massage group, antihypertensive medications had a negative correlation with BMI and all but the SYSDIFF (Post Systolic blood pressure – Pre-systolic blood pressure) change scores, none being significant. Further, the BMI correlation with the medications and change scores appear benign. The Control group has significant positive correlations between antihypertensive medications and BMI, antihypertensive medications and DYSDIFF1 (Post1 Diastolic blood pressure – Pre-diastolic blood pressure), and BMI and DYSDIFF1. Perhaps the relationship could be summed up as the data appear to say there is a negative relationship between body mass index and blood pressure in the 10-Massage group, unlike the other two groups. The antihypertensive medication correlation with blood pressure difference scores over the four time points revealed little evidence of a strong systematic relationship.

Scatter plots of the three groups' relationships of BMI and blood pressure difference scores helps to clarify the nature of the relationship. Figures 11, 12

Table 17

Correlations of Antihypertensive Medication, BMI and Blood Pressure Difference Scores: 10-Massage Group.

	AHBP MED	BMI	SYS DIFF	SYS DIFF1	SYS DIFF2	DYS DIFF	DYS DIFF1	DYS DIFF2
AHBP MED		.318	-.360	-.414	-.326	-.266	-.336	-.178
BMI			-.643**	-.639*	-.636*	-.572*	-.588*	-.433
SYS DIFF				.568*	.784**	.816**	.370	.568*
SYS DIFF1					.576*	.378	.829**	.228
SYS DIFF2						.767**	.399	.681**
DYS DIFF							.403	.823**
DYS DIFF1								.290
DYS DIFF2								

* Pearson's Correlation significant at the .05 level (2-tailed).
** Pearson's Correlation significant at the .01 level (2-tailed).
A-HPN = Antihypertensive Medication (angiotensin converting enzyme inhibitors, angiotensin-receptor blockers, calcium channel blockers, beta-blockers, and diuretics)
BMI = Body Mass Index ($705 * Weight/ Height^2$)
SYSDIFF = Post Systolic blood pressure – Pre-systolic blood pressure
SYSDIFF1 = Post1 Systolic blood pressure – Pre-systolic blood pressure
SYSDIFF2 = Post2 Systolic blood pressure – Pre-systolic blood pressure
DYSDIFF = Post Diastolic blood pressure – Pre-diastolic blood pressure
DYSDIFF1 = Post1 Diastolic blood pressure – Pre-diastolic blood pressure
DYSDIFF2 = Post2 Diastolic blood pressure – Pre-diastolic blood pressure

Table 18

Correlations of Antihypertensive Medication, BMI and Blood Pressure Difference Scores: 5-Massage Group.

	AHBP MED	BMI	SYS DIFF	SYS DIFF1	SYS DIFF2	DYS DIFF	DYS DIFF1	DYS DIFF2
AHBP MED		-.444	.138	-.094	-.181	-.196	-.333	-.451
BMI			.004	.163	-.037	.309	.190	.065
SYS DIFF				.080	.489	.634*	.309	.373
SYS DIFF1					.057	.051	.711**	.367
SYS DIFF2						.205	.018	.609*
DYS DIFF							.502	.644*
DYS DIFF1								.626*
DYS DIFF2								

* Pearson's Correlation significant at the .05 level (2-tailed).
** Pearson's Correlation significant at the .01 level (2-tailed).
A-HPN = Antihypertensive Medication (angiotensin converting enzyme inhibitors, angiotensin-receptor blockers, calcium channel blockers, beta-blockers, and diuretics)
BMI = Body Mass Index ($705 * Weight/ Height^2$)
SYSDIFF = Post Systolic blood pressure – Pre-systolic blood pressure
SYSDIFF1 = Post1 Systolic blood pressure – Pre-systolic blood pressure
SYSDIFF2 = Post2 Systolic blood pressure – Pre-systolic blood pressure
DYSDIFF = Post Diastolic blood pressure – Pre-diastolic blood pressure
DYSDIFF1 = Post1 Diastolic blood pressure – Pre-diastolic blood pressure
DYSDIFF2 = Post2 Diastolic blood pressure – Pre-diastolic blood pressure

Table 19

Correlations of Antihypertensive Medication, BMI and Blood Pressure Difference Scores: Control Group.

	AHBP MED	BMI	SYS DIFF	SYS DIFF1	SYS DIFF2	DYS DIFF	DYS DIFF1	DYS DIFF2
AHBP MED		.689**	.074	.400	-.067	.278	.603*	.259
BMI			.299	.463	.136	.225	.583*	.477
SYS DIFF				.660*	.676**	.568*	.394	.418
SYS DIFF1					.579*	.641*	.703**	.735**
SYS DIFF2						.320	.109	.319
DYS DIFF							.763**	.753**
DYS DIFF1								.755**
DYS DIFF2								

* Pearson's Correlation significant at the .05 level (2-tailed).
** Pearson's Correlation significant at the .01 level (2-tailed).
A-HPN = Antihypertensive Medication (angiotensin converting enzyme inhibitors, angiotensin-receptor blockers, calcium channel blockers, beta-blockers, and diuretics)
BMI = Body Mass Index ($705 * Weight/ Height^2$)
SYSDIFF = Post Systolic blood pressure – Pre-systolic blood pressure
SYSDIFF1 = Post1 Systolic blood pressure – Pre-systolic blood pressure
SYSDIFF2 = Post2 Systolic blood pressure – Pre-systolic blood pressure
DYSDIFF = Post Diastolic blood pressure – Pre-diastolic blood pressure
DYSDIFF1 = Post1 Diastolic blood pressure – Pre-diastolic blood pressure
DYSDIFF2 = Post2 Diastolic blood pressure – Pre-diastolic blood pressure

and 13 show the systolic blood pressure difference scores plotted against the BMI. Appendix 16 shows the same plots for diastolic blood pressure change

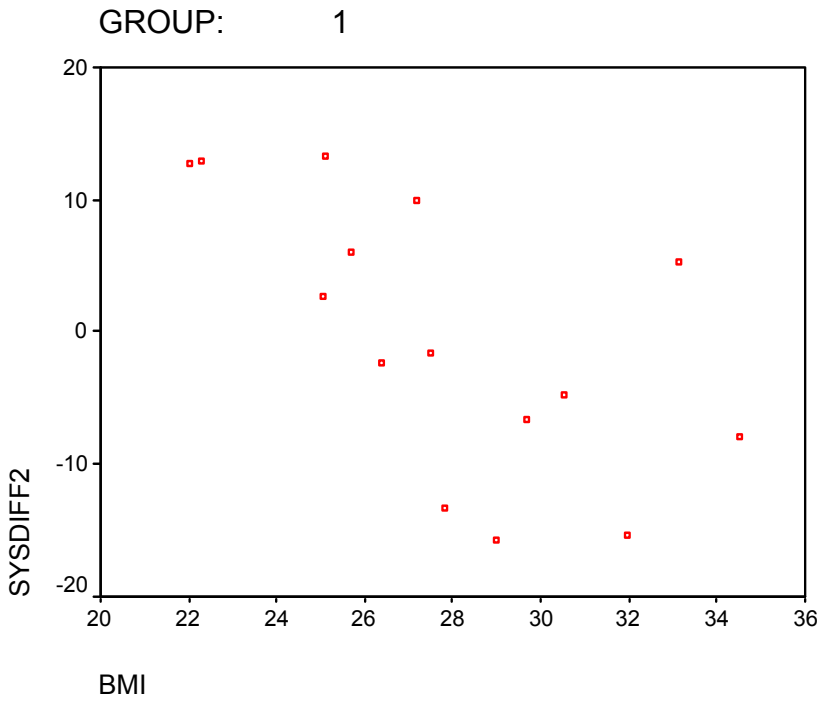

Figure 11: Systolic Blood Pressure Difference and BMI for 10-Massage Group

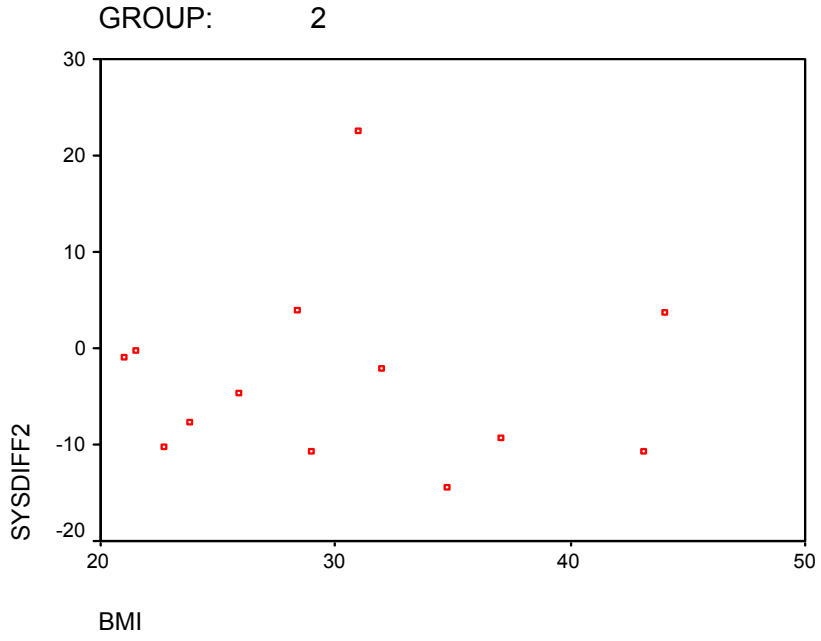

Figure 12: Systolic Blood Pressure Difference and BMI for 5-Massage Group

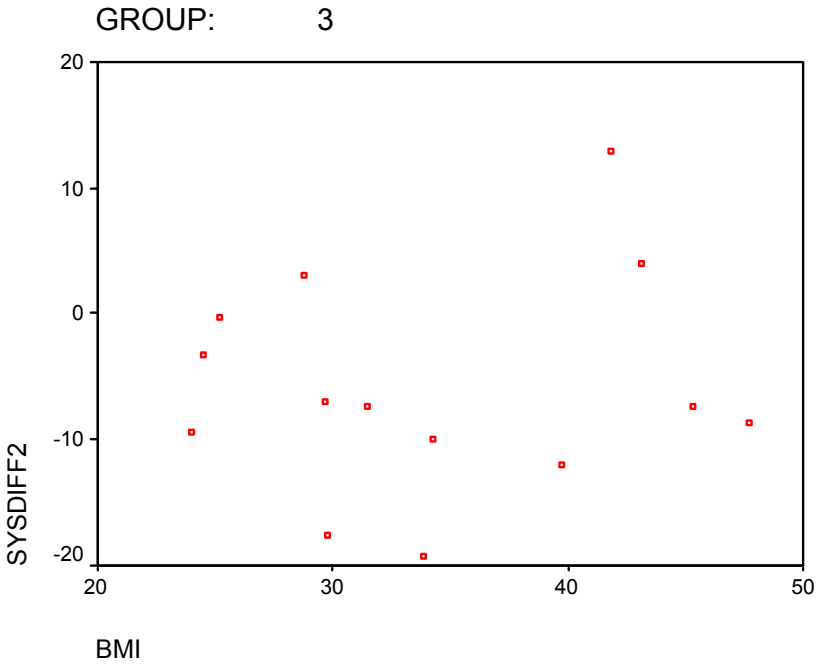

Figure 13: Systolic Blood Pressure Difference and BMI for Control Group scores and BMI. The scatter plots demonstrate a negative slope for systolic blood pressure in the 10-Massage group (Group 1), but not the 5-Masage group (Group 2) and Control group (Group 3). It appears that BMI may be obscuring the relationship of massage and systolic blood pressure. The interpretation might be that for those participants that have a higher BMI the massage routine tended to lower their blood pressure scores and for those persons who were of lower BMI, the massage routine tended to increase their blood pressure. But further analysis is necessary before this or other interpretations can be made. Therefore in Hypothesis 1, analyses were directed to determining the relationship in the context of BMI. With the diastolic blood pressure, the slopes (Appendix 16) in the scatter plots were similar to the systolic blood pressure scatter plots. Appropriate analyses followed in Hypothesis 2.

Hypothesis Testing

Hypothesis 1

The first hypothesis stated that after adjusting for covariates, systolic blood pressure would decrease significantly over time using back massage treatment in subjects with prehypertension and controlled hypertension. When the data were analyzed using an ANOVA without considering any of the covariates, the group x time interactions were not significant $F(6, 117) = 1.38$, $p = .248$. Each covariate with a significant correlation, ($p = .05$), was placed into the analysis, hypothesizing that the covariates would decrease error variance and increase power of the analysis.

The ANCOVA analysis with BMI as a covariate, assuming homogeneity of regression slopes, yielded the same non-significant F-test. Error variance was the same for both ANOVA and ANCOVA tests (MS within + residual = 51.88). The heterogeneity of regression slopes method was then used to determine if adjusting for BMI would decrease the error variance. The test yielded a non-significant group x time interaction, $F(6,108) = 2.08$, $p = .062$.

In the context of the hypothesis in which the study design is expecting to find change over time within the 10-Massage group and 5-Massage group and not the Control group and considering that the interaction was nearly significant, a test for simple main effects was employed. The simple main effect of time for 10-Massage group was significant $F(3, 108) = 3.50$, $p = .018$. Error variance did decrease (MS within + residual = 49.85). No other significant simple main effects

for time were detected (Table 20). The effect size and power of the simple main effects analysis increased from a basic ANOVA with a partial η^2 = .005, power = .083 to partial η^2 = .089, power = .77 when using the heterogeneity slopes method in ANCOVA.

Table 20

Analysis of Covariance of Massage Effects on Systolic Blood Pressure: A Report of Simple Main Effects after Controlling for BMI

Source of Variance	SS (adjusted)*	df	MS	F	P Value
Time within 10-Massage Group	532.70	3	174.57	3.50	.018
Time within 5-Massage Group	12.04	3	4.01	.08	.970
Time with Control Group	145.73	3	48.58	.97	.408
Error					
Within Groups	5383.39	108	49.85		

Note: SME = simple main effects of time. * These tests were based on ANCOVA using heterogeneous slopes adjustment of the covariate BMI.

Further analysis was needed to understand the significant finding in the 10-Massage group, particularly in view of the group means plotted in Figure 9. The scatter plots, Figures 11, 12, and 13, help to conceptualize the significant finding in the 10-Massage group, as the negative slope of the 10-Massage group is visually obvious. The results appear to be obscured by BMI. Therefore a graph was constructed depicting the 10-masssage group data when split at the median of BMI (Figure 14). The heavy line depicts the entire group (n = 15), and appears to have little, if any, slope over time. But when the group is split by the

BMI (Median BMI = 27.48), a variable called “Size”, with “Light” being those with less than a BMI = 27.48 and “Heavy” being those with a BMI equal to or greater than 27.48, the two trends appear very different. Indeed, analysis of BMI x time within the 10-Massage group was significant, $F(3,39) = 5.88$, $p = .002$. Further, a trend analysis was conducted to determine if the slopes were significantly different between the Total and the Light and the Heavy groups. The Total group linear trend was not significant, $F(1, 13) = .02$, $p = .888$ (see heavy line in Figure 14). The size x time trend analysis found significant linear trends $F(1, 13) = 14.08$, $p = .002$. Refer to the upper and lower line on Figure 14. The size x time analysis also yielded nearly significant quadratic effects, $F(1, 13) = 4.37$, $p = .057$. No significant cubic trends were found.

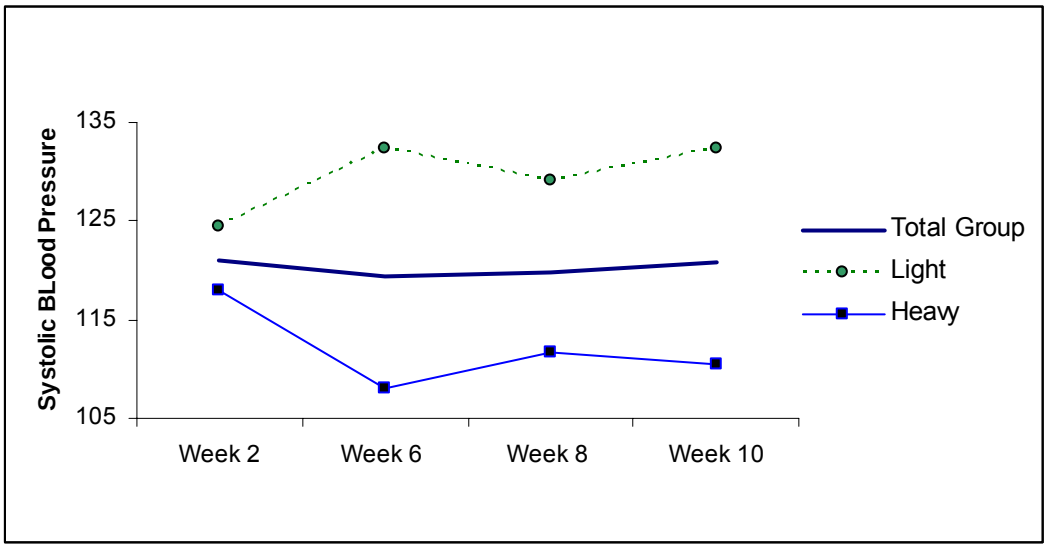

Figure 14: Systolic Blood Pressures over Time, Total Group and Split by BMI: The 10-Massage group

To determine the slope of the Light and Heavy trend lines, further trend analyses were conducted. The linear effect of time in the Light group was

significant F(1, 13) = 7.12, p = .019, (slope coefficient = 4.567) but the quadratic effects was not significant, (F(1, 13) = .93, p = .353 (slope coefficient = -2.261). The linear effect of time in the Heavy group was significant F(1, 13) = 6.97, p = .020, (slope coefficient = -4.229) and the quadratic effect was nearly significant, (F(1, 13) = .4.12, p = .069, (slope coefficient = 4.458). There were no significant cubic effects. Figure 15 depicts the trend lines.

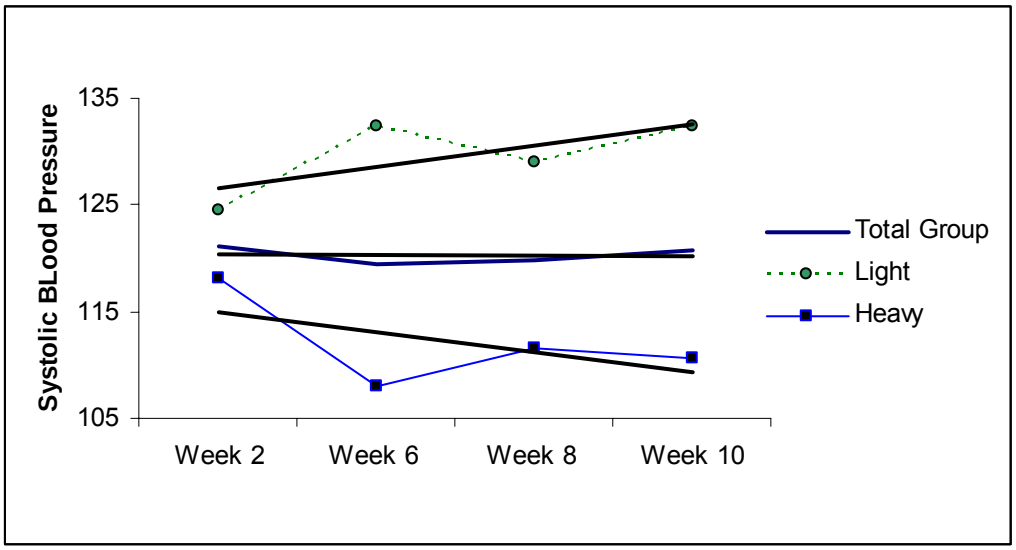

Figure 15: Systolic Blood Pressures over Time, Total Group and Split by BMI with Trend Lines: The 10-Massage group

This hypothesis was partially supported using the heterogeneity of slopes method in ANCOVA (Table 19). The 10-Massage group changed significantly over time whereas the 5-Massage group and the Control group did not change significantly over time in the context of the covariate BMI.

Hypothesis 2

The second hypothesis stated that after adjusting for covariates, diastolic blood pressure would decrease significantly over time using back massage

treatment in subjects with prehypertension and controlled hypertension. This analysis was conducted in the same sequence as the first hypothesis. The data were analyzed using an ANOVA, without considering any of the covariates. The group x time interaction was not significant F(6, 117) = .70, p = .648. An ANCOVA analysis with BMI as the covariate was not significant. Error variance was the same for both tests (MS within + residual = 20.67).

The heterogeneity of regression slopes method was then used to determine if adjusting for BMI would decrease the error variance. The test yielded a non-significant group x time interaction, F(6,108) = 2.02, p = .069. In the context of the hypothesis in which the study design is expecting to find change over time with in the 10-Massage group and 5-Massage and not the Control group and considering that the interaction was nearly significant, a test

Table 21

Analysis of Covariance of Massage Effects on Diastolic Blood Pressure: A Report of Simple Main Effects after Controlling for BMI

Source of Variance	SS (adjusted)*	df	MS	F	P Value
Time within 10-Massage Group	155.61	3	51.87	2.64	.053
Time within 5-Massage Group	23.62	3	7.87	.40	.753
Time with Control Group	85.34	3	28.45	1.45	.233
Error					
Within Groups	2120.57	108	19.63		

Note: SME = simple main effects of time. * These tests were based on ANCOVA using heterogeneous slopes adjustment of the covariate BMI.

for simple main effects was employed. The simple main effect of time for the 10-Massage group was nearly significant F(3, 108) = 2.64, p = .053. Error variance did decrease (MS within + residual = 19.63). No other significant simple main effects for time were detected (Table 21). The effect size and power of the simple main effects analysis increased from a basic ANOVA with a partial η^2 = .003, power = .072 to partial η^2 = .068, power = .63 when using the heterogeneity of regression slopes method in ANCOVA.

In view of the scatter plots in Table 16, the nearly significant simple main effects, further analysis was conducted to determine if there was a similar obscuring of effects by BMI with diastolic blood pressure. As in Hypothesis 1, a graph was constructed depicting the 10-masssage group data when split at the median of BMI (Figure 16). The heavy line depicts the entire group (n = 15), and appears to have little, if any, slope over time. But when the group is split by the BMI (Median BMI = 27.48) with “Light” being those with less than a BMI = 27.48 and “Heavy” being those with a BMI equal to or greater than 27.48, the two lines appear very different. Indeed, analysis of BMI x Time within the 10-Massage group interaction was significant, F(3, 39) = 4.32, p = .010. Further, a trend analysis was conducted to determine if the slopes were significantly different between the Total and the Light and the Heavy groups. The Total group linear trend was not significant, F(1, 13) = .05, p = .824 (see heavy line in Figure 16). The size x time trend analysis found significant linear trends F(1, 13) = 6.80, p = .022. Refer to the upper and lower line on Figure 16. The size x time analysis

also yielded significant quadratic effects, F(1, 13) = 7.01, p = .020. No significant cubic trends were found.

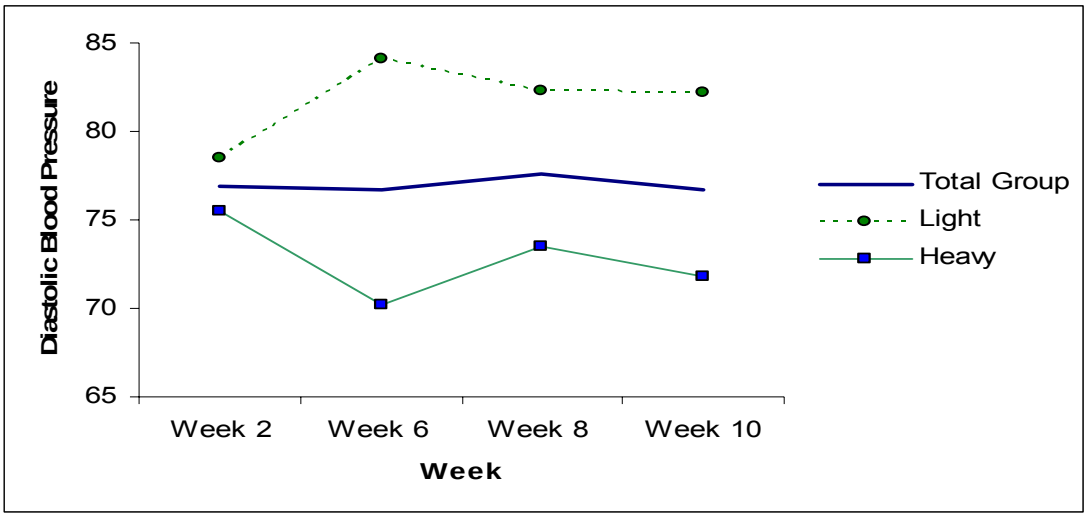

Figure 16: Diastolic Blood Pressures over Time, Total Group and Split by BMI: 10-Massage group

To determine further the slope of the Light and Heavy trend lines, further trend analyses was conducted. The linear effects of the Light group were not significant F(1, 13) = 3.77, p = .0749, (slope coefficient = 2.108) but the quadratic

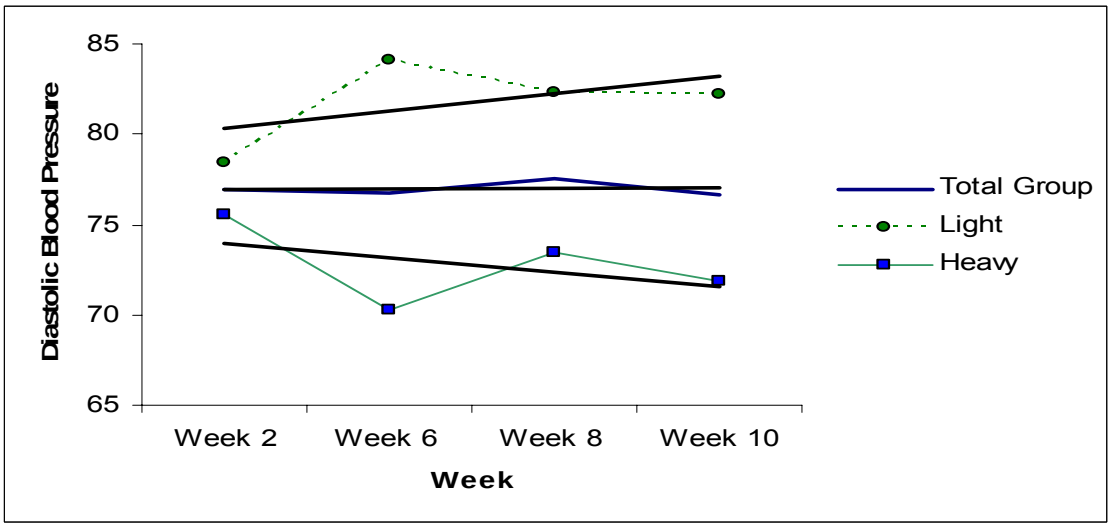

Figure 17: Diastolic Blood Pressures over Time, Total Group and Split by BMI with Trend lines:10-Massage group

effects were significant, (F(1, 13) = 4.88, p = .046 (slope coefficient = -2.857). The linear effects of the Heavy group were not significant F(1, 13) = 3.03, p = .105, (slope coefficient = -1.770) and the quadratic effects were not significant. There were no significant cubic effects. Figure 17 depicts the trend lines.

This hypothesis was not supported using the heterogeneity of slopes method in ANCOVA (Table 20). The 10-Massage group did show trends towards effectiveness in that the participants of the Heavy group had a significant decreasing trend in their diastolic blood pressure over time.

Hypothesis 3

Hypothesis 3 stated that after adjusting for covariates, there would be a significant difference in systolic blood pressure changes using 10 applications of back massage versus five applications of back massage in subjects with pre-hypertension and controlled hypertension. This hypothesis requires a test of interaction between group and time. Contrast statements were designed to compare the effectiveness of the 10-Massage group to the 5-Massage group over time. This group by time interaction was not significant, F (6, 117) = 1.33, p = .248, partial η^2 = .064, power = .505.

A detailed trend analysis was conducted to detect if there were differences in the linear and quadratic effects over time between the two massage groups. The group x time linear effects was not significant, F(2, 39) = 1.43, p= .252. The quadratic group by time effects were significant, F(2,39) = 3.27, p = .048. Further, linear effects contrasting the 5-Massge group

to the 10-Massage group were not significant F(1, 39) = .47, p = .498, but the quadratic effect for this contrast was significant F(1, 39) = 4.82, p = .034. This indicates that the shape of the trend lines for the 10-Massage group and the 5-Massage group are not the same.

Hypothesis 4

Hypothesis 4 stated that after adjusting for covariates, there would be a significant difference in diastolic blood pressure changes using 10 applications of back massage versus five applications of back massage in subjects with pre-hypertension and controlled hypertension. This hypothesis requires a test of interaction between group and time. Contrast statements were designed to compare the effectiveness of the 10-Massage group to the 5-Massage group over time. The group x time interaction was not significant, F (6, 117) = .70, p = .648, partial η^2 = .0354, power = .270.

A detailed trend analysis was performed to detect if there were differences in the linear and quadratic effects over time between the two massage groups. The group by time linear effect was not significant, F(2, 39) = .51, p = .603. The quadratic group by time effect was not significant, F(2,39) = 1.45, p = .246.

Hypothesis 5

Hypothesis 5 stated that there would be a significant change over time in reclining blood pressures compared to sitting blood pressures in the subjects with prehypertension and controlled hypertension in the back massage treatment

Table 22

Laying and Sitting Blood Pressure Group Means (Standard Deviations)

Variable at 4 Time Points*	Group1 (n = 15)	Group2 (n = 13)	Control (n = 14)	Total Group (n = 42)	Group differences p-values
1 Lying SBP	118.60 (10.97)	122.08 (12.81)	121.79 (10.92)	120.74 (11.38)	.672
1 Sitting SBP	120.47 (10.90)	119.54 (13.48)	127.79 (10.16)	122.62 (11.84)	.947
2 Lying SBP	117.27 (16.02)	118.62 (14.83)	119.00 (13.43)	118.26 (14.49)	.935
2 Sitting SBP	120.27 (18.38)	121.92 (11.42)	121.57 (9.70)	121.21 (13.56)	.916
3 Lying SBP	118.67 (12.00)	120.23 (18.90)	118.21 (13.57)	119.00 (14.59)	.132
3 Sitting SBP	120.93 (11.25)	126.15 (17.71)	121.57 (11.37)	122.76 (13.47)	.945
4 Lying SBP	118.40 (14.19)	118.23 (13.06)	120.21 (14.06)	118.95 (13.5)	.557
4 Sitting SBP	122.33 (14.59)	118.38 (11.92)	122.14 (14.71)	121.05 (13.65)	.708
1 Lying DBP	72.33 (6.31)	72.85 (6.39)	70.93 (10.66)	72.02 (7.89)	.812
1 Sitting DBP	78.87 (6.97)	75.62 (6.08)	77.50 (11.74)	77.40 (8.54)	.688
2 Lying DBP	71.73 (9.44)	72.38 (5.04)	69.86 (8.25)	71.31 (7.79)	.469
2 Sitting DBP	75.73 (9.05)	76.77 (6.77)	76.29 (9.44)	76.24 (8.36)	.974
3 Lying DBP	73.80 (8.32)	71.46 (11.18)	69.79 (6.29)	71.74 (8.70)	.614
3 Sitting DBP	78.40 (9.82)	74.15 (10.79)	76.86 (7.78)	76.57 (9.45)	.950
4 Lying DBP	71.60 (8.13)	71.23 (7.38)	70.93 (8.19)	71.26 (7.7)	.502
4 Sitting DBP	75.47 (8.70)	75.08 (9.49)	76.21 (8.27)	75.60 (8.61)	.943

*1 = pre randomization
2 = first post measure (at week 4 for the 5-Massage group and Week 6 for the 10-Massage group)
3= second post measure at week 8
4 = third post measure at week 10.

Systolic lying & sitting blood pressure changes over time.

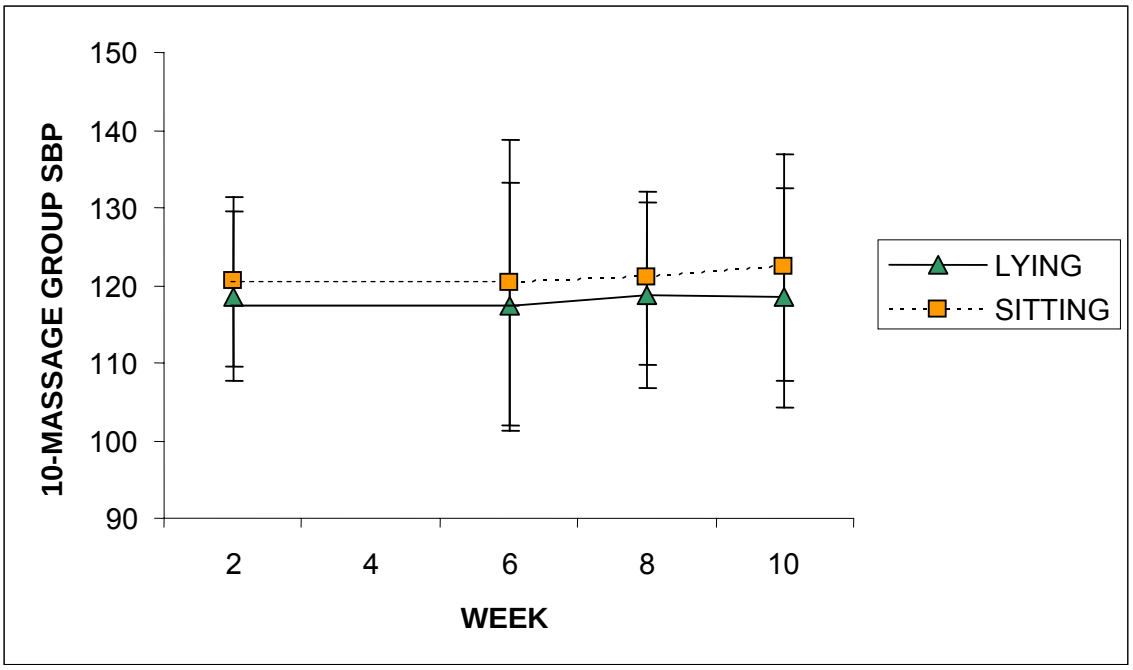

Figure 18: 10-Massage Group Lying & Sitting Systolic Blood Pressure Relationship

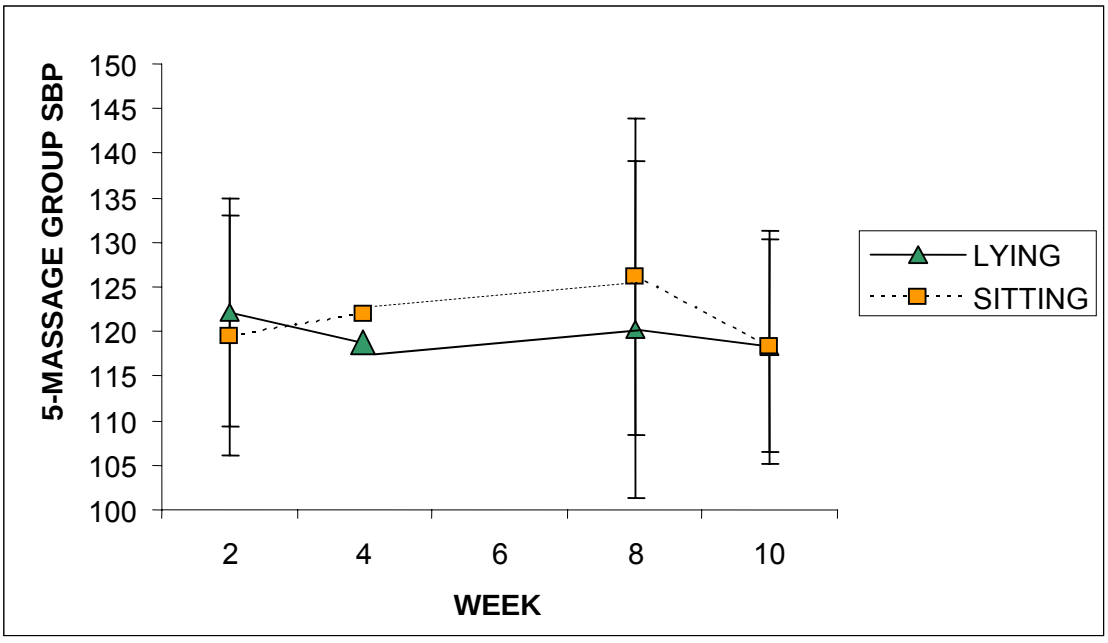

Figure 19: 5-Massage Group Lying & Sitting Systolic Blood Pressure Relationship

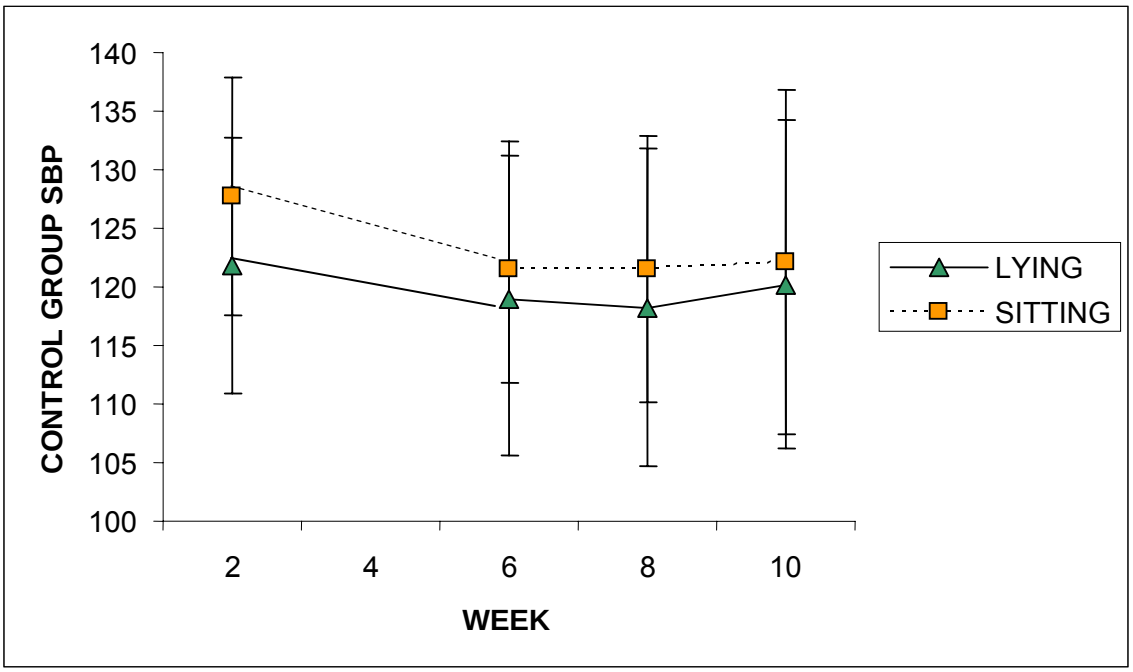

Figure 20: Control Group Lying & Sitting Systolic Blood Pressure Relationship

Diastolic lying & sitting blood pressure changes over time.

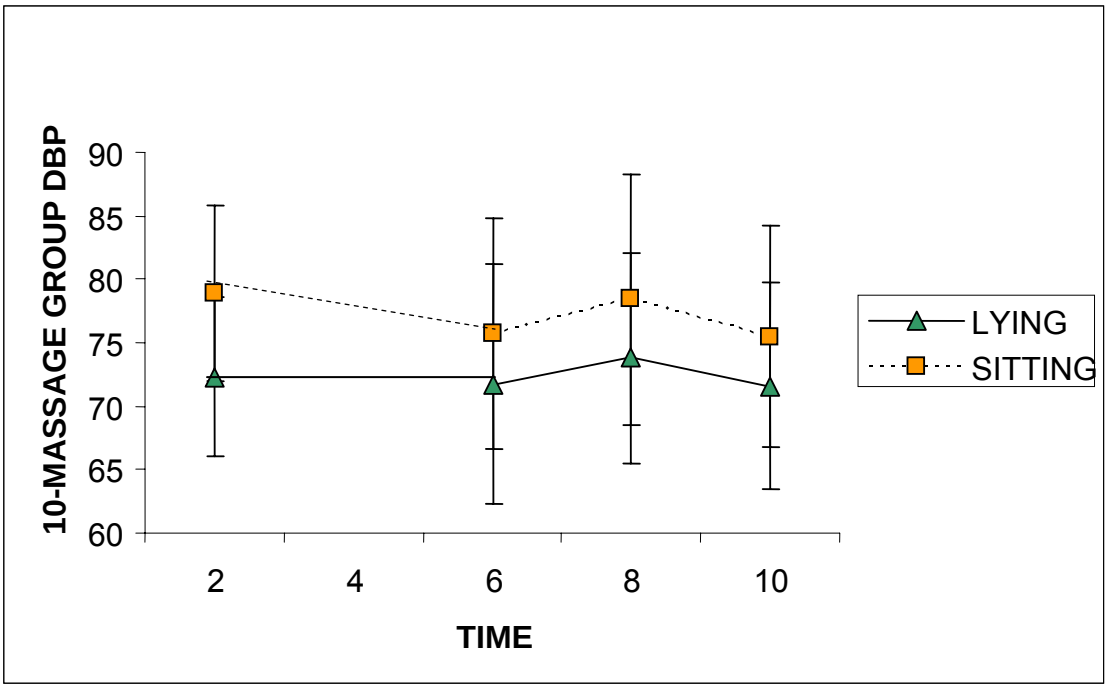

Figure 21: 10-Massage Group Lying & Sitting Diastolic Blood Pressure Relationship

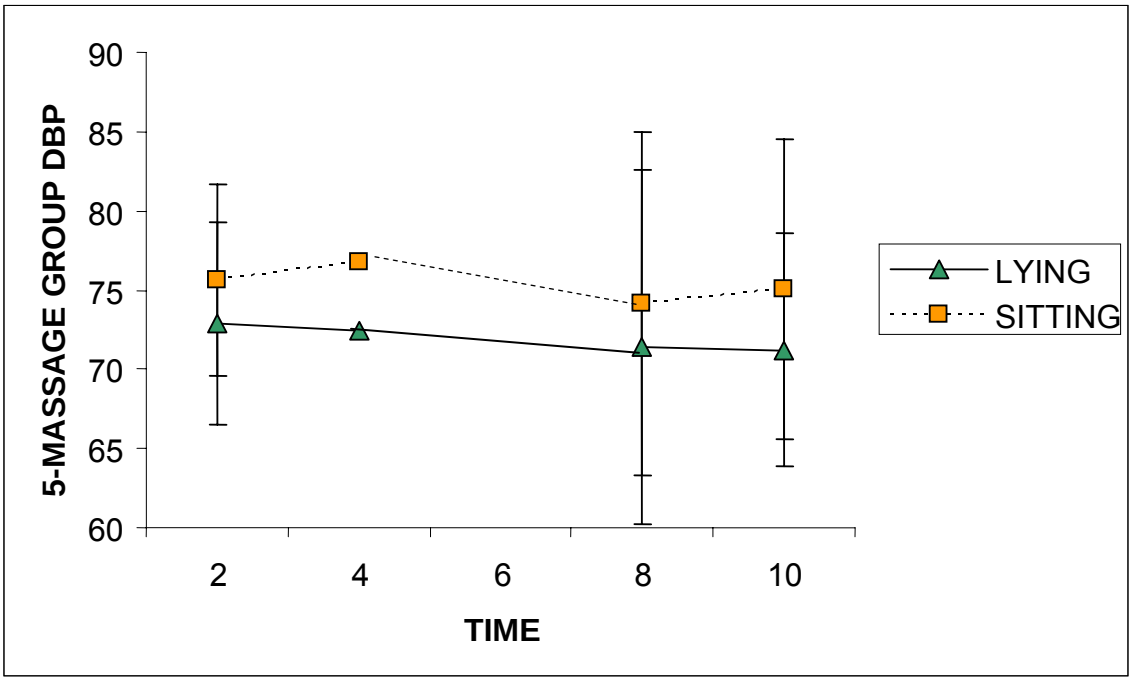

Figure 22: 5-Massage Group Lying & Sitting Diastolic Blood Pressure Relationship

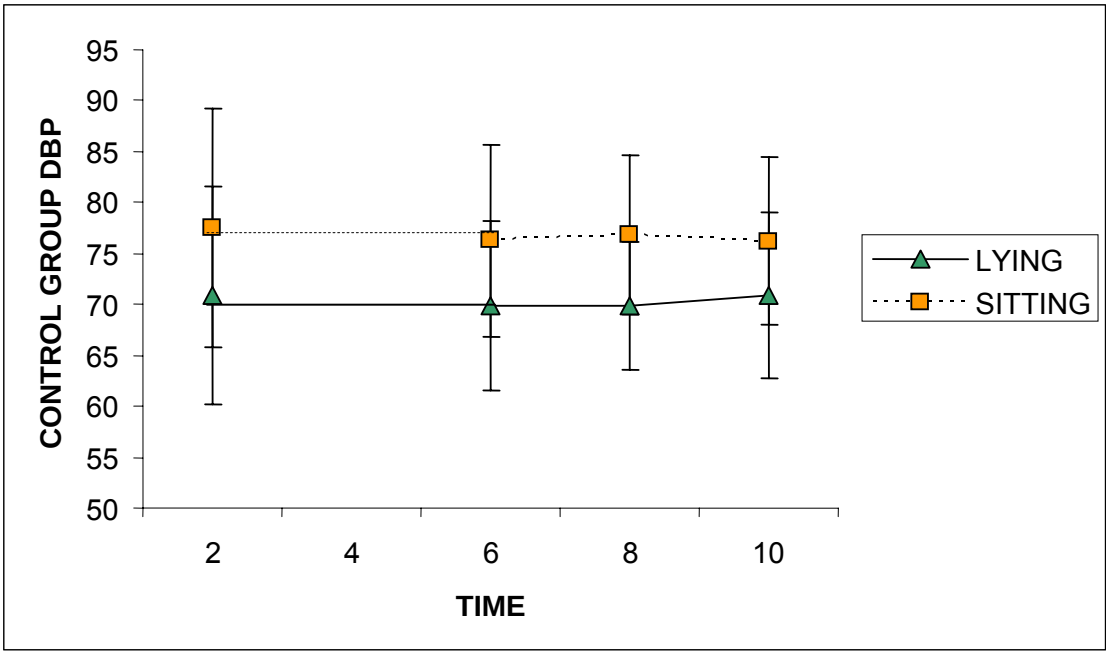

Figure 23: Control Group Lying & Sitting Diastolic Blood Pressure Relationship

group of 10 applications when compared to the control group. The group means for systolic and diastolic blood pressures, lying and sitting, are shown in Table 20. There were no significant differences between groups at any time point. Further, a visual depiction of each group's systolic and diastolic blood pressures, sitting and lying, with standard deviation bars are further depicted in Figures 18 through 23.

Correlation matrices were calculated to view the strength of the relationship between the lying to sitting changes and two covariates in particular. The two covariates, considered for separate reasons. BMI was considered because of its previously established relationship in the previous analysis. Antihypertensive medications (including diuretics) were considered because of their effect on blood pressure. Medications can often cause orthostatic hypotension. Variables depicting the mean change in blood pressure at each time point were established. The matrices are depicted in Appendix 17. As seen in the matrices, when considering groups together, there is a significant correlation between diastolic blood pressure at time 1 (BARO5) and antihypertensive medications (r = .358). Further, the 5-Massage group was the group that reflected this significant correlation with diastolic blood pressure lying to sitting change with medications (r = .598). The analysis therefore was run using the covariate antihypertensive medications.

Analysis of variance was conducted to determine the effect of time on lying to sitting differences in systolic blood pressure for each group. There were no significant findings over time. Analysis of variance was conducted to

determine the effect of position by time on lying to sitting differences in systolic blood pressure for each group. Position X time appears to make a difference with a significant interaction in the 5-Massage group, F (3,117) = 2.77, p = .045, partial η^2 = .066, power = .657 (Table 23). Figure 19 depicts the interaction, thus the significant change, in lying to sitting blood pressure over time for the 5-Massage group. No other significant effects were found in systolic blood pressure lying to sitting differences. Analyses of covariance using BMI and antihypertensive medications as covariates were conducted. Neither medications nor BMI changed the error variance of the analysis.

Table 23

Lying to Sitting Change in Systolic Blood Pressure: Simple Main Effects of Position by Time within Group

Source of Variance	SS	df	MS	F	P Value
Position X Time within 10-Massage Group	18.57	3	6.19	.19	.900
Position X Time within 5-Massage Group	265.03	3	88.34	2.77	.045
Position X Time within 10-Massage Group	67.18	3	22.39	.70	.552
Error					
Within Group	3727.35	117	31.86		

Analysis of variance was conducted to determine the lying to sitting differences in diastolic blood pressure for each group. A significant effect for position was found in all three groups (Table 24). Figures 21, 22, and 23 depict that significant gap between the lying and sitting positions at each time point,

visually supporting this finding. No significant effects for group or group by time by position were found with the diastolic blood pressure comparisons. Analyses of covariance using BMI and antihypertensive medications as covariates were conducted. Neither covariates changed the error variance of the analysis.

Table 24

Lying to Sitting Change in Diastolic Blood Pressure: Simple Main Effects of Position within Group

Source of Variance	SS	df	MS	F	P Value
Position within 10-Massage Group	676.88	1	676.88	14.67	.000
Position within 5-Massage Group	304.65	1	304.65	6.06	.014
Position within Control Group	1125.22	1	1125.22	24.39	.000
Error					
Within Groups	1799.50	39	46.13		

Overall, the analyses do not support the hypothesis of significant differences between the 10-massage group and the control group for baroreceptor response changes over time.

Additional Analyses of Interest

Expectations

The expectation question, a dichotomous response of “yes” or “no”, did not appear to have a relationship with the change in systolic blood pressure changes, t (36) = .988, p = .330, or diastolic blood pressure changes t (36) = -.336, p = .717.

Chapter Five

Discussion

Nursing has a long history using massage, particularly back massage, as a comfort measure for their patients. The knowledge generated regarding the efficacy of massage comes mostly from the nursing literature. However, today massage is usually considered an alternative or complementary therapy rather than a conventional nursing therapy. The general population has embraced it as one of the many alternative non-pharmaceutical treatments for a number of disease processes, including heart disease and hypertension. The efficacy of massage for treatment of persons with pre-hypertension and hypertension is not yet established. Therefore, with the safety of the public in mind, the current study proposed to determine if there are long term effects of massage. The study also compared two dosages of massage for their impact on systolic and diastolic blood pressure and tested for change in baroreceptor response in persons receiving massage treatments.

The study used a 3-group randomized clinical trial design. The sample consisted of 42 adults, (62% female, 86% Caucasian) predominantly from a southwest central United States university setting. The mean age for the total sample was 48.7 years (range 26 to 70 years) and the mean length of time reported to be living with hypertension was 6.1years. The participants in this study exercised, on average, 24 minutes per day. Exercise included walking,

jogging, weight lifting, and aerobic sports. The study sample was obese with a BMI greater than 30, on average. More than half (57%) of the study sample drank alcohol at least occasionally. Most (90.5%) did not smoke cigarettes at the time of the study. Two subjects, older than 70 years of age, were screened for mental capacity (MMSE), each scoring the maximum (30) on the exam.

A majority of the participants believed that participating in this study would impact their blood pressure. Considering the positive expectation, the voluntary nature and willingness of participation, adherence to the study protocol remained tasking for the participants. The study protocol requested participants to visit the research office for 30 minutes, three times per week, totaling 13 or 18 visits, depending on the group to which the participant was randomized. Although only twelve of the 355 treatment (massage and relaxation) sessions were missed and not rescheduled, compliance to the schedule was a challenge for most participants. The average time between visits was greater than the planned 2.3 days. Even though it was difficult for participants to adhere to the regularity of three times per week visits, most were able to stick to the daily allotted 30 minute time slot for their treatments. For example if participant #1 was scheduled for 3 pm, she came on time at 3 pm each visit. Rarely did the treatment times deviate from the schedule.

To achieve a sense of long-term effects of changes in blood pressure due to the back massage, the study was set up so that blood pressures were measured four times during the study: prior to randomization to group (week 2), at the completion of the treatment sessions (week 4 for the 5-Massage group and

week 6 for the 10-Massage group and the Control group), again at week 8 of the study and again at week 10 of the study. The second measurement was planned to take place 48 hours after the last treatment. In reality, this appointment in which the initial effects of massage on blood pressure were to be measured was more than 48 hours but less than 72 hours on average after the last treatment.

In respect to timeliness, however, all participants were able to be present within 30 minutes of the scheduled time for the four data gathering appointments. This was important for the fidelity of the study in that the variables with circadian cycles could be comparable over time.

Although a power analysis was done *a priori* based on effect sizes of a previous study, (Olney, 2005) the analysis showed no significant main effects. However, after adjusting for the BMI heterogeneity of regression slope, the analysis yielded significant simple main effects in the 10-massage group over time. This analysis suggested that giving regular ten-minute back massages over approximately 3.5 weeks, is related to a significant decrease in systolic blood pressure, but is limited to persons with a BMI greater than 27.48 kg/m^2. The long term effect of the back massages routine was four weeks after the back massages were discontinued.

The diastolic blood pressure analysis indicated no significant main effects. Because of the influence of body mass index on systolic blood pressure in the 10-Massage group, a follow up trend analysis was conducted and did reveal significant diastolic blood pressure slope differences between the heavier (BMI

equal to or greater than 27.48 kg/m^2) and the lighter (BMI less than 27.48 kg/m^2) participants within the 10-Massage group.

This is the first study known to the principle investigator designed to analyze long term effects of back massage. The literature has suggested that one back massage can elicit short term (usually measured within 15 minutes after end of massage) decreases in both systolic and diastolic blood pressure (e. g. Cady, & Jones, 1997; McNamara, Burnham, Smith & Carroll 2003). In the majority of massage studies, the blood pressure is measured just prior to the massage and just after the massage. In other reported studies, when the massage is repeated for several days the significant effects were calculated with each massage session (Aourell, Skoog, & Carleson, 2005; Ferrell-Torry & Glick, 1993; Holland & Pokorny, 2001). Hernandez-Reif and colleagues (2000) have applied massage for 30 minutes, three times a week and this resulted in diastolic blood pressure changes over time. Mok and Woo (2004) found significant systolic and diastolic changes, applying a 10-minute back massage for seven evenings and measuring pre and post intervention at day 1, day 7 and three days after stopping the application. Although it is unclear which blood pressure measures (pre-intervention or post intervention or all) they used in their repeated measures analysis, this is the best comparison for the current study, supporting changes over time. Unfortunately, Mok and Woo's study did not discuss BMI. Mok and Woo did measure for effects of age and gender, finding none. The Moyer, Rounds and Hannum (2004) meta-analysis suggested that testing of the long term effects as one of the necessary questions to further the science.

Summarizing, the results of the current study imply that there may be beneficial effects on systolic and diastolic blood pressure in persons of higher BMI (greater than or equal to 27.48 kg/m^2).

The randomization process appears to have equalized all of the potential covariates other than BMI. This study sample was small (n=42). Perhaps a larger, randomized sample would equalize the BMI thus allowing for a better sense of the weight issue. A larger sample would also decrease the possibility of a Type I error.

Dosage of massage is another recommended area of research suggested by numerous studies including the Moyer and colleague meta-analysis (Moyer, Rounds, & Hannum, 2004). The current study evaluated if giving 5 back massages could be as effective as 10 back massages for lowering systolic and diastolic blood pressure. However, in the current study main effect of group by time interaction for dosage was not significant thus recommendations for an appropriate prescription can not be made at this time.

Baroreceptor response can be measured by comparing the lying blood pressure to the sitting upright blood pressure. In this study, systolic and diastolic blood pressure were measured in the lying position and then again immediately upon sitting upright. The current study attempted to establish baroreceptor response as the mechanism that could explain why back massage may have influenced the long term blood pressure.

It was hypothesized that by inducing a therapeutic level of relaxation (repeated experiences of lowered blood pressure) the baroreceptor firing

threshold would be re-set to a healthier level. This resetting to a healthier level would be manifested by a narrower gap between lying and sitting blood pressures. When viewing the position dependent systolic pressure changes over time for each group in Figures 18, 19 and 20, the group that most closely resembles the expectation is the control group (Figure 20). When viewing the position dependent diastolic pressure changes over time for each group in Figures 21, 22, and 23, the group that most closely resembles the expectation is the 10-massage group (Figure 21). The analysis determined the changes were not significant.

Additional Discussion

The intimacy of massage demands that researchers begin to measure the relationship between the massage therapist and the one receiving the massage. This study did measure two concepts to further the understanding of touch perception and perceived rapport for those experiencing the massage. However, the therapist was constant across all participants in this study therefore the findings are not generalizable to other therapists-patient relationships.

To gain a sense of what the participant may be experiencing when receiving the back massage, a Subject Touch Perception Scale was developed. This semantic differential-like scale listed opposing pairs of each characteristic of the massage. The reliability test on the six items used to describe the perception of touch was very poor. Removal of all items but the ‘smooth’ and ‘relaxing’ items from the reliabilities test yielded a higher alpha = .5722. Thus it appears that this instrument needs further development. Keeping the reliabilities issue in

mind, for the purposes of beginning the discussion on perception of touch the following summary of the data is presented. Overall, the massage was perceived as soothing, pleasant, smooth, rhythmic and relaxing. All but the pressure items were scaled such that a score of 1 was perceived as a more positive experience. Mean group scores ranged from 1.00 (example: rhythmic) to 1.27 (example: relaxing) indicating that the perception of the massage touch on these five items was a positive experience for the participants. The pressure-item on this scale interpreted differently from the other five items. Pressure was scaled from too soft (1.00) to too hard (5.00). Thus the resulting score of 3.00 may be interpreted by the participant as "just right". Both groups felt the pressure of the massage was a bit on the soft side with the mean scores for the 10-massage group (2.53) and 5-massage group (2.69).

These data are supported by the verbal requests by several participants to use more pressure. Due to the nature of the study, the researcher explained to the participant the same pressure must be used on all subjects. The implication here may be that response is determined by pressure. For instance, maybe some participants needed a deeper pressure to achieve a "relaxation response". This is clearly an area for future research.

Beyond the touch perception results, anecdotally, there were several comments made by participants about the sound of the massage. Usually there was little sound elicited by the massage strokes using oil. However, on several participants, the massage strokes elicited a loud friction sound when the back was covered by body hair or a suction sound when the back was hair free. In

these particular cases the participants stated that the sound prevented them from truly relaxing.

Touch perception is a phenomenon which has been measured and reported in populations of abused persons. However, measuring the perception of touch in massage research is relatively new. This researcher did not find a developed instrument that measured touch perception from a non-abusive framework. Therefore, the development of an instrument would be helpful to massage researchers when attempting to determine the effects of massage.

The experienced relationship with the massage therapist is of interest to researchers who evaluate the effects of massage (Moyer, Hanum, & Rounds, 2004). To gain a sense of the participant's perceived relationship with the massage therapist a perceived rapport scale was developed. This semantic differential-like scale listed 10 opposing characteristics of what the participant may have been experiencing. A score of 1 related to a more positive experience whereas a score of 5 related to a more negative experience. Scores for the two groups ranged from 1.00 (example: safe) to 1.53 (example: physically relaxed). The two groups were not different in their perception and the participants felt positive about their relationship with the massage therapist.

This information is not as useful as the researcher had hypothesized. The variance was insignificant to determine if there is any influence on the variables being measured in this study. A larger scale, with 10 rather than 5 levels of response may have generated a greater contrast among responses. Content and concurrent validity would add to its interpretability. Also measuring the

control group for their interpretation of the relationship may have added to this analysis. Theoretically, development a valid instrument would be beneficial in future massage research, as it would help explain more of the variance found in the research analysis.

Study Limitations

This study was underpowered for the analyses of diastolic pressure and baroreceptor. The original power analysis was based upon the researcher's pilot work (Olney, 2005). A larger sample would increase the power and better reflect dosage comparison.

This study was conducted on a university campus which is not necessarily reflective of the general hypertensive population. Therefore caution is advised to not generalize these findings beyond like populations.

The participants' characteristics were self-reported. Items such as weight and height, minutes per day of exercise, years on diagnosed with hypertension and years on medications were subject to the participants ability to recall correctly and report accurately the requested data. Therefore it is possible that the self-reported data lack full and accurate disclosure. Inaccurate reporting of the characteristics such as height and weight, which formulate the BMI covariate, could lead to analysis that does not reflect reality.

Another important limitation in this study is that the research assistant left the study during the second month. This created several issues for study fidelity. First, when the researcher took over the measurement sessions, she became unblinded to the data. It is possible that exposure to the data caused bias in the

interactions of the researcher towards the participants. Another possible issue with the research assistant leaving the study was that 14 participants had their pre-randomization data gathered by the research assistant. Only 9 of those participants had their first post measure and none had third and forth measures conducted by the research assistant. This inconsistency of data gatherer across time may have impacted the expectation of some participants, thus outcomes.

Implications for Practice

There are implications for practice resulting from this study. The significant findings of 10-back massage treatment imply that there may be lasting treatment effects for up to 4 weeks for systolic and diastolic blood pressure for persons with elevated body mass index. The linear and quadratic appearance of the analysis indicates there maybe an immediate treatment effect and a sustained effect out to a 4 week period of time. This study did not indicate the duration of effects beyond 4 weeks post application. It is most likely that the effectiveness weakens the further away from the last treatment, based upon the psychophysiology theory. The data are not clear enough to make implications regarding dosage. Further research is needed before definitive recommendations can be made as to exact dosage and length of effects. This study does indicate that systolic and diastolic blood pressure levels did decrease with a regularly applied 10-minute back massage for persons who had a higher body mass index. Back massage is a safe treatment for most persons. Recommending back massage as an adjunct therapy to drug therapy for persons with pre-hypertension or hypertension would certainly cause no harm in those

with body mass index above 27.43 kg/m^2 provided the person is otherwise healthy. But recommending the 10- minute back massage for those with lower body mass index should be done with caution.

It would not be safe to recommend back massage as a sole treatment for persons with pre-hypertension or hypertension. Treatment of elevated blood pressure needs to be multifaceted, to include lifestyle modifications including weight maintenance at a healthy level, exercise, diet management, and stress reduction. Once the diagnosis of hypertension is established, anti-hypertension medications are necessary to help lower and maintain a healthy blood pressure level. At this point, the evidence only supports back massage to be used as an adjunct therapy.

Future Research Recommendations

This study was based on psychophysiology theory and the design built upon previously published research and recommendations. The aim of this study, to determine long-term effects and dosage for person with pre-hypertension or hypertension, was clearly the next step in knowledge building. This study design needs to be expanded to a larger more heterogeneous population. This study did not analyze gender effects. However comparing gender effects would be interesting particularly because there are studies reporting differences among gender. Also, race effects must be tested, in view of the disparate onset of hypertension and heart disease in minority populations. It is possible due to cultural differences, that massage would have a different effect.

Regarding methodological recommendations, first, blinding the researcher to the data to prevent possible bias is necessary. Biological responses to massage need to be measured in future studies. Biological data in particular can add to the knowledge about the physiological response to such interventions. Psychological measurement should continue to be a part of future studies both as in this study as covariates, or as outcome variables. The relationship with the therapist needs to be further explored. Establishment of validity for a touch perception instrument and rapport perception instrument would enhance measurement of these variables.

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Appendices

Appendix 1

List of Music CDs

Benghiat, M. (2002). At Peace: *Flow* [CD]. Riverside, CT: At Peace Media.

Benghiat, M. (2003). At Peace: *Spirit* [CD]. Riverside, CT: At Peace Media.

Frantzich, P. (2005). Lifescapes: *The Best of Massage & Meditation* [2 CD set]. Montreal:Compass Productions.

Gibson, D. (1989). Solitudes: *Harmony* [CD]. Toronto: Solitudes, Ltd.

Nursing Research:
Blood Pressure Management using Back Massage

Who: Healthy persons between ages 18 and 75 years

- with consistent blood pressure above 120/80
- or persons with diagnosed high blood pressure and taking medication
- able to read write and speak English

Interested in participating? Contact Christine Olney MS RN at 813-210-4322 for a free blood pressure screening and possible enrollment in this research study at the College of Nursing.

USF
UNIVERSITY OF
SOUTH FLORIDA

06/30/2006

Christine Olney
University of South Florida
5106 Sterling Manor Dr
Tampa, FL 33647

RE: **Accepted** for Adverse/Unanticipated Event Report
IRB#: 104447D
Title: BACK MASSAGE: LONG TERM EFFECTS AND DOSAGE DETERMINATION FOR PERSONS WITH PRE-HYPERTENSION OR HYPERTENSION

Study Approval Period: 03/23/2006 to 03/13/2007

Dear Christine Olney:

On Tuesday, June 27, 2006 Institutional Review Board (IRB) reviewed and **ACCEPTED** your Adverse/Unanticipated Events Report for the above referenced protocol for the following reported adverse/unanticipated event(s):

AE#: 1

Based on the information provided, the IRB determined that **no further action is required at this time.** You are reminded, however, that it is your responsibility to immediately report any similar occurrences to the IRB and, when applicable, the appropriate funding and/or Federal agency.

Please note, if applicable, **the enclosed informed consent/assent documents are valid during the period indicated by the official, IRB-Approval stamp located on page one of the form.** Valid consent must be documented on a copy of the most recently IRB-approved consent form. Make copies from the enclosed original.

Please note that acceptance of this adverse event report does not impact the overall status of the study. This letter applies only to the review of the adverse/unanticipated event(s) referenced in this letter. Any other IRB requests for information/revisions still need to be addressed appropriately.

Thank you for keeping the IRB informed of the recent developments in the above referenced study. We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to the Human Research Protections Program. If you have any questions regarding this matter, please call 813-974-9343.

Sincerely,

Barry B Bercu MD

Barry Bercu, Chairperson
USF Institutional Review Board

Enclosure: (If applicable) IRB-Approved, Stamped Informed Consent/Assent Document(s)
cc: Sandra Partap, USF IRB Professional Staff

AE-AT-05-01

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Informed Consent for an Adult
University of South Florida

Information for People Who Take Part in Research Studies

Researchers at the University of South Florida (USF) study many topics. To do this we need the help of people who agree to take part in a research study. This form tells you about this study. You should read this form before you decide if you want to take part in this study. You have questions this form does not answer. Ask the person in charge to explain things in a way you can understand. If you choose to be in the study then you can sign the form. If you do not want to take part in this study, do not sign the form.

Title of study: Back Massage and High Blood Pressure
Person in charge of study: Christine M. Olney, MS RN
Where the study will take place: University of South Florida, Tampa, FL

General information about this research study:

The purpose of this study is to find out how back rubs affect high blood pressure. We are asking you to take part in this study because you have told us you have high blood pressure. If you choose to take part in this study, you will be asked to fill out a form about yourself. The first week you will have your blood pressure checked 3 times. The second week, you will be randomly assigned (like a flip of the coin) to one of three groups. One group will receive five back rubs. One group will receive ten back rubs. One group will have ten relaxation sessions. Each visit will take about 30 minutes. You will have your blood pressure checked at each visit. In addition, at four other times during the study, you will be asked to fill out a form about anxiety, anger, curiosity and depression. You will be asked to give a saliva sample and have your blood pressure checked.

If you are assigned to a group that gets ten back rubs or ten relaxation experiences you will visit the research office 18 times. If you are assigned to the group that gets five back massages, you will visit the research office 13 times. This study will take 10 weeks to complete. There will be 54 people in this study. You will be asked to continue your normal daily living routine. For example do not take up a new diet or exercise program and take your usual medications.

Payment: You will not be paid money to take part in this study. If you are in the relaxation group, you will be offered a free one-hour massage once the study is finished.

Your costs: To take part in this study, it will cost you your time and effort.

Your potential benefits: We cannot tell you how much you will gain from taking part in this study. You will most likely be very relaxed. The results of this study may be useful to other people with high blood pressure.

The possible risks: On rare occasions, a person's blood pressure may drop right after the back rub. If this happens, you will be allowed to rest until your blood pressure returns to normal.

If you get sick or hurt while you are in this study:

If you need emergency care while you are in the study you should call 911 or go to the nearest hospital emergency room right away. Tell the doctors at the hospital that you are taking part in this study and contact Mrs. Olney at 813-210-4322. Take a copy of this consent form with you.

If you are hurt or sick and it is not an emergency, go to your regular doctor. Tell your doctor that you are taking part in this study. Take a copy of this consent form with you.

If you are harmed because you are taking part in this study:
We will pay your medical costs if you are harmed because our staff did something they should not have done. Florida law limits how much USF is able to pay. USF cannot pay for lost wages, disability, or discomfort. Read Florida Statute 768.28 to find out how much USF is able to pay. You can get a copy of the law by calling USF Research Compliance at (813) 974-5638. Call the USF Self Insurance Programs (SIP) at (813) 974-8008 and ask them to look into what happened.

Keeping your study records private: Your private information will be kept confidential according to the law. Authorized research personnel, employees of the Department of Health and Human Services, and the USF Institution Review Board may inspect the records from this research study. The results of this study may be published. However, your private information will not be published. Your private information will be assigned a code number. Only code numbers will be used to identify the data. A list of the names, code numbers and telephone numbers will be kept secured in a locked file. The data will be secured in a different locked file. The office will be locked at all times.

Volunteering to be a part of this study:
You should only take part in this study if you want to take part. You will not be in trouble or lose any rights if you choose not to take part. If you decide to stop taking part in the study, tell Mrs. Olney as soon as you can. Sometimes there are reasons we would need to take you out of the study. For example, if it is not safe for you or if you are not coming for your study visits when scheduled. In that case Mrs. Olney will tell you to stop coming for the visits. If it is not safe for you, you will need to see your doctor right away.

Contacts: If you have any questions about this study, call Christine Olney at (813) 210-4322. If you have questions about your rights as a person who is taking part in a study, call USF Research Compliance at (813) 974-5638.

Consent to take part in this research study:
It's up to you. You can decide if you want to take part in this study.

I freely give my consent to take part in this study. I understand that this is research. I have received a copy of this consent form.

Signature of Person taking part in study	Printed Name of Person taking part in study	Date

Statement of Person Obtaining Informed Consent
I have carefully explained to the person taking part in the study what he or she can expect. The person who is giving consent to take part in this study understand the language that is used. This person reads well enough to understand this form. This person does not appear to be taking drugs that may make it hard to understand what has been explained. When this person signs this form, he or she understands what the study is about, what needs to be done, what the potential benefits and risks might be, and that taking part in this study is voluntary.

Signature of Investigator	Printed Name of Investigator	Date

IRB #: 104447

University of South Florida

Research Authorization

For Use and Disclosure of Protected Health Information

Title of Study BACK MASSAGE: LONG TERM EFFECTS AND DOSAGE DETERMINATION FOR PERSONS WITH PRE-HYPERTENSION OR HYPERTENSION

Protocol # (if applicable)

Study Subject Name _____

Medical Record Number _____

Please read this form before you sign it.
If you don't know what something means, you can ask us.
Before you sign this, you can talk it over with someone you trust.

In our research, we use and share information about people and their health. We know that this information is private. Federal law protects health information.

The law lets USF staff use and share information as a part of doing business. This means USF may use and share information about you:

- To treat you.
- To do billing and get payment.
- To make sure our work is of high quality.

The law lets us use and share health information for research if you agree to let us do this. If you let us use and share information about you, we will protect it as required by law.

If you sign this form, it means you are letting us use and share this information for research.

This form explains how we will use and share your health information. It lists who can see and use your information. It explains what we will do to keep your information private.

Who will disclose (share), receive, and/or use your information?

To do this research, USF and the people and organizations listed below may use or share your information. They may only use and share your information:

- With the people and organizations on this list.
- With you or your personal representative.
- As allowed by law.

USF and the people and organizations listed below may use or share information about you to do this research:

1. The research team, including the Principal Investigator, the research assistant, and the advisor to the Principal Investigator.
2. All health care and other USF staff who treat and serve you as a part of this research.
3. Every research site for this study. This includes the research and medical staff at each site and USF.
4. Any labs, persons, and groups that use your information as a part of the approved plan for this research
5. The sponsors of this study: None
6. Any agency of the federal, state, or local government that regulates this research. This includes the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
7. Members of all review boards supervised by the USF Division of Research Compliance that oversee this research, including but not limited to the Institutional Review Boards (IRBs).
8. The members of the USF Privacy Board.
9. Staff in the USF Office of Research, USF Division of Research Compliance, and other USF offices who oversee this research.
10. Data Safety Monitoring Board and staff: None

Who else can use and share this information?

Anyone listed above may use consultants or others to help them understand, analyze, and conduct this study. They may use and share information about you to do this research. If you have questions about who they are, you can ask us.

Once any information leaves USF, we cannot promise that others will keep it private. USF cannot stop others from using or sharing information they have about you. The sponsor may share your information. If the sponsor or others share your information, your information may no longer be protected by federal privacy laws.

Others not listed here may be able to get information about you from those listed above. That is only allowed when the law does not require them to keep your information private.

What information will be used or shared?

By signing this form, you are letting USF collect, use, and share this information:

- Your whole research record
- All of your medical and other records held by USF. This includes, but is not limited to, blood pressure, salivary cortisol levels, medications, physical health, mental health, and/or complementary therapies.

You may not want USF to use or share some kinds of information. List any kinds that you do not want us to use or share in the space below. If you list nothing here, we can use and share all of the information listed above.

_____

_____

_____

_____

Your Rights

You can refuse to sign this form.

If you do not sign this form:

- You will not be able to take part in this research and you will not get the study treatment.
- This will not change your health care outside of this study.
- This will not change your health care benefits.
- This will not change the costs of your health care.

You can revoke this form at any time. This means you can tell USF to stop using and sharing your information. If you revoke this form:

- We will stop collecting information about you.
- You cannot withdraw information that we had before you told us to stop. We may already have used or shared it. Or we may need it to complete the research.
- Staff may follow-up with you if there is a medical reason to do so.

To revoke this form, you must tell us in writing. Please write to:

Principal Investigator
For IRB Study # 104447
College of Nursing, MDC22
University of South Florida
12901 Bruce B Downs Blvd
Tampa, FL 33612

Date This Form Expires

This form will not expire, unless you revoke it in writing.

While we are doing this research, we cannot let you see or copy the information we have about you. After the research is done, you have a right to see and copy the information about you, as allowed by USF policies.

By signing below,

- I agree that I have read this form or someone has read it to me.
- I agree that I have gotten answers to all of my questions.
- I agree to let USF collect, use, and share information about me as explained on this form.

I will be given a copy of this form after I have signed it.

_____
Signature of Subject or Personal Representative

_____
Printed Name of Subject or Personal Representative

_____
Date

Explain authority of Personal Representative: _____

Subject's Contact Information

Subject's Address:
_____
_____
_____
_____

Subject's Phone:
_____ (Day)
_____ (Evening)

E-mail Address (optional):
_____

Appendix 6

Subject Information **No._____**

Name_____

Address_____

Contact Phone Number(s)_____

Date of Birth_____ Gender: Female _____ Male_____

Height_____ Weight_____

Pregnant: Yes_____ No_____ If yes, how many months?_____

Smoke: Yes_____ No_____ Quit (year) _____ Packs per day_____

Alcohol: Yes_____ No _____ Quit (year) _____ Drinks per day_____

Daily Exercise: Yes _____ No_____ Minutes per day_____

Ethnicity: Indian/Alaskan Native _____ Asian_____ Black/African American_____
Hispanic/Latino_____ Native Hawaiian/Pacific Islander _____
White/Caucasian_____ Other/Unknown _____

Primary Physician Name_____

Contact Phone for Physician_____

1. Are you being seen by a physical or mental health care provider at this time?

Yes_____ No_____

1a. If so, for what are you being treated?

_____
_____
_____
_____
_____
_____

1c. Have you ever been told you have high blood pressure or hypertension?

Yes_____ No_____

1d. If you answered “yes”, for how many years? _____

1e. Do you take medication for high blood pressure or hypertension?

Yes_____ No_____

1f. If you answered “yes”, what is/are the name(s) of the medication(s) and how long have you been taking the medication(s)?

_____
_____
_____

2. What other medications are you taking at this time? Include prescriptions, over the counter and illegal medications, herbals, vitamins or any other treatments that you either take orally, rectally, inject or put on your skin. Also include dosage and how often you take the medication.

_____
_____
_____
_____
_____
_____

3. List any allergies you have to medications, food, animals or household items (or other).

_____
_____
_____

4. Check any therapies you are receiving:

_____ Massage therapy
_____ Acupuncture
_____ Herbal therapy
_____ Physical Therapy
_____ Occupational Therapy
_____ Other

3a. If you check any of the above, for what are you being treated?

_____
_____
_____

MMSE

Date of Examination ___/___/___ Examiner _____

Name _____ Age ____ Years of School Completed ____

Instructions: Words in boldface type should be read aloud clearly and slowly to the examinee. Item substitutions appear in parentheses. Administration should be conducted privately and in the examinee's primary language. Circle 0 if the response is incorrect, or 1 if the response is correct. Begin by asking the following two questions:

Do you have any trouble with your memory? **May I ask you some questions about your memory?**

ORIENTATION TO TIME		RESPONSE	SCORE (circle one)
What is the...	**year?**	_____	0 1
	season?	_____	0 1
	month of the year?	_____	0 1
	day of the week?	_____	0 1
	date?	_____	0 1

ORIENTATION TO PLACE*

Where are we now? What is the...

state (province)**?**	_____	0 1
county (or city/town)**?**	_____	0 1
city/town (or part of city/neighborhood)**?**	_____	0 1
building (name or type)**?**	_____	0 1
floor of the building (room number or address)**?**	_____	0 1

*Alternative place words that are appropriate for the setting and increasingly precise may be substituted and noted.

REGISTRATION*

Listen carefully. I am going to say three words. You say them back after I stop. Ready? Here they are... APPLE [*pause*], **PENNY** [*pause*], **TABLE** [*pause*]. **Now repeat those words back to me.**
[*Repeat up to 5 times, but score only the first trial.*]

APPLE	_____	0 1
PENNY	_____	0 1
TABLE	_____	0 1

Now keep those words in mind. I am going to ask you to say them again in a few minutes.

*Alternative word sets (e.g., PONY, QUARTER, ORANGE) may be substituted and noted when retesting an examinee.

ATTENTION AND CALCULATION [Serial 7s]*

Now I'd like you to subtract 7 from 100. Then keep subtracting 7 from each answer until I tell you to stop.

What is 100 take away 7?	[93]	_____	0 1
If needed, say: **Keep going.**	[86]	_____	0 1
If needed, say: **Keep going.**	[79]	_____	0 1
If needed, say: **Keep going.**	[72]	_____	0 1
If needed, say: **Keep going.**	[65]	_____	0 1

*Alternative item (WORLD backward) should only be administered if the examinee refuses to perform the Serial 7s task. →

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Substitute and score this item only if the examinee refuses to perform the Serial 7s task.

Spell WORLD forward, then backward.

Correct forward spelling if misspelled,
but score only the backward spelling.

(D = 1)	(L = 1)	(R = 1)	(O = 1)	(W = 1)	(0 to 5)
____	____	____	____	____	____

RECALL	RESPONSE	SCORE (circle one)	
What were those three words I asked you to remember? [*Do not offer any hints.*]			
APPLE	_____	0	1
PENNY	_____	0	1
TABLE	_____	0	1

NAMING*

What is this? [*Point to a pencil or pen.*]	_____	0	1
What is this? [*Point to a watch.*]	_____	0	1

*Alternative common objects (e.g., eyeglasses, chair, keys) may be substituted and noted.

REPETITION

Now I am going to ask you to repeat what I say. Ready? "NO IFS, ANDS, OR BUTS." Now you say that.
[*Repeat up to 5 times, but score only the first trial.*]

NO IFS, ANDS, OR BUTS.	_____	0	1

Detach the next page along the lengthwise perforation, and then tear it in half along the horizontal perforation. Use the upper half of the page (blank) for the Comprehension, Writing, and Drawing items that follow. Use the lower half of the page as a stimulus form for the Reading ("CLOSE YOUR EYES") and Drawing (intersecting pentagons) items.

COMPREHENSION

Listen carefully because I am going to ask you to do something.
Take this paper in your right hand [*pause*], **fold it in half** [*pause*], **and put it on the floor** (*or* **table).**

TAKE IN RIGHT HAND	_____	0	1
FOLD IN HALF	_____	0	1
PUT ON FLOOR (*or* TABLE)	_____	0	1

READING

Please read this and do what it says. [*Show examinee the words on the stimulus form.*]

CLOSE YOUR EYES	_____	0	1

WRITING

Please write a sentence. [*If examinee does not respond, say:* **Write about the weather.**] 0 1

Place the blank piece of paper (unfolded) in front of the examinee and provide a pen or pencil. Score 1 point if the sentence is comprehensible and contains a subject and a verb. Ignore errors in grammar or spelling.

DRAWING

Please copy this design. [*Display the intersecting pentagons on the stimulus form.*] 0 1

Score 1 point if the drawing consists of two 5-sided figures that intersect to form a 4-sided figure.

Total Score = _____
(*Sum all item scores.*) (30 points max.)

Assessment of level of consciousness.

Alert/ Responsive	Drowsy	Stuporous	Comatose/ Unresponsive

SELF-ANALYSIS QUESTIONNAIRE STPI Form Y-1

Please provide the following information:

Name_____ Date_____ S_____

Age_____ Gender (*Circle*) **M F** T_____

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
1. I feel calm	1	2	3	4
2. I am in a questioning mood	1	2	3	4
3. I am furious	1	2	3	4
4. I feel strong	1	2	3	4
5. I am tense	1	2	3	4
6. I feel curious	1	2	3	4
7. I feel like banging on the table	1	2	3	4
8. I feel blue	1	2	3	4
9. I feel at ease	1	2	3	4
10. I feel interested	1	2	3	4
11. I feel angry	1	2	3	4
12. I feel miserable	1	2	3	4
13. I am presently worrying over possible misfortunes	1	2	3	4
14. I feel inquisitive	1	2	3	4
15. I feel like kicking somebody	1	2	3	4
16. I feel downhearted	1	2	3	4
17. I feel nervous	1	2	3	4
18. I feel like exploring my environment	1	2	3	4
19. I feel like breaking things	1	2	3	4
20. I feel alive	1	2	3	4

SELF-ANALYSIS QUESTIONNAIRE

STPI Form Y-1 Continued

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
21. I am jittery	1	2	3	4
22. I feel stimulated	1	2	3	4
23. I am mad	1	2	3	4
24. I feel sad	1	2	3	4
25. I am relaxed	1	2	3	4
26. I feel mentally active	1	2	3	4
27. I feel irritated	1	2	3	4
28. I feel safe	1	2	3	4
29. I am worried	1	2	3	4
30. I feel bored	1	2	3	4
31. I feel like hitting someone	1	2	3	4
32. I feel gloomy	1	2	3	4
33. I feel steady	1	2	3	4
34. I feel eager	1	2	3	4
35. I feel annoyed	1	2	3	4
36. I feel healthy	1	2	3	4
37. I feel frightened	1	2	3	4
38. I feel disinterested	1	2	3	4
39. I feel like swearing	1	2	3	4
40. I feel hopeful about the future	1	2	3	4

SELF-ANALYSIS QUESTIONNAIRE STPI Form Y-2

Please provide the following information:

Name_____Date_____S_____

Age_____ Gender (*Circle*) **M F** T_____

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you *generally* feel.

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
41. I am a steady person	1	2	3	4
42. I feel like exploring my environment	1	2	3	4
43. I am quick tempered	1	2	3	4
44. I feel gloomy	1	2	3	4
45. I feel satisfied with myself	1	2	3	4
46. I am curious	1	2	3	4
47. I have a fiery temper	1	2	3	4
48. I feel happy	1	2	3	4
49. I get in a state of tension or turmoil as I think over my recent concerns & interests	1	2	3	4
50. I feel interested	1	2	3	4
51. I am a hot-headed person	1	2	3	4
52. I feel depressed	1	2	3	4
53. I wish I could be as happy as others seem to be	1	2	3	4
54. I feel inquisitive	1	2	3	4
55. I get angry when I'm slowed down by others mistakes	1	2	3	4
56. I feel sad	1	2	3	4
57. I feel like a failure	1	2	3	4
58. I feel eager	1	2	3	4
59. I feel annoyed when I am not given recognition for doing good work	1	2	3	4
60. I feel hopeless	1	2	3	4

SELF-ANALYSIS QUESTIONNAIRE

STPI Form Y-2 Continued

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
61. I feel nervous and restless	1	2	3	4
62. I am in a questioning mood	1	2	3	4
63. I fly off the handle	1	2	3	4
64. I feel low	1	2	3	4
65. I feel secure	1	2	3	4
66. I feel stimulated	1	2	3	4
67. When I get mad I say nasty things	1	2	3	4
68. I feel whole	1	2	3	4
69. I lack self-confidence	1	2	3	4
70. I feel disinterested	1	2	3	4
71. It makes me furious when I am criticized in front of others	1	2	3	4
72. I feel safe	1	2	3	4
73. I feel inadequate	1	2	3	4
74. I feel mentally active	1	2	3	4
75. When I get frustrated, I feel like hitting someone	1	2	3	4
76. I feel peaceful	1	2	3	4
77. I worry too much over something that really does not matter	1	2	3	4
78. I feel bored	1	2	3	4
79. I feel infuriated when I do a good job and get a poor evaluation	1	2	3	4
80. I enjoy life	1	2	3	4

Appendix 9

USF
UNIVERSITY OF
SOUTH FLORIDA

February 20, 2006

Christine M. Olney, MS, RN
USF College of Nursing
University of South Florida
12901 Bruce B. Downs Blvd., MDC 0022
Tampa, FL 33612

Dear Ms. Olney:

In response to your recent request, I am very pleased to give you permission to reproduce and use the State-Trait Personality Inventory (STPI) for your dissertation research, entitled:

Back Massage:Long term effects and dosage determination for persons with pre-hypertension or hypertension

It is my understanding that your research will be carried out at:

University of South Florida College of Nursing, Tampa, FL

This permission is contingent on your agreement to share your research findings with us. I look forward to receiving further details about your procedures and the results of your study as such information becomes available.

Best wishes on your research project.

Sincerely,

Charles D. Spielberger, Ph.D., ABPP
Distinguished Research Professor of Psychology
Director, Center for Research in Behavioral
Medicine and Health Psychology
Phone (813) 974-2342; Fax (813) 974-4617

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Appendix 10

Subject Touch Perception Scale:

A back massage feels different to every person that gets one. The researcher would like to understand how the back massages felt to you. Below is a list of words that will help you tell the researcher what the back massages felt like to you.
Directions: Please circle the "X" that most correctly describes the feeling that you experienced when you got your back massages.
Example: On the soothing/irritating word pair, if you felt the back massages were soothing, you would circle the "X" closer to the word "soothing" but if the back massages were irritating to you, you would circle the last "X". The "X" that you circle is the right response for you.

To me the back massages felt:

----------very------less----neutral----less---very----------

1. Soothing	X	X	X	X	X	Irritating
2. Unpleasant	X	X	X	X	X	Pleasant
3. Too soft	X	X	X	X	X	Too hard
4. Rough	X	X	X	X	X	Smooth
5. Rhythmic	X	X	X	X	X	Jerky
6. Relaxing	X	X	X	X	X	Tensing

Appendix 11

Subject Perceived Rapport Scale:

When we interact with another person we experience many feelings. This list of words will help define your feelings about your interaction you have had with your back massage therapist.
Directions: Please circle the "X" that most accurately describes the feelings that you experienced with your back massage therapist.
Example: On the comfortable/ uncomfortable word pair, if you felt quite uncomfortable with the back massage therapist, you would circle the "X" closer to the word "uncomfortable" but if you were absolutely comfortable you would circle the first "X". The "X" that you circle is the right response for you.

My back massage therapist made me feel:

----------very------less----neutral----less---very----------

1. Comfortable	X	X	X	X	X	Uncomfortable
2. Distrustful	X	X	X	X	X	Trustful
3. Less Anxious	X	X	X	X	X	More Anxious
4. Calm	X	X	X	X	X	Annoyed
5. Worse	X	X	X	X	X	Better
6. Physically tense	X	X	X	X	X	Physically relaxed
7. Willing to share feelings	X	X	X	X	X	Unwilling to share feelings
8. Unsafe	X	X	X	X	X	Safe
9. Respected	X	X	X	X	X	Ignored
10. Unpleasant	X	X	X	X	X	Pleasant

Appendix 12: Schedule for Participants

If you are in the group that receives **10 back massages OR 10 relaxation sessions:**

Week	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	8	10
Visit:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Consent		Habituation		T1*		Treatments: Visits 6-15										T2	T3	T4

If you are in the group that receives **5 back massages:**

Week	1	1	1	2	2	2	3	3	3	4	4						8	10
Visit:	1	2	3	4	5	6	7	8	9	10	11						12	13
Consent		Habituation		T1*		Treatments: Visits 6-10					T2						T3	T4

Legend

Consent: the first visit you will read and sign consent and HIPAA forms and fill out a demographics form.

Habituation: At these three visit you will have your blood pressure taken 3 times and you will be adjusting to the research environment.

T1, T2, T3, & T4: These are the days the investigator will take your blood pressure for the actual data base, collect your saliva and have you fill out a personality inventory.

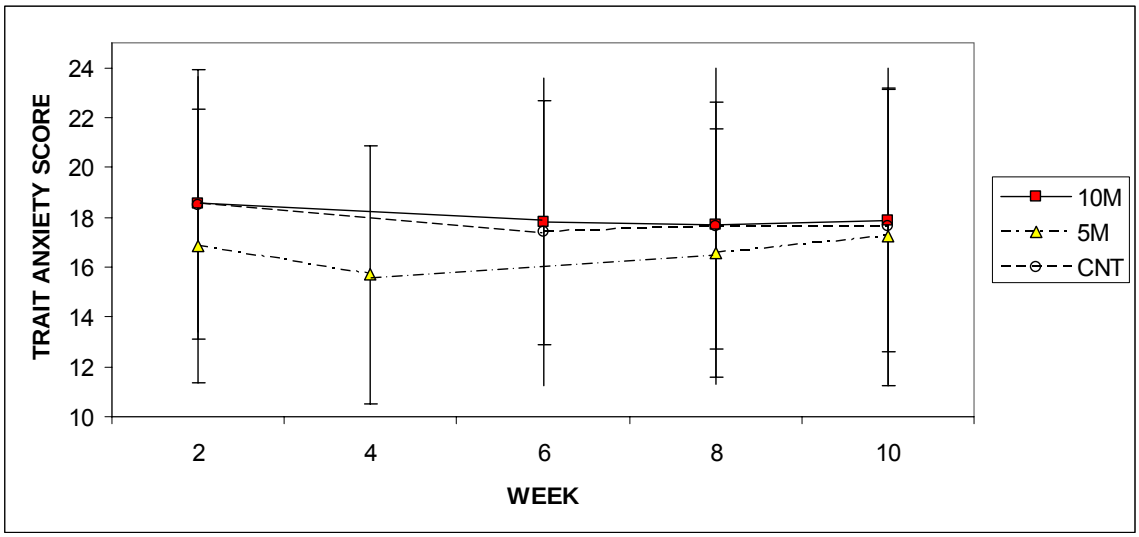
*At the end of the first visit (T1) you will be randomized, in other words, you will draw the group you will be in, for the study.

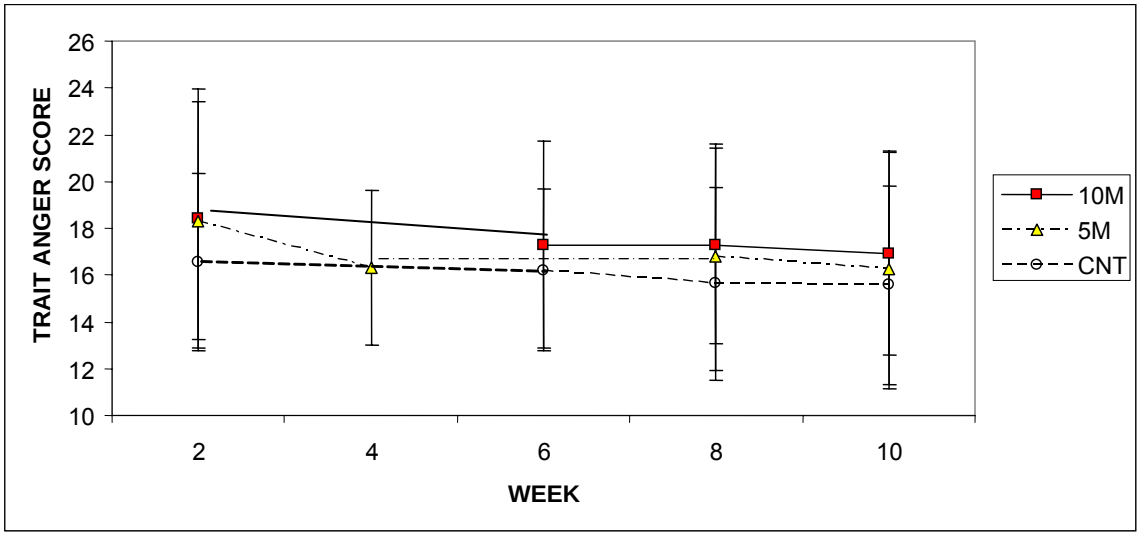
Treatments: You will either be receiving 10 ten-minute back massages, 5 ten-minute back massages or 10 ten-minute relaxation sessions.

Appendix 13: Medications Used by Study Participants

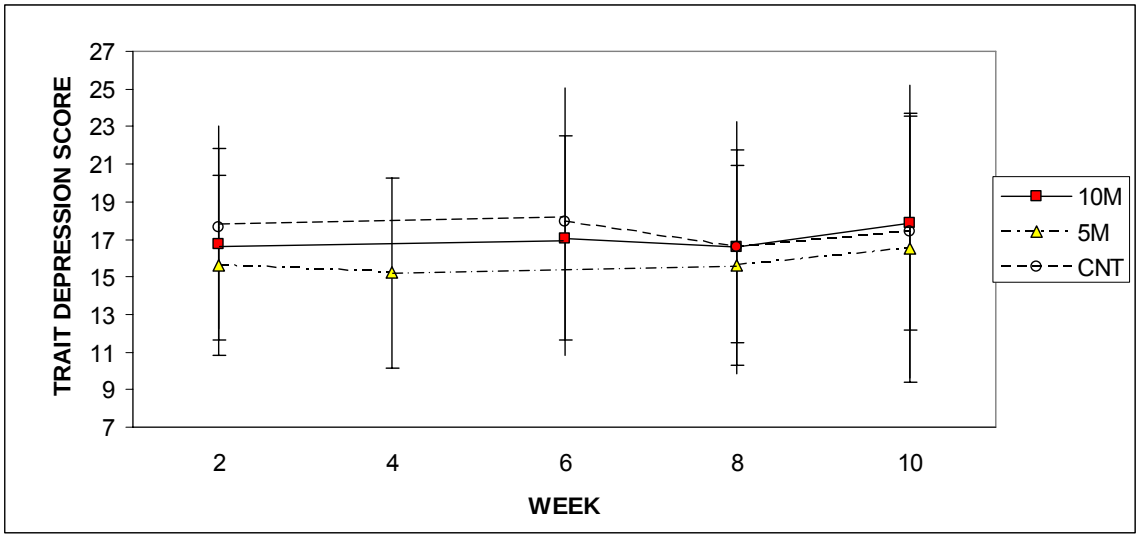
Medication	10-Massage Group # (% of group)	5-Massage Group # (% of group)	Control # (% of group)	Total # (% of total sample)
ACE Inhibitors	3 (20%)	3 (23%)	2 (14%)	8 (19%)
Angiotensin II Receptor Blockers	3 (20%)	3 (23%)	2 (14%)	8 (19%)
Beta Blockers	0	3 (23%)	2 (14%)	5 (12%)
Calcium Channel Blockers	1 (6%)	0	2 (14%)	3 (7%)
Diuretics	4(27%)	4 (31%)	5 (36%)	14 (33%)
# of Participants on HBP meds [# on 2 meds]	11 [3] (53%)	13 [2] (85%)	13 [3] (71%)	37 [8] (69%)
Anti-Lipids	5 (33%)	4 (31%)	2 (14%)	11 (26%)
Anti-Anginal	0	0	1 (7%)	1 (2%)
Hormones	2 (13%)	4 (31%)	1 (7%)	7 (17%)
Bone Reabsorbtion Inhibitor	1 (6%)	2 (15%)	0	3 (7%)
Anti-Histamines	2 (13%)	3 (23%)	2 (14%)	7 (17%)
Nasal Glucocorticoids	1 (6%)	2 (15%)	2 (14%)	5 (12%)
Bronchodilators	0	3 (23%)	0	3 (7%)
Anti-Ulcer/ Appetite Suppressor	3(20%)	2 (15%)	2 (14%)	7 (17%)
Anti-Platelet	0	0	2 (14%)	2 (5%)
NSAID	5 (33%)	6 (46%)	8 (57%)	19 (45%)
Opioid	0	0	2 (14%)	2 (5%)
Anti-Depressant	5 (33%)	4 (31%)	4 (28%)	13 (31%)
Anti-Anxiety	1 (6%)	2 (15%)	1 (7%)	4 (10%)
Anti-Convulsant	1 (6%)	2 (15%)	0	3 (7%)
Anti-Psychotic	0	0	1 (7%)	1 (2%)
Muscarine Receptor Agonist	0	0	1 (7%)	1 (2%)
Muscle Relaxants	0	1 (7%)	2 (14%)	3 (7%)
Oral Diabetic	1 (6%)	1 (7%)	2 (14%)	4 (10%)
Vitamins	10 (67%)	11 (84%)	6 (42%)	27 (64%)

Appendix 14: Means and Standard Deviation Bars for Trait Anxiety, Anger and Depression





Appendix 14: Means and Standard Deviation Bars for Trait Anxiety, Anger and Depression (Continued)



Appendix 15: Correlations of pertinent variables

Correlation of pertinent variables at pre-randomization measurement (Week 2)

	PRE SYS	PRE DIAS	AGE	BMI	YRS HBP	MPD EXC	A-HPN	S-ANX1	S-ANG1	S-DEP1	T-ANX1	T-ANG1	T-DEP1	CORT 1
PRESYS		.490	-.131	.053	-.053	.116	-.438**	.165	.039	.072	.048	.027	.005	.079
PRE DIAS			-.220	-.232	-.033	.187	-.348*	.235	.117	.208	.081	.130	-.051	.040
AGE				-.068	.236	-.443*	.304	-.260	-.319*	-.091	-.075	-.216	-.093	.033
BMI					.140	-.268	.251	.207	.133	.354*	.398*	.087	.407*	-.255
YRSHBP						-.126	.326*	-.168	-.037	-.037	-.197	.034	-.048	.193
MPDEXC							-.415**	-.158	.013	-.216	-.160	.158	-.211	-.015
A-HPN								-.023	.184	.021	-.049	.150	-.042	-.108
S-ANX1									.703*	.636*	.504*	.102	.476*	.028
S-ANG1										.393*	.366*	.362*	.390*	-.121
S-DEP1											.620*	-.015	.622*	-.008
T-ANX1												.327*	.872*	.047
T-ANG1													.258	.019
T-DEP1														.322*
CORT1														

* Pearson's Correlation significant at the .05 level (2-tailed).

** Pearson's Correlation significant at the .01 level (2-tailed).

A-HPN = Antihypertensive Meds (angiotensin converting enzyme inhibitors, angiotensin-receptor blockers, calcium channel blockers, beta-blockers, and diuretics)

PRESYS = Systolic blood pressure measured prior to randomization

PRE DIAS = Diastolic blood pressure measured prior to randomization

BMI = Body mass index

YRSHBP = Years the participant has been diagnosed with hypertension

MPDEXC = Average number of minutes the participant exercises every day

S-ANX1 = State anxiety measured prior to randomization

S-ANG1 = State anger measured prior to randomization

T-ANX1 = Trait anxiety measured prior to randomization

T-ANG1 = Trait anger measured prior to randomization

T-DEP1 = Trait depression measured prior to randomization

CORT1 = Salivary cortisol measured prior to randomization

Appendix 15 (continued)

Correlations of pertinent variables at first post intervention measurement (week 4 for the 5-massage group or week 6 for the 10-Massage group and Control group),

	POST SYS	POST DIAS	AGE	BMI	YRS HBP	MPD EXCS	A-HPN	S-ANX2	S-ANG2	S-DEP2	T-ANX2	T-ANG2	T-DEP2	CORT 2
POSTSYS		.635*	-.013	-.056	.155	.127	-.422**	.443*	.256	.265	.101	.034	.036	.049
POSTDIA			-.123	-.236	.122	.238	-.391**	.401*	.208	.183	.070	.034	-.034	.184
AGE				-.068	.236	-.443*	.304	.008	.084	.012	-.065	-.180	-.011	-.039
BMI					.140	-.268	.251	.128	-.096	.374*	.450*	.261	.493*	.045
YRSHBP						-.126	.326*	.235	.367*	.280	-.080	.084	.100	.308*
MPDEXC							-.415**	.065	.085	-.084	-.104	.019	-.200	.000
A-HPN								-.140	-.021	-.010	-.142	.280	-.069	.122
S-ANX2									.779*	.712*	.420*	.300	.411*	.231
S-ANG2										.429*	.054	.267	.132	.074
S-DEP2											.661*	.436*	.738*	.235
T-ANX2												.268	.857*	.172
T-ANG2													.375*	-.054
T-DEP2														.097
CORT2														

* Pearson's Correlation significant at the .05 level (2-tailed).
** Pearson's Correlation significant at the .01 level (2-tailed).
A-HPN = Antihypertensive Meds (angiotensin converting enzyme inhibitors, angiotensin-receptor blockers, calcium channel blockers, beta-blockers, and diuretics)
PRESYS = Systolic blood pressure measured prior to randomization
PRE DIAS = Diastolic blood pressure measured prior to randomization
BMI = Body mass index
YRSHBP = Years the participant has been diagnosed with hypertension
MPDEXCS = Average number of minutes the participant exercises every day
S-ANX2 = State anxiety measured prior to randomization
S-ANG2 = State anger measured prior to randomization
S-DEP2 = State depression measured prior to randomization
T-ANX2 = Trait anxiety measured prior to randomization
T-ANG2 = Trait anger measured prior to randomization
T-DEP2 = Trait depression measured prior to randomization
CORT2 = Salivary cortisol measured prior to randomization

Appendix 15 (continued)

Correlations of pertinent variables at second post intervention measurement (Week 8)

	POST SYS1	POST DIAS1	AGE	BMI	YRS HBP	MPD EXCS	A-HPN	S-ANX3	S-ANG3	S-DEP3	T-ANX3	T-ANG3	T-DEP3	CORT 3
POSTSYS1		.586*	.063	.061	.015	.068	-.441**	.367*	.201	.299	.142	.213	.189	-.136
POSTDIA1			-.121	-.072	.003	.297	-.367*	.430*	.347*	.278	.217	.276	.155	-.064
AGE				-.068	.236	-.443*	.304	-.107	.062	-.022	.043	-.085	.005	-.014
BMI					.140	-.268	.251	.127	.172	.367*	.485*	.254	.406*	-.005
YRSHBP						-.126	.326*	.066	.118	.096	.010	.067	.096	.256
MPDEXCS							-.415**	.076	-.148	-.151	-.150	.056	-.179	.075
A-HPN								-.115	.107	-.034	.020	.198	-.012	.279
S-ANX3									.839*	.849*	.454*	.256	.417*	.177
S-ANG3										.833*	.409*	.289	.415*	.135
S-DEP3											.689*	.290	.681*	.037
T-ANX3												.370*	.870*	.007
T-ANG3													.347*	-.023
T-DEP3														.008
CORT3														

* Pearson's Correlation significant at the .05 level (2-tailed).

** Pearson's Correlation significant at the .01 level (2-tailed).

A-HPN = Antihypertensive Meds (angiotensin converting enzyme inhibitors, angiotensin-receptor blockers, calcium channel blockers, beta-blockers, and diuretics)

PRESYS = Systolic blood pressure measured prior to randomization

PRE DIAS = Diastolic blood pressure measured prior to randomization

BMI = Body mass index

YRSHBP = Years the participant has been diagnosed with hypertension

MPDEXCS = Average number of minutes the participant exercises every day

S-ANX3 = State anxiety measured prior to randomization

S-ANG3 = State anger measured prior to randomization

S-DEP3 = State depression measured prior to randomization

T-ANX3 = Trait anxiety measured prior to randomization

T-ANG3 = Trait anger measured prior to randomization

T-DEP3 = Trait depression measured prior to randomization

CORT3 = Salivary cortisol measured prior to randomization

Appendix 15 (continued)

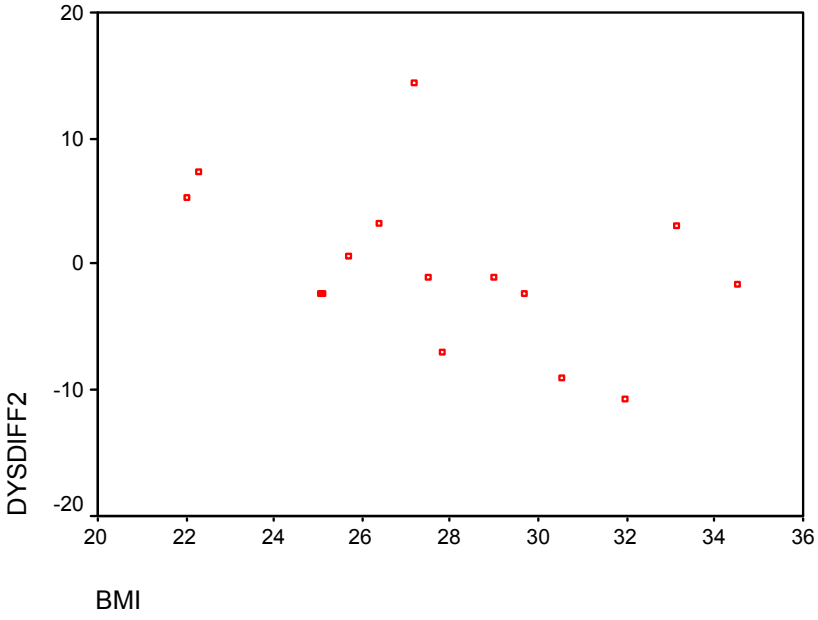
Correlations of pertinent variables at second post intervention measurement (Week 10)

	POST SYS2	POST DIAS 2	AGE	BMI	YRS HBP	MPD EXCS	A-HPN	S-ANX4	S-ANG4	S-DEP4	T-ANX4	T-ANG4	T-DEP4	CORT 4
POSTSYS2		.604*	-.061	-.088	-.009	.059	-.556**	.361*	.166	.080	-.015	-.036	.060	.186
POSTDIA2			-.130	-.115	.195	.127	-.397**	.386*	.406*	.283	.191	.097	.208	.139
AGE				-.068	.236	-.443*	.304	-.057	-.026	.022	-.005	-.080	.011	-.042
BMI					.140	-.268	.251	.147	.072	.365*	.460*	.313*	.338*	.047
YRSHBP						-.126	.326*	.096	.181	.165	-.016	.155	.067	.205
MPDEXCS							-.415**	.089	-.014	-.150	-.221	-.013	-.124	.004
A-HPN								.008	.165	.052	.043	.296	-.084	.064
S-ANX4									.740*	.725*	.460*	.545*	.419*	.334*
S-ANG4										.477*	.248	.504*	.189	.085
S-DEP4											.826*	.552*	.816*	.315*
T-ANX4												.441*	.874*	.166
T-ANG4													.419*	.101
T-DEP4														.127
CORT4														

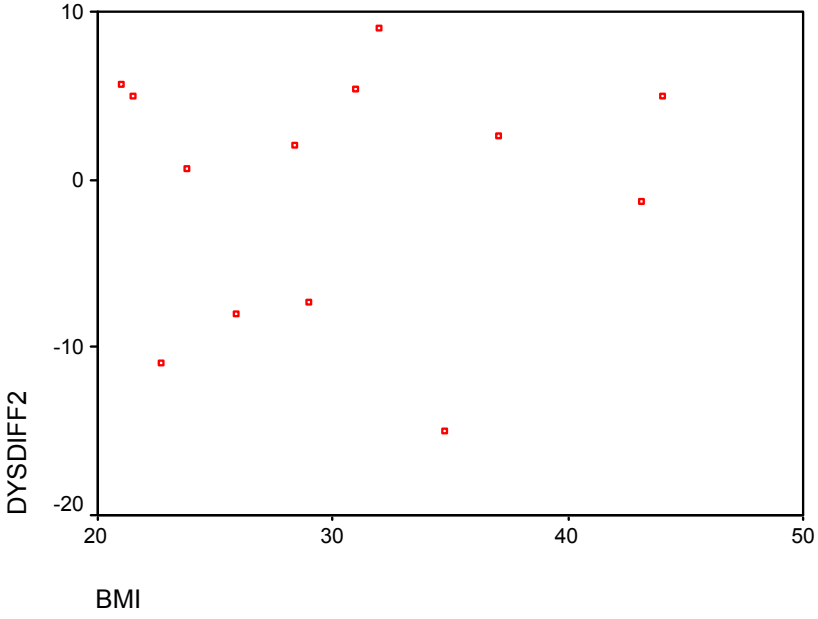
* Pearson's Correlation significant at the .05 level (2-tailed).
** Pearson's Correlation significant at the .01 level (2-tailed).
A-HPN = Antihypertensive Meds (angiotensin converting enzyme inhibitors, angiotensin-receptor blockers, calcium channel blockers, beta-blockers, and diuretics)
PRESYS = Systolic blood pressure measured prior to randomization
PRE DIAS = Diastolic blood pressure measured prior to randomization
BMI = Body mass index
YRSHBP = Years the participant has been diagnosed with hypertension
MPDEXCS = Average number of minutes the participant exercises every day
S-ANX4 = State anxiety measured prior to randomization
S-ANG4 = State anger measured prior to randomization
S-DEP4 = State depression measured prior to randomization
T-ANX4 = Trait anxiety measured prior to randomization
T-ANG4 = Trait anger measured prior to randomization
T-DEP4 = Trait depression measured prior to randomization
CORT4 = Salivary cortisol measured prior to randomization

Appendix 16: Scatter Plots for Diastolic difference scores and BMI

GROUP: 1

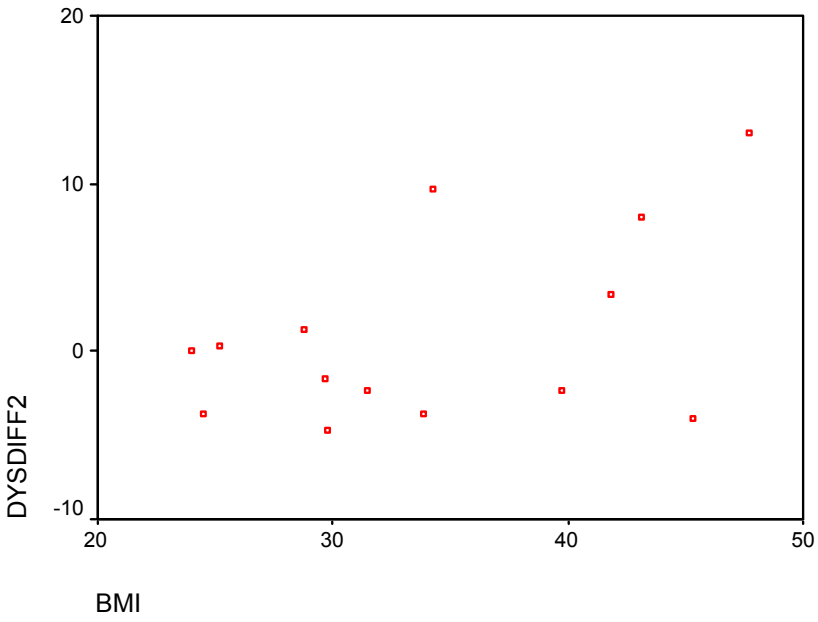


GROUP: 2



Appendix 16: Scatter Plots for Diastolic difference scores and BMI (continued)

GROUP: 3



Appendix 17

ALL Groups: Correlations of Antihypertensive Medication, BMI and Baroreceptor Response

	A-HPN	BMI	BAR01	BAR02	BAR03	BAR04	BAR05	BAR06	BAR07	BAR08
A-HPN		.251	.098	.103	.017	.130	.358*	-.128	.036	.175
BMI			-.074	.114	-.066	-.107	-.130	.025	.003	-.078
BAR01				.280	.536**	.406**	.680**	.385*	.519**	.614**
BAR02					.382*	.493**	.265	.231	.392*	.059
BAR03						.441**	.360*	.324*	.226	.394**
BAR04							.365*	.170	.432**	.270
BAR05								.462**	.483**	.582**
BAR06									.497**	.560**
BAR07										.313**
BAR08										

* Pearson's Correlation significant at the .05 level (2-tailed).

** Pearson's Correlation significant at the .01 level (2-tailed).

A-HPN = Antihypertensive Medication (angiotensin converting enzyme inhibitors, angiotensin-receptor blockers, calcium channel blockers, beta-blockers, and diuretics)

BMI = Body Mass Index ($705 * Weight/ Height^2$)

BARO1 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Pre randomization

BARO2 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Post measure

BARO3 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Post 1 measure

BARO4 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Post 2 measure

BARO5 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Pre randomization

BARO6 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Post Measure

BARO7 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Post 1 Measure

BARO8 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Post 2 Measure

Appendix 17 (continued)

10-Massage Group: Correlations of Antihypertensive Medication, BMI and Baroreceptor Response

	A-HPN	BMI	BAR01	BAR02	BAR03	BAR04	BAR05	BAR06	BAR07	BAR08
A-HPN		.318	.051	.235	.122	.086	.165	-.477	-.168	.238
BMI			-.350	.351	-.162	.109	-.146	-.007	.115	-.294
BAR01				.170	.435	.248	.815**	.420	.492	.824**
BAR02					.156	.219	.208	.047	.220	.045
BAR03						.040	.367	.307	-.077	.339
BAR04							.103	.467	.270	.532*
BAR05								.316	.653**	.597*
BAR06									.523*	.423
BAR07										.308
BAR08										

* Pearson's Correlation significant at the .05 level (2-tailed).
** Pearson's Correlation significant at the .01 level (2-tailed).
A-HPN = Antihypertensive Medication (angiotensin converting enzyme inhibitors, angiotensin-receptor blockers, calcium channel blockers, beta-blockers, and diuretics)
BMI = Body Mass Index ($705 * Weight/ Height^2$)
BARO1 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Pre randomization
BARO2 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Post measure
BARO3 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Post 1 measure
BARO4 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Post 2 measure
BARO5 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Pre randomization
BARO6 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Post Measure
BARO7 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Post 1 Measure
BARO8 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Post 2 Measure

Appendix 17 (continued)

5-Massage Group: Correlations of Antihypertensive Medication, BMI and Baroreceptor Response

	A-HPN	BMI	BAR01	BAR02	BAR03	BAR04	BAR05	BAR06	BAR07	BAR08
A-HPN		-.444	-.109	.093	.057	.397	.596*	-.153	.104	.192
BMI			.201	.111	.245	-.116	-.437	.029	-.001	.205
BAR01				.477	.605*	.535	.433	.189	.559*	.257
BAR02					.556*	.495	.353	.492	.677*	.014
BAR03						.619*	.360	.350	.417	.349
BAR04							.703**	.227	.667*	.103
BAR05								.342	.415	.384
BAR06									.415	.499
BAR07										.150
BAR08										

* Pearson's Correlation significant at the .05 level (2-tailed).
** Pearson's Correlation significant at the .01 level (2-tailed).
A-HPN = Antihypertensive Medication (angiotensin converting enzyme inhibitors, angiotensin-receptor blockers, calcium channel blockers, beta-blockers, and diuretics)
BMI = Body Mass Index ($705 * Weight/ Height^2$)
BARO1 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Pre randomization
BARO2 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Post measure
BARO3 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Post 1 measure
BARO4 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Post 2 measure
BARO5 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Pre randomization
BARO6 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Post Measure
BARO7 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Post 1 Measure
BARO8 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Post 2 Measure

Appendix 17 (continued)

Control Group: Correlations of Antihypertensive Medication, BMI and Baroreceptor Response

	A-HPN	BMI	BAR01	BAR02	BAR03	BAR04	BAR05	BAR06	BAR07	BAR08
A-HPN		.689**	.270	-.005	-.006	-.114	.285	.230	.191	.121
BMI			-.040	.022	-.396	-.261	.134	.230	.193	-.103
BAR01				.245	.781**	.427	.842**	.516	.308	.764**
BAR02					.337	.696**	.268	.163	.199	.131
BAR03						.548*	.507	.353	.246	.581*
BAR04							.162	-.005	.285	.246
BAR05								.673**	.419	.804**
BAR06									.640*	.728**
BAR07										
BAR08										

* Pearson's Correlation significant at the .05 level (2-tailed).
** Pearson's Correlation significant at the .01 level (2-tailed).
A-HPN = Antihypertensive Medication (angiotensin converting enzyme inhibitors, angiotensin-receptor blockers, calcium channel blockers, beta-blockers, and diuretics)
BMI = Body Mass Index ($705 * Weight/ Height^2$)
BARO1 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Pre randomization
BARO2 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Post measure
BARO3 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Post 1 measure
BARO4 = Lying Systolic Blood Pressure - Sitting Systolic Blood Pressure at Post 2 measure
BARO5 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Pre randomization
BARO6 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Post Measure
BARO7 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Post 1 Measure
BARO8 = Lying Diastolic Blood Pressure - Sitting Diastolic Blood Pressure at Post 2 Measure

About the Author

Christine M. Olney received her Bachelor's Degree in Nursing from Montana State University, in 1978. Mrs. Olney's Master's Degree in Nursing was received in May of 2002 from South Dakota State University.

During her doctoral education program at the University of South Florida, Tampa, Mrs. Olney developed a role as a nursing research resident in a local hospital. In the role as a research resident she initiated and maintained a nursing research program. The role led to several nursing research projects and publications.

Mrs. Olney has accepted a fellowship at the James A. Haley Veteran's Administration Patient Safety Center. She plans to continue pursuing the impact of complementary therapies.