An Evaluation of the National Center for Complementary and Alternative Medicine (NCCAM) Grants and Funding Program: Mission and Research Priorities Relating to Massage Therapy

A Dissertation
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Abstract

This dissertation is a program evaluation to investigate the Grants and funding program of the National Institutes of Health (NIH), National Center for Complementary and Alternative Medicine (NCCAM), as it specifically relates to research in massage therapy. This paper evaluated whether the funding program, relative to massage therapy, effectively supported the stated mission of NCCAM, to define, through rigorous scientific investigation, the usefulness and safety of massage therapy and its role in improving health care. NCCAM's funding areas of special interest, involving the public's usage, as well as pain and inflammatory conditions, were also evaluated.

Massage research study designs were assessed for overall quality by using the JADAD scale. Results showed seventeen out of thirty-two studies (53%) scored 3, which is considered good quality. To assess both efficacy and safety, a PICO Table consisting of NIH funded massage research clinical trials was included. The analysis showed that 27 out of 28 clinical trials showed significantly positive results for the groups receiving the massage therapy intervention. No adverse effects were reported as a result of any of these studies. It appears that massage therapy is safe for the conditions that were investigated and with the protocols used in the clinical trials when performed by certified or licensed massage therapists.

Spearman's correlation coefficient was used to compare percentages of funding of topics with percentages of the public's reported reasons for their usage of massage. Based in this assessment, no correlation between the

public's usage and NIH funding of research topics was found. However, funding in massage topics for pain and inflammatory conditions was over 50% of the annual funding in 9 out of the 13 years reviewed. It was concluded that the NCCAM funding program is consistent with its mission statement and funding areas of special interest.

Introduction and Background

"Research is designed to prove, while evaluation is designed to improve."

(Smith & Brandon, 2008, p. 189)

This dissertation is a program evaluation to investigate the grants and funding program of the National Institutes of Health (NIH), National Center for Complementary and Alternative Medicine (NCCAM), as it specifically relates to research in massage therapy. This dissertation evaluated whether the funding program, relative to massage therapy, effectively supported the stated mission of NCCAM. That mission statement is: "to define, through rigorous scientific investigation, the usefulness and safety of complementary health approaches and their roles in improving health care." (http://nccam.nih.gov/about/ataglance?nav=gsa).

In addition, this dissertation assessed whether massage therapy research is in alignment with the stated NCCAM priorities to fund research in areas of special interest. The areas of special interest are described by NCCAM as: "CAM interventions used frequently by the American public and on the conditions for which they are most frequently used ... These would include, but not be limited to, investigations of the impact of CAM modalities in alleviating chronic pain syndromes and inflammatory processes ..." (http://nccam.nih.gov/grants/priorities#siareas).

Program Evaluation

The Centers for Disease Control and Prevention (CDC) *Framework for Program Evaluation* manual defines a program evaluation as "the systematic

collection of information about the activities, characteristics, and outcomes of programs to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development." The term "program" may include any organized action such as media campaigns, service provision, educational services, public policies, research projects, etc. (Center for Disease Control and Prevention [CDC], 1999).

Massage therapy research was the focus of the program evaluation for this dissertation. As such, the dissertation specifically evaluated whether the NCCAM Grants and Funding program as implemented: effectively supported the stated NCCAM mission by investigating whether there is rigorous scientific research to demonstrate the usefulness and safety of massage therapy and its role in improving health care.

NCCAM also promotes a research funding area of special interest which is: "CAM interventions used frequently by the American public." Based on the NHIS national survey analyzed by Barnes, et al. (2008), massage therapy qualifies as a frequently used CAM intervention. This evaluation also assessed whether massage therapy research is consistent with the conditions for which massage therapy is most frequently used by the public. Another objective of this dissertation was to determine whether the funding of research topics in massage therapy is in alignment with NCCAM's stated areas of special interest, including treatment of chronic pain conditions and inflammation.

Choice of Massage Therapy Funding Focus

One of the reasons massage therapy was chosen as the focus is because it is increasing as a popular form of complementary and alternative medicine (CAM). Barnes, et al. (2008) indicated that the use of massage therapies by the adult U.S. population rose from 5% in 2002 to 8% in 2007. Massage may be considered one of the oldest forms of medical therapies, however, research in this area is still in its relatively early stages (Moyer, 2009). It is therefore important to evaluate the progression of massage therapy research and whether it is in alignment with the NIH mission statement and its research funding areas of priority.

NIH and NCCAM has been the major funding source for massage therapy research. Research in massage therapy continues to evolve as improvements are being made in the quality of the study designs. A review of the NIH data indicates that funding for massage therapy research topics has been increasing over the past twenty years. An evaluation of this funding program using massage therapy as the focus was important to perform at this time while massage therapy research remains in its formative years.

This scholarly inquiry evaluated NCCAM's funding program as specifically related to its funding of research in massage therapy. A goal of this program evaluation was to provide accountability to the stakeholders to show if changes in funding patterns are needed in order to be in alignment with their stated policies. Areas evaluated included the appropriateness of funding and the quality of massage therapy research demonstrating safety and efficacy. This study

assessed whether NIH funded massage research provides useful information that may help to increase health and well-being. In addition, this study assessed if there was a need for implementing certain changes in policy, spending, or whether different research is needed. The results of this program evaluation can be used to justify the current NCCAM funding program and possibly support the need for increased levels of funding for massage therapy research. The results of this study can also help stakeholders better understand the NCCAM funding program and its goals as they relate to massage therapy research. To date, a program evaluation has not been conducted to investigate whether NCCAM funding for massage therapy research is in alignment with its stated mission and special interests funding goals.

Program Evaluation Framework

The program evaluation framework used was based on the Centers for Disease Control and Prevention (CDC) *Framework for Program Evaluation* (http://www.cdc.gov/eval/framework/index.htm).

The Centers for Disease Control and Prevention's *Framework for Program Evaluation in Public Health* was chosen as the framework for this dissertation because it incorporates the key components of a broad range of evaluation approaches in an organized and systematic method. It also allows an evaluation to be tailored in design and scope to the specific needs of a program evaluator (Joint Committee on Standards for Educational Evaluation, 2010). This structure can be used to develop of a comprehensive evaluation design that meets the evaluation standards set by the Joint Committee on Standards for Educational

Evaluation and ensures the evaluation produces relevant, useful information (Centers for Disease Control and Prevention, 1999; Joint Committee on Standards for Educational Evaluation, 2010).

Program Evaluation Steps

The CDC framework is comprised of six steps and standards. The steps are:

1) Engaging stakeholders
2) Describing the program
3) Focusing the evaluation design
4) Gathering credible evidence
5) Justifying conclusions
6) Ensuring use and sharing lessons learned.

For the purposes of this program evaluation, the steps are modified as follows:

1) Identifying the stakeholders
2) Descriptions of the NIH and NCCAM funding program, and massage therapy
3) Focusing the evaluation design
4) Gathering credible evidence
5) Justifying conclusions
6) Ensuring use and sharing lessons learned.

Program Evaluation: Step 1 and Step 2

Step 1: Identification of the Stakeholders

The primary stakeholders for this program evaluation are identified as the National Institutes of Health (NIH) and the National Center for Complementary and Alternative Medicine (NCCAM), including the administrators who run this funding program, as well as the U.S. federal taxpayers who ultimately provide the monetary funds. Another group of primary stakeholders are the researchers who depend on the funding from this program. Other stakeholders are the massage therapy community that includes massage therapy clinics, therapists, and massage therapy schools, together with massage therapy clients, and the general public contemplating the use of massage therapy as a complementary and alternative approach to their health care. In addition, health care professionals would also have a special interest in research demonstrating the safety and efficacy of massage therapy.

Step 2: Descriptions of the NIH and NCCAM Funding Programs and Massage Therapy

NIH Funding of Research

The history of The National Institutes of Health (NIH) began with a one room laboratory in 1887. At that time, it was part of the Marine Hospital Service (MHS), which later evolved into the U.S. Public Health Service. Since then the NIH has grown to be recognized as the leading supporter of biomedical research in the world. It is believed that as a result of their investment in research, life expectancy has increased from forty-nine years to seventy-nine years since

1900. The proportion of older people with chronic disabilities has declined by 30% in the last twenty five years (Manton, Manton, Gu, Lowrimore, Ullian, & Tolley, 2009).

As a result of the increasing numbers of Americans pursuing some form of complementary and alternative medicine (CAM), The Office of Alternative medicine (OAM) was established by Congress in 1991 and provided with an initial budget of two million dollars. Seven years later, the OAM became the National Center for Complementary and Alternative Medicine (NCCAM), and continues as one of the centers of the US National Institutes of Health (NIH). One of NCCAM's stated goals is to integrate scientifically proven CAM practices into conventional medicine. (http://nccam.nih.gov/about/aboutnccam/index.htm). To accomplish this, NCCAM plays a crucial, unique role in encouraging basic scientific and clinical research in CAM. The NCCAM budget has grown to $128 million in fiscal year 2012 (Figure 1).

Among NCCAM's duties is disseminating reliable information on CAM to the public and medical professionals. People can turn to NCCAM's official Website (http://nccam.nih.gov/about/ataglance) to access to this information. NCCAM defines "CAM as a group of diverse medical and health care systems, practices, and products not presently considered a component of conventional medicine." These therapies are divided into five categories: alternative medical systems, mind-body interventions, biologically based therapies, manipulative and body-based methods, and energy therapies. NCCAM is committed to expanding the knowledge base in complementary and alternative medicine through rigorous

science by funding, conducting and publishing original research. These clinical trials are freely made available to health care professionals and the general public and can be accessed through their website, (www.ClinicalTrials.Gov).

Types of NIH Grants

NCCAM is a subdivision of NIH dedicated to investigating the safety and efficacy of nonconventional forms of health care. NCCAM accepts grant proposals from researchers and distributes proposals to research review teams for evaluation and to make recommendations for funding. Once an award has been made, NCCAM staff monitors the use of the funds.

The NIH website, (http://nccam.nih.gov/grants/types/general) describes types of research grants that are divided into several categories. The first is R01, which is considered by many to be the gold standard of research. In clinical research, this may involve a randomized, prospective, double blind, placebo controlled clinical trial, or may be basic research. This research is initiated by the investigator and requires a large amount of preliminary information with a detailed research design to test a relevant hypothesis. These trials are lengthy and can continue for three to five years.

The next type of grant is the R21 and considered for more exploratory trials that may last one or two years. The R21 grant requires less preliminary information than R01 grants and is intended to encourage research in new areas. P01 and P50 (P-series awards) are given for large projects that involve several institutions or research centers. The K-awards are for smaller facilities or for career development awards. The next series of awards, R41, R42, R43, R44, are

granted to small businesses mainly to fund the development of biotech projects. Another grant known as the R34 is used to fund preliminary studies to investigate certain areas such as safety, toxicity, optimal dosing, the establishment of appropriate outcome measurements, or to develop an acceptable placebo control. The T32 awards are granted to fund training and fellowship programs. These codes will be used to provide additional information when analyzing the data for NIH funding of research projects in this program evaluation.

It is important to note that NIH funds its grants by the fiscal year. That means, for example, that a five year grant is actually made up of five one year awards. It is for this reason that the same clinical trial and grant will appear in successive years in the annual NIH appropriation reports. However, in these situations, the grants are considered noncompetitive renewals and are usually continued each year, as long as progress reports are submitted indicating that the project is progressing. The two numbers at the end of the code indicate the year of the grant, for example the first year of the grant would be 01, the second, 02, and so on.

NIH Funding Priorities

The NIH budget has grown tremendously, increasing from $11.9 billion in 1996 to over $30 billion in 2012. See Figure 1. As a result, congress and the public have expressed concerns that disease-specific research funding allocations by the NIH did not adequately the reflect burden of disease and incorporate public input. Therefore, congress directed the Institute of Medicine (IOM) to assess the NIH funding apportionment processes. In its 1998 report,

Scientific Opportunities and Public Needs: Improving Priority Setting and Public Input at the National Institutes of Health, the IOM recommended improved tracking of disease-specific funding and development of a new priority-setting process.

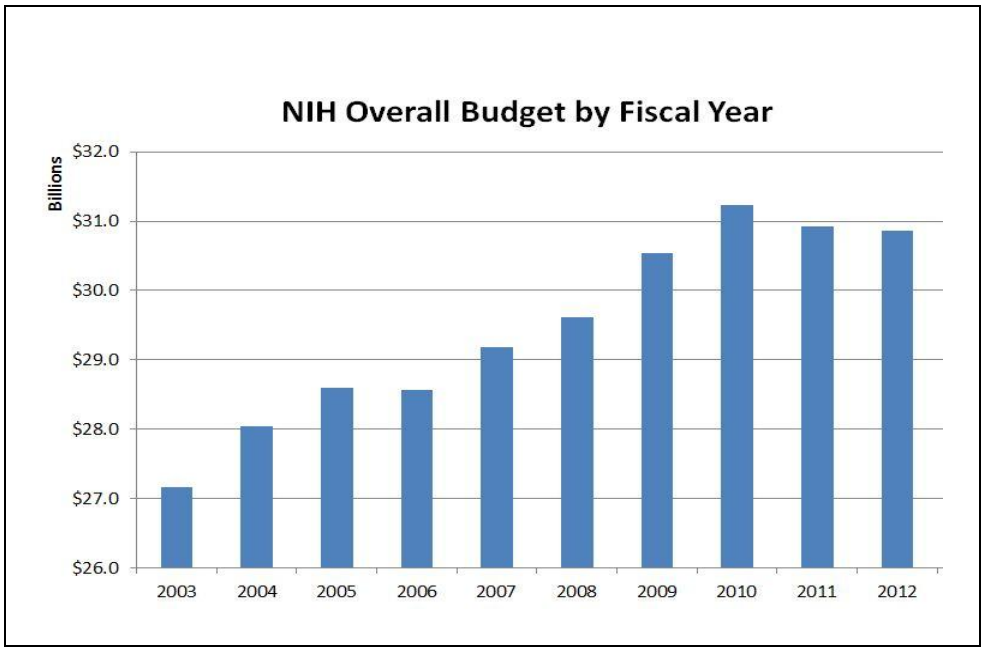

Figure 1. NIH Overall Budget by Fiscal Year
Chart retrieved from (https://www.nidcd.nih.gov/about/plans/2012-2016/Pages/Appendix-A-NIDCD-Funding-History.aspx)

The burden of disease is one criteria that NIH uses in setting funding priorities. Gross, Anderson, and Powe (1999) performed a cross-sectional study to determine whether the amount of funding the NIH allocates to research on particular diseases is associated with commonly available measures of the burden of disease. The authors compared estimates of disease-specific funding in 1996 with data on six measures of the burden of disease. The measures were

total mortality, years of life lost, number of hospital days in 1994 and incidence, prevalence, and disability-adjusted life-years (one disability-adjusted life-year is defined as the loss of one year of healthy life to disease) in 1990. Using these measures as variables in a regression analysis, the predicted funding was calculated and compared with actual funding. The results of this study showed that when looking at the individual measures of the burden of disease, there was no correlation between NIH funding and the incidence, prevalence or number of hospital days associated with each condition or disease. The numbers of deaths and years of life lost were weakly associated with funding. However, the number of disability adjusted life-years showed a positive correlation with NIH funded studies. Gross et al. (1999) also identified several diseases that appeared to be over funded, such as AIDS, breast cancer and diabetes.

A similar study was conducted by Gillum et al. (2011), based on 2006 NIH funding data to determine whether there was any change in the correlation of the burden of disease to NIH funding. The same categories from the Gross (1999) study were used to compare NIH funding patterns. Similar results were obtained as there was no correlation between incidence, prevalence of disease, or number of hospital days. Only the number of disability adjusted life-years continued to show a positive correlation with NIH funded studies a decade later. The same diseases that were identified as being over funded remained constant in this study.

Manton, Gu, Lowrimore, Ullian, and Tolley (2009) undertook a study to determine optimal future National Institutes of Health (NIH) funding levels. The

authors believed that the longitudinal correlation of the level of investment in NIH research with population changes in the risk of specific diseases should be analyzed. This is because NIH research is the primary source of new therapies and treatments for major chronic diseases, many of which were viewed as relatively untreatable in the 1950s. NIH research is also important in developing preventative and screening strategies to support public health interventions. Funding correlations were examined from 1950 to 2004 for 4 major chronic diseases cardiovascular disease (CVD), stroke, cancer, and diabetes and the NIH institutes responsible for funding research for those diseases. Their analysis shows consistent non-linear temporal correlations of funding to mortality rates across diseases. More importantly, Manton's et al. (2009) paper also showed the importance of NIH funding for research because there was a long-term correlation showing that increases in NIH funding resulted in reductions in overall specific mortality rates.

Since the NIH's annual budget increases have been reduced in recent years, understanding NIH funding patterns will be helpful for researchers to streamline requests. Bradshaw et al. (2008) analyzed data on NIH funding for research on pain, nausea and dyspnea for the period 2003 to 2007. Except for a 12% increase in funding for pain in 2004 from 2003, the next three years showed a 9.4% decline in funding. The percent of the total NIH budget going to support pain research increased to 0.78% in 2004 but fell to 0.61% in 2007. Bradshaw et al. (2008) reported that the results of 5 year trends in numbers of grants and

funding for research in pain, nausea, and dyspnea by the NIH show overall declines for pain but slight increases for nausea and dyspnea.

Bradshaw et al. (2008) demonstrated that declining support for pain research that exceeds the reductions in the total NIH budget signals a need for measures to increase pain research funding. They calculated that on 0.6% of the total NIH budget went for pain research, and stated that this is proportionately low, when considering that pain accounts for over 20% of doctor visits, 10% of all drug sales and estimates costs to developed counties of $ 1 trillion annually. Bradshaw et al. (2008) speculated that the number of applications for pain related studies may have declined, and he noted that the NIH is attempting to encourage more research for pain.

NCCAM Funding of Research

Although NCCAM has mainly relied on investigators to initiate topics and propose clinical trials, NCCAM has recently taken the initiative to encourage studies in specific areas that it has identified as requiring additional information. NCCAM is interested in areas of research that have been underdeveloped and has recently issued a Funding Opportunity Announcement (FOA) for smaller exploratory studies. Before investing in large scale clinical trials, NCCAM is aware that preliminary research first needs to be completed. “These smaller studies are essential, to identify the patient population, test an optimal intervention, develop an adequate placebo control, and establish appropriate outcome measurements.” (http://nccam.nih.gov/grants). This program is called,

High Priority Topics for Preliminary Clinical Studies for Large Interventional Trials of CAM, and the funds under this title are coded as PAR-10-163.

NCCAM Funding Priorities

The areas identified as high priority by NCCAM include studies to validate biomarkers, determine safety, appropriate dosages, and their timing. Botanicals are included as another area of high priority. This involves the use of botanicals as a complementary or alternative to pharmaceutical management of chronic pain or functional pain syndromes. NCCAM is also interested in studies involving mind and body interventions that include mindfulness, mediation, yoga, tai chi and hypnosis.

To qualify for PAR-10-163 funding, these studies should be designed to develop and validate treatment protocols that utilize mind-body approaches for the following: management of post-traumatic stress disorder, weight loss and weight loss maintenance, or chronic pain syndromes; including methods to measure treatment efficacy, as well as short-term and long-term adherence (http://nccam.nih.gov/grants).

Another category identified as a high priority by NCCAM is manual therapies. These studies should involve the identification and validation of biomarkers associated with reduction of pain or functional improvement in response to spinal manipulation or massage; and/or assessment of their dose responsiveness in patients with well-defined back pain. Studies are also needed for the validation of a sham control for spinal manipulation or massage for treatment of chronic low-back pain and/or neck pain. NCCAM would also like to

encourage studies on the benefit of massage for low back pain to include populations other than adults, such as youth, elderly, or specific ethnic or racial groups that were not adequately represented in previous studies.

Acupuncture is also listed under manual therapies. NCCAM is interested in studies to help create standardized acupuncture treatment protocols and develop suitable placebo controls or sham procedures that can be used in future trials involving osteoarthritis, back and neck pain, chronic headache, and shoulder pain. As a justification for studying manual therapies, NCCAM cites the most recent HHIS national survey (Barnes, McFann, McFann, & Nahin, 2008), that substantial numbers of Americans receive manual therapies as complementary treatments to conventional medical care, with smaller numbers receiving manual therapies as alternatives to conventional medical care. These treatments include spinal manipulation (as commonly performed by chiropractors and osteopaths), therapeutic massage, and other manipulative and body-based therapies that are used primarily to relieve musculoskeletal problems-commonly low back and neck pain.

NCCAM also points to the current, conventional medical practice guideline (Chou et al. 2007) that includes recommendations for some manual therapies for chronic back pain. They acknowledge that there may still be controversy over claimed benefits and potential risks for other manual therapies. They indicate that there is evidence to suggest that some manual therapies may trigger a cascade of cellular, biomechanical, neural, and/or extracellular events as the body responds to the imposed mechanical loads. A number of recent studies on spinal

manipulation reported correlated changes in the activity of nearby mechanically sensitive neurons, including those that function proprioceptively, which sense body position and muscle movements (Chou et al. 2007). This implies that there are possible responses by the central and autonomic nervous systems to the manipulation. These responses or alterations may, in turn, lead to observed changes in circulating levels of various neuropeptides and regulatory proteins. However, it is not yet known whether this is responsible for any possible clinical efficacy of manual therapy treatments.

Studies of massage-like stimulation in animals indicate that the treatment can stimulate pain-modulating systems working through the action of endogenous opioids. Massage-induced cardiovascular changes in animals have also been observed, and found to be related to the action of the hormone oxytocin at the level of the midbrain. NCCAM admits that these preliminary studies are intriguing and suggest that a number of hypotheses should be explored, since the exact mechanisms of action for purported treatment effects attributable to manual therapies are currently unknown.

The NCCAM website (http://nccam.nih.gov/) states that it is dedicated to studying manual therapies in the context of rigorous science and encouraging outstanding researchers to focus on this research opportunity. Chemists, physicists, psychologists, neuroscientists, endocrinologists, immunologists, geneticists, pharmacologists, biomechanists, and others in relevant fields of inquiry, including scientists based at research-intensive or complementary/alternative medicine (CAM) institutions, who are interested in

applying their expertise and powerful contemporary technologies to help advance the science of manual therapies are encouraged to apply. It appears that NCCAM is attempting to support more clinical trials to study methods of pain management. (http://nccam.nih.gov/grants).

To further promote research, the NIH launched their Roadmap for Medical Research initiative in August 2006 and can be found on the NIH website: (http://commonfund.nih.gov/aboutroadmap.aspx). Three areas of research were identified and targeted. The first is called the New Pathways to discovery, which invest in emerging and needed areas of research, such as biological, that includes metabolism, nanotechnology and bioinformatics. The next title is Research Teams of the Future, which is meant to encourage individual creativity and collaborative team efforts, and is interested in supporting interdisciplinary research, high risk research and includes partnerships between the public and private sectors. The third title is known as Re-engineering the Clinical Research Enterprise. This section will support research by bringing together by combining the works of regulatory policies, multidisciplinary training, and developing new networking and diagnostic tools.

Research studies are essential in order for complementary and alternative treatment modalities, such as massage therapy, to achieve increased acceptance by the medical profession, as well as from the general public. Studies in massage that provide a better understanding of what conditions will benefit and provide a mechanism of action will increase the validity of massage therapy as a legitimate treatment. NIH funding for research in massage therapy

can help accomplish this by making it possible for larger and better quality clinical trials to be undertaken.

Description of Massage Therapy

Massage therapy is described as soft-tissue manipulation for the purpose of normalizing those tissues. It consists of manual techniques that include applying fixed or movable pressure, holding, and/or causing movement of or to the body. The use of massage dates back to at least the second century B.C.E, when it was apparently first used in China, and later in India and Egypt (Goats 1994). In recent years, massage therapy has gained in popularity and many patients are now including massage as an adjunct to their conventional treatment. The classic form of massage, known as Swedish, utilizes various stroke techniques that include effleurage (stroking and gliding), petrissage (kneading), and tapotement (percussion). Although other forms of massage such as Shiatsu, Rolfing, reflexology and craniosacral therapy are also gaining in popularity, most of the published studies mainly involve Swedish massage.

Effects of massage therapy are intended to improve circulation of blood and lymph, reduce muscular tension, affect the nervous system through stimulation or sedation, and relieve stress and aid relaxation, and enhance tissue healing. Massage may help relieve pain through reduction of muscle tension and stiffness and relief of muscle spasms. It may also offer greater flexibility and range of motion. It has been used to relieve stress and aid relaxation. It may also promote deeper and easier breathing.

When a trauma or disorder produces the sensation of pain, an instinctive response is usually to rub the painful area. One could then make the observation that rubbing or massaging an injury may have therapeutic benefits. Moyer et al. (2004) provides a history of massage. The art of massage is believed to have originated before 2000 BCE and can be considered one of the oldest forms of therapy. References to therapeutic touch were found in the ancient Chinese text known as the Nei Ching (2760 BCE). As early as 1800 BCE, massage was also believed to be a component of Ayurveda, the traditional form of medicine practiced in India. Even Hippocrates, the Father of Medicine, believed that rubbing towards the heart enhanced the healing process.

Later in the 19th century Per Henrik Ling and Johan George Mezger are credited with developing what is now considered the classic or Swedish massage. The American Massage Therapy Association (AMTA) reports that between July 2008 and July 2009, roughly 48 million adult Americans (22 percent) had a massage at least once. AMTA estimated that massage therapy is a $16 billion a year industry.

Swedish massage is the most common form of massage used in this country (Tsao et al. 2004) and it is also commonly used in massage therapy research. In addition to Swedish massage, Asian Bodywork is gaining in popularity and many schools of massage therapy teach both modalities. Shiatsu is a form of Asian bodywork that originated in Japan. The term Shiatsu literally means “finger pressure” and it is typically applied to acupressure points along

pathways called meridians. The goal is to improve the flow of energy, called Qi. Shiatsu is often used for many types of pain conditions

Tui Na is another form of Asian Bodywork that uses strokes applied over energy channels to help enhance the flow of energy (Qi). Some of the stokes are similar to Swedish Massage, such as gliding (known as effleurage or Tui), kneading (petrissage or Nie), percussion (tapotement or Da), friction, pulling, rotation, rocking, vibration, and shaking. Tui Na can help relax muscles and it is also used for various pain conditions, such as musculoskeletal pain.

Program Evaluation: Step 3

Step 3: Focusing the Evaluation Design

A program evaluation is the systematic application of scientific methods to assess the design, implementation, improvement or outcomes of a program (Rossi & Freeman, 1993). This program evaluation investigated whether NCCAM's funding program is in alignment with its mission statement as it specifically relates to its funding of research in massage therapy. A goal of this program evaluation was to provide accountability to the stakeholders to show if changes in NCCAM's funding policy are needed and to demonstrate if resources are being utilized effectively. Areas evaluated were the level of funding relative to usage patterns, NCCAM's mission and areas of special interest, as well as the efficacy of massage as indicated by the evidence base of NIH funded massage research.

This program evaluation assessed whether the research results provided useful information about massage therapy that were consistent with the NIH mission to increase health and well-being. It also determined if the results showed how these goals can be attained by implementing certain changes in policy, spending, or that further or different massage research is needed. Results of this program evaluation can be used by stakeholders to assess whether the current NCCAM funding program for massage research is adequate. This report provides a better understanding of the NCCAM funding program and its goals. Furthermore, this program evaluation identified significant areas of unmet

research needs and a lack of utilization of massage in some areas where there is evidence for efficacy.

Evaluation of NCCAM's Mission Statement and Evaluation Question 1

To assess a program, Maher, (2012) suggests using an evaluative form. This goal can be accomplished by creating evaluation questions. This program evaluation investigated NCCAM's funding program as it specifically relates to its funding of research in massage therapy. Areas are: safety & efficacy of massage therapy as indicated by the evidence base of NIH funded research, appropriateness of funding relative to usage patterns, and consistency of funding with NCCAM's mission and areas of special interest.

To evaluate the whether the NCCAM stated mission "to define, through rigorous scientific investigation, the usefulness and safety of complementary health approaches and their roles in improving health care." Is being fulfilled, the following evaluation question was proposed:

- (Evaluation Question 1) What is the quality of the research and evidence-base demonstrating the safety and efficacy of massage therapy and its role in improving health care?

Data Collection for Evaluation Question 1

In addition to obtaining funded massage research studies directly from the NIH website, massage research studies were acquired by using the following keywords in database searches: Massage, massage therapy. The following combinations were used: massage and pain, massage and back pain, massage and sciatica, massage and neck pain, massage and musculoskeletal pain,

massage and joint pain, massage and cancer pain, massage and inflammation. The databases that were searched, using the above keywords and combinations were: Medline data base, OVID database (1996 to present), CINHAL, Pubmed database, High Wire Press, Stanford University database, and Google Scholar.

Data Analysis for Evaluation Question 1

Published massage research studies that have been wholly or partially funded by the NIH were reviewed for overall quality of the research, as well as for efficacy of massage for pain management. The study designs were examined for quality by evaluating the number of subjects and whether they were randomly assigned, the intervention, type of control arm utilized, blinding methods and outcome measurement tools.

The efficacy of massage was assessed based on outcomes obtained in the massage intervention studies. Massage research study designs were assessed for overall quality by using the JADAD scale. The Jadad Scale was selected because it presented the best validity evidence and has been tested for reliability in different settings. Olivo et al. (2008) reviewed seven scales to assess quality and concluded that the Jadad scale has greater validity evidence compared with the other scales.

Data is presented in tables and charts. A PICO table was used to analyze number of subjects, intervention, comparisons and outcomes. In addition, studies were also tracked for reports of any adverse effects resulting from the massage therapy intervention. Studies listed in the PICO table were used to organize and appraise the efficacy of massage therapy. This table was also used to monitor

safety by tracking reports of any adverse effects resulting from the use of massage therapy.

This review of the literature suggested that there is good research in massage therapy showing efficacy for a variety of outcomes and applications. However, some inherent problems have existed in clinical trials involving massage therapy. The dissertation includes a discussion on the quality and strength of the evidence in massage research. There appears to be a trend towards improvement in the quality of massage research designs which has the potential to strengthen the evidence base. This program evaluation addressed this issue and provided suggestions and recommendations for improving the quality of massage research.

Evaluation of NCCAM Funding Areas of Special Interest (Evaluation Question 2 and Evaluation Question 3)

To evaluate whether the stated NCCAM research funding area of special interest which is: “CAM interventions used frequently by the American public and on the conditions for which they are most frequently used ... These would include, but not be limited to, investigations of the impact of CAM modalities in alleviating chronic pain syndromes and inflammatory processes ...” is being met, the following evaluation questions were proposed:

- (Evaluation Question 2) How do the reasons for the utilization of massage therapy in the United States correlate with the research topics funded by the NIH since it began funding massage research in1993?

- (Evaluation Question 3) What is the pattern of funding in massage research topics involving pain and other inflammatory conditions?

To resolve these questions, concerning the public's utilization patterns, this program evaluation investigated the correlations between the reasons given by people in the United States for using massage therapy and the research topics that have been funded by the NIH since 1993.

Data Collection for Evaluation Question 2

Data of massage research topics were obtained from the NIH website beginning with 1993, the first year that NIH began funding massage research, through 2012. The actual funding data amount in dollars for massage study research topics was only publically available on the NIH website beginning with the year 2000.

Data for massage usage was collected from national surveys conducted by the American Massage Therapy Association (AMTA) and released in their industry fact sheets (Table 2). These surveys were national telephone interviews with over one thousand participants. Most of the more complete AMTA usage information was from recent years. Unfortunately, there were gaps in the AMTA annual surveys and usage studies were not done annually. Although the AMTA did surveys for 16 years, much of the information that was obtained from those surveys were more for demographic information, opinions and attitudes towards massage therapy, rather than for specific usage. For several years, AMTA surveys did not include specific massage usage information. This indicates a need for more specific survey research to more accurately reflect the usage of

massage therapy for specific conditions. This information was used to identify research areas of need and indicate whether massage research topics are in alignment with the NIH mission statement and NCCAM's research funding areas of special interest.

Information on the usage of CAM by the Public in the U.S and the use of massage was obtained from the published reports from the NHIS national CAM survey analyzed by Barnes, Powell-Griner, McFann, McFann, & Nahin, 2004; Barnes, Powell-Griner, and McFann, (2008); and the Eisenberg et al. (1993) studies. The NHIS national CAM survey (Barnes et al., 2004) had 31,044 participants, while the second survey (Barnes et al., 2008) survey had 75,764 respondents. It should be noted that the Eisenberg et al. (1993) survey included both chiropractic and massage in the category of manipulative therapies. The Eisenberg et al. (1993) survey was based on random dialing of phone numbers in the U.S. population and involved 1,539 participants.

Data Analysis for Evaluation Question 2

This correlation analysis involved two variables to compare the funded NIH research topics in massage therapy with the reasons given for usage of massage by the U.S. public. Statistical analysis used Spearman's Rank Order Correlation Coefficient to determine whether there was an association between these two variables. Assigning ranks for usage of massage therapy was done in descending order according to percentages of reported usage by people who receive massage therapy. This data was based on national surveys on actual reasons for usage from the annual American Massage Therapy Association

(AMTA) fact sheets. The research done on specific applications in massage therapy was ranked on an annual basis in descending order, based on a percentage of the total National Institute of Health (NIH) funding for research in massage therapy. Funding data was obtained using the Research Portfolio Online Reporting Tools (RePORT) Expenditures and Results (RePORTER), which has replaced the CRISP database that was formerly used by NIH. Only NIH funding reports for massage were reviewed from 1993, the first year some of this information became available, up to and including 2012. Ranking of studies were listed by total number of studies in each category. The variables in this study are considered ordinal, since they can be ordered or ranked. Comparison of massage usage and research were accomplished by dividing usage and research into categories. The variables were ranked in descending order, based on their respective percentages. Comparisons were be made on an annual basis from 1993 to 2012, as well as one final cumulative comparison.

The Spearman's rank-order correlation was selected as the statistical analysis in this study because it is the nonparametric version of the Pearson correlation coefficient. Spearman's correlation coefficient, (signified by r_s) measures the strength of association between two ranked variables. The Spearman correlation coefficient,(r_s,) can take values from +1 to -1. A r_s of +1 indicates a perfect association of ranks, a r_s of zero indicates no association between ranks and a r_s of -1 indicates a perfect negative association of ranks. The closer r_s is to zero, the weaker the association between the ranks (Figure 2).

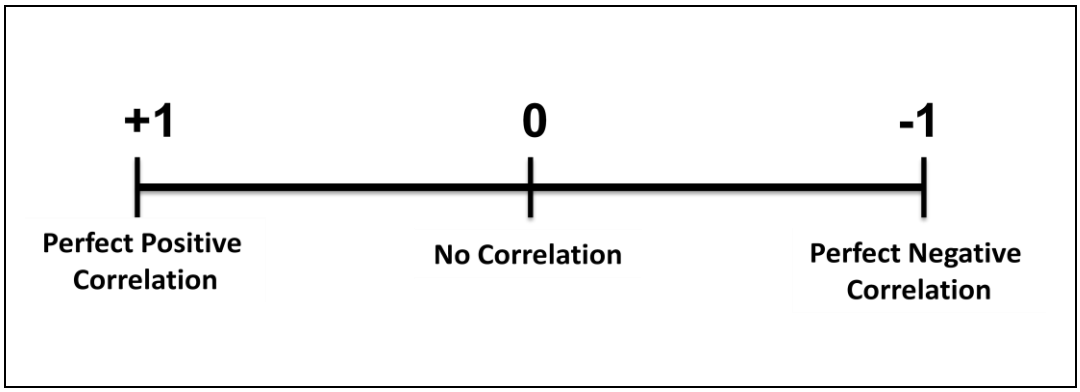

Figure 2. Perfect Positive to Perfect Negative Correlation

Correlation studies can provide the degree of the relationship between the variables under consideration, and it is measured through the correlation analysis. The measure of correlation is called the correlation coefficient .The degree of relationship is expressed by the coefficient which ranges from $-1 \leq r \geq +1$. The direction of change is indicated by either a positive or negative sign. The correlation analysis can enable us to have an idea about the degree and direction of the relationship between the two variables under study. Correlation is a statistical tool that helps to measure and analyze the degree of relationship between two variables. Correlation analysis deals with the association between two or more variables. Causation means cause and effect relation.

Correlation denotes the interdependency among the variables for correlating two phenomena. If two variables vary in such a way that movement in one is accompanied by movement in the other, these variables demonstrate a cause and effect relationship. Causation always implies correlation but correlation does not necessarily imply causation. The correlation is said to be positive correlation if the values of two variables change with same direction.

Conversely, the correlation is said to be negative correlation when the values of variables change with opposite direction.

An advantage of correlation studies is that they can show the amount (strength) of relationship present. They can be used to make predictions about the variables under study. They can be used in many situations and the data is relatively easy to collect.

One disadvantage of correlation studies is that we cannot always assume that a cause-effect relationship exists. There is also often little or no control (experimental manipulation) of the variables. Relationships may be accidental or could be due to a third, unmeasured factor common to the two variables that are measured.

Assumptions and Limitations of Spearman's Rank Order Correlation

Spearman's rank-order correlation requires that the data is ordinal and uses the assumption that the two variables are ordinal, interval or ratio. In this case, the two variables are considered ordinal. A second assumption for Spearman's correlation coefficient is that there is a monotonic relationship between the variables. Spearman's rank-order correlation does not presume any assumptions about the distribution. Data results were presented in the form of tables and charts. The data for usage and funding was also reviewed to indicate their relative proportions and possible trends. Although usage data was not available for all years, there was sufficient data used for indicating patterns and correlations. A limitation was that massage usage data was less consistent than massage research funding information.

NIH funded massage therapy research topics and the reasons given by people in the U.S for using massage therapy was analyzed on an annual basis from 1993 to the present. This was examined on order to determine whether there were trends in correlation between these two variables. This approach was used to indentify significant areas of unmet research needs as well as a lack of the public's utilization of massage in areas where evidence for efficacy does exist.

Data Collection and Analysis for Evaluation Question 3

To evaluate the third question, whether the stated NCCAM research funding area of special interest is being met, NIH funded published clinical trials in massage research for which pain or inflammation are the primary and secondary outcomes were analyzed.

Data for the number of massage research studies in which pain and inflammatory conditions are the primary or secondary outcome measurements were obtained by using the public records that are available through the NIH website. Annual comparisons were done to evaluate whether the topics in massage research were consistent with NCCAM's funding area of special interest.

Program Evaluation: Step 4

Step 4: Gathering Credible Evidence

Credible Evidence for Evaluation Question 1

To evaluate whether the NCCAM stated mission "to define, through rigorous scientific investigation, the usefulness and safety of complementary health approaches and their roles in improving health care" is being fulfilled, the following evaluation question was formulated:

- (Evaluation Question 1) What is the quality of the research and evidence-base of NIH-funded research demonstrating the safety and efficacy of massage therapy and its role in improving health care?

Several approaches were utilized to assess the quality of the evidence base. Published massage research studies that have been wholly or partially funded by the NIH were reviewed for overall quality, and the efficacy of the massage intervention. Study designs were examined for quality by evaluating the number of subjects and whether they were randomly assigned, type of control arm utilized, blinding methods, outcome measurement tools, description of intervention, and qualifications of massage therapists. Efficacy of massage was assessed based on outcomes obtained in the massage intervention studies. Massage research study designs were assessed for quality by using the Jadad Scoring System (Jadad et al., 1996). In addition, NIH funded massage studies were organized into a PICO table (Table 4) to analyze efficacy and safety. Data was also presented in the form of tables, charts and graphs for the purpose of analysis and discussion.

Introduction to the Jadad Scoring System

Jadad et al. (1996) developed a scoring system to evaluate the quality of clinical trials. The Jadad Scale, also known as the Oxford Quality Scoring System, was selected because it is a widely used and validated scale. Ziv et al. (2007) considers Jadad (1996) to be a quality assessment instrument. Sjogren and Halling, (2001) used the Jadad scale to assess the quality of randomized clinical trials in dental and medical research because at the time, it was the only validated quality scale developed. In a systemic review of the quality of research studies of conventional and alternative treatments of primary headaches, Crawford, Huynh, Kepple, and Jonas, (2009) also used the Jadad et al. (1996) scale because it was the most contemporary, popular and the most widely accepted validated tool to access the quality of randomized controlled trials. Olivo et al. (2008) reviewed seven scales to assess quality and concluded that the Jadad scale has greater validity evidence compared with the other scales.

The Jadad scoring system, also known as the Oxford quality scoring system, is a three-item, five-point scale commonly used to rate the quality of clinical trials. The possible range of scores is from 0 to 5. This system focuses on randomization, blinding and accounting for all participants, including withdrawals. Jadad et al. (1996) stated that assessing the validity of primary studies was one of the most important steps in the peer review process. To reduce bias, Jadad et al. (1996) emphasized the importance of randomization and double blinding, so that all participants have an equal opportunity to receive each intervention. In this article, the authors discussed the empirical evidence to support the role of

randomization and double blinding in minimizing bias. Jadad et al. (1996) indicated that nonrandomized trials that are not double blinded are more likely to show an advantage for an intervention over standard treatment. Furthermore, Jadad et al. (1996) indicated that evidence shows that randomized control trials in which treatment allocation was inadequately concealed, produced significantly larger estimates of treatment effects than trials with adequate blinding. The article pointed out that trials not using double blinding tended to yield significantly larger estimates of treatment effects.

The following provides the directions and examples for the use of the Jadad scoring system. The first section involves randomization and allows for a maximum of two points. One point is awarded if randomization is mentioned, such as subjects being randomly assigned to groups. An additional point is added if the method of randomization was described and was appropriately done, such as through the use of a computer generated program. However, one point is deducted if the method was inappropriate, for example, simply using a person's birthday or hospital number.

The second section involves double blinding and is worth up to two points. One point is credited if the study is described as double blinded. According to the Jadad scoring system double blinding was considered appropriate if neither the person doing the assessment nor the study participant could identify the intervention being assessed. Another point can be added if the method of double blinding was described and was appropriate such as using an identical placebo, active placebo or other dummies. According to Edward, Stevens, Braunholtz, and

Lilford. (2005), an active placebo is a treatment that has no therapeutic value. However it may produce similar adverse effects to the original treatment being assessed. A point can be deducted if the method of double blinding was inappropriate or there was incomplete masking. An example of inappropriate blinding was using different treatment modalities, such as tablets vs. injections. In the case of manual trials, inappropriate blinding would involve using another type of treatment modality as the placebo control arm.

The final section is worth one point and it is concerned with the fate of all participants in the study. The number of and reasons for withdrawals and dropouts must be provided. Even if there were no dropouts or withdrawals, It must also be specifically indicated. No point is awarded in this section if there was no statement accounting for withdrawals. Jadad et al. (1996) included this because withdrawals can lead to attrition bias. If more participants withdrew from one group, the sample may no longer be representative of the study population. In this case external validity could be affected. Attrition can also affect the internal validity if the drop outs were at different rates.

Jadad Scoring System Applied to NIH-NCCAM Funded Research Articles

Since NCCAM's mission statement is concerned with safety and efficacy through "rigorous scientific investigation," quality was evaluated using the Jadad scoring system. A total of 32 NIH funded massage therapy clinical trials were evaluated based on the Jadad scoring system. These articles were obtained from the NIH website and the full texts of the articles were obtained through the links to the journals. Review articles were excluded from this evaluation, since

according to Olivo et al. (2008), the Jadad scoring system is mainly used for assessing randomized clinical trials. Table 1 shows publications of NIH funded clinical trials that were evaluated using the Jadad scoring system. The Jadad system is based on a 5 point scoring system as follows:

- Was the study described as randomized? No = 0, Yes = 1 (Table 1 column named Rand)
- Was the method used to generate the sequence of randomization described and appropriate? No = 0, Yes = 1 (Table 1 column named Rdes)
- Was the study described as double blind? No = 0, Yes = 1 (Table 1 column named DB)
- Was the method of double blinding described and appropriate? No = 0, Yes = 1 (Table 1 column named DBdes)
- Was there a description of withdrawals and dropouts? No = 0, Yes = 1 (Table 1 column named WDdes)
- Penalty 1: Deduct one point if the randomization method was described and it was inappropriate? Appropriate = 0, Inappropriate = –1 (Table 1 column named Pen1)
- Penalty 2: Deduct one point if the study was described as double blind and the method was inappropriate: Appropriate = 0, Inappropriate = –1 (Table 1 column named Pen2)

Table 1. Jadad Scores of NIH Funded Massage Therapy Clinical Trials

Study Author	Year	Rand	Rdes	DB	DBdes	WDdes	Pen1	Pen2	Total Score
Moyer-Mileur	2013	1	0	0	0	0	0	0	1
Poland	2013	1	1	0	0	1	0	0	3
Smith	2013	1	0	0	0	1	0	0	2
Toth	2013	1	0	0	0	1	0	0	2
Ali	2012	1	0	0	0	0	0	0	1
Ang	2012	1	1	0	0	1	0	0	3
Field	2012	1	0	0	0	0	0	0	1
Perlman	2012	1	1	0	0	1	0	0	3
Rapaport	2012	1	1	0	0	1	0	0	3
Cherkin	2011	1	1	0	0	1	0	0	3
Rapaport	2010	1	0	0	0	1	0	0	2
Sherman	2010	1	1	0	0	1	0	0	3
Cherkin	2009	1	1	0	0	1	0	0	3
Diego	2009	1	1	0	0	1	0	0	3
Diego & Field	2009	1	0	0	0	0	0	0	1
Haun	2009	1	1	0	0	1	0	0	3
Sherman	2009	1	1	0	0	1	0	0	3
Smith	2009	1	0	0	0	1	0	0	1
Field	2008	1	0	0	0	0	0	0	1
Kutner	2008	1	1	0	0	1	0	0	3
Moraska	2008	1	1	0	0	1	0	0	3
Patterson	2008	1	1	0	0	1	0	0	3
Diego	2007	1	1	0	0	1	0	0	3
Hernandez-Reif	2007	1	0	0	0	0	0	0	1
Feijo	2006	1	0	0	0	1	0	0	2
Field	2006	1	1	0	0	1	0	0	3
Shor-Posner	2006	1	0	0	0	0	0	0	1
Diego	2005	1	1	0	0	1	0	0	3
Shor-Posner	2004	1	0	0	0	0	0	0	1
Dieter	2003	1	1	0	0	1	0	0	3
Birk	2000	1	0	0	0	1	0	0	2
Ahles	1999	1	0	0	0	1	0	0	2
Total Score		32	17	0	0	24	0	0	72
Mean Score		1	0.53	0	0	0.75	0	0	2.25

Analysis of Evaluation Question 1

Table 2 provides a summary of data from the Table 1 Jadad scores of NIH funded massage therapy studies. Table 2 provides the total number and percentage of the individual scores for all the studies evaluated showing the total number and percentage of the individual scores for all the studies evaluated. According to Jadad et al. (1996), a score 3 to 5 is considered high quality, while a score below 3 is considered poor quality. Figure 3 displays the same data in a chart.

Table 2. Jadad Scoring Summary for NIH Funded Massage Therapy Clinical Trials

Jadad Score	Number of Studies	Percent of Total Studies
0	0	0%
1	9	28%
2	6	19%
3	17	53%
4	0	0%
5	0	0%
Total	32	100%

No study scored higher than 3; however, seventeen out of thirty-two studies (53%) scored 3. According to the Jadad et al. (1996) criteria, 3 points is the minimum score for a study to be considered high quality. There were six studies that scored 2 (19%), nine studies scored 1 point (28%). All studies (100%) received a point for being randomized. Fifteen trials did not receive an additional point because they either failed to describe the method of randomization or they utilized a method that was not considered appropriate based on the Jadad (1996) scoring system. Eight studies (25%) did not receive a

point because they either neglected to account for withdrawals or failed to mention that there were no withdrawals in their study. The overall mean score for all of the clinical trials was 2.25 out of a possible 5 points.

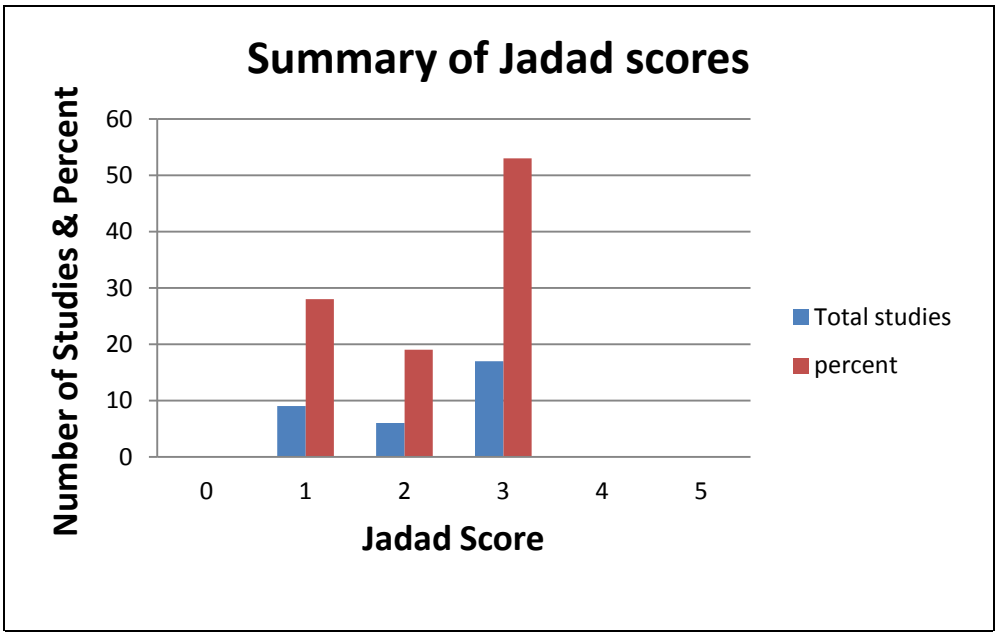

Figure 3. Jadad Scoring Summary for NIH Funded Massage Therapy Clinical Trials

It is should be noted that none of the study designs were described as double blinded. This serves to highlight a deficiency that needs to be addressed in future massage research studies. In addition to including a validated placebo (sham) massage control arm to conceal treatment to participants, therapist would also have to be blinded. It is encouraging that massage researchers are exploring the use of light touch massage as a placebo control that could be used in future massage therapy trials. An in-depth discussion of the challenges of massage placebos and double blinding is included in Step 5.

The mean score for all studies reviewed was 2.25. Since this is below 3, it is considered poor quality according to the Jadad scoring system. The results of the Jadad scores pointed out several areas concerning the limitations that are common to manual trials. However, massage therapy randomized clinical trials currently have the ability to consistently receive 3 points on the Jadad scale, indicating a high quality study. Suggestions and recommendations will be provided for improving the overall quality of the research in massage therapy within the design paradigm of the randomized controlled trial and other research designs in Step 5.

Table 3. Mean Jadad Scores by Publication Year for NIH Funded Massage Therapy Clinical Trials

Publication Year	Mean Jadad Score	Number of Studies
2013	2.0	4
2012	2.2	5
2011	3.0	1
2010	2.5	2
2009	2.3	6
2008	2.5	4
2007	2.0	2
2006	2.0	3
2005	3.0	1
2004	1.0	1
2003	3.0	1
2002	----	0
2001	----	0
2000	2.0	1
1999	2.0	1
	Total	32

The mean Jadad scores were calculated and grouped by year (Table 3). This data was then placed into a scatter chart (Figure 4) that was used to identify possible trends in improvement in quality of studies, over time, as rated by the Jadad scoring system. Based on the Jadad criteria, the results indicated that there was no trend established showing any changes in the quality of the research in massage therapy clinical trials over time. When and if an adequate placebo (sham) massage is available, massage trials will have the potential to attain a perfect score of 5 on the Jadad scale.

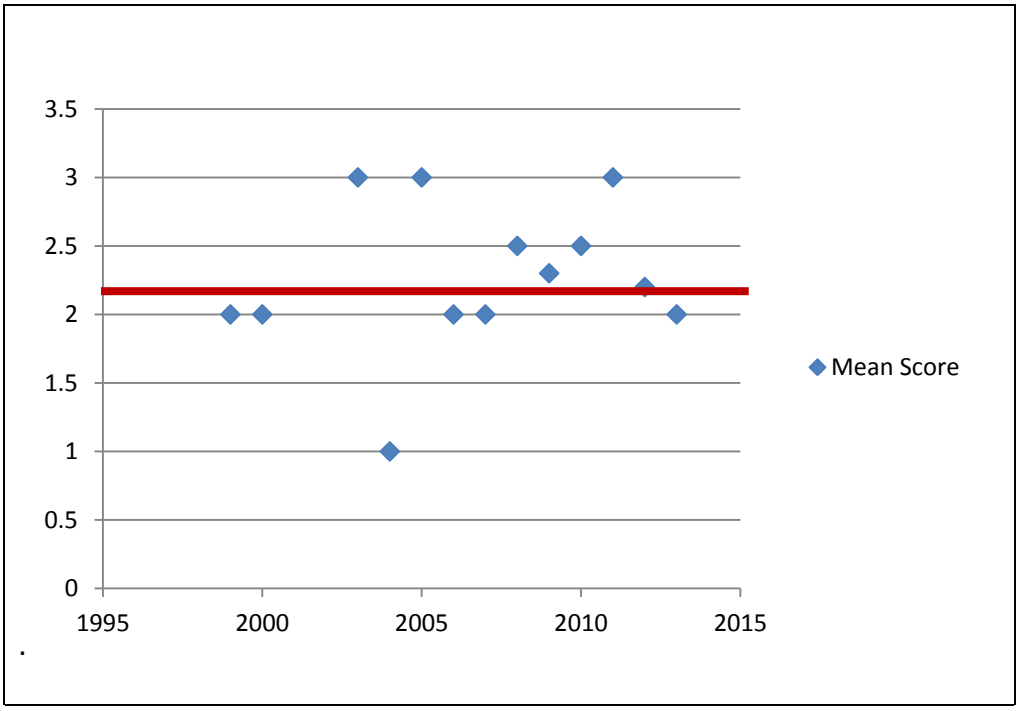

Figure 4. Mean Jadad Scores by Publication Year for NIH Funded Massage Therapy Clinical Trials

Assessing Efficacy and Safety of Massage Therapy

To assess both efficacy and safety, a PICO Table consisting of NIH funded massage research clinical trials was included (Table 4). A total of 28 NIH funded massage therapy clinical trials, involving 2138 participants were reviewed and entered into the PICO table (Table 4). Studies that were not included in the PICO table were review articles or clinical trials that although funded, were not completed.

The analysis showed that 27 out of 28, or 96% of the clinical trials demonstrated significantly positive results for the groups receiving the massage therapy intervention compared to the controls. This indicates that there is evidence for the efficacy of massage therapy for a variety of disorders, including chronic pain conditions. A further detailed discussion of the efficacy of massage therapy is included in Step 5.

These studies were also reviewed for any possible adverse effects. All of these massage clinical trials used licensed massage therapists to administer the intervention. No adverse effects related to massage therapy were reported from any of the NIH funded studies that were reviewed. NCAAM's mission statement expressed concerned for public safety with regard to the use of CAM. Based on this review, it appears that massage therapy is safe for the conditions that were investigated and with the protocols used in the clinical trials when performed by certified or licensed massage therapists.

To corroborate these safety results, a literature review was conducted to investigate the safety of massage therapy. A review article by Ernst (2003)

explored the safety of massage therapy. A computerized data base search utilizing Medline, and Embase, the Cochrane Library and AMED from January, 1995 to December, 2001 was conducted. This search performed by Ernst (2003) yielded a total of sixteen reports of adverse effects attributed to massage therapy. The most serious adverse effects were mainly associated with massage techniques other than Swedish massage. In addition, the author indicated that the use of an apparatus or exotic type of manual massage administered by non-professional or non-licensed lay persons would be more likely to result in an adverse effect. Exotic massage was described as forceful techniques such as shiatsu and Rolfing.

Only three adverse effects were found to be attributed to licensed massage therapists and it was noted that all three patients made full recoveries. Adverse effects were mainly associated with massage techniques other than Swedish massage that were performed by non-licensed massage therapists. This review article found that serious adverse effects associated with Swedish massage, and other forms of massage therapy, when performed by licensed massage therapists, are extremely rare. It should be noted that most massage trials use Swedish massage as the intervention.

Cambron, Dexhiemer, Coe, and Swenson, (2007) conducted a study to investigate whether there were possible side effects of massage therapy. The authors noted that massage therapy is gaining in popularity, and that approximately 47 million Americans receive a massage annually. They also point out that research studies on massage therapy are severely lacking and that a

literature review only found one study concerned with side effects. A review article by Ernst (2003) indicated that serious adverse effects were mainly associated with exotic massage or massage performed by laypersons rather that from massage therapists. Cambron et al. (2007) performed the first known study conducted to investigate whether massage therapy produced any negative side effects, any positive effects or whether there were any unexpected effects. It is interesting to note that the one hundred subjects enrolled in this study were all treated by student massage therapists. Most clients received massage for relaxation, while others were interested in pain relief, particularly in the low back, neck or shoulder areas. Depending on the client's condition, the massage treatments consisted of either Swedish, deep tissue, or trigger point therapy. Subjects were interviewed within 3 days of their massage and asked if they experienced any additional discomfort or any unpleasant reactions. Questions concerning positive effects or unexpected changes were also asked.

Results indicated that only 10% of the clients reported minor negative effects and most subsided within 12 hours following massage therapy. No negative effects were reported to last more than 36 hours. Majority of the clients reported positive effects that lasted more than 38 hours. In addition, 23% of the clients reported unexpected non-musculoskeletal positive effects such as improved mood and a feeling of emotional well-being. Others reported improvement in digestive function and respiration. Overall, the average benefit rating was an 8, on a scale of 0 to 10 (no benefit to extreme benefit).

Safety for participants in massage clinical trials is a paramount concern with respect to the ethical issues surrounding the use of human subjects in clinical studies. Referring to data demonstrating the overall safety of massage therapy can help assuage Institutional Review Board concerns about safety of the intervention and facilitate the approval process.

Table 4. PICO Table Summary of NIH Funded Randomized Clinical Trials Demonstrating Efficacy and Safety of Massage Therapy

Citation	Patients/ Subjects	Interventions	Comparisons	Outcomes	Adverse Effects
Moyer-Mileur, 2013 Massage improves growth quality by decreasing body fat deposition in male preterm infants	44 preterm infants	Soft tissues compression strokes with kinesthetic movement of extremities	**Group 1**:15 minute massage of soft compression strokes twice daily for 6 days a week for a maximum of 4 weeks **Group 2**: No massage	Massage did not promote greater weight gain in preterm infants. Massage did, however, limit body fat deposition in male preterm infants.	No
Poland, 2013 Open-label, randomized, parallel-group controlled clinical trial of massage for treatment of depression in HIV infected subjects	37 subjects over age 16	Swedish massage	**Group 1**: Swedish massage for 1 hour twice a week **Group 2:** No massage, only touch with light pressure	Massage significantly reduced depression.	No
Smith, 2013 Heart rate variability during care giving and sleep after massage therapy in preterm infants	21 preterm infants	Moderate pressure and stroking of soft tissues followed by kinesthetic movement of extremities	**Group 1**: 20 minute massage twice daily for 2 weeks **Group 2**: No massage	Only male infants had an increased heart rate but not statistically significant when compared to controls and no difference for female with controls.	No

Table 4. PICO Table Summary of NIH Funded Randomized Clinical Trials Demonstrating Efficacy and Safety of Massage Therapy (continued)					
Citation	**Patients/ Subjects**	**Interventions**	**Comparisons**	**Outcomes**	**Adverse Effects**
Toth, 2013 Massage therapy for patients with metastatic cancer: A pilot randomized controlled trial	39 patients with metastatic cancer	Swedish and non-Swedish massage and no touch (energy) therapy	**Group 1**: 3 sessions of massage in the first week for between 15 to 45 minutes depending on patient's tolerance and preference **Group 2**: No touch (energy) therapy **Group 3**: Usual care	The terminally ill cancer patients in the Massage therapy group had improved quality of life.	No
Ang, 2012 A randomized placebo controlled trial of massage therapy on immune system of infants	120 preterm infants	Infant massage	**Group 1**: Infant massage 5 times weekly until discharge for a maximum of 4 weeks **Group 2**: (Sham) light touch	Although there was no difference in the numbers of NK cells, those in the massage group demonstrated increased cytotoxicity. However, it was also important to note that those in the massage group also showed greater daily weight gain, which may also help to improve their overall outcome.	No
Field, 2012 Yoga and massage therapy reduce prenatal depression and prematurity	84 prenatally depressed women	Massage yoga	**Group 1**: Yoga (20 minutes weekly for 12 weeks) **Group 2**: Massage (20 minutes weekly for 12 weeks) **Group 3**: Standard prenatal care	Both interventions (yoga & massage) significantly lower depression, along with contributing to reduced back and leg pain compared to the control.	No

Table 4. PICO Table Summary of NIH Funded Randomized Clinical Trials Demonstrating Efficacy and Safety of Massage Therapy (continued)					
Citation	**Patients/ Subjects**	**Interventions**	**Comparisons**	**Outcomes**	**Adverse Effects**
Perlman, 2012 Massage therapy for osteoarthritis of the knee: A randomized dose-finding trial	125 adults with osteoarthritis of the knee	Swedish massage	Dosing study: **Group 1**: 60 minute massage biweekly **Group 2**: 60 minute massage weekly **Group 3**: 30 minute massage biweekly **Group 4**: 30 minute massage weekly Control: usual care	Changes in the WOMAC provided the primary outcome measurements. Results showed significant improvements in all four treatment groups. Both of the sixty minute massage groups outperformed the thirty minute groups. However, there was no significant difference between both sixty minute groups (weekly vs. biweekly). It was concluded that the optimal massage dosage could effectively be achieved with one weekly sixty minute massage, over an eight week period.	No
Rapaport, 2012 A preliminary study of the effects of a single session of Swedish massage on hypothalamic–pituitary–adrenal and immune function in normal individuals	53 healthy adults	Swedish massage	**Group1**: Single 45 minute session of Swedish massage **Group 2**: Single session Light touch control	Single session massage group had significant increase in lymphocytes, reduced arginine-vassopressin levels, small decrease in cortisol, but surprisingly, no significant increase in oxytocin levels when compared to light touch control.	No

Table 4. PICO Table Summary of NIH Funded Randomized Clinical Trials Demonstrating Efficacy and Safety of Massage Therapy (continued)					
Citation	**Patients/ Subjects**	**Interventions**	**Comparisons**	**Outcomes**	**Adverse Effects**
Cherkin, 2011 A comparison of the effects of two types of massage and usual care on chronic low back pain	401 adults with low back pain	Swedish massage	**Group 1**: Relaxation massage **Group 2**: Structural massage to receive massage treatment designed to alleviate back pain. **Group 3**: Used as the control, and those participants received no massage and continued with usual care.	Outcome measurements in this study used the Roland Disability Questionnaire (RDQ) and were measured at baseline, then after 10, 26, and 52 weeks. The results showed that both types of massage were found to be more effective than usual care alone. It was found that significant improvement continued throughout the 26 week follow up period. However, no significant improvement was reported after 52 weeks.	No
Diego, 2009 Procedural pain heart rate responses in massaged preterm infants	56 preterm infants	Either moderate or light pressure massage	**Group 1**: 15 minutes of moderate pressure massage **Group 2**: 15 minutes light pressure massage **Group 3**: No massage	Infants in the moderate pressure massage group had less of an increased heart rate response to stressor than either light pressure or control groups.	No
Diego & Field, 2009 Moderate pressure massage elicits a parasympathetic nervous system response	20 healthy adults	Moderate or light pressure massage	**Group 1**: 15 minute moderate pressure massage while seated in a massage chair **Group 2**: 15 minute light pressure massage while seated in a massage chair	Those receiving a moderate pressure massage showed an increase in parasympathetic nervous system response, while those who received light pressure had an increased sympathetic nervous system response.	No

Table 4. PICO Table Summary of NIH Funded Randomized Clinical Trials Demonstrating Efficacy and Safety of Massage Therapy (continued)					
Citation	**Patients/ Subjects**	**Interventions**	**Comparisons**	**Outcomes**	**Adverse Effects**
Haun, 2009 Children with cancer and blood diseases experience positive physical and psychological effects from massage therapy	30 children under age 17	20 minute session of Swedish massage	**Group 1**: 20 minutes sessions of Swedish massage either over 4 consecutive days or once weekly for 4 weeks **Group 2**: No massage	Massage group had improved quality of life with reduced pain and anxiety when compared to the non treatment controls.	No
Sherman, 2009 Randomized trial of therapeutic massage for chronic neck pain	64 adults with neck pain	Swedish massage	**Group 1:** 10 massage treatments over a 10 week period **Group 2**: Control group only received a self care book entitled, *What to Do for a Pain in the Neck*, by Jerome Schofferman, MD	There was a significant reduction in scores on the Neck Disability Index, compared to those in the self-care control group. This difference remained throughout the 26 week follow up period. After 26 weeks, there was no longer a significant difference between the two groups.	No
Field, 2008 Massage therapy reduces pain in pregnant women, alleviates prenatal depression in both parents and improves their relationships	47 prenatally depressed women	20 minute massage sessions	**Group 1**: 20 minutes massage sessions twice weekly for 12 weeks (Note: Massages were provided by the women's partners who were taught the procedure and given a DVD) **Group 2**: No massage	Those in the massage group had decreased depression, anxiety, as well as reduced back and leg pain. Their partners who provided the massages also reported decreased anxiety and depression.	No

Table 4. PICO Table Summary of NIH Funded Randomized Clinical Trials Demonstrating Efficacy and Safety of Massage Therapy (continued)

Citation	Patients/ Subjects	Interventions	Comparisons	Outcomes	Adverse Effects
Kutner, 2008 Massage therapy versus simple touch to improve pain and mood in patients with advanced cancer: A randomized trial	380 adults with advanced cancer and experiencing moderate to severe pain	30 minute massage or simple touch	**Group 1**: Six 30 minute massage sessions over 2 weeks **Group 2:** Six 30 minutes sessions of simple touch	Improvements were noted in both groups with reduced pain and improved mood; however, group 1 had a statically significant difference.	Adverse effects reported from both groups, but not appeared related to treatment
Moraska, 2008 Comparison of a targeted and general massage protocol on strength, function, and symptoms associated with carpal tunnel syndrome: A randomized pilot study	27 adults with carpal tunnel syndrome (CTS)	30 minute sessions of either general massage or carpal tunnel syndrome targeted massage	**Group 1**: Twice weekly sessions over 6 weeks of CTS targeted massage **Group 2**: Twice weekly 30 minutes sessions over 6 weeks of general massage	The carpal tunnel syndrome targeted massage group had greater gains in grip strength compared to the general massage group.	No
Patterson, 2008 A novel clinical trial design for the study of massage therapy	46 adult cancer patients undergoing chemotherapy	Swedish massage	**Group 1**: Medium intensity body work **Group 2**: Light touch (sham) massage **Group 3**: Control – no intervention	The results showed a favorable response from all the subjects in group one, who had the medium intensity massages, while there was mixed results in the light tough massage group. The non-intervention control has negative responses.	No

Table 4. PICO Table Summary of NIH Funded Randomized Clinical Trials Demonstrating Efficacy and Safety of Massage Therapy (continued)					
Citation	**Patients/ Subjects**	**Interventions**	**Comparisons**	**Outcomes**	**Adverse Effects**
Diego, 2007 Temperature increases in preterm infants during massage therapy	72 preterm infants	15 minute sessions of infant massage	**Group 1**: Three standardized 5 minute phases with 5 minutes of tactile simulation in the beginning and end and kinesthetic stimulation in the middle phase **Group 2**: No massage (standard care)	Massage group had a significantly greater increase in body temperature compared to the controls.	No
Hernandez-Reif, 2007 Preterm infants show reduced stress behaviors and activity after five days of massage therapy	36 preterm infants	Three 15 minute massages daily for 5 days	**Group 1**: Three 15 minutes massages daily for 5 consecutive days. **Group 2**: No massage (standard care)	The preterm infants in the massage group showed fewer stress behaviors than the control group.	No
Feijo, 2006 Mothers' depressed mood and anxiety levels are reduced after massaging their preterm infants	40 mothers of preterm infants who were about to be discharged from the hospital	One 8 minute massage divided into 2 consecutive 4 minute segments	**Group 1:** Mothers first observed a therapist giving their infants a 4 minute massage and were then instructed on the technique and the mothers then gave the second 4 minute massage to their infants. **Group 2**: Mothers only observed their infants receiving two consecutive 4 minute massages.	Both groups of mothers had lower depression levels, however on the group that massaged their infants had lower anxiety levels.	No

Table 4. PICO Table Summary of NIH Funded Randomized Clinical Trials Demonstrating Efficacy and Safety of Massage Therapy (continued)					
Citation	**Patients/ Subjects**	**Interventions**	**Comparisons**	**Outcomes**	**Adverse Effects**
Field, 2006 Moderate versus light pressure massage therapy leads to greater weight gain in preterm infants	68 preterm infants	15 minute Moderate pressure or light pressure massages 3 times daily for 5 days	**Group 1:** 5 days of 15 minute moderate pressure massage that consisted of three standardized 5 minute phases with 5 minutes of tactile simulation in the beginning and end and kinesthetic stimulation in the middle phase **Group 2:** 5 days of 15 minute (sham) light pressure massages in 3 five minute phases (light pressure, kinesthetic stimulation and light pressure	The moderate pressure massage group had significant greater weight gain. And appeared more relaxed and less aroused than the light pressure group.	No
Shor-Posner, 2006 Impact of a massage therapy clinical trial on immune status in young dominican children infected with HIV-1	54 HIV postive children ranging in ages from 2 to 8 years	20 minute massage therapy twice a week for 12 weeks	**Group 1**: 20 minute massage twice a week for 12 weeks **Group 2**: No massage, either only standard care or a friendly visit twice a week	Children in the massage group maintained stable or increased CD4 counts, while more of the children in the control showed declines in CD4 counts. In addition, the younger massage treated children also had significant increase in natural killer cells.	No

Table 4. PICO Table Summary of NIH Funded Randomized Clinical Trials Demonstrating Efficacy and Safety of Massage Therapy (continued)					
Citation	**Patients/ Subjects**	**Interventions**	**Comparisons**	**Outcomes**	**Adverse Effects**
Diego, 2005 Vagal activity, gastric motility, and weight gain in massaged preterm neonates	48 preterm neonates	15 minute Moderate pressure or light pressure massages 3 times daily for 5 days	**Group 1:** 5 days of 15 minute moderate pressure massage that consisted of three standardized 5 minute phases with 5 minutes of tactile simulation in the beginning and end and kinesthetic stimulation in the middle phase **Group 2**: 5 days of 15 minute (sham) light pressure massages in 3 five minute phases (light pressure, kinesthetic stimulation and light pressure	Neonates receiving moderate pressure massage had greater weight gain, increased vagal tone, and gastric motility compared with the light touch (sham) massage group.	No
Shor-Posner, 2004 Massage treatment in HIV-1 infected Dominican children: A preliminary report on the efficacy of massage therapy to preserve the immune system in children without antiretroviral medication	24 HIV positive children ranging in age from 2 to 8 years	20 minute massage therapy sessions twice a week for 12 weeks	**Group 1**: 20 minute massage twice a week for 12 weeks **Group 2**: A friendly visit twice a week for 12 weeks	Children in the control group had a significantly greater decline in both CD4 and CD8 counts than the massage group.	No

Table 4. PICO Table Summary of NIH Funded Randomized Clinical Trials Demonstrating Efficacy and Safety of Massage Therapy (continued)					
Citation	**Patients/ Subjects**	**Interventions**	**Comparisons**	**Outcomes**	**Adverse Effects**
Dieter, 2003 Stable preterm infants gain more weight and sleep less after five days of massage therapy	32 preterm neonates	Three daily 15 minute sessions of massage therapy for five days	**Group 1:** 5 days of 15 minute moderate pressure massage that consisted of three standardized 5 minute phases with 5 minutes of tactile simulation in the beginning and end and kinesthetic stimulation in the middle phase **Group 2**: No massage	Neonates in the massage group showed significantly greater weight gain and slept less than the control group.	No
Birk, 2000 The effects of massage therapy alone and in combination with other complementary therapies on immune system measures and quality of life in human immune-deficiency virus	42 HIV positive adults	One 45 minute massage therapy session weekly for 12 weeks either alone or in combination with exercise or stress management	**Group 1:** One 45 minute massage weekly for 12 weeks **Group 2:** One 45 minute massage weekly for 12 weeks combined with exercise. **Group 3:** One 45 minute massage weekly for 12 weeks combined with stress management **Group 4:** Only usual care	There was no significant difference in CD4 and CD8 counts among the 4 groups.	No
Ahles, 1999 Massage therapy for patients undergoing autologous bone marrow transplantation	35 adults scheduled for autologous bone marrow transplantation	Up to 9 twenty minute massages	**Group 1:** 3 twenty minute massages per week for 3 weeks **Group 2:** Usual care	Those in the massage group had less stress, fatigue, nausea and anxiety than the control group.	No

Table 4. PICO Table Summary of NIH Funded Randomized Clinical Trials Demonstrating Efficacy and Safety of Massage Therapy (continued)					
Citation	**Patients/ Subjects**	**Interventions**	**Comparisons**	**Outcomes**	**Adverse Effects**
Scafidi, 1993 Factors that predict which preterm infants benefit most from massage therapy	93 preterm infants	Three daily 15 minute massages for 10 days	**Group 1:** Three daily 15 minute massages for 10 days **Group 2:** Usual care	Infants in massage group gained significantly more weight per day (32 versus 29 grams) than the controls.	No
Total of 28 studies	**Total of 2138 participants**			**27 out of 28 (96%) clinical trials showed significantly positive results.**	**No adverse effects**

Analysis of NCCAM's Research Area of Special Interest

The next step was to evaluate whether the stated NCCAM research funding area of special interest, which is "CAM interventions used frequently by the American public and on the conditions for which they are most frequently used ... These would include, but not be limited to, investigations of the impact of CAM modalities in alleviating chronic pain syndromes and inflammatory processes ..." is being met, the following Evaluation Questions 2 and Evaluation Question 3 were formulated:

- (Evaluation Question 2) How do the reasons for the utilization of massage therapy in the United States correlate with the research topics funded by the NIH since it began funding massage research in1993?
- (Evaluation Question 3) What is the pattern of funding in massage research topics involving pain and other inflammatory conditions?

Data Analysis of Evaluation Question 2

The first step was to investigate which CAM interventions were most commonly used by the American public and for the conditions most frequently used. Establishing that massage therapy qualified as a frequently used CAM intervention, this program evaluation, examined the public's usage of massage therapy. Data collection for the usage of massage therapy by the U.S. population was obtained from national surveys conducted by the American Massage Therapy Association (AMTA) and released in their industry fact sheets (Table 5). These surveys were national telephone interviews with over one thousand participants each. Most of the more complete AMTA usage information was from

recent years. There were gaps in the AMTA annual surveys and usage studies were not done annually. For some years, AMTA surveys did not include specific massage usage information.

Table 5. Usage of Massage Therapy Obtained from the Annual AMTA Industry Fact Sheets

Year	Percent receiving massage	Massage for medical conditions	Massage for relaxation/ stress	Massage for pain condition	Massage for soreness/ stiffness/ spasms	Massage for injury recovery/ rehab	Massage for pampering/ general wellness
2012	11%	43%	32%	19%	13%	9%	12%
2011	12%	44%	30%	19%	12%	9%	12%
2010	18%	N/A	40%	15%	7%	N/A	N/A
2009	22%	32%	32%	25%	N/A	N/A	17%
2008	20%	31%	36%	N/A	N/A	N/A	N/A
2007	24%	N/A	N/A	N/A	N/A	N/A	N/A
2006	13%	30%	26%	N/A	N/A	N/A	11%
2005	16%	32%	26%	N/A	N/A	N/A	N/A
2004	15%	N/A	N/A	N/A	N/A	N/A	N/A
2003	21%	N/A	N/A	N/A	N/A	N/A	N/A
2002	18%	N/A	23%	N/A	N/A	N/A	N/A
2001	17%	35%	25%	10%	10%	8%	31%
2000	16%	29%	30%	6%	10%	4%	N/A
1999	15%	N/A	N/A	N/A	N/A	N/A	N/A
1998	13%	N/A	N/A	N/A	N/A	N/A	N/A
1997	8%	N/A	N/A	N/A	N/A	N/A	N/A
Mean	16.2%	34.5%	30.0%	16.0%	10.0%	7.5%	17.0%

N/A: Data not available

Although the AMTA did surveys for 16 years, much of the information that was obtained from those surveys were more for demographic information, opinions and attitudes towards massage therapy, rather than for specific usage. There appears to be a need for more specific survey research to more accurately reflect the usage of massage therapy for specific conditions. This information can be used to identify research areas of need and indicate whether massage research topics are in alignment with the NIH mission statement and NCCAM's research funding areas of special interest.

Use of CAM

NCCAM is the primary funding source for complementary and alternative medicine (CAM). Since interest in CAM is increasing in popularity in this country, it is important to understand the usage of massage in relation to overall CAM usage by the public. One of the first major studies outlining the use of Complementary and Alternative Medicine was conducted by Eisenberg et al. (1993). He found that in 1990, one out of three adults in the U.S. had used some type of "unconventional therapy." His study found that massage was ranked as the third most popular form of CAM, behind relaxation techniques and chiropractic. Subsequent studies by other researchers, such as Barnes et al. (2008) reported that the use of alternative therapies has remained strong and that massage was being used to treat a variety of medical conditions such as back pain, arthritis, muscle sprains and fatigue.

The Barnes et al. (2008) report of the national CAM survey sponsored by the Department of Health and Human Services provided statistical evidence to

indicate that almost 40% of Americans admitted to using CAM in the prior year. It was found that the most common form of therapy involved the use of non-vitamin, and non-mineral natural products. See Figure 5. Following the use of these supplements, Barnes et al. (2008) reported that the next most common CAM therapies used were deep breathing exercises (12.7%), meditation (9.4%), chiropractic or osteopathic manipulation (8.6%), followed by massage (8.3%), and yoga (6.1%). It was also noted that the use of massage, acupuncture, and naturopathy has been on the rise during the previous five years.

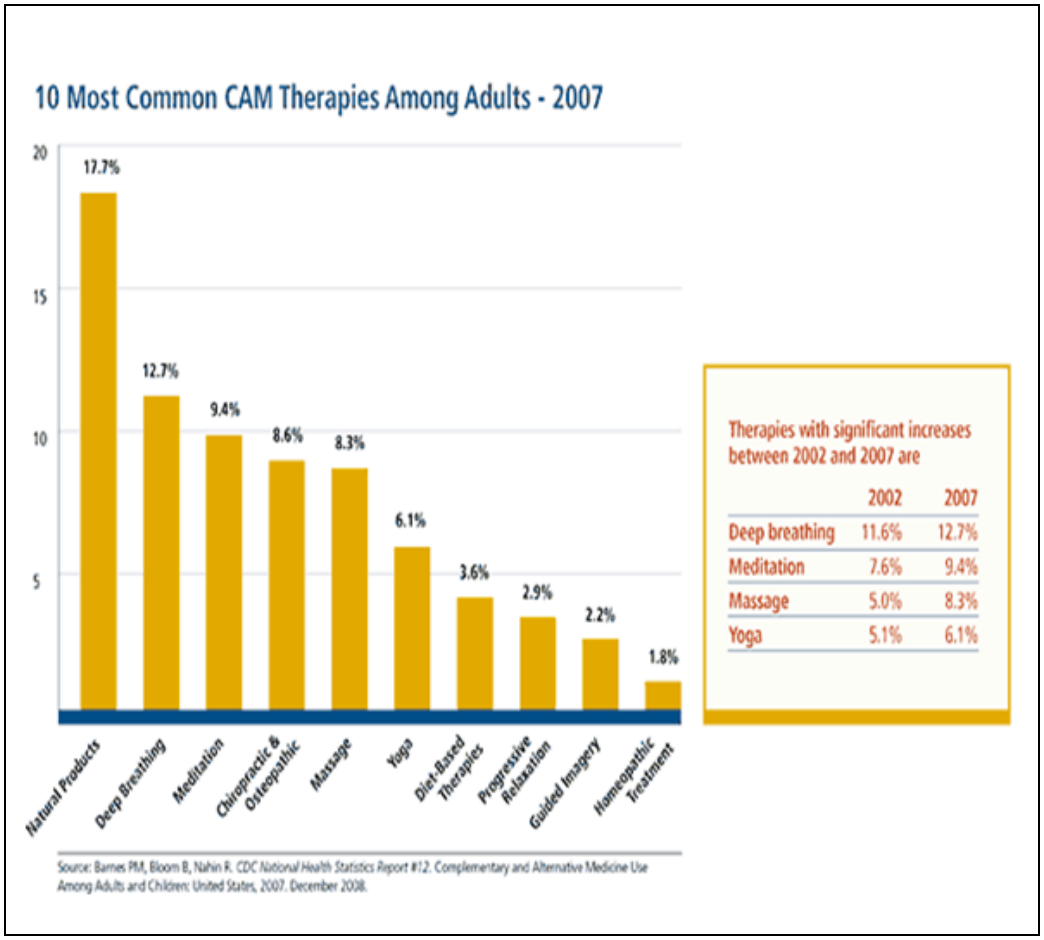

Figure 5. Ten Most Common CAM Therapies Among Adults – 2007
Chart retrieved from
(http://nccam.nih.gov/news/camstats/2007/camsurvey_fs1.htm)

Overall, massage therapy was the fifth most commonly used form of CAM. Based on U.S. census data, of 317 million people, 8.3% of the population translates to over 26 million people used massage therapy. This should qualify massage therapy as a frequently used form of CAM intervention.

Some basic demographic information on the use of CAM indicated that it was more likely to be used by women and non-poor adults between the ages of 30 to 69. It was found that those within the middle income range (with annual household incomes between $50,000 and $75,000) comprised the majority of people using massage therapy (AMTA, 2011). In addition, the use of CAM was more likely to be used by those with private health insurance, rather than publically insured or uninsured individuals. However, uninsured adults would consider using CAM if it was more affordable than conventional treatment. A positive correlation was also found between higher education levels and likelihood of using CAM.

Given the popularity of CAM, a review, citing the advances in complementary medicine was done by Vickers, (2000). This article indicated that although still lagging, research in CAM was increasing and that the quality was also improving. The trend also appears to be in complementary pain related research. The greater use of CAM and better acceptance by health care professions is fueling the increased funding for CAM related research. As more research studies emerge, the opposition by traditional healthcare providers that CAM is “unproven” should diminish. Vickers (2000) also points out that complementary medicine is increasingly practiced in conventional medical

settings, particularly acupuncture for pain, and massage, music therapy, and relaxation techniques for mild anxiety and depression. With clinical trials showing that CAM can be an effective treatment for some conditions, it is beginning to be referred to as evidence based medicine.

An article by Bodane and Brownson (2002) indicated that as the perception increases that conventional medicine does not offer all the answers to preventing illness and curing disease, patients are looking towards more towards CAM. World Development statistics shows that the U.S. life expectancy rate was only 21st and the U.S. infant mortality rate ranked 27th of other nations studied. The U.S. spends more dollars on health care than other nations and has failed to be one of the leaders in actually providing a healthier quality of life (Bodane & Brownson, 2002). This fact has opened the door for alternative or complementary medicine (CAM) to be pursued and researched. According to the National Library of Medicine, the terms complementary medicine and alternative medicine are used interchangeably. Mosby's Medical, Nursing, & Allied Health Dictionary defines alternative medicine as any of the systems of medical diagnosis and treatment differing in technique from that of the allopathic practitioner's use of drugs and surgery to treat disease and injury.

During 1997, consumers spent between $4 billion and $6 billion on visits to massage therapists, making up approximately 27 percent of the $21.2 billion spent on CAM, and demand continues to increase. The validity of alternative medicine is increasing throughout the medical industry as consumers experiment and demand options to conventional medicine. The road to acceptance has been

a long and hard fought battle for some of the alternative therapies, but with more clinical research studies, CAM can become more accepted and integrated into conventional healthcare.

More information in the form of articles and studies describing the benefits of various complementary and alternative treatments may contribute to increasing public awareness of these treatments and their use. It is hoped that this dissertation may provide additional information and support in maintaining awareness of complementary and alternative medicine treatments, such as massage therapy, in the consciousness of adults.

Although currently there may be more public interest in CAM, scientific research has been lagging. Increased credible research in CAM in general, and massage therapy in particular is the key to maintaining acceptance by the conventional health care community. Barnes et al. (2008) pointed out that between 2002 and 2007, literature searches that included the National Library of Medicine journal database and PubMed revealed only 40 studies involving acupuncture, massage therapy, naturopathy and yoga. Unfortunately, only ten of those studies found significant evidence to demonstrate that a type of CAM was effective for a specific condition, such as acupuncture for back pain.

Denneson, Corson, Dobscha, and Steven, (2011) reported that the use of complementary and alternative therapy (CAM) has become more popular in recent years. It appears to be more frequently used by people to treat musculoskeletal conditions, such as back and neck pain, joint pain and arthritis. It is estimated that half of the population have used at least one form of alternative

and complimentary therapy. Denneson et al. (2011) conducted a survey to study the specific use and interest of Complementary and alternative treatments. The study population was obtained from veterans with chronic non-cancer pain. This study used the Haythornthwaite et al. (2003) pain treatment willingness scale to assess the use of CAM and also the willingness of people to use four specific types of CAM: massage therapy, chiropractic treatment, herbal medicine, and acupuncture.

Pain intensity was measured using a validated three item Pain Intensity Subscale of chronic pain grade, with scores ranging from 0 (no pain) to 100 (highest pain imaginable). Treatment satisfaction was measured by using a five point scale that ranged from poor to excellent. The validated Roland Morris Disability Questionnaire, with scores ranging from 0 to 24, was used to measure limitations associated with pain. To measure depression, the Patient Health Questionnaire was also used. This is a nine item validated questionnaire that provides scores for depression related symptoms ranging from 0 (not at all) to 3 (nearly every day).

The results showed that a large proportion of the study participants (81.5%) indicated that they had used one of the four CAM treatments, with chiropractic being the most common. However when asked about their willingness to try one or more of the CAM treatment options, massage therapy (96.8%) was the most preferred. Interestingly, this study found that the use of CAM was not associated with any dissatisfaction of conventional pain treatment, but was simply used an additional treatment for pain management.

Cherkin et al. (2002) conducted a survey to explore the most common primary reasons for patients to visit complementary and alternative medicine providers, such as chiropractors, acupuncturists, naturopathic physicians and massage therapists. Except for visits to naturopathic physicians, in which fatigue was listed as the primary reason, back pain was the most common cause for visits to the other three alternative practitioners. For massage therapy, it was found that the second most common reason was wellness, followed by neck pain.

Anxiety and depression was listed as fourth, and shoulder pain was fifth. In general, it was found that massage therapists saw a relatively limited range of problems, as compared to the other CAM professionals. In addition to musculoskeletal conditions, massage therapists were more likely to see patients with anxiety and depression, and for stress reduction. It was also noted that most patients receiving care from alternative practitioners were self-referrals, and that massage therapists were most likely to receive referrals from other health care professionals.

Chenot, (2007) wrote an article that examines the issue of low back pain and the use of complementary and alternative treatments (CAM). Although it is a common medical complaint, there are few treatments with proven clinical benefits. The authors explained that the dissatisfaction with conventional treatment is causing individuals to explore complementary and alternative approaches. A total of 1342 subjects were surveyed to determine the extent and efficacy of CAM usage. The researchers used the Hanover Functional Ability

Questionnaire (HFAQ), which they rated as comparable to the Roland and Morris scale. Results showed that 69% of the subjects received some type of CAM at some point in their past. Results indicated that massage was not only the most popular, but also rated as the most effective form of CAM. This article helps to confirm the validity of massage as an effective treatment for reducing low back pain. This further justifies the need for more randomized double blinded, placebo controlled clinical trials to test the efficacy of massage therapy and to increase its acceptance in the scientific community and insurance industry.

Some surveys have explored the acceptance and usage of complementary and alternative therapies in general. More information, including reasons that people use massage therapy were provided by the massage therapy industry. A Massage Therapy Industry Fact Sheet, published in 2012, by the American Massage Therapy Association (AMTA) indicated that the massage therapy is projected to be a 10 to 11 billion dollar a year industry. During a twelve month period between July 2010 and July 2011, AMTA estimated that about 38 million or 18% of Americans had at least one massage. The use of massage therapy for medical reasons is on the rise. The AMTA fact sheet indicates that 44% of adults who had a massage during that period did so because of a medical condition, as compared to 35% in the previous year. The most common medical situations reported involved pain management, rehabilitation of an injury, migraine headaches, or simply overall wellness. Overall, 29% of people surveyed admitted to having a massage for relaxation or to relieve stress.

The Barnes et al. (2008) report on the NHIS national CAM survey provided useful information on the types of medical conditions that the various CAM modalities were used to treat. Barnes et al. (2008) indicated that musculoskeletal problems were the most popular medical conditions for which people turned to CAM. Figure 6 shows that back pain at 17.1% was the most common, followed by neck pain (5.9%), joint pain, stiffness or other discomfort (5.2%).

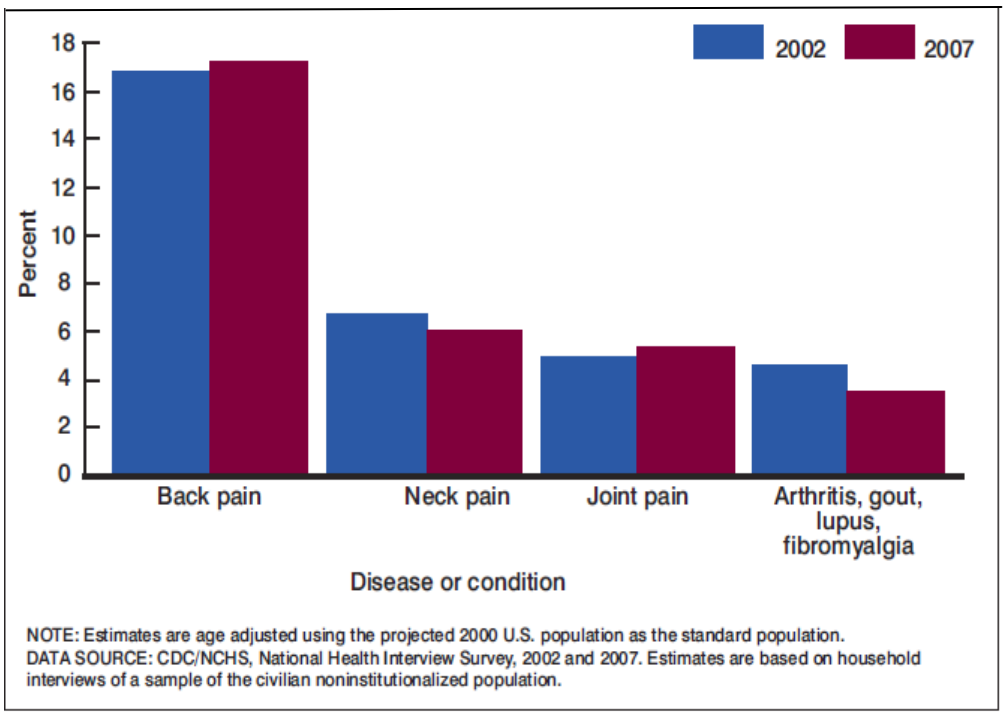

Figure 6. Percentage of Adults Using CAM for Selected Musculoskeletal Diseases and Conditions. Chart retrieved from (http://nccam.nih.gov/news/camstats/2007/camsurvey_fs1.htm)

Arthritis (3.5%) and other non specific musculoskeletal conditions (1.8%) were at the bottom of the list. Although these various musculoskeletal problems comprised the most use of CAM, Barnes et al. (2008) found that there was no significant increase in its usage for these conditions in the five years prior this survey.

Table 5 shows data obtained from the American Massage Therapy Association (AMTA) industry fact sheets indicating the annual usage of massage therapy by the U.S. population. These surveys covering a 16 year span between the years 1997 to 2012. The AMTA indicated that this data was received from telephone surveys with at least 1000 respondents, however the exact number was not provided. The mean usage data from the AMTA surveys for this period was calculated to be 16.2%.

Figure 7 shows a trend in massage usage over this period and it appears that 2012 may have begun a reversal of a downward trend that began in 2007. It is possible that the downturn in the U.S. economy may have been a factor in the decline in the number of people receiving massages during that period. This data is from the American Massage Therapy Association (AMTA).

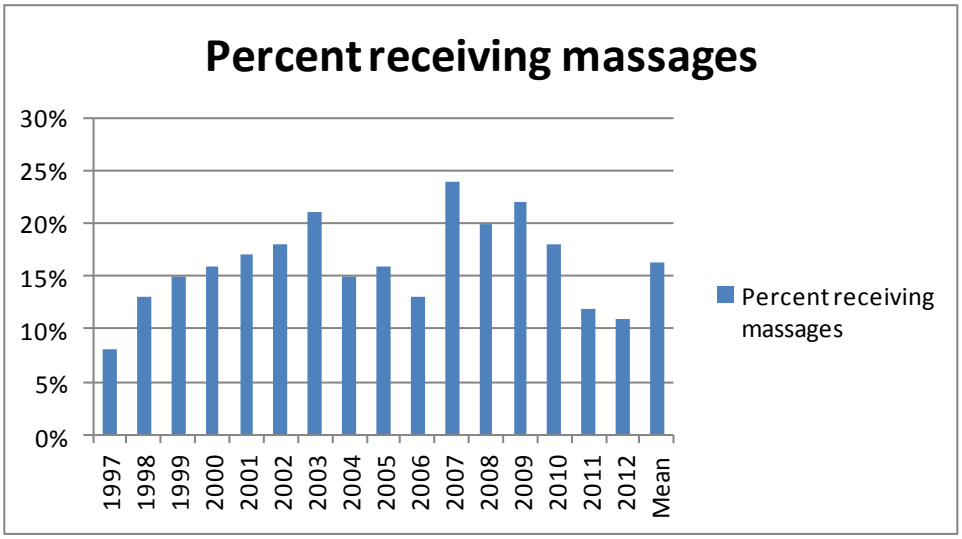

Figure 7. Percent of U.S. Population Receiving Massages on an Annual Basis

A comparison of the AMTA industry usage data to three other non-industry associated national surveys reveals a discrepancy between massage usage data. These surveys (Table 6 & Table 7) show that the highest annual percentage for the usage of massage by the U.S. population was 8.3% in 2007 (Barnes et al., 2008).

This was much lower when compared to the 24% reported by the AMTA that same year. Usage data for 2003, from the Barnes et al. (2004) report based in the NHIS national survey indicated that 5% of the U.S. population used massage therapy, while the AMTA data says it was 21%. Eisenberg, (1993) indicated that 7% of the U.S. public used massage therapy during 1993. Although there was no comparison point for the 1993 percentage for the use of massage, the Eisenberg survey appeared to be more consistent with the data supplied by the NHIS national survey (Barnes et al. 2004; Barnes et al. 2008). A t-test was used to compare difference for the mean percentages between the AMTA industry massage usage data to the three combined non- industry sources (NHIS surveys Barnes et al. 2004; Barnes et al. 2008; Eisenberg1993).

Table 6. Industry (AMTA) and Non-Industry Survey Results Comparison on the Population Percentage Use of Massage by Year

Year	Percent Receiving Massages: AMTA Survey	Percent Receiving Massages: NHIS Survey	Percent Receiving Massages: Eisenberg Survey
2012	11%		
2011	12%		
2010	18%		
2009	22%		
2008	20%		
2007	24%	8%	
2006	13%		
2005	16%		
2004	15%		
2003	21%	5%	
2002	18%		
2001	17%		
2000	16%		
1999	15%		
1998	13%		
1997	8%		
1993			7.0%
Mean	16.2%		6.7%*

***6.7% represents the combined mean for the three non-industry surveys (NHIS as reported by Barnes 2004 & 2008, and Eisenberg (1993)**

Table 7. Comparison of Usage Surveys on Conditions for the Use of CAM

Source	Use of CAM	Use of Massage	CAM Use for Back Pain	CAM Use for Neck Pain	CAM Use for Arthritis	CAM Use for Joint Pain, Sprains and Strains	CAM Use for Other Chronic Pain Conditions
Eisenberg (1993)	34%	7%	36%	N/A	12%	12%	N/A
NHIS* (2004)	33%	5%	16.8%	6.6%	4.9%	4.9%	2.4%
NHIS* (2008)	39%	8%	17.1%	5.9%	3.5%	0.7%	5.2%

*** NHIS national surveys as reported by Barnes (2004 & 2008**

Table 8 shows results of the t-test indicating that there is a statistically significant difference (p = 0.007) between these two means. This discrepancy may be due to the large difference in the number of respondents between the industry and the non-industry surveys.

Table 8. T-Test Comparing Percentage of Massage Therapy Usage Reported by Industry Sources to Non-Industry Sources

Statistics	Group One: Industry Sources (1997 to 2012)	Group Two: Non-Industry Sources (2003, 2007)
Mean	16.19	6.50
SD	4.28	2.12
SEM	1.07	1.50
N	16	2

p (two-tailed): 0.007
Confidence interval: Group One mean minus Group Two mean equals 9.69; 95% confidence interval of this difference from 3.05 to 16.33
t = 3.0935
df = 16
Standard error of difference = 3.132

Table 9 compares the total number and mean of respondents per survey between the industry and non-industry surveys. The combined number of respondents from the three non-industry surveys on the public's usage of massage therapy was 108,307, with a mean of 36,116. The AMTA industry fact sheets did not provide exact number of respondents, only stated that the telephone surveys consisted of at least 1000 people. Therefore the total number of respondents from the 16 annual surveys was estimated to be 16,000 people, with a mean of 1000. The results of a t-test comparing these two means (Table 10) showed a very significant statistical difference (p> 0.0001). The non-industry surveys, with the larger respondent base, appeared to have more statistical

power. This would place more credence on the non industry data for the utilization of massage therapy by the U.S. public.

Table 9. Comparison of Number of Respondents in National Surveys

Year	AMTA Survey Number of Respondents	NHIS Survey Number of Respondents	Eisenberg Survey Number of Respondents
2012	1,000		
2011	1,000		
2010	1,000		
2009	1,000		
2008	1,000		
2007	1,000	75,764	
2006	1,000		
2005	1,000		
2004	1,000		
2003	1,000		
2002	1,000	31,044	
2001	1,000		
2000	1,000		
1999	1,000		
1998	1,000		
1997	1,000		
1993			1,539
Total	16,000	106,808	108,347*
Mean	1,000	53,404	36,116*

***These represent the combined total and mean from the NHIS surveys completed in 2002 & 2007, and included the Eisenberg (1993) survey.**

Table 10. T-Test Comparing the Number of Respondents Used in the Industry Surveys to the Non-Industry Surveys

Statistics	Group One: Industry Sources (1997 to 2012)	Group Two: Non-Industry Sources (2003, 2007)
Mean	1000.00	53404.00
SD	0.00	31621.82
SEM	0.00	22360.00

p (two-tailed): <0.0001
Confidence interval: Group One mean minus Group Two mean equals –52404.00; 95% confidence interval of this difference from –64973.10 to –39834.90
t = 8.8385
df = 16
Standard error of difference = 5929.090

Analysis of Evaluation Question 2: Comparison of the Public's Utilization of Massage Therapy with the NIH Funded Massage Research Topics

Spearman's Rank Order Correlation was used to determine whether there was an association between the reasons for the utilization of massage therapy by the U.S. public with the NIH funded massage research topics. The categories in Table 13 provided the NIH funding data for massage research topics and the categories from Table 5 provided the massage usage data (Table 15). NIH funded massage researched topics and the public reasons for using massage therapy were ranked in descending order according to percentage. A computer program, provided by Social Science Statistics, was used to calculate Spearman's R values for the years that data was available for both the public's reasons for usage of massage along with NIH funding data. Spearman's R values have five levels of significance: .00 to.19 is very weak, .20 to.39 is weak,

.40 to .59 is moderate, .60 to .79 is strong and .80 to 1.0 is very strong (Zar, 1972).

Spearman's R values (Table 11, Figure 8, Figure 9) fail to reveal either a strong positive or negative correlation. Four out of the five years had a weak negative correlation based on the results of the Spearman's R values. Only the earliest year (2001) had a positive R value, but it is considered weakly positive. The mean for the Spearman's R values (-.164) also indicated a weak negative overall relationship. The source of funding data was the NIH website. The source of utilization data was AMTA industry fact sheets.

Table 11. Spearman's R Value for Massage Utilization and NIH Funded Massage Research Topics (Five Years)

Year	Spearman's R Value
2001	0.058
2009	–0.182
2010	–0.241
2011	–0.257
2012	–0.200
Mean	–0.164

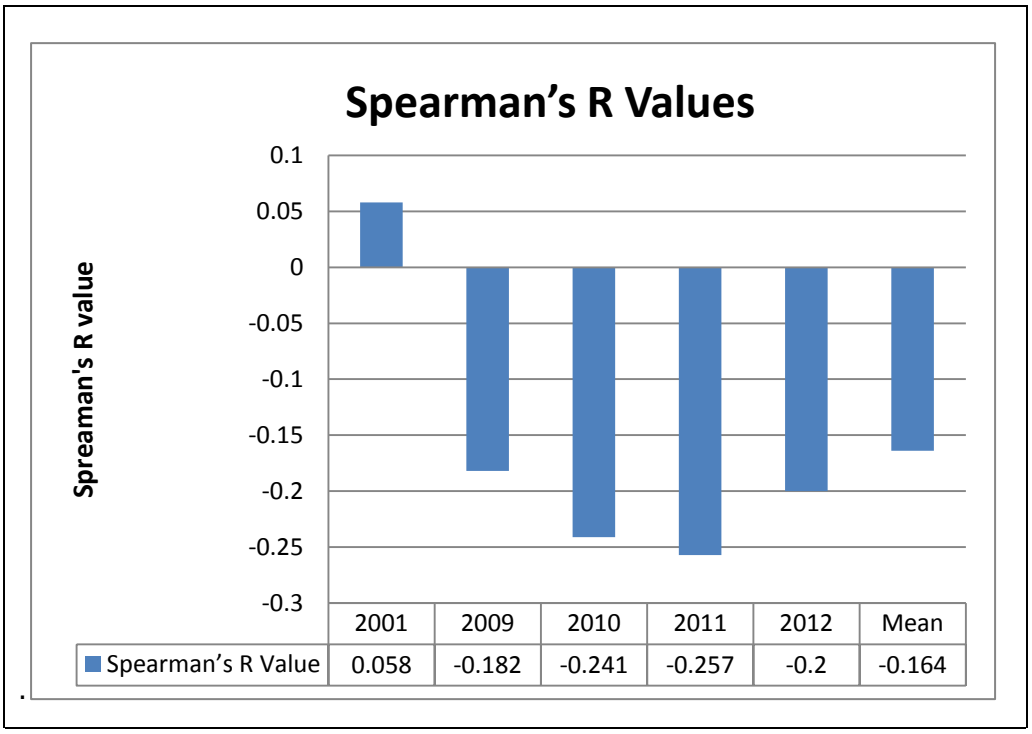

Figure 8. Spearman's R Value for Massage Utilization and NIH Funded Massage Research Topics (Five Years)

A Spearman's Rank Order Correlation computer program by Social Sciences Statistics was used to calculate the R values (Table 12, Figure 10) in order to compare the use of CAM from the NHIS national surveys, as analyzed by Barnes et al. (2004 & 2008) utilization data and the NIH funding of massage therapy topics for those years. There was a weak positive relationship (.099) in 2003 and a weak negative relationship (-.025) in 2007. The mean (.037) was weakly positive. These results also failed to demonstrate any significant relationship between the prevalence of the reasons for CAM usage and the research funding of massage topics or applications on an annual basis.

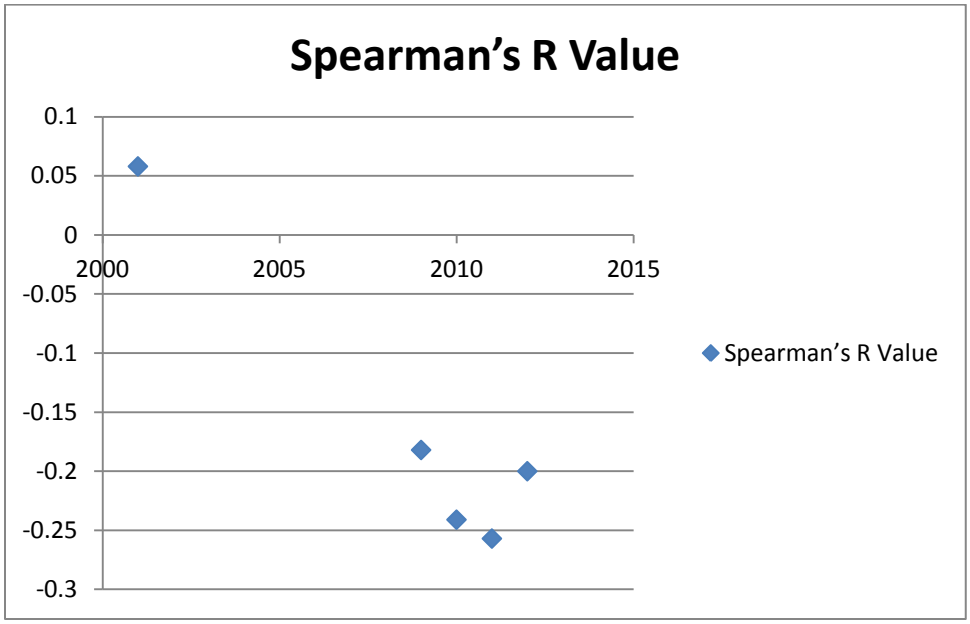

Figure 9. Scatter Chart Showing Spearman's R over Time to Check for Trend in Correlation (Five Years)

It is interesting to note that the NIHS survey (Barnes et al. 2008) also found that there is no meaningful correlation between the number of published studies of a CAM therapy and the prevalence of its use by the U.S. public. The source of funding data was from the NIH website. The source of CAM utilization data was from NHIS national surveys (Barnes et al. 2004; Barnes et al. 2008).

A possible cause for the lack of coordination between the research topics in massage therapy and the public's utilization patterns may be due to the lack of adequate massage usage survey studies to guide researchers and funding organizations. Researchers writing grant proposals may justify a need for study topics by referring to utilization patterns that indicate a possible deficiency of studies in that area. On the other hand, research studies demonstrating efficacy of massage therapy can create more awareness from the general public and

health care professionals. Recognition of the efficacy of massage therapy for particular conditions, such as pain, can subsequently influence utilization patterns.

Studies demonstrating that massage can reduce back pain, may increase interest in massage therapy as another possible treatment modality. There may be a positive feedback relationship involved because increased utilization in an area may spur more research, and conversely increased research may encourage more utilization. It is anticipated that as research emerges and is disseminated about the efficacy of massage for various conditions, particularly pain, that the public would respond and that referrals to massage therapists would increase in these areas. It is therefore expected that a positive correlation between research topics and public utilization patterns will be established.

Table 12. Spearman's R Value for CAM Utilization and NIH Funded Massage Research Topics (Two Years)

Year	Spearman's R Value
2003	0.099
2007	–0.025
Mean	–0.037

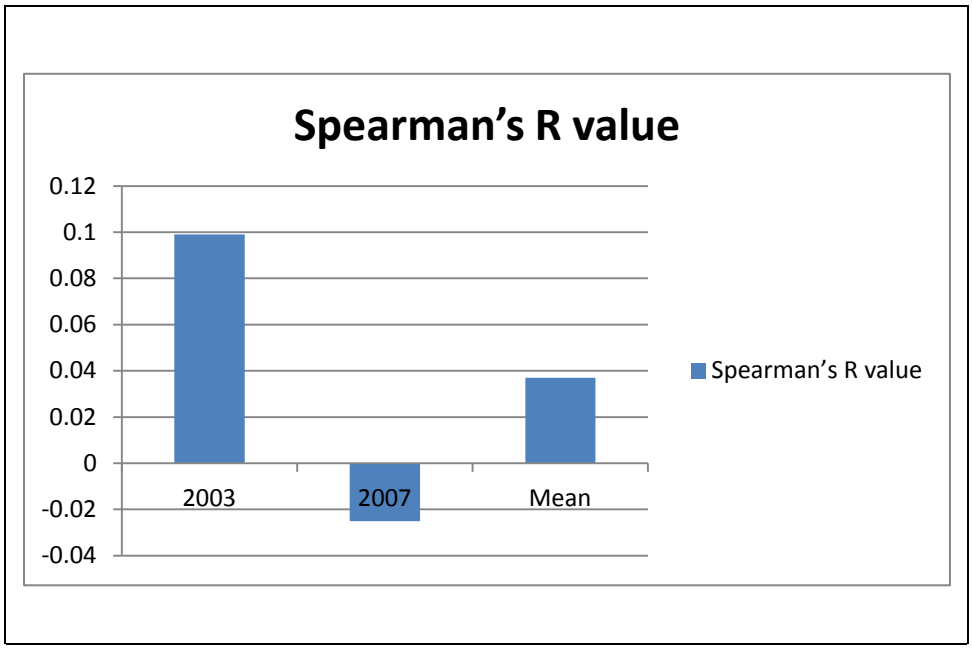

Figure 10. Spearman's R Value for CAM Utilization And NIH Funded massage Topics

Review of NAACAM's Funding Area of Special Interest

NCCAM's funding area of special interest includes, but not limited to investigations of the impact of CAM modalities in alleviating chronic pain syndromes and inflammatory processes. NCCAM's interest in pain is based on the high prevalence of pain conditions along with its major impact on the U.S. economy. NCCAM points to the public's dissatisfaction with conventional pain management treatments contributing to the exploration of CAM. Current drug-based treatment options may only be partially effective, and can be accompanied by serious adverse effects. There is also the concern for the addictive potential associated with some prescription narcotic analgesic medications. This program evaluation assessed whether pain conditions are being appropriately funded in massage therapy research.

Prevalence of Pain

Since NCCAM included pain conditions as a funding area of special interest, a literature review was conducted to understand the prevalence of pain. According to Deya, Mirza, and Martin (2006), pain is considered the fifth most common reason for patients to visit a physician. The Department of Health and Human Services (HHS), along with the National Institutes of health (NIH) commissioned the Institute of Medicine (IOM) to study the effects of pain as a public health problem. In their 2011 report, the Institute of Medicine found that 116 million American adults suffer with a chronic pain condition. Costs of medical care and lost productivity are estimated to be $635 Billion annually.

A National Institute of Health Statistics survey indicated that low back pain was the most common (27%), followed by severe headache or migraine pain (15%), neck pain (15%) and facial ache or pain (4%). They also report that back pain is the leading cause of disability in Americans less than 45 years of age. More than 26 million Americans between the ages of 20-64 experience frequent back pain. Many of these patients are suffering with low back pain in particular. According to Freburger et al. (2009), low back pain (LBP) is the second most common cause of disability in US adults and a common reason for lost work days. Low back pain alone is estimated to cost up to $200 Billion in health care and lost productivity and wages.

During a three month period, approximately one in four Americans complained of low back pain lasting at least an entire day. A study by Strunin and Bodin (2004) investigated the family consequences of chronic back pain. Patients

reported a wide range of limitations that impact on family and social roles including physical limitations that hampered patients' ability to perform household chores, care for children, and engage in social and leisure activities. Spouses and children often took over family responsibilities once carried out by the individual with back pain. These changes in the family often lead to depression and anger among the patients with back pain, and to stress and strain in family relationships.

Use of Massage for Pain Management

Pain conditions in general and chronic back pain in particular, have a major impact on health and well-being in the general population. Those suffering with back pain tend to be dissatisfied with their current treatment and appear to be turning towards alternative approaches. Sherman, Dixon, Thompson, and Cherkin (2006) found that the most common reason for visits to acupuncturists, chiropractors and massage therapists was chronic back pain. A total of 12% of all patient visits to massage therapists was for some type of back pain. A common factor among these three modalities is the involvement of some hands-on treatment. Those who sought massage therapy, for example, usually received a tissue assessment and range of motion was also evaluated.

The typical massage treatments involved deep tissue, Swedish and trigger point. Some demographic information indicated that the median age of those receiving massage therapy for back pain was 44, women outnumbered men and this patient population was 95% white. Sherman et al. (2006) believed that more information about people receiving complementary and alternative care would

help physicians to have a better understanding of their popularity. Although there are relatively few studies demonstrating effectiveness of alternative approaches for back pain, Sherman et al. (2006) concluded that all three of these modalities are considered safe.

Surveys are indicating that pain relief is becoming a principal motivating factor for people to seek massage. Pain conditions can pose a powerful motivating agent for patients to seek conventional, as well as alternative treatments. As noted by its increased usage, massage therapy is becoming a popular option for pain management. While massage provides the benefit of reducing pain in general, it may also be important to study the effects of massage on the specific types of pain conditions that patients present with. To improve the awareness and acceptance of massage therapy as a legitimate complementary and alternative approach, better quality research studies should be conducted. Rather than exploring the efficacy of massage for pain in general, specific pain conditions should be considered for study, such as osteoarthritis, low back pain and sciatica. Future research funding should be appropriated to investigate the efficacy of massage for particular pain issues since many people seek massage to help alleviate a variety of pain conditions.

Pain is a common complaint in this country and many patients are receiving some type of pain management treatment. Surveys indicate that people are dissatisfied with conventional treatments for pain management. Some consider current drug based treatment options to be partially effective and may be accompanied by adverse effects. Drug treatment may also possess the

potential for addiction. As a result, it appears that massage therapy is gaining in popularity as a complementary and alternative approach to pain management. Studies are demonstrating that massage therapy can be an effective treatment for pain conditions. Cherkin et al. (2001) and Chenot (2007) have surveyed subjects' attitudes towards massage as well as other forms of alternative and complimentary pain therapies in general. It was found that massage therapy had the highest satisfaction rating when compared to other conventional and CAM treatments.

A comprehensive review of the literature concerning the effectiveness of massage therapy on various forms of pain was explored by Tsao (2007). This article begins with a brief introduction on the history of massage therapy and also describes various forms of massage. An exclusion criterion for this paper eliminated combination therapies in which massage was included. The author was solely interested in the effects of massage on pain. It is interesting to note that of the 51 studies reviewed, only one involved the use of a placebo and that placebo was in the form of a sham laser treatment (Preyde, 2000), rather than an actual placebo massage. All of the other studies compared massage to other treatment modalities.

In general, massage therapy was beneficial in reducing sub-acute and chronic low back pain when compared to relaxation, acupuncture, and education. Massage was equal to corsets and exercise, but inferior to spinal manipulation and transcutaneous electrical nerve stimulation (TENS). One study showed that acupressure/pressure point massage techniques provided more pain relief than

classical Swedish massage. It is important to note that the author points out that there are relatively few studies investigating the effects of massage therapy on pain and cites a need for research in this area.

This review article provides some important information, such as the history of massage therapy on pain mechanism. It also discusses some theories related to the effect of massage on pain. More importantly, this review did not find a study that involved the use of an actual placebo (sham) massage. The development and use of a placebo massage would therefore be an important component to include in future massage trials.

To determine the effectiveness of massage therapy for low back pain, an early non NIH funded trial (Preyde, 2000), divided 98 subjects into four groups. This prospective, randomized, placebo controlled trial divided the subjects into four groups. Group 1 received comprehensive massage therapy, which included soft tissue manipulation techniques such as friction, trigger points, neuromuscular therapy, as well as remedial exercise and posture education. Subjects in Group 2 only received the soft tissue manipulation similar to those in Group 1, but no other therapy. Those in Group 3 only received remedial exercise and posture education. Group 4 was used as a control and given a placebo treatment in the form of a low level sham laser therapy.

Unfortunately, this study was not blinded because the choice of interventions for the four groups made it difficult to mask. Traditionally, placebos are similar to the intervention so that subjects would believe they are receiving an actual treatment. However, a criticism with this study was that the author used a

different modality, a sham laser treatment, as the placebo control. As a result, it was difficult to blind the subjects and therapists. A single blinding variation involved range of motion studies conducted by physiotherapists who were blind to which treatment group participants were assigned to. Using different modalities as the placebo control arm may not adequately account for potential bias and the effects of patient expectations.

Determining appropriate outcomes and accurately measuring them is crucial aspect of many research studies. In the above study, Preyde (2000) was also interested in comparing functionality and pain as the outcome measures. The author selected the Roland Disability Questionnaire (RDQ) to test functioning and the McGill Pain Questionnaire (MPQ) to assess pain. The RDQ consists of 24 “yes or no” questions and 14 or more “yes” responses represents a poor outcome. The RDQ is generally accepted as a valid and reliable measuring tool and has been used in other studies involving low back pain (Roland et al., 2000).

To measure pain, this trial used the McGill Pain Questionnaire (MPQ) which is composed of two indexes. The Present Pain Index (PPI) to measure intensity of pain, and the Pain Rating Index (PRI) to measure quality of pain. The PPI uses a sliding scale from 0 to 5 representing no pain to excruciating pain. The PRI is used to assess quality of pain and is based on the total of 79 qualitative words selected by participants as a descriptive indication of their pain. This index is also accepted as a valid and reliable measuring tool (Reading, 1982).

In addition, two secondary outcome measures included in this study were anxiety and lumbar range of motion. The State Anxiety Index (SAI) was selected to measure anxiety levels and scores range from 20 (minimal anxiety) to 80 which would indicate a maximum level of anxiousness. Lumbar range of motion was assessed by physiotherapists using a Modified Schober Test, which has been used in other studies comparing efficacy of treatments for low back pain.

Recruitment of subjects appeared adequate and was done with email notifications, flyers to physicians and local media announcements. Subjects experiencing back pain lasting greater than eight months were excluded since it was considered chronic rather than sub-acute. Subjects with severe pathology causing back pain such as a herniated disc were also excluded.

ANOVA was an appropriate statistical test used in this trail to analyze the data from the four groups. Results showed that group 1 had significantly better scores than all three of the other groups for RDQ, PPI , PRI and SAI. Subjects in Group 2, who only had soft tissue manipulation, were also found to be significantly better in their outcome measures than the subjects in Groups 3 and 4. The secondary outcome measures showed that there was no significant difference in the four groups with respect to lumbar range of motion.

A follow-up period is often used in many studies and it helps to strengthen the findings. A long follow-up period is preferable, however even a one month follow-up can be useful to determine continuation of the effectiveness of treatment. This trial incorporated a one month follow- up and results showed that Group 1 maintained a significant difference over the other three groups. It was

interesting to note that Group 2 which only received soft tissue manipulation no longer showed any significant improvement as compared to Groups 3 and 4. However, using posture and exercise as part of the main intervention makes it difficult to determine if massage alone was an effective intervention.

Some may question the selection of only using soft tissue manipulation for back pain instead of a more therapeutic deep tissue massage. It may not have been necessary to also use posture education and exercises in a massage study. Rather than using a different treatment modality as a placebo, it would have been preferable to use a similar modality such as non-therapeutic light touch massage as a placebo control. Perhaps, even a soft tissue massage could have been compared to a deep tissue massage. This could be more valuable when evaluating efficacy of massage in future studies, particularly when measuring the possible longer term benefits of massage therapy. It should be noted that second (massage only) group of the Preyde (2000) study reported no benefit one month later.

There may be an issue with the choice of interventions in this study. Although auxiliary services such as posture education and remedial exercise can be considered part of a comprehensive massage therapy program, some may question whether it should be included in an exclusive massage study. Some may question whether the massage or the exercises was the actual therapeutic aspect of the intervention. There may be intervening variables to using these additional services as part of an intervention, such as the lack of a standardized schedule for performing the exercises. There are no assurances that the subjects

properly followed through with the instructions for posture or exercise or performed these activities properly. For example, subjects in group 3 may not have been motivated to continue with this regiment which could have affected the outcome.

Another problem with this study could have been an inadequate amount of treatments used. Outcomes were assessed after only six treatments within a 30 day period. The massage intervention was standard and areas that may have had severe muscle spasms which would ordinarily require additional attention during a massage session were not permitted to be addressed. It may have been helpful to establish the etiology of the back pain so that a more specific form of massage therapy could have been provided. All massages were performed by two massage therapists, but their training, qualifications and skill levels were not indicated.

Since this trial was not blinded, it is difficult to determine whether the quality of the massages in groups 1 and 2 were equivocal. Subjects in group 1 obviously received more attention than those in group 2 because they also received additional information concerning posture and exercise. This could have intensified the Hawthorne effect since they may have taken better care of themselves such as being more careful not to lift heavy objects. It was interesting that the subjects in Group 2 who only received soft tissue manipulation had significantly better results than Groups 3 and 4. It would have been preferable to use some sort of non-therapeutic massage as the placebo control rather than the sham laser treatment.

Field et al. (2002), a non-NIH funded study, investigated the efficacy of massage therapy for fibromyalgia, a chronic pain condition. Twenty-four patients with fibromyalgia were randomly assigned to compare the use of massage therapy versus relaxation therapy on sleep, Substance P, and pain. Both groups received 30 minute biweekly treatments for five consequent weeks. Although both groups reported a decrease in anxiety and depressed mood, only the massage therapy group indicated that they had an increase in the number of sleep hours and they also showed a significant decline in substance P. and had lower tender point ratings. Although this was a small study without a control group and did not use a placebo or sham treatment, it shows that massage can be helpful in alleviating pain associated with fibromyalgia.

Melancon and Miller (2005) compared the effects of massage therapy, for low back pain, to traditional therapy. The investigators noted that their literature search showed that there are not enough studies to reliably show the efficacy of massage therapy as a treatment for low back pain. Outcome measures were based on the Oswestry Disability Index (ODI). Sixty patients were divided into two groups. Group 1 received massage therapy. The other group was asked to continue with their traditional therapy, which was described as guided imagery, muscle relaxants and NSAIDS. Participants were asked to complete three ODI questionnaires, one before beginning the study, the second immediately after and the third was to be submitted one month after the study was terminated. This trial found that although traditional therapy was slightly better than massage with respect to pain relief, both therapies showed significant improvement from

baseline scores on the ODI. Since massage therapy has a low risk of adverse effects, the investigators concluded that it can play an important role in the management of low back pain and could offer patients a viable alternative or adjunct to traditional therapies.

The investigators stated that one reason for conducting this study was because of the shortage of studies involving massage therapy and low back pain. They also expressed a desire to correct design flaws in prior studies. This study did not have a valid placebo control arm. The massage group was compared to subjects continuing to receive traditional therapy. Although the types of traditional therapy varied, no attempt was made to separate these treatments into individual subgroups. It is possible that one form of therapy could have affected the overall results of that entire group.

In a CDC funded randomized controlled trial Perlman, Sabina, Williams, Njike, and Katz (2006) studied the efficacy of massage therapy on a total of 68 subjects with a confirmed diagnosis of osteoarthritis of the knee. The experimental group received standard Swedish full body massage therapy twice a week for the first four weeks and then once weekly for the next four weeks. The control group received no massage therapy during the first eight week period but continued receiving their conventional therapy. A crossover design was utilized. The subjects in the weigh-list control group then received the same eight week therapeutic massage intervention.

Outcome measurements compared changes in the scores on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain and

functional scores, along with a visual analog scale (VAS) of pain assessment. Other measurements included how many seconds it took to walk 50 feet and range of motion studies. A paired t test ($p<.05$) was used to compare scores from baseline and at the end of the treatment period. The experimental group showed significant improvement ($p<.001$) in both the WOMAC scores and the VAS. The control group had no change from baseline to the end of the experimental group's treatment period. The control group, which became a new experimental group also showed significant improvement ($p<.001$) in both WOMAC and VAS scores from baseline.

The WOMAC scale was an appropriate measurement tool because it is primarily intended to assess pain and disability in patients with osteoarthritis of the knee. The visual analogue scale (VAS) is a more general validated method for assessing pain. It can be utilized by physicians in clinical practice, and can also be a useful measuring tool in research studies involving pain conditions (Breivik et al., 2008). The Perlman et al. (2006) study indicated that using the commonly practiced Swedish massage therapy technique is safe and effective for reducing pain and improving function in patients with symptomatic osteoarthritis of the knee. It is believed that this was the first prospective, randomized trial assessing the efficacy of massage for osteoarthritis of the knee.

Sherman, Cherkin, Hawkes, Miglioretti, and Deyo (2009) was interested in studying the effectiveness of massage therapy for chronic neck pain. This randomized study involving subjects with chronic neck pain, compared the use of ten massage treatments over a ten week period to a control group who only

received a self care book. Neck pain is a very common condition in this country, and it is estimated that 70% percent of the population has experienced it at least once in their life. About 5% of adults are currently experiencing severe neck pain. For those with neck pain, massage therapy is a popular form of complementary and alternative treatment. Subjects in the experimental group received one massage per week, over a ten week period. There was a significant reduction in scores on the Neck Disability Index, compared to those in the self-care control group. This difference remained throughout the 26 week follow up period. After 26 weeks, there was no longer a significant difference between the two groups.

Wolsko, Eisenberg, Davis, Kessler, and Phillips (2003) indicated that massage is one of the most popular complementary and alternative medical therapies for neck and back pain. Cherkin et al. (2002) found that these conditions account for more than one third of the more than 100 million annual visits to massage therapists in the United States. A randomized controlled trial by Cherkin et al. (2011) found that two types of massage therapy, given over a period of ten weekly treatments were more effective for back pain than usual care and had long lasting effects. This randomized study divided participants into three groups. Group 1 had a relaxation massage and Group 2 had structural massage specifically designed to alleviate back pain. Group 3 was a usual care control.

Outcome measurements in this study used the Roland Disability Questionnaire (RDQ) and were measured at baseline, then after 10, 26, and 52 weeks. The results showed that both types of massage were found to be more

effective than usual care alone. It was found that significant improvement continued throughout the 26 week follow up period. However, no significant improvement was reported after 52 weeks.

Data Analysis for Evaluation Question 3

The final step was to evaluate whether NCCAM's research funding area of special interest is consistent with the pattern of NIH funding for massage therapy research topics, which involves pain and inflammatory conditions. To accomplish this, the total annual funding for individual topics was listed along with the percentages of the funding received (Table 13). This data was obtained from the NIH website. Overall, pain was consistently the single most funded massage research topic throughout the years that funding information was available. The total mean funding for pain topics was 41%, and 9% for inflammatory conditions. The combined percentage of funding for pain and inflammatory conditions was 50%. Table 13 shows number of massage therapy studies by categories and dollar amounts funded by NIH on an annual basis.

Table 13. NIH Funded Massage Therapy Studies 1993 to 2012

Year	Number of NIH Funded Studies	Total NIH Funding Dollars/ Year	Funded Pain Studies	Funded Anxiety, Depression, Stress, Relaxation Studies	Funded Immune Function, HIV Studies	Funded Substance Abuse Studies	Funded Infant Studies	Funded Lymphedema Inflammation Studies	Other Funded Studies – Mechanism and Biological Effects
2012	9	$3,285,901	4 studies $1,877,421	1study $201,094	0	1 study $569,189	2 studies $251,259	1 study $386,968	0
2011	10	$3,456,821	3 studies $1,565,779	1 study $313,706	1 study $129,060	1 study $586,344	3 studies $475,847	1 study $386,085	0
2010	8	$2,482,301	3 studies $982,058	1 study $130,000	1 study $129,060	1 study $622,396	1 study $229,625	1 study $389,162	0
2009	11	$3,655,211	3 studies $1,488,304	0	1 study $129,060	2 studies $803,688	1 study $188,125	2 studies $581,308	1 study $461,274
2008	8	$1,483,087	2 studies $622,972	1 study $74,223	1 study $129,060	1 study $216,817	1 study $225,500	1 study $157,500	1 study $57,015
2007	9	$1,757,324	1 study $521,734	1 study $265,083	1 study $129,060	0	2 studies $353,390	0	4 studies $488,057
2006	12	$2,854,030	2 studies $738,766	1 study $273,000	0	0	4 studies $862,235	0	5 Studies $980,029
2005	12	$2,950,057	4 studies $1,043,994	2 studies $389,010	0	0	3 studies $773,415	0	3 studies $743,638
2004	12	$1,907,769	4 studies $1,084,171	2 studies $20,814	0	0	4 studies $724,021	0	2 studies $78,763
2003	5	$1,168,257	2 studies $605,198	0	0	0	2 studies $373,684	1 study $189,375	0
2002	11	$1,869,464	4 studies $677,050				2 studies $394,150	2 studies $378,750	3 studies $419,514
2001	8	$1,094,414	3 studies $300,322	1 study $172,411	0	0	1 study $206,523	1 study $189,375	2 studies $225,783
2000	3	$456,620	1 study $241,086	0	1 study $3,034	0	1 study $212,500	0	0

Table 13. NIH Funded Massage Therapy Studies 1993 to 2012 (continued)

Year	Number of NIH Funded Studies	Total NIH Funding Dollars/ Year	Funded Pain Studies	Funded Anxiety, Depression, Stress, Relaxation Studies	Funded Immune Function, HIV Studies	Funded Substance Abuse Studies	Funded Infant Studies	Funded Lymphedema Inflammation Studies	Other Funded Studies – Mechanism and Biological Effects
1999	2	N/A	0	1 study	1 study	0	0	0	0
1998	0	----	----	----	----	----	----	----	----
1997	0	----	----	----	----	----	----	----	----
1996	1	N/A	0	0	0	0		0	1 study
1995	2	N/A	0	0	0	0	1 study	0	1 study
1994	1	N/A	0	0	0	0	1 study	0	N/A
1993	5	N/A	0	0	1 study	0	2 studies	0	2 studies
Totals	129	$28,421,256	36 studies $11,748,855	13 studies $1,833,793	8 studies $648,334	6 studies $2,798,434	31 studies $5,270,274	10 studies $2,658,523	25 studies $3,454,073

Table 14. Total Annual NIH Funding and Percentage for Funding of Massage Topics

Year	Total NIH Funding	Percent for Pain Topics	Percent for Inflammation Topics	Percent for Anxiety Depression Stress Topics	Percent for Immune Topics	Percent for Substance Abuse Topics	Percent for Infant Weight Gain Topics	Percent for Other Topics
2012	$3,285,901	57%	12%	6%	0%	17%	8%	0%
2011	$3,456,821	45%	11%	9%	4%	17%	14%	0
2010	$2,482,301	40%	16%	5%	5%	25%	9%	0
2009	$3,655,211	41%	15%	0%	4%	22%	5%	13%
2008	$1,483,087	42%	11%	5%	9%	14%	15%	4%
2007	$1,757,324	30%	0	15%	7%	0	20%	28%
2006	$2,854,030	26%	0	10%	0	0	30%	34%
2005	$2,950,057	36%	0	13%	0	0	26%	25%
2004	$1,907,769	57%	0	1%	0	0	38%	4%
2003	$1,168,257	52%	16%	0	0	0	32%	0
2002	$1,869,464	36%	20%	0	0	0	21%	23%
2001	$1,094,414	27%	17%	16%	0	0	19%	21%
2000	$456,620	52%	0	10%	1%	0	47%	0
Mean	$2,186,250	41%	9%	7%	2%	10%	19%	12%
Total	$28,421,256							

Table 14 provides the percentage of NIH massage therapy funding that involved pain and inflammatory conditions. Table 14 shows an increasing trend in the funding of topics in pain and inflammatory conditions. This upward trend began in 2008 and continued through 2012 when 69% of NIH funding for research in massage therapy involved pain and inflammation. NCCAM stated that its areas of special interest would include, *but not be limited to*, investigations of the impact of CAM modalities in alleviating chronic pain syndromes and inflammatory processes. This indicates that NCCAM's intention was to not solely fund research in pain and inflammation at the exclusion of all other topics. NCCAM did not state a specific goal for the amount of funding that should go towards its areas of special interest.

For the purposes of this evaluation, it is believed that dedicating at least half (50%) of its funding for these topics would be adequate to meet these needs, while the remaining 50% would be divided among all other research topics. Funding in massage topics for pain and inflammatory conditions was over 50% of the annual funding in 9 out of the 13 years reviewed (Table 14; Figure 11; & Figure 12). The current trend indicates that funding has been increasing in this area. It should be noted that NCCAM indicated that 30% of its overall funding was devoted to investigating pain and inflammatory conditions. As such, it would appear that the research funding patterns in massage therapy is consistent with NCCAM's funding area of special interest. Table 15 and Figure 13 show the annual percentage of total NIH funding for research in massage therapy that

involved topics in pain and inflammatory conditions, based on primary and secondary outcome measures.

The data for NIH funding of massage research indicated that topics involving preterm infants was second to pain conditions. The NHIS survey (Barnes et al., 2008) was also the first survey to include detailed information on the usage of CAM among children. This study found that although 11.8% of children used CAM, alternative modalities other than massage were listed as the most commonly used. Children were most likely to have used non-vitamin and non-mineral natural products, chiropractor or osteopathic manipulation, deep breathing exercises, yoga, and homeopathic supplements. This may be identified as an area that massage therapy is severely underutilized, since NIH data funded studies in massage therapy involving infants and children is second to pain conditions as the most commonly researched topic. Table 16 shows the rank orders used for analysis of Spearman's R values.

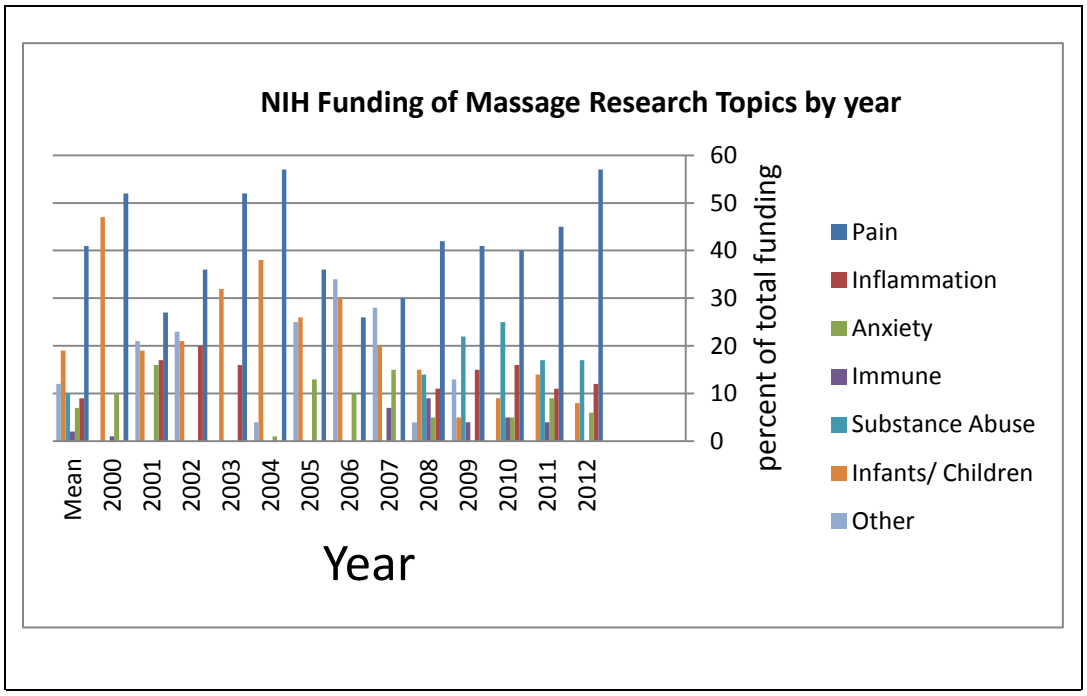

Figure 11. Percent of NIH Funding of Massage Therapy Topics by Year

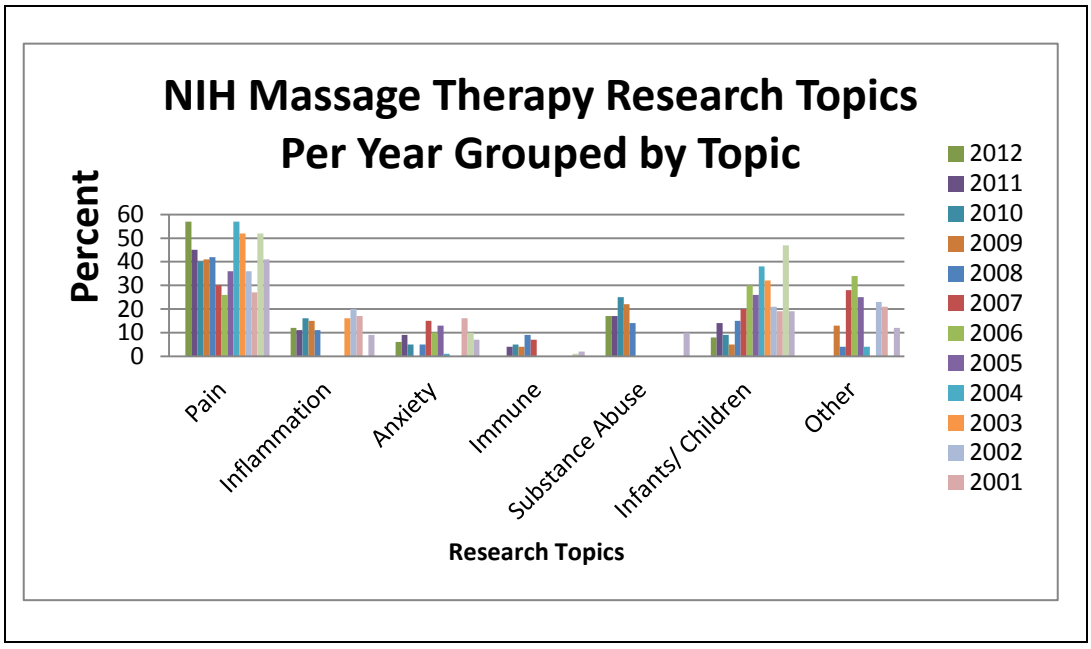

Figure 12. Individual Massage Therapy Research Topics Grouped Together

Table 15. Combined Percentage of Funding for Pain and Inflammation Combined by Year			
Year	**Pain**	**Inflammation**	**Pain and Inflammation Combined**
2012	57%	12%	69%
2011	45%	11%	56%
2010	40%	16%	56%
2009	41%	15%	56%
2008	42%	11%	53%
2007	30%	0%	30%
2006	26%	0%	26%
2005	36%	0%	36%
2004	57%	0%	57%
2003	52%	16%	68%
2002	36%	20%	56%
2001	27%	17%	44%
2000	52%	0%	52%
Mean	41%	9%	50%

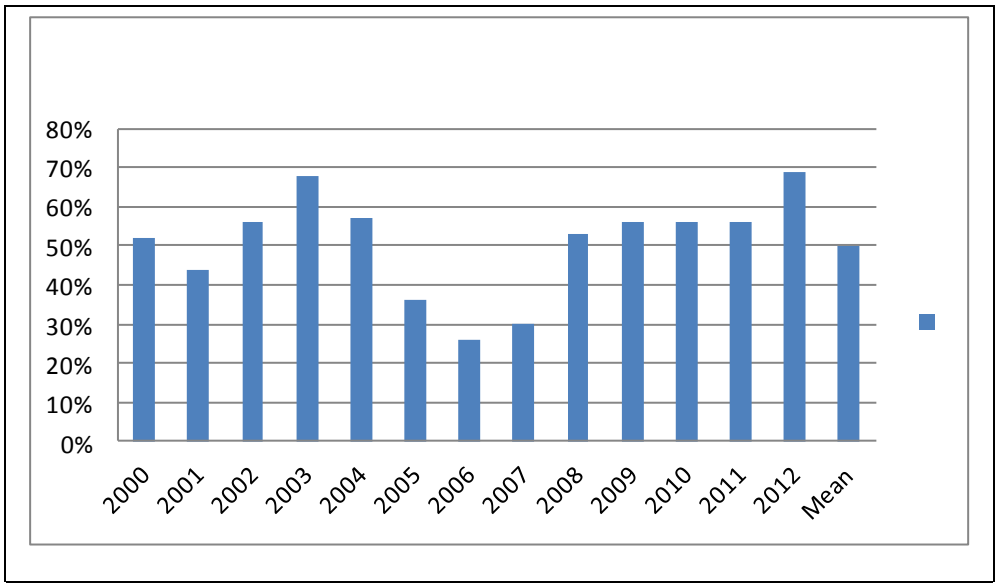

Figure 13. Combined Percentage of Funding for Pain and Inflammation Combined by Year

Table 16. Rank Orders Used for Analysis of Spearman's R Values

Year 2012 (R = –0.200)			
NIH Funded Studies	**Percent**	**AMTA Massage Usage**	**Percent**
Pain	57	Pain	19
Substance abuse	17	Substance abuse	0
Inflammation	12	Inflammation	9
Infants/Children	8	Infants/Children	0
Anxiety/depression/stress	6	Relax/Stress	32
Other (wellness)	0	Pampering	12
Stiffness	0	Stiffness	13
Year 2011 (R = –0.257)			
NIH Funded Studies	**Percent**	**AMTA Massage Usage**	**Percent**
Pain	45	Pain	19
Substance abuse	17	Substance abuse	0
Inflammation	11	Inflammation	9
Infants/Children	14	Infants/Children	0
Anxiety/depression/stress	5	Relax/Stress	30
Other (wellness)	0	Pampering	12
Stiffness	0	Stiffness	12
Year 2010 (R = –0.241)			
NIH Funded Studies	**Percent**	**AMTA Massage Usage**	**Percent**
Pain	40	Pain	15
Substance abuse	25	Substance abuse	0
Inflammation	16	Inflammation	8
Infants/Children	9	Infants/Children	0
Anxiety/depression/stress	5	Relax/Stress	40
Other (wellness)	0	Pampering	15
Stiffness	0	Stiffness	8

Table 16. Rank Orders Used for Analysis of Spearman's R Values (continued)			
Year 2009 (R = –0.182)			
NIH Funded Studies	**Percent**	**AMTA Massage Usage**	**Percent**
Pain	41	Pain	25
Substance abuse	22	Substance abuse	0
Inflammation	15	Inflammation	5
Infants/Children	5	Infants/Children	0
Anxiety/depression/stress	0	Relax/Stress	32
Other (wellness)	13	Pampering	17
Stiffness	0	Stiffness	8
Year 2001 (R = 0.058)			
NIH Funded Studies	**Percent**	**AMTA Massage Usage**	**Percent**
Pain	27	Pain	10
Inflammation	17	Inflammation	8
Infants/Children	19	Infants/Children	0
Anxiety/depression/stress	16	Relax/Stress	25
Other (wellness)	21	Pampering	31
Stiffness	0	Stiffness	10
Mean Cumulative Data (R = 0.024)			
NIH Funded Studies	**Percent**	**AMTA Massage Usage**	**Percent**
Pain	41	Pain	16.0
Infants/Children	19	Infants/Children	0.0
Other (wellness)	12	Pampering/Wellness	17.0
Substance abuse	10	Substance abuse	0.0
Inflammation	9	Inflammation	7.5
Anxiety/depression/stress	7	Relax/Stress	30.0
Immune	2	Immune	0.0
Stiffness	0	Stiffness	10.0

Program Evaluation: Step 5

Step 5: Justifying the Conclusions

Massage may be considered one of the oldest forms of medical therapy, believed to have originated in China, India and Egypt between 3000 B.C. and 2500 B.C. The earliest documentation finds references to therapeutic touch in the ancient Chinese text known as the Nei Ching (2760 BC). Massage has been used throughout the centuries to help relieve pain and heal injuries. The popularity of massage as a form of complementary and alternative medicine has not only endured, but continues to rise.

At one time, people primarily received massage therapy for relaxation and stress relief. However, NHIS and AMTA surveys indicate that more people are using massage therapy to treat medical conditions. AMTA usage surveys are also showing that pain conditions are becoming the most common reason for visits to massage therapists. Research in massage therapy can play an important role to sustain its popularity, while increasing its acceptance by the medical community. Although massage is an ancient form of therapy, some believe that scientific research in this field is still in its relative infancy and its overall quality needs to be improved (Moyer, Dryden, & Shipwright, 2009).

Increased credible research in massage therapy is the key to its recognition by the health care community as a viable form of health care. Barnes et al. (2008) points out that between 2002 and 2007, literature searches that included the National Library of Medicine journal database and PubMed, revealed only 40 studies involving acupuncture, massage therapy, naturopathy

and yoga. Only ten of those studies found significant evidence to demonstrate that a type of CAM was effective for a specific condition, such as acupuncture for back pain. Moyer et al. (2009) presented an article reviewing various aspects of research on massage therapy. This article stated that although massage therapy has been in existence for centuries, “scientific research in this field is still in its earliest stages.”

A literature search between 1988 and 2008 conducted by Moyer et al. (2009) found relatively few original research articles involving research in massage therapy. It was also concluded that a small portion of them would be considered high quality trials. Patterson, Maurer, Adler, and Avins, (2008) stated that massage therapy is a “promising modality that currently lacks a solid evidence base to better understand its benefits and risks.” Moyer et al. (2009) found it encouraging that there was a rising trend in the number of clinical trials in massage over that twenty year period.

In order for massage therapy to maximally grow as an industry, it needs to gain acceptance by conventional medical practitioners, become part of health care institutions and be accepted for medical insurance reimbursement. The most efficient method of achieving these goals is by demonstrating its safety and efficacy through rigorous scientific investigation, which is coincidentally in accord with NCCCAM’s mission statement.

Most of the NIH funded clinical trials reviewed in this evaluation were found to be of good quality with a score of 3 on the Jadad scale. However, it is feasible that these scores and the subsequent quality of massage therapy

research can improve. With modifications in designs, it is possible for future massage therapy clinical trials to consistently achieve the highest possible quality scores. The quality assessment based on the Jadad scale, highlighted two deficiencies common to all massage clinical study designs. There is the difficulty associated with double blinding massage trials, and the absence of an appropriate placebo (sham) massage control arm. Some may argue that failure to include these components could contribute to bias that may adversely affect the study's internal validity. This evaluation will address these issues along with other aspects of massage therapy research, while providing suggestions and recommendations for improving the quality of massage therapy research.

Double Blinding Massage Therapy Clinical Trials

The concept of double blinding means that the participants and the treating clinicians participating in clinical trials do not know which treatment the person is receiving. Double blinding is recognized as an important method to minimize expectation effects and reduce bias on the part of both the participant and the clinician (Viera & Bangdiwala, 2007).

The difficulty of including the double blind component with hands on studies such as massage therapy admittedly can be a challenge (Ali, Kahn, Rosenberg, & Perlman, 2012). Blinding the therapist may be difficult since massage therapists would likely know if they were administering a therapeutic massage. Even if they were told that light touch was not a sham, therapists would probably realize that they were not giving a complete therapeutic treatment. Moyer et al. (2009) stated that double blinding with the use of a

placebo that is identical to the real treatment would be ideal. However, Moyer et al. (2009) admitted that adapting a placebo control arm to massage trials that allows double blinding can be challenging.

Jadad et al. (1996) emphasized the importance of double blinding in clinical trials to reduce bias. It is an important component in the Jadad scale for rating the quality of clinical studies. In a study assessing effects outcomes in comparisons of therapies, Colditz, Miller, and Mosteller (1989) concluded that randomized controlled trials that did not use a double-blind design had a higher likelihood of showing a gain for the intervention than did double-blind trials. Double blinding was considered appropriate if it was stated or implied that neither the person providing the treatment nor the study participant could identify the intervention being assessed (Colditz et al., 1989).

To illustrate the importance of double blinding, McPherson and Britton (1999) studied the possible effects that patient preferences for treatment may have on outcomes in randomized control trials. It was found that patient preferences can influence the effectiveness of treatments. McPherson and Britton (1999) concluded that effects from un-blinded randomized controlled trials may be overstated. Patient preference may influence outcomes in manual trials that are not blinded. For example, a participant favoring massage over a different treatment modality, such as acupuncture, may bias the outcome. The disappointment of a participant in a massage trial, assigned to a non treatment control, may also be reflected as lower scores in pain assessment

questionnaires. Comparison of the intervention with a non treatment control group may tend to produce exaggerated results of efficacy.

Cherkin et al. (2011) admitted that “the potential failure of blinding to treatment assignment may have led to less favorable self-assessments of function and symptoms, making massage therapy seem more superior than it really is.” This may be a reason that double blinding is heavily weighted in the Jadad scoring system, accounting for 40% of the total score.

Adequate double blinding is particularly a “concern in massage trials since techniques are often practitioner-dependent and patient oriented” (Ali et al. 2012). A possible solution is to inform the subjects that the study involves testing several therapeutic bodywork interventions, including light touch, and that it is not using a placebo control. The therapists could be given instructions that the effects of light touch massage can be therapeutic and that its results are being measured as part of the study. Therapists could also be asked if they believe that light touch massage had therapeutic value.

Although it is the basis of placebo controlled trials, some contend that using deceit to compensate for the potential influence of expectations may not be justified. It is possible that this may raise ethical issues if full disclosure was not provided. Another possible method to control for bias is to survey subjects following the trial to determine whether or not they believed that they received the therapeutic intervention. Blinding may also be facilitated by recruiting participants who had never received a therapeutic massage. In this situation, it may be more likely that they would not realize they were receiving a placebo massage.

Single blinding may also be a problem. Unlike drug studies that can use an identical appearing placebo pill, subjects who might have had therapeutic massages in the past may recognize that they are receiving a placebo (sham) massage. Enrolling participants who have never had a massage may be one possible solution to the double blinding issue, while also reducing selection bias. This may facilitate their blinding and also reduce bias from expectations. Those who have never had a massage may not realize that they are receiving a sham massage and may not be as disappointed. This may also reduce the intervening variable that the effect of patient expectations may play in the outcome.

Since massage therapists would likely know if they were administering a therapeutic massage blinding the therapist may involve deceit. They would have to be convinced that the trial is also comparing the therapeutic effects of light touch massage. Sherman, Dixon, Thompson, and Cherkin (2006) pointed out that massage therapists believe that creating a warm and caring relationship is important to the healing process and that touch itself is the healing factor. As a result, massage therapists may not believe that a "placebo" massage exists. At the very least, whenever blinding of participants and therapists is not feasible, bias should be reduced by blinding the statisticians.

Need for Placebo (Sham) Control in Massage Therapy Clinical Trials

Patterson et al. (2008) stated that "the most difficult challenges in bodywork studies has been the lack of an adequate control group." A literature search conducted by Patterson et al. (2008) failed to locate a massage trial that used a sham bodywork as a control. Patterson et al. (2008) emphasized that the

developing and testing of a sham bodywork control would represent an important advance in clinical trial designs involving massage and other manual therapies. They concluded that the use of other modalities or even the use of a sham therapy was not an acceptable substitute as a control arm.

Bias may result from the failure to adequately mask an intervention. A randomized controlled trial is strengthened by masking the treatments. The goal of masking is to eliminate, or at least minimize, remaining potential biases (Forder, Gebski, & Keech , 2005). According to Viera and Bangdiwala (2007) subjects who are unmasked, and know their assignments, are more likely to alter their behavior or their self assessment of key study endpoints, such as quality of life, or pain questionnaires. It was also found that masked participants are more likely to adhere to their assigned treatment and are less likely to drop out of the study entirely.

Besides the Jadad scoring scale, masking is also included in the CONSORT (2010) checklist. Moher et al. (2010), the authors of the CONSORT checklist, contended that well designed and properly executed randomized controlled trials provide the most reliable evidence on the efficacy of healthcare interventions. Trials with inadequate methods are associated with bias that may exaggerate treatment effects. Biased results from poorly designed and reported trials can mislead decision making in health care at all levels.

On its website, NCCAM acknowledges that designing double blind studies can be challenging in manual therapies. This may be nearly impossible without an adequate placebo control arm that is identical to the treatment being

tested, but not therapeutic. To facilitate this NCCAM is encouraging the validation of a sham control for spinal manipulation or massage for treatment of chronic low-back pain and/or neck pain.

Some may question the quality of clinical trials in massage therapy due possible bias from the lack of an adequate placebo control arm. Most of the massage research studies involved comparison to other treatment modalities, to no treatment, or to usual care. It is possible that comparing different treatment modalities may not have accounted for the effects of patient expectations in the outcome (Moyer et al. 2009). Relatively few massage studies incorporated what would be considered an appropriate placebo (sham) massage treatment.

A study by Schulze et al. (1995) found that compared with adequately concealed treatment allocation, trials in which concealment was either inadequate or unclear (did not report or incompletely reported a concealment approach) actually yielded larger estimates of treatment effects. In addition, Schulze, Chalmers, and Altman (1995) found that trials that were not double-blind yielded larger estimates of effects. The authors concluded that studies using poor allocation concealment are more susceptible to bias. Schulze et al. (1995) advised readers to be wary of these pitfalls when assessing studies, and stressed that investigators must improve their design, execution and reporting of clinical trials.

An early, non NIH funded clinical trial, used light touch massage as a placebo control (Melzack, Vetere, & Finch, 1983). However, it was not used to study the efficacy of massage. Instead, this study investigated the use of

transcutaneous electrical nerve stimulation (TENS) for relief of low back pain, using light touch massage as the control. Subjects were divided into two groups with 20 in the experimental group receiving the TENS treatment. The control group consisted of 21 subjects receiving a placebo massage, described as a gentle massage. This study used a non-traditional massage as the placebo because it used four suction cups applied to the skin. The cups were kept in place for thirty minutes while mild pressure was applied. This was achieved by using a custom designed device that produced slowly varying changes in pressure so that a constant, gentle massage was applied to the skin.

Although this study design is listed as a double blind study, using two different treatment modalities may not provide for adequate masking of the two groups. Subjects were most likely aware of which treatment they were receiving, which could have affected the outcome. For example, the application of electrical stimulation from the TENS unit may have been more impressive to subjects, as a treatment modality, than the use of suction cups as a massage. Those receiving the TENS treatment may have had higher expectations, which could have been reflected in the improved MPQ scores.

Another issue with this study is that both treatments were conducted by physical therapists and not licensed massage therapists. As a result, the placebo massage may not have been properly performed. The authors claim that this was a double blind study. However, it would seem implausible that a physical therapist would not understand the therapeutic difference between a TENS unit and a massage involving light touch and suction cups. As part of the attempt to

mask the treatments, subjects were aware of both possible treatments and informed that both were beneficial. However, it was not noted whether subjects had prior experience with either treatments. It is possible that those who had received a therapeutic massage from a licensed massage therapist would be able to discern the difference and understand the decreased efficacy of this type of massage.

This study permitted the subjects to discontinue participation prior to completing the full ten sessions whenever it was determined that the treatments were not beneficial or if the condition worsened. That may have also accounted for the higher withdrawal rate in the placebo massage group. It is possible that this early termination policy may have diminished the placebo effect. This could have affected the validity of the results, since most of the early withdrawals were from the placebo group. In this situation, the results could have been affected by attrition bias. A disproportionate number of withdrawals from one group can impact external validity, since the sample may no longer be representative of the study population. This should be considered in future massage trials when using a different modality as a control.

The investigators used a different treatment modality (light touch massage) as their placebo in this TENS pain study rather than a sham TENS unit. It is possible that the application of a placebo TENS unit may have produced a more powerful placebo effect when compared to the light touch massage. In this case, the use of a different treatment modality as a placebo may have also threatened the internal validity of this study.

Although the Melzack et al. (1983) study was intended to test the effectiveness of TENS treatment for low back pain, it is relevant because it is one of the first to describe the use of a light touch massage as a placebo control. It is difficult to locate a research study that compares therapeutic massage to a placebo (sham) massage. The authors commented on the validation of using this type of massage as a placebo control by indicating that the efficiency of pain relief was about 50 percent of the TENS unit. They contended that this percentage was comparable to other double-blind pharmaceutical pain studies that used a placebo. This study may have inspired the development of more appropriate light touch massage as a placebo control.

However, it should be noted that the results of the Melzack et al. (1983) study could be misleading. This study only demonstrated that a TENS unit was better than a gentle non-traditional massage that simply involved the use of suction cup devices placed in various areas, without any actual deep tissue manipulation. Therefore the results of this study should not be used to imply that massage therapy would not be an effective analgesic treatment for low back pain, or that a TENS unit is superior to a legitimate therapeutic massage. Unfortunately, it appears that some may have misinterpreted the results of this study.

For example, a review article (Tsao et al. 2007) appeared to have erroneously stated that massage therapy was not as effective as a TENS unit by referring to this (Melzack et al. 1983) study. An earlier systemic review (Furlan, Brosseau, Imamura, & Irvin, 2002) also cited this study and stated that a TENS

unit was more effective than massage for reducing low back pain. Both articles failed to indicate that the light touch (sham) massage was only used as a placebo control that did not resemble any traditional massage techniques. In this study, the nontraditional massage was used as a placebo and it was not intended to be therapeutic. This study also erroneously concluded that a TENS unit was better than massage for relief of pain and it should not be cited as a comparison of the efficacy of these two different treatment modalities.

Review of the literature found that relatively few studies incorporated what would be considered a sham (placebo) massage treatment. However, Ezzo (2007) indicated that the nonspecific effects of any touch sham may also have the potential for bias. Mehling, DiBlasi, and Hecht (2005) expressed concern that bias can be a cause for changing the outcome. This review of twenty studies failed to find the use of a credible placebo control. He also found that none of these studies accounted for measures of patient expectations. Mehling et al. (2005) stated that rigorous clinical trials of hands on CAM interventions are scarce. However the authors suggested that there are options to minimize investigator, therapist and patient bias.

Mehling et al. (2005) suggested measures that can be used to maintain internal validity until researchers in massage therapy can agree on a sham touch treatment that is accepted as a placebo control. According to Mehling et al. (2005) two similar treatments could be utilized, but the control group would not receive what would be believed to be the actual effective technique in the massage. For example, the therapist would avoid the body part being assessed

in participants in the control group. These studies could also include a third non-treatment group that can be used for comparison to the placebo control group. This can be used to check for nonspecific effects.

In the absence of a credible sham (placebo) massage, Mehling et al. (2005) also proposed that a couched study intervention should be considered. In this procedure, the modality being tested for specific effect is combined in a large multimodal package with other treatments. Besides massage, other therapies are included such as exercises, nutritional, and educational therapies. The control group receives the same package except the massage. Although this may provide some blinding and help to decrease bias, Mehling et al. (2005) was concerned that the overall treatment interactions might modify the effect of the treatment of interest.

A proposal to help establish a placebo massage was initiated by Patterson et al. (2008). A study design was investigated that could be acceptable for future massage therapy clinical trials to include a valid sham massage as a placebo control. The authors described a literature search that produced 21 studies involving Swedish massage. The authors indicated that 17 of those studies reported significant improvement with massage therapy. The investigators remarked that since none of those studies used a sham form of massage as the control arm, it was difficult to determine whether the physical act of muscle tissue manipulation was solely responsible for the outcomes. Patterson et al. (2008) further stated that a follow up literature review was conducted after their trial was completed and they were still unable to find a massage study that used a sham

massage, such as a light touch massage. The authors indicated the importance of developing and using a sham body work control in future massage trials.

To study the effects of a sham massage, Patterson et al. (2008) enrolled 44 cancer patients into a clinical trial who were either undergoing chemotherapy or had recently completed chemotherapy. Their outcome measures were fatigue and quality of life. Fatigue was measured by the Piper Fatigue Scale and the Modified Schwartz Cancer Fatigue Scale. Quality of life was tested by the European Organization for Research and Treatment of Cancer QLQ-C30 questionnaire which was a cancer specific quality of life measure, the Center for Epidemiological Studies Depression Scale (CED-D), the Sleep Impairment Index and symptomatic side-effect profile.

Participants were randomized into three groups. Subjects in Group 1 received medium intensity bodywork; Group 2 received a placebo or sham bodywork that was described as a low intensity or light touch bodywork. The third group consisted of an observational group of subjects receiving usual care. Interventions were given twice a week over a six week period. The placebo involved placing the hands lightly on major muscle groups without actually manipulating those areas directly. Massage therapists were instructed to lightly touch and hold the area, then release and then repeat in another area. The placebo massage was designed to take 50 minutes in order to approximate the amount of time a regular massage therapy session would last. The investigators found that the therapists were able to correctly perform the light touch intervention.

The Patterson et al. (2008) study was important because its intention was to establish a placebo control for massage trials. The investigators stressed the need for a true massage control study. They outlined a specific light touch massage that did not involve direct manipulation of any major muscle groups. The authors were confident that this type of sham massage could easily be incorporated in future massage therapy studies.

Developing a sham intervention as a control in hands-on studies may be complicated because nonverbal human touch can convey messages. A possible method of compensating for this would be to insure that the length of time and setting of the sham treatment is as identical as possible to the intervention. Subjects in the control group should receive the same amount of attention, empathy and intent to heal as those in the experimental group.

Mehling et al. (2005) theorized that even the un-blinded therapists may not have the same passion, and the intent to heal aspect may be minimized. The cooperation of the therapist to provide this therapeutic environment during a sham control also needs to be obtained. Even if a credible sham treatment was utilized, a third non treatment arm can be compared to the placebo's non-treatment specific effects.

In another study to test the validity of using light touch as a placebo or "sham" massage, (Patterson et al., 2008) randomized 46 cancer patients undergoing chemotherapy into three groups. The primary outcome measurement used in this trial was the Revised Piper Fatigue Scale. This tool was selected because it was specifically targeted for use with cancer patients. The Modified

Schwartz Cancer Fatigue scale was used to measure secondary outcomes. Other information was provided by a visual analogue scale for overall perceived levels of fatigue, the European Organization for Research and Treatment of Cancer scale was used to assess quality of life. Depression was assessed with the Center for Epidemiologic Studies Depression Scale. To rule out possible confounding effects of anemia, participants' hematocrits were checked.

Subjects in the first group received Swedish massage described as medium intensity bodywork. The second group received the sham bodywork which consisted of a light touch massage. Both of these interventions used full body work and frequencies of sessions were at least once per week over a six week period. Those in the third group were the controls and did not receive massages during the trial. The investigators felt that it was important to determine whether the effect of massage therapy is actually from the manipulation of muscle tissue or merely from the prolonged touch from a massage therapist. To date, they were unable to find any other studies that specifically addressed this issue.

The results showed a favorable response from all the subjects in group one, who had the medium intensity massages, while there were mixed results in the light tough massage group. In this study, the participants in the non-intervention control group had negative responses. The authors felt that they had successfully developed a light touch control intervention that could be accepted as a placebo. Massage therapists could be trained to provide this intervention and participants assigned to the control group would accept it. Reducing the

dropout rate from the control group can help minimize attrition bias. The investigators concluded that the utilization of this sham massage would greatly improve the quality of future studies involving massage therapy. Researchers in massage therapy should consider this option when designing their clinical trials. It is encouraging to note that a clinical trial (Rapaport, Schettler, & Bresee, 2012) investigating the biological effects of massage therapy incorporated the use of a light touch protocol as a control.

The difficulty of including the double blind component with hands-on studies such as massage therapy remains a concern. Simply blinding the therapist may not be effective, since massage therapists would likely know if they were administering a therapeutic massage. Even if they were told that light touch was not a sham, therapists may suspect that they were not administering a complete therapeutic treatment.

The debate over the need for a placebo massage in clinical trials is ongoing. Those opposed do not believe that light touch could be a real placebo massage because they believe even light tough has therapeutic benefits. As a control, most massage trials used a no treatment group, usual care or different modality. Bias may be reflected through the effects of expectations, or the disappointment of not receiving the intervention. Others in a usual care control may already be disappointed with their current form of treatment. Ezzo (2007) pointed out that the type of controls used in massage research cause results to be questioned. Bias may be a factor in studies by producing more favorable subjective outcomes for the intervention. Therefore, it is important to ensure that

treatments are equally credible and acceptable to patients to minimize placebo effects and high dropout rates (Haraldsson et al., 2006). “The dialogue about the best ways to research this increasingly popular modality will likely translate into better trials and ultimately more informative systematic reviews” Ezzo (2007, P. 294).

Miller, Emanuel, Rosenstein, and Straus (2004) describes the randomized, placebo controlled trial as the most rigorous method of determining true treatment effects and that it should be the design of choice for evaluating efficacy of treatments. Some argue that the placebo controlled trial should not be applied to CAM research because it is not a fair method for evaluating its treatments and it may interfere with the holistic healing environment. The fear is that this may bias CAM research and lead to the conclusion that the treatment is ineffective because it may not be superior to the placebo. Miller et al. (2004) pointed out that similarly to CAM, conventional medicine may also provide a symbolic healing environment with nonspecific therapeutic attention and expectations.

Therefore, this should not be used to preclude placebo controlled trials, which are still recognized as an efficient method of testing the specific effects of isolated treatments. Although there is evidence to support and encourage the use of placebo controlled trials, Miller et al. (2004) admits that blinding may be difficult with some CAM therapies, particularly manual trials. However, when randomized trials cannot adequately mask the intervention, the design should concentrate on minimizing bias in the outcome assessments. In the absence of

an adequate placebo (sham) intervention, Miller et al. (2004) suggested that the design could include a no treatment control and specifying a priori significant target outcome. One method of isolating a CAM placebo effect is to compare an intervention and a placebo control to non treatment. Some CAM outcomes have shown that the intervention and placebo were both superior to the non treatment group. In this situation, even though the placebo control demonstrated benefit over no treatment, some may argue that it may not be ethical to withhold CAM treatment even if it is only benefit is derived from the placebo effect.

While some believe that it would not be ethical to withhold or discourage a treatment that only produces benefits through its placebo effects, it should still be identified through scientific research. Miller et al. (2004) stated that treatments with specific efficacy have greater clinical value than those merely associated with it placebo effects. Enhanced scientific value will be associated with treatments that have greater therapeutic effects over placebo. This would also increase the likelihood of insurance reimbursement for CAM therapies identifying as having specific therapeutic benefits, rather than merely a placebo effect.

Rigorous scientific research is important to the complementary and alternative medicine industry. Poorly designed studies demonstrating efficacy of massage would have diminished value to those in conventional medicine. Miller et al. (2004) stated that there is no merit to the argument that randomized placebo controlled clinical trials for evaluating most CAM treatments are not appropriate. Just like conventional treatments, CAM research should focus on therapeutic value beyond the placebo effect. Miller et al. (2004) concluded that

CAM therapies should be rigorously evaluated for reasons of both public safety and health promotion. This is in direct alignment with the NCCAM mission statement. In addition, Miller et al. (2004) expresses the opinion that the ethical principles that guide conventional biomedical research should also be applied to CAM research.

It appears that clinical research in massage therapy should be able to comply with these recommendations. Efforts are being made to develop an appropriate placebo (sham) massage control. Once this is established, the blinding of participants and even the therapists would be feasible. It is anticipated that the ability to design a double blinded placebo controlled trial in massage therapy in the near future is a reasonable and attainable goal.

Influence of Patient Expectations and Preferences

Another dilemma with manual trials is that patient expectations may influence clinical outcomes. This can be a factor contributing to bias in some trials. A study by Kalauokalani, D., Cherkin, D. C., Sherman, K. J., Koepsell, T. D., and Deyo R. A. (2001) found a positive correlation associated with expectations and clinical outcomes. In some instances, it is possible that patient expectations may be as powerful as the placebo effect. Those with higher expectations had significantly better outcomes than those with lower expectations. If the effect of expectations on treatment is not controlled, it may influence the favorable results in clinical trials. A non-treatment control may affect comparisons if it generates negative expectations.

In randomized trials, subjects may be disappointed if they believe that they were assigned to an inferior treatment or simply to an observational group. A survey of subjects' expectations can be included in the study. Mehling et al. (2005) found that often during recruitment for CAM trials, participants usually want the CAM intervention. Not receiving the intervention or being in a non treatment group may produce a nonspecific negative effect on the outcome. The type of control that is selected may influence the outcome, especially if the control is a different modality from the treatment, or non treatment. The effects of expectations may need to be acknowledged and possibly factored into the results. Mehling et al. (2005) proposed that a measure of expectations should be included as a covariate in a regression analysis, or that data can be compared by stratifying it according to expectations. This may permit an un-blinded study to control for patient expectations.

A possible method to address the issue of patient expectations is to change recruiting strategies. For example, subjects for massage trials should not be recruited from massage clinics. In his article, Bias Control in Trials of Body Work, Mehling et al. (2005), indicated that blinding the participants helps control for patient expectations that may result in bias on self reporting outcome tools.

A novel approach suggested by Tilbrook (2008) was to obtain participants preference beforehand and assigning them to their preferred treatment. Only those expressing no preference should be randomized. This method could also be used to monitor the effects of patient expectations. Accounting for patient preferences in randomized manual trials would be important for maintaining

internal validity. However, the potential loss of a heterogeneous sample may affect external validity if a large number of people refuse to participate because they do not wish to be randomized. Conversely, a large number of participants with preferences agreeing to randomization may affect internal validity. Tilbrook (2008) describes this phenomena as “resentful demoralization” that may be reflected on pain questionnaires.

There may be another possible solution to deal with participants’ blinding and expectations. Those enrolled in a placebo controlled massage trial can be informed that the study involves testing several massage therapeutic techniques rather than mentioning an actual placebo. This may involve modifying the informed consent that is required in human trials, and require Institutional Review Board approval. The therapists could also be instructed that the effects of light touch massage (placebo) are being measured.

To help account for bias, subjects can be surveyed following the trial to determine whether or not that they believed that they received the actual intervention. If a double blind study is not possible, a single blinded design may be substituted. Even if therapists are aware that the light touch they are performing is not the therapeutic intervention, participants may be sufficiently masked to reduce the effects of expectations. Some may argue that ethical issues may be raised, if full disclosure was not provided, in the attempt to compensate for the potential influence of expectations.

Establishing Dosing Criteria

The combination of poorly qualified therapists and substandard treatments in massage studies can lead to false negative outcomes. Massage therapy may encompass a broad range of modalities that should be defined in the study. In addition, a proper massage technique without adequate dosage may fail to produce the desired results. Standardized massage treatment protocols for use in massage studies should be considered. Protocols in studies defining the type of massage, duration, frequency, and total number of treatments necessary have not been established. Ezzo (2007) indicated that researchers have not identified an optimal dosage. Dose findings studies are not typically done in massage trials, but should be performed before larger studies are conducted. This may be another indication that massage research in still its relatively infant stages.

Establishing dosing criteria for massage therapy studies is important in order to standardize massage therapy research protocols. A major step in this direction was taken in a trial in by Perlman et al. (2012). Subjects were assigned to groups to receive one of four treatments over an eight week period. There were two groups who received a full sixty minute Swedish massage, but one of the sixty minute groups received treatment twice a week, while the other was treated once a week. There were two groups who received a thirty minute Swedish massage, also either weekly or biweekly for eight weeks. The control group only continued with their usual care.

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was used as the primary outcome measurement tool. This 24 item

system is divided into three subcategories to assess pain, stiffness and physical function. Secondary outcomes included a visual analog pain scale, and range of motion studies to indicate flexibility. Results showed significant improvements in all four treatment groups. Both of the sixty minute massage groups outperformed the thirty minute groups. However, there was no significant difference between both sixty minute groups (weekly vs. biweekly). It was concluded that the optimal practical massage dosage could effectively be achieved with one weekly sixty minute massage, over an eight week period. This was the first dose finding study for osteoarthritis of the knee and it is hoped that this will inspire additional research for finding optimal dosage for other massage studies.

Rapaport et al. (2012) was interested in investigating the biological effects of massage in healthy adults. Although massage has been used to help relieve symptoms associated with anxiety, depression, back pain, and asthma, the author expressed reservations about the quality of the published studies. This article also raised concerns that there are not enough studies to investigate the mechanism of action of massage. The effects of one session vs. the possible cumulative effects of repeated massages were not well understood. In addition, the length of time between sessions may also have an effect on the result of massage trials. The issue of dosages associated with massage therapy was not standardized when performing clinical trials. This study was designed to investigate the effects of Swedish massage vs. light touch over a five week period of intervention. It was hypothesized that biweekly massages for both

Swedish and light touch would have better cumulative effects over weekly massages.

Forty five subjects were randomly divided into one of four groups, a twice weekly or a once weekly Swedish massage, and controls of a twice weekly or once weekly light touch massage. The experimental group had a full forty-five minute Swedish massage session. The controls also had forty-five minute sessions, however, they were receiving light touch massage that was administered by stroking using the back of the hand. While using light massage as a possible placebo control, administering it with the back of the hand may cause subjects to question the procedure and suspect that they were not receiving the intervention. The massage therapists would be aware that by only using the back of their hand that they might be administering a non-therapeutic placebo massage. This could jeopardize attempts to maintain a blinding effect in the trial. The outcome measurements in this study were levels of: cortisol, ACTH, oxytocin, arginine vasopressin, lymphocyte markers and cytokine levels.

Results showed that once weekly and twice weekly massages produced some different effects. This indicates that determining correct dosages is also an important component for effective massage therapy. The results of this study showed that those receiving weekly massages had increased circulating phenotypic lymphocyte markers and decreased cytokine production when compared to the weekly light touch controls. In addition, the once weekly Swedish massage group did not show any significant increases or difference with controls in Arginine vasopressin, oxytocin or ACTH levels. However, the twice

weekly Swedish massage group displayed a different response pattern. They did have increases in oxytocin levels, while cortisol and arginine vasopressin decreased. It was also found that there was minimal effect on phenotypic lymphocyte markers in this group.

However, the twice weekly group also had increases in pro-inflammatory markers. This clinical trial provided some important issues to consider, such as evaluating the effects of dosages for various conditions. This information can also influence massage therapy schools to include information on the effects of dosages in their training programs. Massage therapists would be more aware of dosage requirements for various conditions and differences on biological effects. The other important contribution of this study was to investigate the use of light touch as a placebo control in massage trials.

Discussion on the Quality of Massage Therapy Research

This program evaluation investigated the Grants and funding program of the National Institutes of Health (NIH), National Center for Complementary and Alternative Medicine (NCCAM), as it specifically relates to research in massage therapy. The first assessment evaluated whether the funding program, relative to massage therapy, effectively supported the stated mission of NCCAM. That mission statement is: “to define, through rigorous scientific investigation, the usefulness and safety of complementary health approaches and their roles in improving health care.” Based on the results of the Jadad scale, most of the massage therapy studies attained a score of 3 out of 5, which is considered high quality. Since no adverse effects were reported from the NIH studies reviewed, it

can be concluded that massage therapy is safe for the conditions that were investigated and with the protocols used in the clinical trials when performed by licensed massage therapists.

Evidence-based medicine is based on the concept that individual clinical decisions and broader health policy decisions concerning treatments be based on the published results of rigorous studies of efficacy and effectiveness. It should be distinguished that “efficacy” is not synonymous with “effectiveness.” While double blinded, placebo controlled randomized trials are considered the gold standard in evaluating the effects of treatment, they may not always be clinically relevant. Efficacy studies provide information about how well a treatment works in an ideal or controlled environment such as a clinical trial. Effectiveness studies investigate how well that treatment works under real world conditions (Gartlehner, Hansen, Nissman, Lohr, & Carey, 2006).

Published scientific evidence is relied upon for information concerning treatment options. Published research in massage therapy has been increasing over the past twenty years and has demonstrated the efficacy and safety of massage therapy for various medical conditions and particularly for pain. However, it was important to examine whether the quality of the research was sufficient to be considered rigorous scientific investigation. The studies were assessed for quality using the Jadad scoring system. Although the overall mean Jadad score for all studies was 2.25, it was found that 53% of the studies scored 3 out of 5 points, with 3 being the minimum amount required to be considered high quality.

Reviewing the Jadad scores reveals that most, if not all, of the massage studies could have achieved the minimum high quality score of 3 simply by making adjustments in their design and reporting. All study designs were described as randomized clinical trials. However 15 studies failed to receive a point because the randomization method was either not described, or was not appropriate. This aspect of the clinical trial could have easily been improved, for example, if it the method of randomization was achieved through a computer generated program.

It appears that most of the massage clinical trials could have easily achieved a high quality score of three on the Jadad scale. After appropriate randomization, simply accounting for withdrawals would have provided the third point. Eight studies failed to receive a point because they neglected to report participant withdrawals. This item in the Jadad scoring scale involves accounting for any loss of participants. To earn one point, a researcher only needs to report on any withdrawals. If no participant dropped out of the trial, a statement indicating that there were no withdrawals should be included in the report. Failure to account for withdrawals can not only result in the loss of a point on the Jadad scale, but can also contribute to attrition bias. If the groups no longer resemble the original makeup, then external validity can be threatened since the results may not be generalized to the population.

Clinical trials that last a long period of time may tend to be more susceptible to attrition. This may not affect massage trials sine most are of relatively short duration, lasting several months. However, massage trials may

need to be more concerned with selective attrition. This may involve more participants withdrawing from one group. The control or non treatment group may be more susceptible to withdrawals, especially if participants feel that they are not receiving any therapeutic benefits. Selective attrition can affect the internal validity of the study by showing greater effects for the treatment.

The concept of randomization was originally introduced as a component of clinical trials by RA Fisher in the 1920s. Twenty years later Austin Bradford Hill was credited with promoting randomization as the only means of avoiding systemic bias between groups of participants (Amitage, 2003). Since then, randomization has become a crucial part of the gold standard of clinical research trials. Randomized trials increase the ability to establish a cause and effect relationship. Non-randomized studies are not considered high quality and looked upon as quasi experiments. All of the NIH funded studies reviewed were randomized clinical trials.

Assessing the results of the Jadad scale for the NIH funded studies reviewed, highlighted a deficiency that is common in massage therapy clinical trials. None of these studies were double blinded or used a placebo (sham) massage as the control arm. The Jadad scale manifests the importance of double blinding and an appropriate placebo control. The proper utilization of double blinding, as well as including an appropriate placebo control, accounts for 80% of the total Jadad score. A systemic review of reviews by Kumar et al. (2013) found that although evidence exists for the effectiveness of massage therapy for low back pain, the overall quality of the studies was poor. The lack of

double blinding and placebo control was identified as the main issue reducing the quality of the evidence base. As a result, Kumar, Beaton, and Hughes (2013) recommends caution when interpreting the results of massage therapy research studies.

Crawford, C.C., Huynh, M.T., Kepple, A., and Jonas, W. B. (2009) conducted a systematic review comparing the quality of research studies of conventional and alternative treatments involving headaches. The authors also used the Jadad scoring system to compare the quality of the randomized controlled trials because it was widely accepted and well validated. Scientific evidence is important to physicians in order to inform their patients of treatment options and to be able to make appropriate evidence based decisions. Based on the Jadad scale, their results found that the quality of conventional medicine studies was significantly higher than the studies involving alternative treatments. The Jadad mean score for conventional medicine trials was 3.21 while the mean for alternative treatments was 2.23. It is interesting to note that this was consistent with the Jadad mean score of 2.25 for massage clinical trials that was reported in this program evaluation.

Crawford et al. (2009) had a similar assessment about the quality of alternative treatments. Although all of their studies received a point for being randomized, some of the studies failed to receive an addition point because they either did not describe the randomization procedure or it was not appropriate. Furthermore, the investigators noted that the lack of double blinding was the primary reason that the Jadad scores were lower in the alternative group when

compared to the conventional studies. Crawford et al. (2009) acknowledged that achieving a well designed double blinded study can be problematic.

The authors pointed out that the lack of an accepted or standardized sham treatment can be an obstacle to conducting blinded studies. They found that a common issue with CAM study designs was that many studies compared different treatments. The authors concluded that it is important to review and possibly revise CAM research methodologies because rigorous scientific evidence is crucial in order to successfully progress to an integrated healthcare system. They also suggested that CAM institutions, particularly CAM schools should be more involved with CAM research and provide resources such as facilities and patient access.

While double blinding and the use of a placebo control is challenging in manual trials, these components are not impossible to achieve. Positive steps in this direction are being taken by researchers in massage therapy. Researchers, such as Patterson et al. (2008); Perlman et al. (2012); and Rapport et al. (2012) are investigating the feasibility of using light touch as a sham massage. Including an accepted sham massage as a placebo control arm will facilitate the utilization of double blinding in study designs. It will then be possible for massage therapy clinical trials to consistently achieve Jadad scores above three and even five out of five. Massage therapy clinical studies that are randomized, double blinded, placebo controlled trials would be equivalent to the gold standard of randomized controlled trial research designs.

Use of the CONSORT to Improve Quality

Inadequate reporting and designs can be associated with biased estimates of treatment effects (Moher, 2002). Systemic errors and poorly designed clinical trials can be regarded as poor scientific methods which in turn may reduce the impact of the treatment's efficacy findings. An efficient method of enhancing the rigor of randomized controlled trials is by the routine usage of the CONSORT checklist. Originally developed by a group of scientists and editors, CONSORT (Consolidated Standards of Reporting Trials) was updated in 2010 (Schulz et al., 2010). The intent of the CONSORT 2010 is to improve the quality of reporting of randomized clinical trials.

The statement consists of a checklist and flow diagram that authors can use for reporting a randomized clinical trial. Many leading medical journals and major international editorial groups have adopted the CONSORT statement. The CONSORT statement facilitates critical appraisal and interpretation of RCTs by providing guidance to authors about how to improve the reporting of their trials (Schulz et al., 2010). Researchers in massage therapy should be encouraged to use the CONSORT when designing their clinical trials.

Potential for Conflicting Results

Another consideration to be aware of is the possibility that massage can produce conflicting results. Hippocrates (460 to 380 B.C.) commented that "The physician must be experienced in many things. But assuredly also in rubbing; for things that have the same name have not always the same effects. For rubbing can bind a joint that is too loose and loosen a joint that is too rigid" (Calvert,

2002). To illustrate this point, during a study Chambron, Dexhiemer, Coe, and Swenson (2006) found that Swedish massage may reduce blood pressure, while sports or trigger point massage may increase blood pressure. It was believed that any massage that could potentially elicit pain would stimulate the sympathetic nervous system, causing a rise in blood pressure.

It was also found that Swedish massage would not reduce blood pressure if sports or trigger point massage was also performed during the same session. Interestingly, this study found that deep tissue massage, which may also be considered potentially painful, did not increase blood pressure. The authors concluded that since students were used to provide the massages in this study, they did not provide the same amount of pressure during deep tissue massage than a more experienced therapist would. It was noted that cranial-sacral massage used in another group also produced in a significant decrease in blood pressure. This effect was explained because cranial-sacral massage involves stroking the sternocleidomastoid muscle which in turn stimulates the carotid sinus. This in turn activates the parasympathetic nervous system that ultimately causes a reduction in blood pressure.

Therefore, it is important to carefully define the type of massage given and a standard treatment protocol should be established. With the potential for variations from using several individual therapists during massage interventions, therapists involved in the trial should be specifically trained in the procedure. Therapists should be careful to apply the same amount of pressure. Treatment interventions should be closely monitored during the trials. Detailed massage

logs should be completed by each therapist to describe the type of massage performed, what body parts were massaged, along with the length of time, and include the amount of pressure applied. These logs should be reviewed by an administrator to help maintain uniformity. Even with established protocols, a lingering problem is that the individual application of touch can also differ among therapists. That may produce fluctuating outcomes in the studies. This may be more of a problem with massage studies involving many practitioners.

Use of Validated Pain Outcome Assessment Measurement Tools

The accurate assessment of outcome measurements is the key to good quality research studies. The use of validated pain assessment tools should be a major element of massage research trials involving pain conditions.The McGill Pain Questionnaire, developed by Melzack and Torgerson (1975), was one of the first self report pain-measuring instruments that continues to be widely used. This process first began in 1971 when Melzack and Torgerson (1971) were interested in finding words to describe experiences of pain. They surveyed doctors and college graduates to organize various adjectives into groups to describe different aspects of pain. As a result, they originally identified three major psychological dimensions of pain: Sensory**:** what the pain feels like physically —where it is located, how intense it is, its duration and its quality (for example, 'burning', 'throbbing').

Affective**:** what the pain feels like emotionally, such as whether it is frightening, or worrying. Evaluative**:** what the subjective overall intensity of the pain experience is (for example, 'unbearable', 'distressing'). These three main

groups were then divided into sixteen sub-classes. For example, the affective class was sub-divided into tension (including the adjectives ‘tiring’, ‘exhausting’), autonomic (including ‘sickening’, ‘suffocating’) and fear (including ‘fearful’, ‘frightful’, ‘terrifying’). Melzack & Torgerson (1971) then asked the group of doctors, patients and students to rate the words in each sub-class for intensity. The first 20 questions on the McGill Pain Questionnaire consist of adjectives set out within their sub-classes, in order of intensity. Questions 1 to 10 are sensory, 11 to 15 affective, 16 is evaluative and 17 to 20 are miscellaneous.

There are two components of the MPQ, the first is a pain rating index (PRI) and the second is a present pain intensity (PPI) scale which is scored from 1 to 5 (0= none 1 = mild, 2 = discomforting, 3 = distressing, 4 = horrible, 5 = excruciating). This will be used to test a secondary hypothesis that most people receiving massage therapy for a pain condition would have at least moderate pain intensity, as measured by a mean Present Pain Intensity (PPI) score of at least 2.0.

Patients are asked to check the word in each subclass that best describes their pain. Based on this, a pain rating index (PRI) is calculated: each sub-class can be used as a verbal rating scale and is scored accordingly (1 for the adjective describing least intensity, 2 for the next one and continuing throughout). Scores are given for the different classes (sensory, affective, evaluative and miscellaneous), and also a total score for all the sub-classes. In addition, patients are asked to indicate the location of the pain on a body chart (using the codes E

for external pain on the surface of the body, I for internal pain and El for both external and internal).

To indicate present pain intensity (PPI), a 6-point verbal rating scale is also included. Finally, patients complete a set of three verbal rating scales describing the pattern of the pain, either as brief, rhythmic or continuous. Some limitation and criticism of the McGill Pain Questionnaire concerned the need to have extensive understanding of the English language in order for participants to be able to distinguish between certain words, for example, such as "Smarting" and "Stinging."

An example of using appropriate outcome measurements can be found in a study by Cherkin et al. (2001). This trial compared massage with other popular forms of alternative treatments for chronic back pain. A total of 262 subjects were randomly assigned to one of three groups. The first group received traditional Chinese Medical Acupuncture, the second group received therapeutic massage, while the third group, considered the control, only received self-care educational information in the form of printed materials and video tapes demonstrating exercises and stretching techniques. Participants in both treatment groups were permitted to receive 10 treatments within a 10 week period.

The acupuncture group received standard Traditional Chinese Medicine (TCM) which included needling techniques, electrical stimulation and manual stimulation, manual manipulation of the needles, indirect moxibustion, infrared heat, cupping, and exercise recommendations. The massage protocol used a combination of Swedish, deep tissue, moist heat or cold, neuromuscular and

trigger and pressure point techniques. This study is also significant because, it provides an example of a massage protocol for low back pain.

Outcome measures were symptoms and dysfunction. Patients rated how bothersome" back pain, leg pain, and numbness or tingling had been during the preceding week, each on a scale from 0 to 10. The score for the most bothersome symptom was used. The authors point out that this question has demonstrated substantial construct validity (Dunn & Croft, 2005). In addition, a modified Roland Disability Scale was used to measure patients' dysfunction. The score was the number of positive answers to 23 questions on limitation of daily activities attributable to back pain. The authors also described this instrument as being reliable, valid, and sensitive.

At the end of the 10 week trial, the TCM group reported significantly less pain than the control group; however the massage group was better than both the TCM and control group. A secondary outcome measure looked at the use of pain medications and the massage group showed significant improvement over both groups. Decreased dependency on pain medications can be another indicator of the treatment's effectiveness during pain studies.

The use of a pain rating instrument such as the single bothersomeness question and the modified Roland Disability Scale are considered to be appropriate outcome measurement tools. A problem with this study was that it did not use any type of a control group, such as no intervention, or standard care or some type of placebo. Another issue may have been randomizing subjects to compare two very different forms of treatments. It could have been possible that

some subjects in the acupuncture may have had more anxiety related to the needles, and those in the massage group may have felt more relaxed. The effects of patient expectations may not have been taken into consideration.

To investigate the validity of using the single “bothersomeness” question as a measure of low back pain a specific study was conducted (Dunn & Croft, 2005). The need for this question came about because of the difficulty assessing low back pain due to its variability. This question appeared valuable for measuring non-specific forms of back pain and is considered particularly useful for patients with sciatica. Patients are asked about their back pain with the question “In the last 2 weeks, how bothersome has your back pain been? This single bothersomeness question has five possible responses: “not at all,” “slightly,” “moderately,” “very much,” and “extremely.” 935 patients participated in this study and were sent the bothersomeness question along with two other instruments; the Roland-Morris Disability Questionnaire (RMDQ) and the Chronic pain Guide (CPG). The results showed that the bothersomeness question correlated well ($p<.001$) and had 80% sensitivity when compared to other pain measuring instruments.

This single question can provide a simple yet reliable method of assessing back pain in patients. Incorporating the bothersomeness question, as an outcome measurement; to assess back pain in patients suffering from sciatica can be a valuable addition to research studies investigating sciatica.

An article by Roland and Fairbank (2000) reviewed two pain questionnaires**,** The Roland–Morris disability questionnaire (RDQ) and the

Oswestry disability index (ODI) questionnaire. These questionnaires were designed and intended to be used as tools to monitor pain in a clinical setting or in research studies as an outcome measure in clinical trials. The purpose of this article is to provide evidence of the validity and reliability of the RDQ and ODI and to discuss comparative results of these two questionnaires. The RDQ consists of 24 questions that are checked for yes and unchecked for a negative response.

Possible scores therefore range from 0 to 24. An advantage of the RDQ is that is short, instructions are simple to understand, and it is quick to complete. Evidence of its scientific validity makes the RDQ a popular choice among researchers. In addition, the RDQ is currently available in 12 languages, and there are no restrictions on its use. A recent modification to the question format from “because of my back” to “because of my back or leg problem” actually makes this more suitable for use in studies involving patients with sciatica. Construct validity of the RDQ has been established by comparing it to other existing pain and disability questionnaires. It was found that the RDQ correlated well with questionnaires such as the SF-36, the SIP, the Quebec Back Scale and the Owsestry questionnaire. The RDQ scores also correlated well with pain ratings.

Similarly, the ODI, as a measure for both assessment and outcome, was also found to be a favorite choice. This questionnaire is simple to use and can be completed in less than 5 minutes and scored in less than a minute. Since its inception in 1976, several modifications were proposed. The most significant was

the inclusion of a simple question on the “bothersomeness” of back pain. The use of this question was found to be a valid and reliable measurement tool for back pain (Dunn & Croft, 2005). Although the ODI did not correlate well with the McGill Pain Questionnaire, it was found to beneficial for clinicians, since it was a better predictor of return to work than other pain questionnaires.

The authors indicate that both the RDQ and ODI are comparable and have been widely used and have been extensively tested. However, certain situations may favor the use of one questionnaire over the other. For example, the RDQ is better suited for telephone interviews. Also, since the RDQ has a maximal score (24), the ODI can continue to show progressive disability. Therefore, it may be preferable to use the RDQ when there is mild to moderate disability involved, while the ODI would better reflect progression in patients with more severe disability. Nevertheless, the authors conclude that both instruments perform as well or better than most of the other available measurement instruments. This article helps to validate an important assessment instrument for measuring pain.

A review article (Kopec, 2000) discussed several validated back pain questionnaires that are commonly used in research studies or for monitoring results of treatment. The author indicates that there are two general types of outcome measures, described as generic or disease-specific. Generic questionnaires are basically used to measure pain or functional limitations that are associated with a variety of conditions. On the other hand, disease-specific measures reflect measures that are affected by a particular condition. The article

begins with a comparison of two of the more widely used questionnaires, the Oswestry Low Back Pain Disability Questionnaire (ODQ) and the Roland-Morris Disability Questionnaire (RMDQ). The ODQ questionnaire for low back pain uses 10 items to measure pain and limitations to activities of daily living. The RMDQ is also specific to back pain that contains 24 items to assess pain and functional limitations. Adding the phrase “because of my back,” has increased its popularity for use in research involving back pain.

The Low Back Outcome Score (LBOS) contains 13 questions specifically designed for patients with low back pain that can also be used to assess daily activities and the use of drugs and medical treatment. The Clinical Back Pain Questionnaire (CBPQ) can also be used for those complaining of low back pain. Besides assessing limitations of daily activities, the CBPQ looks at the level, location and duration of pain, use of pain medications and weakness. Another questionnaire, the Low Back Pain Rating Scale (LBPRS) measures three aspects that include pain, disability and physical impairment. Since the LBPRS requires a clinician to test endurance and flexibility, this questionnaire is not self-administered.

An outcome measure known as the Quebec Back Pain Disability Scale (QBPDS) consists of 20 items that are specifically interested in assessing physical disability associated with back pain, but not used to measure pain intensity. Another tool, known as The Resumption of Activities of Daily Living (RADL) is a questionnaire that was intended to monitor improvement in a

subject's condition that can be used to compare the efficacy of various interventions.

In conclusion, the author indicates that without a standardized questionnaire, researchers would need to consider the type of subjects participating in the study, as well as the objectives of the trial prior to selecting a particular outcome measurement tool. For example, some questionnaires are more heavily weighted to measure pain, while others look at disability and limitations of daily activities. Some questionnaires may attempt to assess a combination of outcome measures. Also, different questionnaires might be used based on the type and severity of the back pain being studied.

This article provided a good review of various tools designed to measure outcomes in clients with back pain. Although, the author did not discuss the strengths and weakness of the various scales, he did list several of validated outcome measures that can be considered for use in a trial designed to study low back pain. This points out the importance of reviewing the questionnaire before selecting one that would be most appropriate for a particular study design.

Need for Qualified CAM Therapists in Research Trials

To illustrate the potential for variations of the results achieved in massage studies, Ezzo (2007) pointed to a Cochrane review of low-back pain studies. It was found that studies showing the greatest benefits were associated with the use of more experienced licensed massage therapists. This problem may be complicated by inaccurate reporting by the therapists of their actual experience. Variations in experience and skill levels in trials may be more complicated when

the study involves sites in several states. The differences in individual state requirements for licensure can vary from as much as 1000 hours of training to as little as 100 hours. At the very least, experienced licensed massage therapists should be used in these trials, rather than other healthcare practitioners, such as chiropractors, who provide massage, but have not actually had formal training.

Moyer, Dryden, and Shipwright (2009) suggested guidelines, while encouraging more high quality research in massage therapy. This article pointed out that improving research literacy among massage therapists would be beneficial to this field. Many would agree that conducting high quality research studies is beneficial to the massage therapy industry. However, many massage therapists may not have the ability to fully comprehend its significance. Requiring a basic research methods course as part of the curriculum for massage students can help them better appreciate the importance of clinical trials to their profession. Massage therapists selected to participate in clinical trials will be more supportive of the need to follow designated protocols. More importantly, massage therapists will be better able to understand studies and be encouraged to search databases for massage clinical trials. Therefore, massage therapy schools should consider including a basic research methods course in their curriculum.

In order to produce more qualified licensed massage therapists to conduct research, it is important to include research training in the curriculum of massage schools. Although massage schools may not have the infrastructure to develop and conduct research, this should be a priority.

To ensure that research reflects as much as possible the actual ways in which massage therapy is practiced, it is important to have licensed massage therapists involved in the clinical trials. “Studies might provide more accurate and applicable information when professionals with a profound understanding of the therapies participate in the research design, ensuring that studies accurately evaluate the safety and efficacy of treatments without compromising the integrity of the medicine” (Shaw et al., 2003).

It is encouraging that efforts are being made to increase research literacy for CAM practitioners. For example, Georgetown University began a program to address the need to train CAM practitioners to participate in research by offering a master’s program that not only teaches students to critically analyze current research, but also provide training in designing research studies. Students also learn to identify areas requiring further research. These Georgetown University graduates receive a master’s degree in physiology.

In another effort to expand research, ten massage therapy schools have formed the Massage Therapy Research Consortium (2004) with the aim of enhancing each member school’s research capacity and activity, as well as to advance massage therapy education and practice generally. The initial focus will be on education about research designs and methods. More massage therapy schools should be involved in all aspects of research.

The University of Pennsylvania Health System has a 2-year program, based in the Center for Epidemiology and Biostatistics that focuses on teaching CAM practitioners how to conduct research. The first year is devoted to learning

research methodologies while the second year concentrates on the methodology. The Oregon Center for CAM (based at Kaiser Permanente's Center for Health Research) has begun a program aimed at training CAM practitioners to conduct and collaborate in research. This is a postdoctoral fellowship that is open to graduates who hold a PhD (Doctor of Philosophy), MD (Doctor of Medicine), ND (Doctor of Naturopathy), DDS (Doctor of Dentistry), DO (Doctor of Osteopathy), or DC (Doctor of Chiropractic) degree.

Others such as acupuncturists, dental hygienists, massage therapists, nurses, and physician's assistants are welcomed to apply for the part-time clinician fellowship. The program includes individual mentoring and training. There are courses in clinical research and the development of a research proposal. Mentoring is a key component of the training, as mentors and fellows establish goals for the training, select projects. The clinical research component includes courses in grant writing, study administration, and writing for publication. The research proposal includes electronic literature searches, matching research design to research questions; exploring research methodologies appropriate to CAM and how and when qualitative and quantitative techniques should be applied. Selecting outcome measures, options for data analysis, and issues related to the protection of human participants in research studies are also covered (Shaw et al., 2003)

NCCAM's strategic Plan 2011recognizes that CAM practitioners should be research literate. On their website, NCCAM states that it is important to encourage researchers from within the CAM disciplines. However, NCCAM

admits that lead investigators, training, and funding support have been limited to date. Their plan is to support a variety of research training, encourage interdisciplinary collaboration and partnerships, and collaborate with the scientific information resources of other fields and organizations (NCCAM website).

Researchers are recognizing that massage therapists are necessary to designing and implementing significant massage research projects. Many hire therapists as consultants and providers. Some funders such as the Massage Therapy Foundation require that research projects actively involve massage therapists in order to receive funding. Licensed massage therapists participating in research designs will help insure that the intervention is consistent with the manner that massage therapy is usually practiced. As a result NCCAM intends to support research training programs to enable CAM practitioners to critically evaluate biomedical literature and participate in clinical research (NCCAM website).

Need for Taxonomy

As research in massage therapy increases, the need for the development of taxonomy to accurately describe massage treatments becomes more apparent. Sherman, Dixon, Thompson, and Cherkin (2006) was the first to indicate that another challenge in conducting research in massage therapy was the lack of consistent terminology to accurately describe the intervention provide by massage therapists. Different forms and variations of massage can create confusion in clinical trials. Proper taxonomy would provide a more consistent

language terminology for researchers to accurately describe treatment protocols. This would enable trials to be more reproducible.

Different names for massage styles, such as Structural Integration and Rolfing are similar. Deep tissue and neuromuscular therapy are common used terms to describe styles of massage techniques, but they can be inconsistent. While some massage therapists consider “deep tissue” to be similar to neuromuscular therapy, others associate “deep tissue” with Swedish massage strokes that use strong pressure, and employing acupressure, or the use of myofascial release. Confusion can occur when the same technique or stroke has different names (e.g. deep effleurage, muscle sculpting, and longitudinal friction). In this case, massage therapists with different training may not realize when they are applying the same technique (Sherman et al., 2006).

Sherman et al. (2006) developed a taxonomy for researchers to use when describing their treatments. To maintain consistency and avoid confusion, this taxonomy should be also used by instructors when training students in massage therapy schools. Universal use of taxonomy will provide consistency with the language used and help to standardize the descriptions of interventions used in massage therapy clinical trials. In a review article on integrated health care, Coulter, Khorsan, Crawford, and Hsiao (2010) commented that there are relatively few randomized controlled trials and observation studies. In addition, “The lack of consensus on a clear definition and taxonomy for integrative health care represents a major methodological barrier on conducting systematic literature reviews and meta-analysis in this emerging field” Coulter et al. (2010).

Comparative Effectiveness Research (CER)

Recently, Integrative medicine studies are utilizing Comparative Effectiveness Research (CER). This type of research is designed to provide evidence on the effectiveness, benefits, and harms of different treatment options. The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, as well as other complementary modalities.

The main focus is to determine which treatment would be best suited for a person and under what circumstances. Rather than comparing one treatment to a control group, CER. compares a combination of treatment options to other available treatment(s). The goal is to determine which treatment is safer and more effective. According to the Department of Health and Human Services, seven steps are involved in conducting this type of research:

1. Identify new and emerging clinical interventions.
2. Review and synthesize current medical research.
3. Identify gaps between existing medical research and the needs of clinical practice.
4. Promote and generate new scientific evidence and analytic tools.
5. Train and develop clinical researchers.
6. Translate and disseminate research findings to diverse stakeholders.
7. Reach out to stakeholders via a citizen's forum.

A randomized clinical trial by Witt et al. (2013) still in progress is investigating the comparative effectiveness of a complex Ayurvedic treatment to conventional standard care for osteoarthritis of the knee. This study, being

conducted in Germany, is an example of CER involving massage therapy. The researchers are investigating the effectiveness of a variety of Ayurvedic treatments in combination, compared to receiving conventional Western medical care. Those in the Ayurvedic group will receive a combination of treatments including massage, nutritional advice, supplements, lifestyle changes and yoga. The conventional care group will receive standard medical care as provided by orthopedists, surgeons and physiotherapists. Outcome measures will be based on results from the WOMAC questionnaire, a disability index, a visual analog scale for pain and sleep quality, a pain experience scale, a quality of life index, a profile of mood states and Likert scales for patient satisfaction.

Proponents of CER may regard this type of research as being more consistent with real world situations since people may resort to a combination of treatments. It would be important to understand how these treatments interact. They feel that this would provide better health care decision making. Others may be concerned about bias with Comparative Effectiveness Research. Although this type of study is randomized, it is not blinded and does not use a placebo control. It should be pointed out that Ornish et al. (1990) published what could be considered an early comparative effectiveness study. This randomized clinical trial known as the Lifestyle Heart Study investigated whether a combination of interventions including nutrition, stress reduction, exercise and meditation could reverse atherosclerosis.

Outcomes were clinically based on laboratory results comparing angiographic evidence of the two groups before and again one year later at the

conclusion of the study. Although the results demonstrated that the experimental group had significant regression of coronary arterial stenosis, compared to the control group, the American Heart Association (AHA) refused to endorse it. Shortly after the Ornish et al. (1990) study was released, Robert H Eckel, M.D., chair AHA nutritional program was quoted as saying, “His study and similar others, however do not make clear which aspects of Ornish’s program work.”

It is encouraging to note that as of August, 2010, Medicare began covering Dr. Dean Ornish’s Program for Reversing Heart Disease. This program became the first integrative medicine program covered by Medicare, and this reimbursement is provided under a new benefit category known as Intensive Cardiac Rehabilitation (http://www.cms.gov/).

However, private health insurance providers such as Aetna are not covering the Dr. Dean Ornish Program because they continue to consider it experimental and investigational. Their objection centers on the lack of studies in the medical literature involving large cohorts of subjects. They concurred with the American Heart Association’s objections that the Ornish Program is too demanding for most patients to follow. They concluded that there are no assurances that many would be able to adhere to this type of treatment plan on a long term basis or how many would actually benefit from this type of program (http://www.aetna.com/).

A Cochrane review was conducted by Ezzo (2007) to not only outline problems associated with research studies involving massage therapy, but also to suggest strategies for future research. This review focused on four issues that

involved combination trials, practitioner qualifications, adequate doses, and appropriate control groups. One option for massage research is to use a factorial design, in which massage therapy can be studied alone, or in combination with other treatments. This may help to maintain the holistic aspect of complementary and alternative treatments. Future researchers in massage may also wish to consider examining the effects that massage therapy has on the entire body in general rather than limiting outcome measurements to specific systems. Using multi arms in studies may help show a positive effect or combination studies may also be used to identify redundancies that may help eliminate unnecessary treatments.

Another problem outlined in massage trials is the variations in qualifications, training, experience and skill levels of the massage therapists. To demonstrate optimal effectiveness, massage trials should ensure that the therapists involved have a high level of expertise in the intervention being utilized. Although a lesser skilled practitioner may not achieve similar results with the general population, using highly qualified therapists in trials would help insure that better outcomes are achieved for the intervention being studied.

Ethical Issues in CAM Research

In an article describing ethical issues concerning research in complementary and alternative medicine, Miller, Emanuel, Rosenstein, and Straus (2004) affirms the need for rigorous studies. In addition to the ethical considerations that are applied to conventional biomedical research, CAM research should also include the validity of randomized, placebo controlled trials.

Ethical issues in research are described by Emanuel, Wendler, and Grady (2000). This article indicates that informed consent is not the only factor necessary for ethical research. Seven requirements are outlined for evaluating the ethics of clinical research studies. The first is value for the enhancement of health or knowledge that is derived from the research. The second involves scientific validity that is obtained through methodologically rigorous clinical trials. The third item is randomization. This involves the fair selection and assignment of the study participants. In this case, bias may be a problem with some randomized controlled trials comparing CAM to other treatments, including conventional medicine. Participants who firmly believe in CAM may not want to volunteer for a study in which they may get assigned to the conventional treatment group.

Conversely, those who are more committed to conventional medicine may not want to submit themselves to CAM treatments. In this case external validity would be compromised, while expectations may bias the outcome. The fourth factor involves a favorable risk to benefit ratio. A paramount concern in clinical trials is maintaining a low risk to all participants. Based on the assessment of prior studies, massage therapy appears to be a safe intervention. The next item requires incorporating an independent review board (IRB) composed of unaffiliated individuals to review the research, approve, amend or terminate it. The sixth section mandates that each individual must be provided with informed consent and give their voluntary consent. The final item is to maintain respect for

all enrolled participants that includes confidentiality, as well as their right to withdraw from the study.

Future of Massage Therapy

Massage therapy continues as a popular form of complementary and alternative medicine and the future of massage therapy appears to be optimistic. Based on information provided by the American Massage Therapy Association's industry fact sheets, employment for massage therapist is expected to increase by 20% in the next 6 years. The passage of the Affordable Care Act (ACA) is shifting the focus of health care from disease to prevention and wellness. Section 3052 of the ACA stipulates that health care delivery must include integrated approaches: "Insurers must establish community health teams that include complementary and alternative (CAM) providers."

The ACA adopted the definition of Integrative medicine from the Consortium of Academic Health Centers for Integrative Medicine (CAHCIM) as "the practice of medicine that reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, health-care professionals, and disciplines to achieve optimal health and healing."

Section 2072 of the ACA states that every insurance company must provide at least one plan that includes reimbursement for all licensed providers operating within their scope. That implies, for example, that any patient who requires rehabilitation services, should be able to choose any licensed health-care provider who can provide appropriate rehabilitation services (including a

licensed massage therapist). It is ultimately the responsibility of each individual state to enact this legislation, and currently only a few states have included massage in conventional health care.

The State of Washington (WA) appears to have taken the lead in recognizing the role that massage therapy plays in health care. In 1995, Washington state passed an "alternative provider" statute (House Bill 1034), which required insurers to cover services provided by all of the state's licensed categories of health care providers which included massage therapists.

Massage therapists in WA provide care in numerous settings such as wellness centers, physicians' offices, and hospitals, as well as private practice. Massage therapist receive reimbursement through the WA Department of Labor and third party payers (Cherkin et al., 2002). Physicians in Washington prescribe massage therapy for a broad variety of orthopedic, pain, and mental health conditions. Massage therapy has assigned codes for insurance reimbursement in Washington. Other than in Washington, insurance reimbursement for massage therapy is not common. Currently, few insurance plans include coverage for alternative medicine.

Growth of the massage therapy industry can be accelerated through expansion into health care institutions, such as hospitals, nursing homes and hospice care facilities. Improved quality of research may be the key to unlocking this resource. Health care institution administrators, having liability concerns, are more confident providing services that have backing of rigorous scientific research showing safety and efficacy.

Results of positive cost benefit studies for massage therapy would encourage the inclusion of licensed massage therapists in health care facilities. Studies demonstrating benefits to patients in health care settings, while also saving costs, would increase demand for massage therapy and make massage therapists an integral part of a heath care team.

A promising study (Taylor et al., 2003) points to the benefits of incorporating massage therapy as a complementary approach in a hospital setting for surgical patients. A total of 105 women who were status post abdominal laparotomy for removal of suspected cancerous lesions were divided into three groups. All groups received usual care that included analgesic medications. The first group only received usual postoperative care and the second group received usual care plus 45-minute sessions of gentle Swedish massage on the 3 consecutive evenings after surgery, while the third group received usual care plus along with 20-minute sessions of inaudible vibration therapy (physiotones) on the 3 consecutive evenings after surgery.

Results showed that on the day of surgery, massage was more effective than usual care alone for affective (p = 0.0244) and sensory pain (p = 0.0428), and better than vibration for affective pain (p = 0.0015). On the second postoperative, massage was more effective than usual care for distress (p = 0.0085), and better than vibration for sensory pain (p = 0.0085). Vibration was also more effective than usual care for sensory pain (p = 0.0090) and distress (p = .0090).

Adams and White (2010) demonstrated the importance of incorporating the complementary use of massage therapy for pain management in a hospital or critical care environment. This non-randomized study involved a convenience sample of 53 patients from medical, surgical, and obstetrics units. A limiting factor in the design was that this cohort study did not include a control group. Each participant received one or more 30 minute Swedish massages, depending on length of hospital stay. Results showed that scores on the mean pain level were significantly reduced following massage. In addition to reduced pain, other areas of improvement involved relaxation, sleep, emotions, recovery, and finally, helping with the overall healing process. This promising study points to the benefits of incorporating massage into the treatment plan during inpatient hospital stays.

Studies are demonstrating that using massage therapy in hospitals may be beneficial for preterm infants. An early study by Scafidi, Field, and Schanberg (1993) found that they were able to predict which preterm infants would benefit most from massage therapy. The investigators found that the pattern of greater caloric intake and more days in Intermediate, along with more obstetric complications could be used to indicate which preterm infants would benefit more from massage therapy. Using these criteria, the results showed that massage therapy group gained significantly more weight per day (32 vs. 29 g) than the control infants. The authors concluded that these variables could be used to identify infants who would benefit most from massage therapy.

Another benefit of massage therapy in a hospital setting involves improving the effects of the immune system in preterm infants. A study by Ang et al. (2012) randomly assigned 120 infants into two groups to compare the effects of massage therapy to a sham control. Infant massages were provided five days per week either until discharge, or to a maximum of four weeks. Results showed that although there was no difference in the numbers of NK cells, those in the massage group demonstrated increased cytotoxicity. However, it was also important to note that those in the massage group also showed greater daily weight gain, which may also help to improve their overall outcome. This study demonstrates the potential advantage of incorporating massage therapy in a critical care environment. A review of NIH funding for massage therapy research found that studies involving preterm infants was second to studies involving back pain. Usage surveys do not indicate that massage is being utilized to any great extent with preterm infants. Perhaps more awareness of these studies may increase involvement of massage therapy in critical care settings.

In 1998, the American Hospital Association (AHA) first began collecting survey information about hospitals offering CAM services. At that time, only 6% of hospitals reported offering some type of CAM services. Only three years later, that number almost doubles to 15%, indicating a steady growing interest by hospitals in this area. A 2011 survey indicated that 42% of hospitals offered at least one or more CAM therapies. Although patient demand was cited as a motivating factor by the hospitals offering CAM, ultimately, the final decision was based on clinical safety and efficacy. The AHA surveys also noted that massage

therapy was listed as being in the top two CAM services for both inpatient and outpatient care.

More cancer treatment centers are offering CAM to both inpatients and outpatients. Memorial Sloan Kettering Cancer Center developed an Integrative Medical Service that offers inpatients and outpatients massage therapy, music therapy, reflexology, as well as mind-body therapies. Cassileth (2002). The University of Texas M.D. Anderson Cancer Center created an integrative medicine program that incorporates research, education, and a clinical program. Massage therapy is among the various CAM therapies offered (M.D. Anderson Cancer Center, 2004).

The Dana-Farber Cancer Institute has established the Zakim Center for Integrated Therapies. This center defines integrated therapies as "individual treatments that are used in addition to (or as a complement to) traditional cancer treatment such as chemotherapy and radiation" (Dana-Farber Cancer Institute, 2004). Therapies include massage therapy, acupuncture, and nutritional guidance. The center's website states, "When patients integrate these therapies into their medical and surgical care, they are creating a more comprehensive treatment plan and helping their own bodies to regain health and vitality" (Dana-Farber Cancer Institute, 2004).

An institution that won an American Hospital Association sponsored Circle of Life award for innovation in palliative and end of life care, Summa's Palliative Care and Hospice Services (SPCHS) in Akron, Ohio initiated massage therapy services to all it patients in 2002. As of 2009 they employed two full time

and four part time massage therapists and provided 3200 massage therapy treatments. This program was funded through a United Way grant and there were no extra costs to patients. “Massage therapy can be so helpful for managing both pain and anxiety;” according to SPCHS director Kim Kousaie, who added that “This is a vital part of our program.”

It is becoming apparent that CAM modalities, such as massage therapy, that are scientifically proven to be safe and effective are more likely to be a factor contributing to the increased use of CAM by health care institutions. Health care professionals would be more confidence referring patients to massage therapists.

The increased acceptance and incorporation of CAM into conventional medicine can then be more favorably referred to as integrative medicine. Integrative medicine is described as more than just the sum of conventional medicine plus CAM. Maizes, Schneider, Bell, and Weil (2002) defined integrative medicine as “healing-oriented medicine that reemphasizes the relationship between patient and physician, and integrates the best of complementary and alternative medicine with the best of conventional medicine.” Berndtson (1998) had a similar definition, but emphasized the use of evidence. He said “integrative medicine refers to a clinical approach that combines the strengths of conventional and alternative medicine with a bias toward options that are considered safe, and which, upon review of the available evidence, offer a reasonable expectation of benefit to the patient.”

Coulter et al. (2010) describes integrative medicine as an emerging field and this may mark the future of research in health care by studying the combined

effects of CAM, such as massage therapy, and conventional medicine. It is anticipated that that high quality studies demonstrating efficacy, coupled with cost effectiveness studies will increase the probability that massage therapy will be included as part of a standard treatment of care for pain and other medical conditions.

Need for Cost Effectiveness Studies

A goal of CAM practitioners is not only to achieve acceptance by the conventional medical community, but more importantly, for their treatment modality to qualify for insurance reimbursement. Many practitioners believe that CAM "will never fulfill its promise if it cannot be delivered via direct pay insurance" (Clohesy Consulting, 2003). Research evidence for efficacy is generally supportive of insurance coverage, but does not guarantee it. Sometimes public and organizational pressure, as well as enacting new laws may be needed. In addition, coverage decisions by payers can be dependant on treatments that not only have proven safety records, but also demonstrate cost effectiveness. A treatment that is effective, but considered too costly may not qualify for coverage (Pelletier, Astin, & Haskell, 1999). While studies indicate that massage therapy is beneficial for pain and other conditions, to date cost effective studies have not been conducted.

Cost effective studies should go beyond simply comparing massage sessions to the cost of a prescription analgesic medications. Besides individual suffering and loss of function, the costs of doctor visits, and the overall impact on the economy should also be assessed. The Institute of Medicine reports that 100

million Americans have chronic pain conditions and that the economic cost, including loss of productivity, is estimated to be between $560 to $635 billion annually. In addition to the potential for abuse, the CDC (2011) reported that overdoses of prescription pain medications was responsible for almost 15,000 deaths in 2008, which was up from 4000 in 1999. Positive cost effectiveness studies involving massage therapy coupled with efficacy should create an exponential increase for the massage therapy industry.

A review of the literature only yielded one study that included a cost analysis. Cherkin et al. (2001) compared massage therapy, acupuncture and self-care education for relief of low back pain. The findings showed that massage was superior to acupuncture on both the symptoms and disability scales. The cost of massage was also 40% lower than acupuncture. Cost savings were due to reduced need for analgesic medications as well as requiring fewer medical follow up visits. These findings were significant because it demonstrated the efficacy of massage therapy while also showing its potential cost savings benefits. It is anticipated that duplication of this cost analysis study, coupled with rigorous evidence of efficacy, would result in the exponential growth of the massage therapy industry. Massage therapy could assume an integral role in health care settings, while making insurance reimbursement more realistic.

Conclusion

The double blinded placebo control study design is considered an important component of the gold standard of research. Some alternative practitioners may be more tolerant of lesser quality designs and believe that CAM

research should not be held to the same standard as conventional medicine. Attempting to maintain a double standard in research would not be feasible in the current paradigm, since the medical community continues to regard the gold standard as the highest level of rigorous scientific investigations in research. Recently, researchers in massage therapy have begun to recognize the importance of raising the level of quality by investigating the use of a validated light touch or other placebo (sham) control.

Validated light touch bodywork will facilitate the introduction of a double blind, placebo controlled design in future massage clinical trials. Massage research designs that are consistent with the gold standard will not only increase the acceptance of massage as a viable form of treatment by the medical community, but also make insurance reimbursement more likely. Addressing the above issues will help improve the quality and validity of research designs.

“Clinical trials of massage therapy are inherently challenged by an inability to blind practitioner and recipient” (Ali et al., 2012). While these concerns persist with randomized controlled trials in manual therapies, they are not impossible to overcome. Raising the level of the quality of research designs will provide more support for the acceptance of massage therapy as a viable treatment option for pain management as well as other conditions. A report commissioned by the Institute of Medicine and released by the National Research Council in 2005 reviewed the impact of complementary and alternative medicine including the quality of the evidence base.

This report concluded that: “The committee recommends that the same principles and standards of evidence of treatment effectiveness apply to all treatments, whether currently labeled as conventional medicine or CAM. Implementing this recommendation requires that investigators use and develop as necessary common methods, measures, and standards for the generation and interpretation of evidence necessary for making decisions about the use of CAM and conventional therapies.” (National Research Council, 2005).

CAM practitioners may be more accepting of randomized clinical trials that are not double blinded and masked. However, the major current paradigm within conventional medicine believes that rigorous science involves limiting bias through double blinding and the use of a placebo control. Without an accepted change in this model, research in massage therapy should focus on establishing an appropriate placebo (sham) control that can be available for use in future study designs. When it is developed, adequate concealment of the intervention would facilitate the incorporation of double blinding in massage trials. It is encouraging to note that progress is being made in this area, as researchers are exploring the use of a placebo such as light touch or non-manipulative bodywork. Once one or more validated sham treatments are accepted and utilized, few would be able to doubt the efficacy of massage therapy through rigorous scientific investigation.

As such, this evaluation report recommends that researchers in massage therapy not only continue to maintain the quality of clinical trials, but should also be committed to improving the designs, to include a placebo control, so that it

more closely reflects the gold standard for randomized controlled trials. Massage therapy research has demonstrated efficacy through a solid evidence base, but it is time for investigators to raise the level of quality. Therefore, it would be essential for funders and researchers in massage therapy to work cooperatively in order for research in massage therapy to improve to the highest rigorous standards. Otherwise, continued funding of similar study designs will not contribute to the improvement of the research quality.

Massage therapy research that reaches the same level as conventional medicine will leave little doubt that massage therapy can be synonymous with evidence based medicine and consequently increase its acceptance. As the quality of massage therapy research improves, information becomes disseminated when more researchers publish their findings in peer-reviewed journals and make more presentations at scientific symposiums. This may enable the medical community to not merely regard massage therapy as a form of complementary and alternative medicine, but rather as integrative medicine, or even conventional.

The purpose of this evaluation of the NIH & NCCAM grants and funding program as it specifically relates to research in massage therapy was to help the stakeholders determine whether the NCCAM mission statement and research area of special interest is being met.

A review of NIH funded studies in massage therapy demonstrated its safety and efficacy. Since there was a good quality scientific evidence base to support the efficacy and safety of massage therapy, this program evaluation

concluded that the funding program supports its Mission Statement, "To define, through rigorous scientific investigation, the usefulness and safety of complementary health approaches and their roles in improving health care."

The quality of the research in massage therapy was determined to be good, based on the Jadad scoring system. It is currently possible for massage therapy clinical trials to consistently score at least 3 points on the Jadad scale, which is considered high quality. This can be achieved with appropriate randomization of participants and accounting for any withdrawals. The development of an appropriate placebo (sham) control has the potential to further elevate the quality of massage therapy designs. Progress is being made in this area and research should continue to focus on this objective.

Evaluation of NCAAM's funding area of special interest showed that on an annual basis, pain and inflammatory conditions were the most funded massage therapy research topic. As a result, it was found that the funding for massage therapy research is in alignment with the stated NCCAM priorities. "CAM interventions used frequently by the American public, on the conditions they are most frequently used…These would include investigations of the impact of CAM modalities in alleviating chronic pain syndromes and inflammatory processes."

This program evaluation established that the current NCCAM funding program is justified and that additional funding should be should be directed towards the development of an adequate placebo control for use in future massage therapy clinical trials. Funding should also be appropriated for cost effectiveness studies for massage therapy. Positive findings, coupled with quality

research showing efficacy and safety would promote the massage therapy industry. With increased knowledge of utilization patterns and NIH funding for massage therapy research, health care professionals will feel more confident about integrating the use of massage therapy. Advanced public awareness of research in massage therapy should increase client base and student enrollment. More importantly, the likelihood of insurance reimbursement for massage therapy would become more favorable. This will not only benefit massage therapists but also provide greater access for the public to avail themselves of this effective and safe therapeutic modality.

This program evaluation also identified areas where there is evidence of efficacy, but a lack of utilization. While pain appears to be the most funded research topic, the public's utilization of massage therapy for pain conditions is second to using massage for relaxation and stress relief. Following pain conditions, research in preterm infants was the second most funded topic. However, it appears that this area is being underutilized by the public. It is anticipated that as research becomes disseminated to hospitals, that more facilities will consider implementing a massage treatment program for preterm infants.

Finally, the NCCAM website describes its vision for CAM as "Scientific evidence informs decision making by the public, by health care professionals, and by health policymakers regarding use and integration of complementary and alternative medicine" (NCCAM website). This vision also appears to be consistent with the future of massage therapy.

Program Evaluation: Step 6

Step 6: Ensuring Use and Sharing Lessons Learned

This program evaluation is intended to provide NCCAM and other funding sources more information for the alignment of funding priorities for various topics of research in massage therapy. It is also believed that greater understanding of utilization patterns and NIH sponsored research in massage may generate more referrals from other health care professionals. This may develop interest in people who have not previously considered massage therapy. Massage clients will feel more confident when using massage therapy.

To ensure use and sharing of the lessons learned, this program evaluation will be made available to all stakeholders. The first step will be the public defense of this dissertation, followed by submission of the findings for publication. In addition to NIH and NCCAM, this evaluation will be accessible to other massage therapy research funding agencies and researchers in massage therapy. Besides massage therapists, clinics and other health care providers, this paper will also be available to national massage therapy associations, as well as massage therapy schools. Any individual or organization can request a complimentary copy of this program evaluation.

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