

A CRITICAL ANALYSIS OF HEALING TOUCH FOR SYMPTOMS OF
DEPRESSION AND ANXIETY

by

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A Practice Inquiry Project Submitted to the Faculty of the

COLLEGE OF NURSING

In Partial Fulfillment of the Requirements
For the Degree of

DOCTOR OF NURSING PRACTICE

In the Graduate College

THE UNIVERSITY OF ARIZONA

2013

THE UNIVERSITY OF ARIZONA
GRADUATE COLLEGE

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ACKNOWLEDGEMENTS

I would like to thank Dr. Kate Sheppard for her energy, dedication, and clarity she gave to me and this project. She was an incredible resource and support and I would still be spinning circles without her. I aspire to become more like her as my career advances. I would also like to thank Dr. Cathy Michaels for her brilliance and perspective where I needed it the most. She challenged me to be a better student and scholar and I appreciate it very much. I also am very thankful for Dr. Audrey Russell-Kibble for stepping onto the committee last minute, and how she inspires better work through kindness and care. I am also grateful for Dr. Janice Crist, as she was a wonderful advocate as an early committee member and was a constant source of support.

I want to thank my Mom, Celia, for flying from Canada to babysit on multiple last minute occasions, for glasses of wine and good conversation, and for teaching me as a child that I could do anything I wanted to do in this life. I want to thank my friends in Del Norte, CO as they put up with hours of conversation while running and biking about Healing Touch. I especially want to thank Joanne Kaufman for introducing me to Healing Touch and her gentle way of helping me through a bout of postpartum depression.

DEDICATION

I dedicate this project to my husband, Nat. Without your love, support, and feedback this would still be a distant dream for me. Thank you for taking care of our beautiful daughter while I study and work, getting me outside to play, and for being my sounding board for ideas. Thank you for believing in me as I went through this difficult process, and for your unfailing love. You have inspired me as I watch your compassion and care with your patients. You have taught me that good medicine has little to do with medications.

I also dedicate this project to my daughter, Juliana, who was born during my last year of school and who taught me the beauty of time management and what truly matters in this life. She inspires me to be the best person I can be. I love you both!

Finally, this project is dedicated to the memory of my brother, Scott Travis Ramsden who suffered from mental illness and died of suicide at age 21. He has inspired me to become a nurse and do what I can do make a positive difference for just one person suffering from mental illness. Scott was an incredible brother, artist, and friend and is terribly missed.

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ABSTRACT

The use of provider based alternative medicine therapies such as chiropractic, massage, and acupuncture, has grown exponentially over the past decade as the price of traditional Western treatments has skyrocketed. Patients are seeking complementary treatments for a variety of ailments, including mental health. People with profound mental illness also have a reduced life expectancy and higher rates of chronic health problems than non-sufferers; and roughly 20% of people who used alternative therapies in the past year also had one or more psychiatric disorders. Healing Touch (HT) is based on the belief that humans have energy fields that change with states of illness; these energy fields can be manipulated to achieve wholeness or wellness. As nurses, touch has always been a part of our practice therefore it should not be a significant departure to entwine HT into our practice. Both anecdotal and research evidence has found that using HT for patients reduces anxiety and stress, helps support the life transition process, promotes self-empowerment, and enhances spiritual development. The implication of this evidence is that people suffering from anxiety and depression could benefit from HT in the primary care setting. When compared to the high cost of treating these illnesses, HT and other energy therapies are cost effective and have evidence supporting that treatment is effective enough to be inclusive. Depression and anxiety are extremely common and cross cultures, generations, and economic statuses. This describes the burden related to these conditions and why integrating HT in primary care practice is a viable, sustainable option. Current literature and research are discussed, and recommendations for practice in the form of a clinical practice protocol are presented.

CHAPTER 1: INTRODUCTION

Healing Touch (HT) is based on the belief that humans have energy fields that change with illness; the energy fields can be manipulated to optimize health or wellness. Many health care disciplines utilize touch during assessment or treatment, so incorporating HT into primary care should not feel completely foreign. For the purpose of this practice inquiry, the term primary care provider is intended to include physicians, physician assistants, and advanced practice registered nurses that provide primary care in the outpatient clinical setting. This practice inquiry describes the burden related to depression and anxiety, and why integrating HT into treatment is a viable, sustainable option.

Background

The use of provider based alternative medicine therapies such as chiropractic, massage, and acupuncture, has grown exponentially over the past decade as the price of traditional Western treatments has skyrocketed. Patients tend to be underinsured or uninsured, and access to traditional medicine is limited for many Americans (Su & Li, 2011). A recent study reported that over 60% of people in the United States used some type of complementary, alternative medicine (CAM) in 2002, which is a 100% increase from the previous 10 years (Su & Li, 2011). Although access and cost are major factors for patients choosing CAM, some prefer holistic treatments (Su & Li, 2011).

Patients are seeking CAM for a variety of ailments, including mental health. It is known that persons with profound mental illness also have a reduced life expectancy and higher rates of chronic health problems than non-sufferers (Shattell, Donnelly, Scheyett, & Cuddeback, 2011). A survey of CAM users found that roughly 20% of people who used CAM in the past year also had one or more psychiatric disorders (Shattell et al., 2011). Other interesting findings are that of

the people who reported a psychiatric disorder, half of them see a CAM practitioner specifically for their disorder, and the most common psychiatric disorders were anxiety and major depression (Niv et al., 2010). The Shattell study (2011) was replicated in people older than 65, and those with depression and anxiety were almost 30% more likely to use CAM than those who didn't suffer mental health symptoms (Niv et al., 2010). In a separate study, Hawk, Ndetan, and Evans (2012) found that most patients who used CAM used it for disease prevention and health promotion instead of treating a specific illness (Hawk, Ndetan, & Evans, 2012).

Both anecdotal and research evidence has found that using HT for patients can not only reduce anxiety and stress, it helps support the life transition process, promote self-empowerment, and enhance spiritual development (Van Aken & Taylor, 2010). Therefore, it is quite possible that people suffering from depression and anxiety could benefit from HT in the primary care setting (Van Aken & Taylor, 2010). Different biofield therapies, including HT, have been used for a variety of symptoms since the 1970's, but both research and widespread use is lacking (Jain & Mills, 2010).

Definitions of Therapies and Certification Processes

According to the National Center for Complementary and Alternative Medicine, complementary alternative medicine (CAM) is defined as a broad variety of systems, products, and applications that are not usually considered part of traditional medicine (USDHHS, 2012). CAM includes many different types of healing therapies, including the biofield therapies (USDHHS, 2012). The term biofield describes the concept that humans are surrounded by energy fields and this energy can be manipulated or changed for the purpose of healing. Biofield therapy is relatively rare as it is estimated that less than 1% of Americans have utilized biofield healing for their health (USDHHS, 2012).

The three biofield therapies highlighted in this paper have also been called touch healing (TH) therapies. These therapies are practiced by either light touch, near touch, or self-directed mindful meditation (Kerr, Wasserman, & Moore, 2007). Kerr, Wasserman, and Moore (2007) theorize that although the modes of delivery among the TH therapies are diverse, they share a common mechanism of action. The article suggests this mechanism is repeated sensory input, relaxation, attentional modulation, and behavioral relevance that has proven efficacy in many trials (Kerr et al., 2007).

Healing Touch (HT) is a treatment modality used by specially trained practitioners who are often nurses. As described, it is biofield based and is considered complementary therapy by the National Health Center for Complementary and Alternative Medicine of the National Institutes of Health (Wardell & Weymouth, 2004). HT therapy consists of either light touch or near touch. Unfortunately quality studies focusing specifically on healing touch are limited (Healing Touch International, 2012).

The primary organization for HT is Healing Touch International. This is a non-profit, professional organization whose goals include providing continuing education for medical and biofield professionals such as nurses, promoting HT research, certifying professionals in HT, and community education regarding the biofield therapies (Healing Touch International, 2012). In order to become certified as a healing touch practitioner, there are five individual levels of training. Each level has set objectives and provides 17-25 continuing education hours. The program is approved by the American Holistic Nurses Association and continuing education hours are awarded for each completed level. Levels must be completed in numerical order, and within each level are time commitments and mentorships. A mentorship typically includes a period of independent practice with oversight and guidance provided by a mentor (J. Kaufman,

HT practitioner, personal communication, March 1, 2013). During training for Levels 4-5 community projects and work activities are mandatory (Healing Touch International, 2012). Levels 1-3 are typically taught in two day sessions, whereas levels 4-5 are four day sessions. Prices vary from \$350 per session to upwards of \$1,000 per session (Healing Touch International, 2012).

Therapeutic Touch (TT) is an older modality than HT, and has also been traditionally used by nurses (Samarel, 1992). Unlike HT, it is hands-off only and requires no spiritual context of healing (Samarel, 1992). The process of becoming certified in TT is slightly different and less rigorous than HT. The student must complete both a beginner and an intermediate level class, each worth approximately 13 hours of continuing education. The intermediate level must be taken at least six months after completing the beginner level. Then the student must work with a mentor for 36 hours over the course of a year and provide documentation of six single session case studies and three longitudinal case studies (Therapeutic-Touch International Association, 2013). Both TT and HT outline professional codes of ethics and guidelines, which are posted on their websites (Healing Touch International, 2012; Therapeutic Touch International Association, 2013).

Reiki is an Eastern medicine practice that also uses both hands on and hands off techniques, as well as visualization with the intent of improving the flow of energy. Reiki is used to treat problems on emotional, physical, and spiritual planes of healing (Hallett, 2004). It is the most well-known and utilized biofield therapy; therefore most biofield studies focus on Reiki as an intervention. However, Reiki is the more spiritually based of the three, and training in Reiki is much less standardized than both HT and TT (Jain & Mills, 2010). Like TT there are three levels of Reiki: a beginner, intermediate, and master level. There is no consistency with cost or time

required to complete each level and there is no governing body that dictates consistency. The art of Reiki urges the student to choose the class he or she feels most spiritually aligns with the instructor (Natural Healers, 2013).

For this practice inquiry, healing is defined as a process that occurs on three levels. The first level of healing is a way of providing care, such as a nurse to a patient, with the intention of eliciting a feeling of well-being (Levin & Mead, 2008). The second level of healing is changing the course of disease by way of restoring the patient to his or her previous state, or assisting with fighting a disease into remission (Levin & Mead, 2008). The third level of healing is creating health, known as the concept of salutogenesis, which is thought to be the opposite of pathogenesis. Salutogenesis is achieved when a healthy atmosphere within the patient is created and prevents disease from happening (Levin & Mead, 2008).

The concept of spirituality is often discussed in regards to complementary alternative therapies. There is no common definition of spirituality within CAM. In this practice inquiry, spirituality is defined as having inner peace and connectedness. Spirituality is a common concept in all cultures and usually involves searching for meaning in life (National Cancer Institute, 2012).

Statement of Problem

Treating depression and anxiety in the primary care setting is challenging, expensive, and requires substantial follow-up. Many patients with mild to moderate symptoms desire alternative therapies to medication. Many primary care providers are uninformed about complimentary therapies such as HT, and without understanding adjunctive and complementary therapies, will be less able to discuss these modalities with their patients. Conditions such as depression and anxiety are extremely common worldwide. Both depression and anxiety cross cultures,

generations, and economic statuses. These disorders will affect most primary care providers at some point either personally, professionally, or both.

Purpose

The purpose of this practice inquiry was to critically analyze existing literature and develop best practice recommendations in the form of a clinical practice protocol. The aim was to weigh the evidence, including strength and quality of evidence, to identify gaps in knowledge, and to develop recommendations to inform primary care providers about HT for patients with depression and anxiety.

Significance of Problem

Healing Touch (HT) is a modality that has been effective in relieving pain, anxiety, and other symptoms in patients. HT is an easy modality to learn and can be implemented into practice (Healing Touch International, 2012). HT may also hold great potential for primary care providers as an adjunct to treating depression and anxiety in primary care. HT is currently being used by non-medical providers to treat symptoms of depression and anxiety (Healing Touch International, 2012).

Issues still exist in regards to implementing HT into practice. Research is still lacking on efficacy, and many primary care providers are not trained in touch therapy (Hooper, 2005). Studies have indicated that primary care providers are not familiar or comfortable recommending HT as an adjunct therapy (Hooper, 2005). This critical analysis of the literature led to the development of a clinical practice protocol which informs the primary care provider about best practices regarding HT as a therapeutic adjunct modality for patients.

Significance to Nursing Practice

The nursing profession can be described as holistic, with a connection between mind, body, and spirit (Zender & Olshansky, 2012). It has been stated that a nurse's personal spiritual perspective will have an impact on his or her ability to attend to the spiritual needs of their patients (Ronaldson, Hayes, Aggar, Green, & Carey, 2012). There is a growing need for a holistic approach with the integration of spirituality into nursing care, especially for the advanced practice registered nurse working in the primary care setting. This approach allows the development of a patient-provider relationship that supports holistic assessments (Chrash, Mulich, & Patton, 2011).

This project is significant to advanced practice nursing because of the influx of advanced practice registered nurses (APRN) in primary care. For example, Newhouse et al. (2012) estimate that approximately 250,000 APRNs provided patient care in an autonomous setting. Newhouse et al. (2012) performed a systematic review of 20 years of research to compare patient outcomes of an APRN to those of a physician. The authors conclude that both types of providers had equivalent patient outcomes (Newhouse et al., 2012). The majority of APRN's practice in primary care, often working with rural and minority populations, because of the great shortage of family practice physicians (Newhouse et al., 2012). A clinical practice protocol outlining the application of HT in the primary care setting can help the APRN to utilize HT as an adjunct treatment for depression and anxiety. The practice inquiry and clinical practice protocol was guided by two nursing theories; the theories are described in the following discussion.

Conceptual Model and Theoretical Foundations

Two specific nursing theories have influenced this practice inquiry. The first is Martha Rogers' Science of Unitary Human Beings (Rogers, 1990). Rogers is most commonly known for

her belief that the central focus of nursing is the relationship between the human and the environment. She advocated for nursing science to embrace the concept of space as well as Earth important human environments. She recognized both the human and the environment as energy fields and believed in the evolutionary transcendence of humankind (Parker & Smith, 2010). She was an important theorist in the biofield realm, and theorized that, “in a universe of open systems, energy fields are continuously open, infinite, and integral with each other” (Parker & Smith, 2010, p. 255). One important concept regarding the relationship between the human and environmental energy fields are that the two are always in mutual process and cannot be separated (Parker & Smith, 2010). It is this theory that most identifies with HT as a biofield therapy.

Another theory that influenced this project is the Theory of Self-Transcendence by Pamela G. Reed (1991). Reed (1991) was also influenced by Rogers when defining her theory. The assumptions of her theory are that humans are capable of an awareness that extends beyond physical and temporal dimensions, and the person reaches out to sources of transcendence. Secondly, the theory assumes that self-transcendence is a developmental process and therefore integral to a person’s well-being (Smith & Liehr, 2008). Well-being is an outcome of transcendence which is why it is applicable and integral to the HT modality and its use for depression and anxiety.

Mental Conditions

Some form of mental illness touches nearly every life worldwide. Many psychiatric disorders and mental health concerns are complicated by additional psychiatric conditions or physical illnesses (Lyness, Yu, Tang, Tu, & Conwell, 2009). It is beyond the scope of this inquiry to discuss cognitive disorders (mental retardation and autism), psychotic disorders,

somatoform disorders, or personality disorders because these are not typically managed in primary care. This practice inquiry focused on mild to moderate depression, and anxiety disorders with or without physiological components. Current treatment in the primary care setting for psychiatric disorders and mental health conditions are largely pharmacological, with mood and anxiety disorders having a broader spectrum of non-pharmacologic therapies than other mental illnesses (Lyness et al., 2009). Non-pharmacologic treatments for depression include psychosocial, electroconvulsive, and light therapies. Also utilized for mood disorders and anxiety are a variety of psychotherapy sessions that can be either inpatient or outpatient based (Lyness et al., 2009). Many types of mental health conditions, including depression, are best treated with a combination of medications and therapy; CAM may be of benefit as a non-pharmacological therapy (Dodd et al., 2011).

Depression

Depression is a significant problem in the United States. In fact, approximately 5% of men and 10% of women in the United States experience depression at any time, and the lifetime prevalence is 25%; as many as 70% will experience recurrent depression and 20% will live with chronic depression (Lyness et al., 2009). Depression has a huge economic burden and is cumulatively more debilitating than all cardiovascular diseases combined (Lyness et al., 2009). Depression can be difficult to diagnose, and is often missed completely. Determining the etiology of depression is also difficult, especially when we consider contributing factors such as genetics and environment (Lyness et al., 2009).

The symptoms of depression vary between patients, but typical symptoms include sadness, anxiety, irritability, or loss of sense of pleasure. Patients often experience ideational symptoms such as guilt, feelings of worthlessness or helplessness, or suicidal ideation.

Depression is also manifested with physical symptoms such as anorexia, insomnia, or trouble with concentration or libido. Uncommonly a patient with depression can even experience psychotic symptoms of hallucinations and delusions (Lyness et al., 2009).

Major Depressive Disorder, as outlined in the DSM-IV-TR manual, can be confused with other psychiatric and medical diseases so it is imperative the primary care provider evaluates physical, mental, and emotional aspects of the patient's health status (Carey, 2010). Diagnostic criteria for Major Depressive Disorder include having at least five of the following symptoms for most of the day, most every day, for a minimum of two weeks: depressed mood, anhedonia with anorexia or appetite increase, change in sleep habits, anergia, feelings of guilt or worthlessness, inability to concentrate, impaired decision making, and recurrent thoughts of death and/or suicide including formulating a suicide plan or attempt (Goldman & Schafer, 2012; DSM-IV-TR, 2000). One milder form of major depressive disorder is dysthymia, where the patient will meet two or more criteria of symptoms, for at least two weeks (DSM-IV-TR, 2000).

Some patients may not fit the diagnostic criteria for major depression, but may have a different type of depression. These types include seasonal affective disorder and postpartum depression. Postpartum depression has the same criteria as major depressive disorder but typically presents within three months after delivery of a child (Neil, 2013). A less severe form, similar to dysthymia, is called the "baby blues" and usually resolves within 10 days of delivery. The primary care provider must be aware that a patient experiencing postpartum depression is also at an increased risk for postpartum psychosis (Neil, 2013). Seasonal affective disorder will also have similar criteria and is associated with people that live in dark latitudes, have long winters, or are socially isolated in these two situations (Auerbach, 2012).

Depression in Primary Care

As discussed, depression is a major cause of morbidity in the United States, affecting many aspects of life in depression sufferers. Depression affects 300 million people worldwide, but only 50% of depressed people seek treatment (Van Aken & Taylor, 2010). Recent studies identify mental illness as one of the nation's top un-met health needs (Mims, 2006). Some reasons people may not seek treatment is that there is a strong culture of independence, work ethic, religiosity and patriotism that historically stigmatizes mental disorders. This could deter patients with symptoms of mental illness from seeking care (Hirsch, 2006). In fact, even when resources are available, some populations are more likely to seek out religious leaders instead of traditional Western medicine (Hirsch, 2006).

Of the patients who are seeking care for symptoms of depression, many may first be seen in the primary care setting. This means that often the initial evaluation and treatment is provided by primary care providers (Anthony et al., 2010). The decision to evaluate and treat the patient in the primary care setting, or to refer the patient to a mental health provider, stems from the comfort level of the primary care provider (Anthony et al., 2010). However, primary care providers may feel uncomfortable treating patients with depression. Factors that influence the primary care provider's discomfort include the perceived severity of a patient's symptoms, the primary care provider's practice environment, and the primary care provider's experience (Anthony et al., 2010).

Treatment for Depression

Treatment for depressed patients in primary care is typically a combination of pharmacologic and non-pharmacologic interventions. The prescribing of antidepressants by primary care providers has increased tremendously over the past 20 years. In fact, anti-

depressants are the third most commonly prescribed medications in a primary care setting (Mojtabai & Olfson, 2011). However, many patients who receive antidepressants may not actually benefit from their use. For example, antidepressants may only be effective for depressive disorders and some of the anxiety disorders (Mojtabai & Olfson, 2011). Furthermore, some patients are prescribed antidepressants and yet do not even have a diagnosed psychiatric disorder; they may therefore bear the expense and adverse reactions without experiencing symptom reduction (Mojtabai & Olfson, 2011). Primary care providers may also consider the use of non-pharmacological interventions for treatment of depression. For example, after years of treating depression with medications only, primary care providers in Italy have successfully incorporated psychological interventions to their treatment regime (Bortolotti, Menchetti, Bellini, Montaguti, & Berardi, 2008). In a meta-analysis of psychological therapy done in primary care, Bortolotti et al. (2008) describes 10 studies in which providers utilized psychological therapies in conjunction with medications. The psychological therapy was administered by a trained primary care provider in two studies, and in eight studies was administered by other trained health care providers. Adding psychological therapies as an adjunct to medication significantly improved clinical outcomes in patients (Bortolotti et al., 2008).

Anxiety

Anxiety disorders are a very common group of disorders that are frequently co-morbid with other mental illnesses. The major types of anxiety include panic disorder, agoraphobia, obsessive-compulsive disorder, generalized anxiety disorder, specific phobias, social anxiety, and post-traumatic stress disorder (DSM-IV-TR, 2000). Anxiety disorders are thought to be caused by an inappropriate stress response with involvement of cognitive, neuro-endocrine, autonomic, and motor systems. Most patients with anxiety will present with both somatic and

psychiatric complaints (Lyness et al., 2009). Different than mood disorders, anxiety disorders are best treated first with psychotherapy, such as cognitive behavioral therapy, and secondly with medications (Lyness et al., 2009). Anxiety treatment using a collaborative care model has been found to be extremely effective as well (Woltmann et al., 2012).

The focus of anxiety and worry is not confined to cognitive disorders, phobias, somatization disorders, or more extreme anxiety disorders such as eating disorders. The disturbance does not occur exclusively during a mood disorder, a psychotic disorder, pervasive developmental disorder, substance use, or general medical condition. The anxiety, worry, or physical symptoms cause clinically significant distress or impairment in social or occupational functioning (Carey, 2010).

If a person has anxiety he or she will have excessive anxieties about events or activities. Criteria for diagnosing anxiety include at least three of the following symptoms that persist most days for at least 6 months: restlessness or feeling on edge, easily fatigued, difficulty concentrating, irritability, muscle tension, and/or sleep disturbances (DSM-IV-TR, 2000). Anxiety is a spectrum disorder with many variations of symptoms, but all are caused by an underlying abnormal stress response (Carey, 2010).

A diagnosis of PTSD is made if symptoms have been present for more than 1 month and the disturbances cause clinically significant distress or impairment in social, occupational, or other important areas of functioning (Carey, 2010). PTSD stems from a traumatic event in which an individual experienced, witnessed, or was confronted with an event that threatened death, serious injury, or physical integrity; the event caused feelings of tense fear, helplessness, and/or horror (DSM-IV-TR, 2000). In addition, the individual re-experiences the event persistently by having recurrent or distressing memories with thoughts, images, or perceptions. The individual

may also have distressing dreams, a sense the event is recurring (often with psychotic symptoms), and intense stress at exposure to symbolic cues. As a result the individual will go to great lengths to avoid stimuli that are reminders of the trauma, which is a numbing technique (DSM-IV-TR, 2000). In an individual with PTSD at least three of the following occur: effort to avoid thoughts, feelings, or conversations related to trauma, unable to recall details of the trauma, attempts to avoid places, people, or activities that are reminders of the trauma, reports of feeling detached or estranged from other people, significantly decreased interest or participation in usual activities, and/or a diminished or blunted affect (DSM-IV-TR, 2000). Increases arousal leads to difficulty falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, hyper-vigilance, and/or an exaggerated startle response (DSM-IV-TR, 2000).

Co-Morbidities

Individuals with chronic illnesses are much more likely to have co-morbid anxiety or depression (Carey, 2010). Some of the more commonly associated chronic illnesses are: asthma, diabetes, cancer, heart diseases, multiple sclerosis, chronic obstructive pulmonary disease, and epilepsy (Carey, 2010). An individual presenting with depression may also have anxiety symptoms, and these can be secondary to a depressive event or a co-morbid anxiety disorder (Carey, 2010).

Screening Tools

The following screening tools can assist the primary care provider in identifying a patient at risk for depression or anxiety. The screening tools can be used to guide the dialogue, but should not take the place of the important dialogue (Carey, 2010). No tool is necessarily better than another, and the primary care provider may find it most helpful to develop familiarity with one or two instruments (Trangle et al., 2012).

Depression

One screening tool is called the BATHE technique as described by Stuart and Libermann, (1993). This tool asks pointed questions about Background, Affect, Trouble, Handling, and Empathy to help patients to discuss emotions (Stuart & Libermann, 1993). This tool is also effective for assessing anxiety related conditions (Carey, 2010). A very common tool used in clinical practice, and one that was used often in the studies reviewed in this project, is the Beck Depression Inventory (BDI-II) (1996). This tool assesses 21 points on a self-report questionnaire and is commonly used to assess chronic depression. A score of 10-23 might indicate mild to moderate risk for depression (Beck, Steer, & Brown 1996). The Center for Epidemiologic Studies Depression Scale (CES-D) is another common scale used to screen for depression and has 20 points of measurement on a self-report questionnaire (Radloff, 1977). A score of 16 or greater indicates risk for depression (DSM-IV-TR, 2000). A common screening tool for depression is the Patient Health Questionnaire 9 (PHQ-9) which is a nine point self-report questionnaire taken from the larger mental health diagnostic instrument, the PRIME-MD (Spitzer, Kroenke, & Williams 1999).

Anxiety

Several instruments to screen for anxiety may be of use to primary care providers. One tool that is highly adaptable to the primary care setting is the Generalized Anxiety Disorder Severity Scale (GADSS), which is a seven point questionnaire that can also be shortened to the first two questions to identify anxiety in a patient (Ebell, 2008; Shear, Belnap, Mazumdar, Houck, & Rollman 2006). These two questions ask the patient if she or he (1) feels on edge, nervous, or anxious; and (2) if he or she is having uncontrollable thoughts or worry (Ebell, 2008). Another effective screening tool that measures both depression and social phobia (anxiety

spectrum) is called the mini-SPIN (social phobia inventory) (Conner et al., 2001). This is a brief three question scale that can help primary care provider to discuss depression and anxiety with patients (Ebell, 2008). Finally, another widely utilized tool that measures anxiety is the Hamilton Anxiety Scale (HAS) (Hamilton, 1969). Ultimately it is the decision of the primary care provider to choose a tool he or she is comfortable with and use it consistently.

Conclusion

As discussed, depression and anxiety are extremely common chief complaints in the primary care setting and penetrate all ages, populations, and cultures. They can be exceedingly difficult to treat, and as previously mentioned many people are seeking alternative treatments that are less invasive than medications. Primary care providers can either refer patients to a HT provider or as previously discussed can pursue certification in HT. HT practitioners can be found in most communities in the United States (Healing Touch International, 2012). The caveat to this, however, is there are no current evidence-based practice guidelines for utilizing HT to reduce symptoms of psychiatric disorders or mental health conditions such as depression or anxiety.

Chapter 1 has briefly discussed the definitions of complementary alternative medicine and biofield therapies as they pertain to this practice inquiry. A detailed background discussion has been presented, and significance of the problem and how it relates to the primary care provider has been discussed. In Chapter 2, methodology and procedures are presented.

CHAPTER 2: METHODS

The purpose of this practice inquiry is to describe best practice recommendations for using Healing Touch (HT) to treat symptoms of depression and anxiety in a primary care setting as defined in Chapter 1. The critical analysis led to the development of a clinical practice protocol. The process of critically analyzing existing literature consists of systematically evaluating studies by means of a scientific method (Duffy et al., 2009). Strengths and quality level of the various research studies were evaluated, as well as pros and cons. Lastly, gaps in research and common underlying themes in HT that support implementation into practice were identified.

Methodology

The methodology applied in this critical review included a systematic review of the literature, followed by a critical analysis. The systematic review was guided by a process outlined by Thomas, Ciliska, Dobbins, and Micucci (2004). Thomas et al. (2004) describes a process of identifying a problem, systematically reviewing existing literature, assessing quality of evidence, extracting data, and disseminating the findings to a target audience. After completing the systematic review, the quantitative studies were critically analyzed for quality of evidence and strength of recommendations following methods developed by the Effective Public Health Practice Project (EPHPP, 2009) tool. Qualitative studies were critically analyzed using a tool designed by the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) (Cessario, Morin, & Santa-Donato, 2002). The strength of evidence was influenced by authors Djulbegovic, Trikalinos, Roback, Chen, and Guyatt (2009) as they clearly define the importance of also assessing strength of recommendations as they are related to quality of evidence.

The quality of evidence and strength of recommendations for each study are described in Chapter 3. Findings and recommendations are synthesized in Chapter 4. Finally the evidence was synthesized into a clinical practice protocol for use in the primary care setting that is described in Chapter 5.

Literature Retrieval

Literature retrieval was performed by a comprehensive search of available literature. Medline (PubMed) was the initial database utilized for the literature review. In PubMed the MeSH thesaurus with “healing touch” as the term searched was used. Therapeutic Touch was the associated term found through MeSH and all subheadings were included in the PubMed search. Subheadings were adverse effects, classifications, contraindications, economics, ethics, history, methods, nursing, psychology, standards, trends, statistics, and utilization. Entry terms were Touch, Therapeutic, Reiki, and Laying-on-of hands; 314 Articles were found. The search was then narrowed to documents within the past 10 years, from 2002 – 2012, and 192 articles were found. Then the search was limited to available full text and 133 articles were identified. Next articles posted on *www.healingtouchresearch.com* and *www.therapeutic-touch.org* were identified and cross-referenced. The therapeutic touch website (*www.therapeutic-touch.org*) directs those interested in more information to seek the PsychINFO and Medline databases for articles. The Healing Touch website (*www.healingtouchresearch.com*) refers those interested to PubMed and the National Center for Complementary and Alternative Medicine (NCCAM). The NCCAM site refers to a Cochrane summary search (NCCAM, 2013). Using Healing Touch as a search term and looking for reviews, guidelines, and protocols; 220 articles were found. Specifically, five articles described aspects of mental health; four addressed dementia, and one focused on anxiety. All were peer-reviewed.

Finally a combination database search was done with CINAHL, MEDLINE, and PsychINFO. The terms Healing Touch OR Therapeutic Touch OR Reiki were used, and limited to full text, peer-reviewed articles published within the past 10 years. A total of 515 articles were found. Results were narrowed to include only studies with identified methodology resulting in 33 original results; the rest were duplicates of the same study. Studies that did not have depression or anxiety as outcome variables were eliminated as they did not contribute to evaluating HT as an adjunct therapy for HT for symptoms of depression and anxiety in the primary care setting. There were 23 total studies evaluated. Each study is discussed in detail with findings in Chapter 3.

Evaluating Quality of Evidence

The third step of this process was to evaluate the quality of evidence in each study. Evidence cannot stand alone when making recommendations for clinical practice. Instead a distinction must be made between the quality of evidence and the strength of recommendations (Djulbegovic, Trikalinos, Roback, Chen, & Guyatt, 2009). In this practice inquiry, the quality of evidence is defined as the confidence that the reported effect is accurate, and the strength of recommendation is defined as confidence that the quality of evidence is strong enough to support the practice recommendations (Djulbegovic et al., 2009).

Quantitative Studies

The author considered several tools used to evaluate quality of evidence and chose the Effective Public Health Practice Project (EPHPP) (2009) for evaluating quantitative studies. Not all quality assessment tools address blinding or randomization, therefore the quality of results may be exaggerated (Armijo-Olivo et al., 2012). However, the EPHPP (2009) does address blinding and randomization. Following the EPHPP (2009) guide, quantitative studies were

evaluated on six criteria: study design, bias, confounding variables, withdrawal rates, sample size, blinding, and data collection methods.

One criterion that affects the quality of a study is the amount of bias. There are many different types of bias, which are important to identify as they are a threat to internal validity (Polit & Beck, 2008). Selection bias is defined as variables such as gender or age being either unequal or not fully accounted for; this was assessed by identifying the demographics and descriptions of the reported sample (Polit & Beck, 2008). Attrition bias is defined as findings that may be skewed because of a high drop-out rate from a study, and attrition was identified by assessing drop-out rates within each study (Polit & Beck, 2008). Publication bias is defined as a result skewed by failing to include all available publications, such as during a systematic review; in this project each review study was evaluated for publication bias based on methods of attaining data (Anderson & Taylor, 2011). Although not all aspects of bias are addressed in the EPHPP (2009) tool, selection bias is evaluated by assessing the sample as a reflection of the population.

Another criterion that affects the quality of the study is the existence of confounding variables (EPHPP, 2009). These are defined as contaminating factors that cannot be controlled (Polit & Beck, 2008). The EPHPP (2009) tool evaluates for confounding variables by identifying if confounding variables were accounted for and addressed in the study and if there were important differences between each group prior to the study intervention (EPHPP, 2009).

Having a high withdrawal rate also threatens validity of a study and thus the quality of evidence (EPHPP, 2009; Polit & Beck, 2008; Thomas et al., 2004). The researchers must account for treatment adherence in analysis and interpretation of results (Polit & Beck, 2008). Each study was assessed for attrition. If the dropout rate was less than 20% it contributed to a

higher quality of evidence. A dropout rate of 21 - 40% contributed to a moderate quality ranking. If the dropout rate was greater than 41% it was associated with a low quality of evidence (EPHPP, 2009).

Blinding is another criterion used to assess for quality of evidence (Thomas et al., 2004). Blinding addresses subject bias, or how aware subjects are of the intervention (Polit & Beck, 2008). This is an important concern in researching biofield therapy since there is a suspected placebo effect (Wilkinson et al., 2002). Each study was assessed for blinding of participants, practitioners, and analysts when applicable. Having a double-blinded study contributed to a high quality rating. Single blinded studies contributed to a moderate quality rating, and no blinding was suggestive of a poor quality study (Polit & Beck, 2008).

Qualitative Studies

Qualitative studies have different criteria for weighing quality of evidence. Traditionally studies are measured by evaluating the scientific rigor used to develop evidence (Cessario, Morin, & Santa-Donato, 2002). Researchers Cessario et al. (2002) developed a tool with the intent of going beyond evaluating scientific rigor and assessing the characteristics of the actual findings and rank the study with a specific level of evidence. This tool has five categories of evaluation: descriptive vividness, methodological congruence, analytical preciseness, theoretical connectedness, and heuristic relevance (Cessario et al., 2002). The following discussion elaborates the categories of evaluation outlined by Cessario et al. (2002). Descriptive vividness is defined as having credible and rich information. The information stems from descriptive narratives, and returning to the participants to confirm mutual understanding. Additionally, the amount of time spent at the data collection site is evaluated, as this helps to formulate a vivid description. Methodological congruence is determined by considering the scientific rigor of the

qualitative study. The study should clearly and accurately outline methods of data collection and analysis, sampling method, how bias was avoided, and how the findings were obtained.

Methodological congruence is also impacted by ethical rigor including informed consent and maintaining the rights of the study participants.

Confirmability of the qualitative study is reviewed by evaluating if the results are repeatable, if methods of judgment are described, and if nature and reasoning of decisions is documented. Analytical preciseness includes comparing theoretical statements from the literature with findings, to ascertain that the whole picture is depicted. Theoretical connectedness is evaluated by the clarity, definitions, or validity of the concepts. Preciseness is also addressed if the relationships between the concepts are clearly defined and if the theory demonstrates a comprehensive picture of the study. Finally an evaluation is made of any connection between the data and nursing frameworks (Cessario et al., 2002). The fifth category is heuristic relevance, which describes the phenomenon studied. Heuristic relevance is achieved if the phenomenon is clearly described and is easily recognized by the participants. Any relationship the phenomenon may have to an existing body of knowledge is evaluated. Findings are evaluated as to their important to nursing practice and contributions to theory development (Cessario et al., 2002).

Strength of Recommendations

The quality of evidence helped determine the strength of recommendations. Strength of recommendation is defined as confidence that the quality of evidence is strong enough to support the practice recommendations. When the quality of evidence is high, there is greater likelihood that the strength of recommendation will correspond (Djulbegovic et al., 2009). If the strength of recommendation is high, it is more likely to be adapted into clinical practice (Djulbegovic et al., 2009). Additional factors considered in the strength of recommendation may include cost and

risk versus benefit (Djulbegovic et al., 2009).

Conclusion

Chapter 2 has outlined the method of critical analysis used to guide this practice inquiry. The critical analysis included an evaluation of quality and strength. The following chapter describes the critical analysis.

CHAPTER 3: CRITICAL ANALYSIS

As described in Chapter 2, a search of multiple databases using the search terms “healing touch,” “therapeutic touch,” “reiki,” “biofield therapy,” “laying-on-of-hands,” and “touch therapy” was done. Subheadings included in this search were adverse effects, classifications, contraindications, economics, ethics, history, methods, nursing, psychology, standards, trends, statistics, and utilization. This comprehensive search was performed in order to review all known literature about Healing Touch (HT), Therapeutic Touch (TT), and Reiki. Pertinent and relevant findings are discussed in this chapter. Three methods of biofield therapy are discussed in this critique, because researchers often used the terms “touch therapy,” “energy field therapy,” or “biofield therapy” interchangeably to describe interventions. A number of biofield therapy studies have been completed over the past 10 years, but very few have focused on biofield therapy for depression and anxiety.

The quality of evidence and strength of recommendations for each study is discussed. Results are listed first by biofield method studied, and then by quality of evidence (high, moderate, or weak) as evidenced by evaluation criteria described in Chapter 2. Studies that did not contain depression or anxiety related outcome variables were eliminated as they did not contribute to evaluating HT as an adjunct therapy for HT for symptoms of depression and anxiety in the primary care setting. Twenty three studies were critically analyzed. A critical analysis table is presented in Appendix A.

Current Healing Touch Research

Healing Touch (HT) as a modality has been researched in a variety of settings. The literature critique begins with the studies that have the highest quality of evidence. The following studies have been completed within the past 10 years.

The quality of evidence for each quantitative study was evaluated by following the guidelines outlined by EPHPP (2009). Eight quantitative HT studies were identified: one had high quality of evidence and six had poor quality of evidence. In addition, one qualitative study with poor quality of evidence was identified. This study was evaluated by methods described by Cessario, Morin, and Santa-Donato (2002).

Hersch, Juraskova, Price, and Mullan, 2009

Authors Hersch, Juraskova, Price, and Mullan (2009) performed a systematic literature review of 22 studies published from 1980 to 2008; involving more than 1900 subjects with gynecological cancers. Inclusion criteria for the review included: experimental controlled trials that used a psychosocial intervention, studies that utilized a control group, and studies that included a quality of life variable as the primary outcome. The purpose of the review was to evaluate interventions including HT, cognitive behavioral interventions, and counseling, on quality of life. Eighteen of the 22 studies reviewed were randomized control trials, 12 of which were described as having strong scientific rigor. Limitations reported are that the studies included generally small sample sizes and the majority of subjects were Caucasian, although other races were represented. No statistical significance was noted and a relative risk or odds ratio was not discussed. Although a comprehensive comparison of the 22 studies is offered, it is presented in the form of a discussion and it is difficult to extract findings.

The quality of evidence is affected by the following factors: the methods of data extraction included searching databases, reference lists, grey literature databases, and consulting with experts. The studies were ranked based on levels of evidence, study design, eligibility criteria, withdrawal rate and sample size, intervention, study schedule, outcome measures, and results. Two researchers independently evaluated each study and then compared the results; the

results were compiled into a table. The studies included in the systematic literature review appear to be a representative sample of the intended population; patients with gynecological cancer who received a psychosocial intervention. No confounding variables were identified by the authors. Blinding was done in some of the studies reviewed, however only four were double-blinded. Selection bias in most of the studies, and high withdrawal rates in two studies are noted. One risk of performing a systematic review is publication bias. It is possible that some pertinent studies were omitted from the review, and that any missing studies may have changed the findings. In this case, the description of the literature search is extensive and clearly articulated, so it is a reasonable assumption that available evidence was well represented. It seems likely that the quality of the study was not affected by selection bias. All of these factors contribute to this study having high quality of evidence (EPHPP, 2009).

The recommendation that stemmed from the systematic review of randomized control trials was that counseling is most beneficial as a psychosocial intervention among patients with gynecological cancer, and HT was least beneficial. Overall psychosocial interventions did have a positive impact on both depression and anxiety in patients with gynecological cancers. Although recommendations for HT are weak, findings are not sufficient to recommend against HT (Djulfbegovic et al., 2009). It is also possible that newer evidence may have emerged since the 2008 review.

Anderson and Taylor, 2011

A systematic review of randomized control trials of HT was performed by Anderson and Taylor (2011). This systematic review incorporated two independent reviews using the Cochrane (Jadad et al., 1998) classification for allocation concealment and modified Jadad scoring for quality evaluation (Jadad et al., 1998). This scoring format awarded points to each article based

on type of study, blinding, and withdrawal or drop-out rates. Data were extracted through a search of both electronic databases and reference lists of identified studies to find peer-reviewed articles. Five studies were selected from 332 potential studies, based on inclusion and exclusion criteria. Inclusion criteria included use of random assignment, HT as a single intervention, and contrast of HT with a comparison group. Exclusion criteria included: no statistical information reported, methodology not aimed at outcomes, or HT was used as part of a complex intervention. No specific outcomes were identified. No statistical significance was noted and a relative risk or odds ratio was not discussed. Results of each study are contrasted in discussion format.

The quality of evidence in this study is affected by the following. The identified sample size of five studies is possibly representative of the total population of HT studies, because there is a significant lack of studies regarding HT. More than 80% of available studies are presumably represented based on data extraction method. No confounding variables were identified by the authors. Because of these limitations the quality of evidence is moderate (EPHPP, 2009).

Important findings included no known side effects of HT; and a “significant” decrease in heart rate and respiratory rate, blood pressure, pain, and total mood disturbances, although none of these variables are associated with statistical evidence. A critique was offered that many biofield practitioners have no research expertise therefore the level of scientific rigor cannot be addressed. This is suggested through review of the five RCT’s; in each case the studies were described as poorly controlling for controls, blinding, or sample size. The studies also used subjective assessments such as fatigue and quality of life as outcomes. Recommendations included more rigorous randomized trials with quantitative outcomes and blinding, because it is difficult to implement biofield therapies into mainstream health care without more scientific rigor (Anderson & Taylor, 2011). Unlike the Hersch et al. (2009) systematic review, this

systematic review only used search terms “healing touch” and did not use grey databases or unpublished manuscripts to identify studies. Failing to include all available data resources limits the quality of evidence and also the strength of recommendations. Based on these limitations, this article is evaluated as having moderate strength of recommendation (Djulbegovic et al., 2009).

Hardwick, Pulido, and Adelson, 2012

Hardwick, Pulido, and Adelson (2012) performed a prospective, block-randomized, quasi-experimental design study of patients (N=41) receiving bilateral total knee arthroplasty (BTKA), with the intervention group receiving HT. The two arm intervention had a control group receiving treatment as usual (N=20), and a treatment group (N=21) that received HT. The intervention consisted of four separate 30 minute HT sessions by one of two practitioners. The intervention was 17.5 hours of HT given over two days. Inclusion criteria were individuals 18 years or older receiving BTKA and able and willing to fill out questionnaires. Exclusion criteria included prior knee implants, physical or medical limitations, having an indwelling anesthesia catheter, having rheumatoid arthritis, or having post-operative complications. Outcome measures were the Pain VAS scale and State-Trait Anxiety Inventory (STAI). The outcome of interest was reduced symptoms of anxiety. Statistical significance was considered if a *p* value of < 0.05 was obtained. Findings included reduction in anxiety (P=0.045), although pain reduction did not reach statistical significance.

The quality of evidence is affected by the following. A power analysis stipulated 43 subjects but due to financial constraints only 41 participants were recruited. An ad hoc power analysis based on actual enrollment found the study power to be 60%. The population was predominantly female, which may speak to a selection bias. One confounding variable identified

is that pain is a subjective experience and is difficult to quantify. Another variable not accounted for was pain medication given prior to procedure, which may have affected outcomes. No one prematurely withdrew from the study. One limitation of this study includes multiple types of anesthesia used prior and during the intervention that were not accounted for. Another limitation was no blinding of subjects, and no discussion as to whether or not subjects had previous experience with HT. Because of these limitations and variables the quality of evidence is poor (EPHPP, 2009).

To strengthen this study the researchers could have blinded participants, or used non-subjective variables such as vital sign measurements. Both the STAI and VAS are quantitative measures of subjective findings. The major recommendation of this study is that HT can be used as an adjunct therapy to decrease pain and anxiety. The quality of evidence is poor overall, but because the recommendation made by authors is for adjunctive HT and no adverse effects were noted it is a moderately strong recommendation. However, because of the profound impact the quality of evidence has on the strength of recommendation this study has an overall quality rating of poor (Djulgovic et al., 2009).

Maville, Bowen, and Benham, 2008

Maville, Bowen, and Benham (2008) performed a quasi-experimental pilot study to evaluate how HT affects anxiety and physiologic changes in the healthy adult. The intervention was a single group repeated measure design where the participants were given HT by one practitioner in a specific sequence for 50 minutes. Each participant (n=30) received the same intervention. A convenience sample of 30 students enrolled in a health sciences course were selected for participation. The only other inclusion criterion was being otherwise healthy and speaking English. The only exclusion criterion was currently taking medication for

cardiovascular disorder. Outcome measures were state of anxiety as measured by the STAI tool, heart rate (HR), blood pressure, skin conductance, muscle tension, and skin temperature, and the outcome was changes in anxiety in response to HT. Findings demonstrated significant changes in both heart rate ($t[25] = 5.19, P < .001$) and body temperature ($Z = 3.08, P = .002$), both which were decreased from baseline. Systolic blood pressure after the intervention was significantly changed ($M = 116.7, SD = 13.9; t[29] = 4.02, P < .001$), but there was no change in diastolic pressures. There was also a statistically significant change in anxiety ($t[29] = 7.85, P < .001$).

The following variables contributed to the poor quality of evidence. Unfortunately strong selection bias was present in that the sample included 73% women, 80% Hispanic, and 17% of the participants had prior experience with HT. No power analysis was reported for this study, and the nature of a pilot study is having small, and therefore unstable, samples (Polit & Beck, 2008). Body temperature may have been a confounding variable, as it is possible that changes resulted in part when subjects went from a hot and humid climate to an air-conditioned room. No one withdrew from the study. No one was blinded, and each subject only received one session of HT. Each these conditions had a negative impact on the overall quality of this study (EPHPP, 2009).

As noted, one limitation of this study is a small sample with no control group. Results may have been skewed because the subjects were able to enter a relaxing environment. Based on results, HT decreases anxiety and promotes relaxation. However because of substantial threats to the quality of evidence and no definitive recommendations made by the authors, the statistically significant findings cannot be validated and therefore the quality of evidence and strength of recommendations are weak (Djulfbegovic et al., 2009).

Wilkinson, Knox, Chatman, Johnson, Barbour, Myles, and Reel, 2002

Authors Wilkinson, Knox, Chatman, Johnson, Barbour, Myles, and Reel (2002) conducted a study evaluating the clinical effectiveness of HT. This study was a mixed method repeated measures with quasi-experimental and naturalistic approach. The intervention included a control group, HT only group, and HT with guided imagery and music group. Each subject had two treatments of each intervention over a two week period, and treatments lasted at least 30 minutes. Outcome measures were secretory immunoglobulin (sIgA) levels in saliva and a perceived health enhancement questionnaire and the outcome of interest was improvement in perceived health enhancement. The only documented inclusion criteria was being naïve to HT. A statistically significant change in IgA levels between the first and sixth stages $F(1) = 5.63, p \leq 0.014$ (one-tailed), observed power = 0.617 with a reported effect size of 0.32. Also, significant changes in stress levels and relaxation were reported after the intervention for both HT by itself $t(20) = 6.086, p = 0.0003$ (one-tailed) and also HT with GI $t(21) = 4.879, p = 0.0003$ (one-tailed).

The quality of evidence presented is overall poor. Selection bias exists because the study was a convenient sample of predominantly Caucasian females with no specific diagnosis. A power analysis (N=25) was done and 88% (N=22) of power analysis was recruited for the study. The major confounder is that there were nine different practitioners with varying levels of experience performing the intervention. No one was blinded during the study and no one withdrew from the study (EPHPP, 2009).

Approximately 60% of subjects believed their health was enhanced, 55% reported a decrease in pain, and significant positive sIgA changes occurred. Limitations of this study are a reported strong placebo effect and varying levels of experience by practitioners which could yield a different result on participants. One significant finding noted by the IgA changes is that

HT is clinically significant at reducing stress levels. However because of substantial threats to the quality of evidence and no definitive recommendations made by the authors, the statistically significant findings cannot be validated and therefore the strength of recommendation is weak (Djulbegovic et al., 2009).

Tang, Tegeler, Larrimore, Cowgill, and Kemper, 2010

Tang, Tegeler, Larrimore, Cowgill, and Kemper (2010) studied how HT directly affects nurses in a quasi-experimental, single group, pre-test post-test study that evaluated stress levels in nurse leaders through experiencing HT. Inclusion criteria were being an RN, nurse leader, and employed at specified location. Both subjective and objective measures were taken and included a visual analog scale (VAS) and heart rate variability (HRV) one-to-two weeks before and four weeks after training; the outcome was reported feelings of well-being. HRV was included because it has been associated with an overall sense of well-being. There was a statistically significant improvement in heart rate, and self-reported stress, anxiety, depression, well-being, (overall negative symptoms $p=0.01$ and positive symptoms $p=0.004$).

The quality of evidence is diminished because a power analysis was not performed ($N=22$) and the sample consisted of nurse leaders; it is not clear that the sample represents an intended population. Confounding variables included selecting an all-female population with varying experience levels with HT. There was a 23% withdrawal rate and no blinding was done. Because of these variables this study has poor quality of evidence (EPHPP, 2009).

The authors make a recommendation of HT for stress relief in this population. However because of substantial threats to the quality of evidence, the statistically significant findings cannot be validated and therefore the strength of recommendation is poor (Djulbegovic et al., 2009).

Rexilius, Mundt, Megel, and Agrawal, 2002

Researchers Rexilius, Mundt, Megel, and Agrawal (2002) conducted a quasi-experimental repeated measure pre-test/post-test design evaluating how HT or massage affected symptoms of caregiver burden such as fatigue, depression, and anxiety. The intervention was six 30-minute treatments over a six week period. Inclusion criteria were healthy adults that were caregivers of patients undergoing autologous hematopoietic stem cell transplant. Subjects were excluded if they were not the primary caregiver, were being treated for an acute health problem, or were a HT or massage practitioner. Outcome measures consisted of the: Demographic Data Form (DDF), Beck Anxiety Inventory (BAI) for anxiety, Center for Epidemiologic Studies Depression (CES-D) Scale for depression, Multidimensional Fatigue Inventory-20 (MFI-20) and Subjective Burden Scale (SBS) for fatigue, and a post-study questionnaire (PSQ), and outcomes of interest were reduction in fatigue, depression, or anxiety. The sample size was 36 subjects with 13 in control group, 13 in massage therapy group, and 10 in HT group. Results demonstrated decreased anxiety in the massage group ($p=0.004$). Statistical significance was also reached in the massage group ($p=0.002$) for improved depression symptoms. The HT group had improved symptoms of depression and anxiety but without statistical significance.

The quality of evidence is affected by substantial issues with internal validity (EPHPP, 2009). This study had significant treatment bias, as the intervention was provided by the researchers. One confounding variable is that some of the subjects also had prior experience with massage and/or HT. Withdrawal rate of subjects was 18% and no blinding was done.

Recommendations suggest that HT and massage are feasible in the oncology setting for depression and anxiety. However, because of poor evidence this is not a strong recommendation

(Djulbegovic et al., 2009). Since HT is non-invasive, it may still be of benefit as adjunct treatment to reduce symptoms of depression or anxiety among primary caregivers.

Wardell, Rintala, Duan, and Tan, 2006

Wardell, Rintala, Duan, and Tan (2006) examined HT use for veterans with chronic neuropathic pain and psychological stress secondary to spinal cord injury. Study design was a mixed method design measuring both qualitative and quantitative data. Qualitative data was obtained through pre- and post-intervention surveys of open-ended questions and focus groups. Quantitative data collected was the Brief Pain Inventory (BPI), Profile of Mood States (PMS), Diener Satisfaction with Life Scale, Center for Epidemiological Studies-Depression Scale short form (CESD-10), and a Visual Analog Scale (VAS), and the outcome of interest was reduced psychological stress. The intervention was HT given by a certified HT practitioner in subjects' homes for a total of six sessions one week apart. Criteria included ability to read and write English, older than 18, more than six months since spinal cord injury, having pain greater than 5/10 on VAS scale, on stable pain medication plan, and having chronic neurologic pain. Total sample size was 12, with seven in the treatment group and five in the control group. Results showed that there was some decrease in pain but nothing that was considered statistically significant. Additional findings included improved mood and higher satisfaction of life after HT sessions when compared to control group, although these were again not statistically significant. Of interest to this paper, the PMS findings were not significant ($p=0.51$), nor were the scores from the CESD-10 ($p=0.29$).

No power analysis was conducted although the small sample size is probably sufficient for a pilot study. Confounding variables are that each participant received treatment from a different practitioner, and inter-rater reliability was not addressed. One other confounder is that

the experience level varied between practitioners. Confounding variables between demographic information was addressed and analyzed by participant characteristics using a two-sided chi-square test. The only statistically significant difference between the two treatment groups was a higher education level in the HT group ($p=0.029$). No one withdrew from the study. No one was blinded. Because of variables such as inappropriate sample size, unreliable intervention, no blinding, and substantial confounders this study has an overall poor quality of evidence (EPHPP, 2009).

Although some change is evident no conclusions are made because of high variability and small sample size. A second compromise to quality is that each there was no consistency between treatments of the participants; instead the treatment was dictated by the participants' "energy reading." A multi-pronged approach to treatment is recommended. This recommendation cannot be substantiated because of the poor quality of evidence (Djulgovic et al., 2009). It would also be beyond the scope of a pilot study to develop a high strength of recommendation. However, no adverse events were reported and subjects did have an overall positive experience from HT and therefore a moderate recommendation for HT cannot be refuted.

Van Aken and Taylor, 2010

Van Aken and Taylor (2010) evaluated the effect of healing touch on symptoms of depression through a qualitative grounded theory and case study. The purpose of the study was to explore factors associated with recovering from depression. As stated by the authors, there was an intervention which consisted of five weekly HT sessions. Results were obtained from the HEALTH tool (holistic assessment, intake, history, pre & post intervention assessment). The sample consisted of fifteen individuals who self-identified with a diagnosis of moderate

depression. Diagnosis was verified using the Beck Depression Inventory (BDI). This study was of interest to this paper because it specifically looked at HT as an intervention for depression.

Because this study is qualitative in nature the quality assessment tool described by Cessario, Morin, and Santa-Donato (2002) was used. The methodological congruence is not clear, as there is no distinct methodology and in fact the study appears to contain examples of methodological blurring (qualitative grounded theory, use of interventions, instruments). Furthermore, procedural and ethical rigor is not clearly defined in the study. In addition, analytical preciseness and confirmability are not clearly defined which contribute to an overall poor quality of evidence (Cessario, Morin, & Santa-Donato, 2002).

Only qualitative data was reported. Patients had enjoyable experiences from HT and no adverse events were reported. There was never a specific number of HT sessions identified for reducing symptoms of depression. A vague recommendation was made that people can learn to work with their own energy field to help symptoms of depression. The strength of recommendation is weak because it stems from poor quality of evidence with only vague findings and without specific practice recommendations (Djulgovic et al., 2009).

Current Therapeutic Touch Research

Therapeutic Touch (TT) is an older modality than HT, and has also been traditionally used by nurses (Samarel, 1992). It is different than HT because it is hands-off only and requires no spiritual context of healing (Samarel, 1992). It is included in this literature review for depth and breadth of findings.

Woods, Beck, and Sinha, 2009

A study led by Woods (2009) evaluated therapeutic touch among patients with dementia at a nursing home. The study design was a randomized control trial, double blinded experimental

interrupted time series design. The intervention consisted of three arms: a control group (N=22), a placebo mimic treatment group (N=21), and a therapeutic touch (TT) treatment group (N=22) for a total of 65 participants. Each arm received two treatments a day for three days. The TT group received head & shoulder treatment, the placebo group received identical mimicking treatment, and the control group had treatment as usual. The outcome measures were defined as morning cortisol levels by ELISA, and behavior changes related to dementia measured by the modified Agitated Behavior Rating Scale (mABRS). Outcomes of interest for this study were stress as related to cortisol levels and decreased anxiety. Statistically significant findings were restlessness in therapy group ($p=0.03$), and significant variability in salivary cortisol levels in therapy group ($p<0.0001$) across time periods.

Selection bias may exist because all the participants (N=65) were recommended for the study. Limitations of the study included the inability to control variables such as current medications, foods, exercise, and other confounders that could affect salivary cortisol levels. There was no one that withdrew from the study. Participants were blinded to the intervention and researchers were blinded as to who got which intervention. Both of these variables improve the quality of the study. Because of these factors this study has a high quality of evidence (EPHPP, 2009).

A limitation of this study is the intervention was potentially short (only three days) and no discussion about what a recommended intervention length is included. Findings from the study suggest that decreased stress and restlessness can be a result of therapeutic touch in this population. Recommendations from the study suggest that agitation and stress secondary to dementia can be reduced with TT. This is a strong recommendation based on the quality of evidence, and because no adverse events were reported (Djulgovic et al., 2009).

Zolfhagari, Eybpoosh, and Hazrati, 2012

Zolfhagari, Eybpoosh, and Hazrati (2012) completed a randomized control trial evaluating therapeutic touch on symptoms of anxiety and dysrhythmia, as well as on vital signs for women about to undergo cardiac catheterization. The intervention included a three arm trial with an intervention group (N=23) receiving 10-15 minutes of treatment one hour prior to undergoing catheterization, a placebo group (N=23) that received 10-15 minutes of simulated touch one hour prior to treatment, and a control group (N=23) that had treatment as usual. Subjects were randomly assigned into treatment groups. The sample was chosen from a population of Iranian women ages 35-65 that were electively admitted to a hospital with a diagnosis of coronary artery disease undergoing non-emergent cardiac catheterization for the first time. Inclusion criteria included having no history of prior cardiac related admission, no history of psychiatric illness, being able to read, and being conscious. Exclusion criteria included consumption of opiod or anxiolytic medications 24 hours prior or post procedure. Outcomes were measured with STAI, vital signs, and evaluation of cardiac dysrhythmias. Vital signs (blood pressure, heart rate, and respiration rate) were measured before and after intervention. The outcome measure of interest was reduction in anxiety and dysrhythmias. The chief finding of the study was that both control and placebo groups had decreases in anxiety, blood pressure, and heart rate. Statistically significant decreases in cardiac dysrhythmias ($p < 0.05$) were found; except for premature ventricular contractions in the treatment group. Mean scores of vital signs were significantly lowered in the treatment group ($p < 0.001$). No statistically significant findings from the STAI were reported.

Some selection bias was present as the sample was homogenous. One confounding variable is that some subjects were menopausal; this was not addressed in the data analysis.

Some participants were also taking Valium prior to treatment that was not controlled for, and no one withdrew from the study. Subjects and researchers were blinded to treatment and results. Because of the presence of blinding, adequate collection methods, and some attempt to control for confounders this study has a high quality of evidence (EPHPP, 2009).

Recommendations include further studies with larger sample size and broader patient characteristics. Recommendations for practice include considering TT as a strategy to decrease anxiety in patients undergoing a procedure. This is a strong recommendation based on the quality of evidence presented (Djulgovic et al., 2009).

Papathanassoglou and Mpouzika, 2012

The only study of moderate quality for TT was a critical review evaluating existing literature of therapeutic touch on critically ill patients (Papathanassoglou & Mpouzika, 2012). Studies that were excluded were: unreported physiological measurements, studies of animals or children/neonates, post-exercise interventions, or any study of qualitative, case study, or conceptual nature. Findings support decreased physiological stress as evidenced by an improvement in vital signs and other variables. In addition touch, both contact and non-contact, reduced both psychological symptoms of stress such as pain and depression. Physiological symptoms such as neuro-endocrine effects and enhanced immunity were also positively, though not statistically, affected. Notable findings from all eleven studies indicate that amount of pressure from touch, location of touch, and multiple sessions of touch had impacts on depression, anxiety, and pain.

Eleven different studies were reviewed. Publication bias may exist because it is possible that researchers were not able to identify all existing studies. There were no known confounding variables. The data collection method was comprehensive. Limitations of the study are based on

limitations of reviewed studies and inconsistency in interventions among studies reviewed. All of these variables contribute to an overall moderate quality of evidence (EPHPP, 2009).

A recommendation is made for more studies on healing touch with stronger methodology. A recommendation that TT may benefit critically ill patients is introduced. The quality of evidence, the study design, and the findings from this study suggest this is a moderate recommendation (Djulbegovic et al., 2009).

Current Reiki Research

Reiki is an eastern medicine practice that also uses both hands on and hands off techniques, as well as visualization with the intent of improving the flow of energy. Reiki is used to treat problems on emotional, physical, and spiritual planes of healing (Hallett, 2004).

Described below are articles that had depression, anxiety, or other mood related outcomes as measured variables.

Shore, 2004

Shore (2004) conducted a study of Reiki for people with depression. A 3x3 factorial MANOVA study with three arms of treatment was used. Treatment one group had six treatments of at least 60 minutes of Reiki (n=13). Treatment 2 (n=16) had at least 60 minutes of six treatments of distance Reiki. The third group (n=16) received six treatments of 60 minute distance placebo Reiki. The intervention was weekly for a total of 61 weeks. Inclusion criteria consisted of having symptoms of depression and stress. Symptoms were measured using the Beck Depression Inventory (BDI), Beck Hopelessness Scale (BHS), and perceived stress scale (PSS). The outcome of change in depression symptoms was of interest to this paper. PSS results: Reiki was statistically more therapeutic than placebo distance Reiki (p=0.004). Distance Reiki was also more therapeutic than placebo distance Reiki (p=0.005). No significant differences were

found between distance and regular Reiki. Results of BDI: Again Reiki was more therapeutic than placebo distance Reiki ($p=0.05$), and distance Reiki was more significant than placebo distance Reiki ($p=0.004$). Again no differences were found between regular and distance Reiki techniques. Finally for BHS results were similar as other two groups with significance differences in perceived hopelessness ($p=0.01$) between Reiki and placebo distance Reiki, between distance Reiki and placebo distance Reiki, ($p=0.02$) and no significant difference between Reiki and distance Reiki. Participants were tested pre-intervention, post-intervention, and at one year after termination of intervention.

Variables that contributed to the quality of evidence are as follows: the sample consisted of 45 participants that self-volunteered for the study which creates substantial bias as the subjects were more likely to have pre-conceived notions or dispositions regarding Reiki treatments. No confounding variables were discussed, however participants with previous Reiki experience may be considered a confounding variable. The participants were randomly assigned to treatment groups and were blinded to which group they were in. No one withdrew from the study. Limitations of this study were short duration of interventions (six sessions) and small sample size. However, based on criteria of the EPHPP (2009) the blinding, randomization, outcome measurement tools, and sample size contribute to an overall high quality of evidence.

Recommendations include combining Reiki with other depression treatments because it is effective and cost efficient. Further studies of biofield therapy for symptoms of mental conditions are also recommended. Both of these are strong recommendations based on the quality of evidence presented in the study (Djulbegovic et al., 2009).

Shiflett, Nayak, Bid, Miles, and Agostinelli, 2002

Researchers Shiflett, Nayak, Bid, Miles, and Agostinelli, (2002) conducted a double blinded randomized control trial involving Reiki. Patients receiving treatment for sub-acute ischemic stroke and at least two weeks of treatment remaining were invited to participate. No other inclusion or exclusion criteria were required for participation in the study. Outcome measures were functional independence and depression measured with the CES-D scale, and outcome of interest was change in depression symptoms. The intervention was three different arms – first arm was Reiki performed by a Reiki master. The second arm was Reiki performed by a Reiki practitioner. The third arm was sham Reiki performed by an untrained individual. The treatment protocol was consistent across all three arms and consisted of the Reiki provider placing hands on twelve specific locations on the subjects head and torso over a 30 minute session. Each subject had 10 treatments over two-and-a-half weeks. The minimum number of treatments required for inclusion was six. A power analysis was performed and 50 subjects were recommended for inclusion in the study. Thirty patients with sub-acute ischemic stroke who were currently receiving treatment were randomly assigned for treatment arms, and a control group obtained from hospital records for historical analysis with 20 subjects was created. The only statistically significant data found was in gender differences ($F=4.24$, $p<0.05$). No significant difference was noted for either depression or functional independence.

Selection bias exists because of the method of creating the control group. No confounding variables are addressed in the study and are difficult to assess because no inclusion or exclusion criteria or specific participant demographics are discussed. Blinding was present, and there was an 8% withdrawal rate. Limitations of the study are the lack of standardized education of Reiki practitioners and use of historical data instead of patients receiving placebo

Reiki. However, based on criteria from the EPHPP (2009) tool this study has an overall evidence quality of high.

No adverse effect from Reiki was reported. Recommendations include more studies of Reiki on health outcomes. A recommendation for Reiki as treatment for depression in patients with sub-acute ischemic stroke is made. Even though there were no clinically significant findings and this is a very specific population, this is a strong recommendation based on the quality of evidence presented (Djulbegovic et al., 2009).

Lee, Pittler, and Ernst, 2008

Authors Lee, Pittler, & Ernst (2008) conducted a systematic review of randomized control trials involving Reiki. Quality and type of study were evaluated using Cochrane classification and modified Jadad scoring. Inclusion criteria consisted of trials where human subjects were used in a Reiki intervention as primary or secondary intervention. Excluded studies had Reiki as a complex intervention, no statistical data, no clinical outcomes, and trials with healthy individuals. Nine trials were identified. Two studies were identified that reported symptoms of depression were reduced by Reiki but not by placebo Reiki.

Quality of evidence is influenced by bias and method of data collection and extraction. A publication bias potentially exists because there may be other Reiki studies that were not included in the systematic review that may have changed findings. No confounding variables were documented. No statistical analysis of findings was done, instead a meta-analysis with comparison and contrast of the nine studies was presented in discussion format. This study is limited by overall poor methods used in available studies. These variables contribute to an overall moderate quality of evidence (EPHPP, 2009).

Recommendations suggest that differences in results between studies may be because of different tools used and how applicable the different tools are for the study. No compelling evidence was found, but no evidence was refuted either. It is also reported that Reiki is generally safe with no adverse reactions. These recommendations are of moderate strength based on the quality of evidence (Djulgovic et al., 2009). Therefore Reiki may be a safe adjunctive therapy, although no specific population is identified.

Potter, 2007

Researcher Potter (2007) conducted a randomized control trial with two parallel groups. The treatment group received one session of Reiki within one week of biopsy and another session within one week after biopsy. The control group received treatment as usual. Inclusion criteria were 18 years of age and over, scheduled for breast biopsy, no current breast cancer diagnosis, able to speak and read English, cognitively capable of answering study instruments, and capable of giving informed consent for participation in the study. Outcome measures of anxiety and depression in the study were state trait anxiety inventory (STAI) and depression measured with the CES-D and HADS scoring and outcomes of interest were changes in depression and anxiety from the intervention. The sample consisted of 35 patients that were randomized into a treatment group (n=18), and a control group (n=17). There were no significant changes in anxiety or depression in any of the patients. No adverse events were reported. No other findings were reported.

A population bias existed because this group may experience higher levels of distress than general population. The sample was also not representative of gender or race. The sample is particularly homogenous which could also qualify as a confounding variable. Investigator only was blinded. No one withdrew from the study. The biggest limitation of this study is the subjects

only received two sessions of Reiki. These factors contribute to an overall quality of evidence as moderate as described by the EPHPP (2009) tool.

No conclusions gleaned from the study but a recommendation for longer and more frequent Reiki for patients with anxiety and depression undergoing biopsy is made. This is a moderately strong recommendation based on the strength of evidence presented (Djulgovic et al., 2009). Although not a strong recommendation, this study is encouraging for biofield therapy for symptoms of depression and anxiety as no adverse reactions were noted and some improvement was seen in this population.

Birocco et al., 2012

An observational study of Reiki was done by researchers Birocco et al. (2012). The study lasted over three years. Inclusion and exclusion criteria not clearly specified, but all patients in any stage of cancer receiving any type of chemotherapy were invited to participate. The intervention consisted of each patient receiving between one and four sessions of Reiki lasting about 30 minutes each. Outcome measures of VAS and qualitative descriptors of the physical experience of Reiki were taken at the end of each session. The sample totaled 118 subjects: 67 women, 51 men, and with a mean sample age of 55. Twenty-two subjects received four treatments, and this group achieved statistically significant changes in anxiety. This finding is reported as participant scores on the VAS ($p < 0.000001$) of a decrease from 6.77 to 2.28. The mean VAS pain score was not statistically significant ($p = 0.091$). Limitations of the study were very short intervention length, data mostly qualitative in nature, inclusion and exclusion criteria not specified.

Because this study is qualitative in nature the quality assessment tool described by Cessario, Morin, and Santa-Donato (2002) was used. The methodological congruence is not

clearly documented, most likely because it was such a broad sample with unclear criteria.

Procedural and ethical rigor is not clearly defined in the study. In addition, analytical preciseness and confirmability are not clearly defined which contribute to an overall poor quality of evidence (Cessario, Morin, & Santa-Donato, 2002).

Recommendations suggest Reiki is helpful for improving anxiety, relaxation, pain, and sleep quality in the inpatient setting. This is a weak recommendation because outcome results are not clearly defined and are discussed in a vague manner (Djulbegovic et al., 2009).

Current Biofield Research

Also included in this literature review are studies that did not specify one specific biofield therapy, or used a different therapy such as “touch therapy.” In addition, studies that had combined interventions, such as HT and guided imagery, are discussed. These studies are described below.

Jain, McMahon, Hasen, Kozub, Porter, King, and Guarneri, 2012

Jain, McMahon, Hasen, Kozub, Porter, King, & Guarneri (2012) enrolled 123 participants in a two-arm randomized control trial for one month. The first arm was HT with Guided Imagery (GI) along with standard care, and the second arm received “treatment as usual” which included cognitive behavioral therapy (CBT), medications, and biofeedback. The HT group received six treatments over a three week period. Standardized GI was used in combination with HT, and is described as a CD with imagery and affirmations to enhance relaxation and improve self-esteem. Sessions were one hour long, twice a week, for three weeks. Nurses trained in HT provided the intervention. Inclusion criteria were 18 years or older, back from fighting in a combat zone, had a physician referral, and identified through assessment as having PTSD. Exclusion criteria were being pregnant, lactating, currently using HT or GI, or

unable to sign consent. The primary outcome measure was PTSD symptoms as indexed by the gold-standard PTSD Checklist (PCL)-Military that scores between 17 and 85, with a score > 50 indicating a PTSD diagnosis. A secondary outcome measure of depression was measured by the Beck Depression Inventory II. Quality of life was assessed for both mental and physical improvements with the SF-36, and hostility traits were measured with the Cook-Medley Hostility Inventory. Results indicate significant and substantial reductions in PTSD symptoms, depression, and cynicism as well as improved mental quality of life for those receiving the intervention. No adverse effects were noted. Data were analyzed with repeated measures analysis of covariance. Medication was found to be a significant covariate and was accounted for in relation to primary outcome measure. Alcohol use was also a significant covariate for depression as a secondary measure. There was a marked decline in primary outcome in subjects receiving HT & GI ($p < 0.0005$ Cohen's $d=0.85$) as well as a marked decrease in depression symptoms in the experimental group ($p < 0.0005$ Cohen's $d=0.70$)

Covariates were as described above and were accounted for in data analysis. Selection bias noted with low representation among racial groups. Dropout rate was 17%. Both the data analyst and principal investigator were blinded. Limitations of this study include no follow-up due to nature of military life, no adherence monitoring to patient directed intervention of listening to CD at home. Based on these variables this study has a high quality of evidence for HT with GI (EPHPP, 2009).

Another limitation of this study is the intervention was combined therapies, which weakens the study. Recommendations are more studies of HT in the military setting for symptoms of PTSD and depression. This is a strong recommendation because there is a high

quality of evidence, and there are also statistically significant findings (Djulgovic et al., 2009). Studies in this population with an isolated intervention of just HT are recommended.

Jain and Mills, 2010

Jain and Mills (2010) performed a systematic literature review with best-evidence synthesis and quality assessment of biofield therapies. Inclusion criteria were English published articles that had been peer reviewed, client and biofield practitioner in same room, and quantitative measures used. Exclusion criteria was distance healing, multiple modalities in the same intervention, non-human, purely descriptive, or non-published. Jadad scoring was used for quality assessment. Sixty-six studies were found and had multiple methods with multiple interventions in multiple populations. The findings were split in half with four studies reporting significant decrease in anxiety and improved mood after biofield therapy, and four studies reporting no significant results. Eighty-five percent of the studies also reported psychological or self-report outcomes. Eight of the studies reviewed used mood variables like depression and anxiety as measures, and conflicting results are reported.

Publication bias may exist because it is possible that researchers were not able to identify all existing studies. Data collection method was comprehensive. Limitations of the study are based on limitations of reviewed studies and inconsistency in interventions among studies reviewed. All of these variables contribute to an overall moderate quality of evidence (EPHPP, 2009).

A recommendation is made for more studies done on biofield therapies with stronger methodology. Of the studies identified no statistically significant improvements in depression and/or anxiety symptoms were isolated and reported in this review. Based on the quality of

evidence and the findings from this study this is a strong recommendation (Djulbegovic et al., 2009).

Bardia, Barton, Prokop, Bauer, and Moynihan, 2006

Another systematic review was performed by authors Bardia, Barton, Prokop, Bauer, and Moynihan (2006). Jadad scoring was used to evaluate 18 randomized control trials that had management of cancer pain as an outcome. Seven studies were ranked as high quality studies, three moderate level, and eight poor quality studies. All RCT's that had complementary alternative therapies as an intervention for cancer pain in humans were included. One limitation is that of the 18 studies, only four had performed a power analysis. No confounding variables were noted.

Limitations of this study are probable publication bias as extraction methods were not clearly defined, difficult to extract reliable data based on poor quality findings, and no studies were evaluated that didn't have pain as a primary outcome so many others may exist for different outcomes. All of these variables contribute to an overall moderate quality of evidence (EPHPP, 2009).

Recommendations made are that future research should focus on methodology. This is a moderate recommendation because of the limitations of the studies reviewed for this systematic review (Djulbegovic et al., 2009). This could be a strong recommendation if the researchers had reported their extraction methods clearly and attempted to minimize publication bias.

Judson, Dickson, Argenta, Xiong, Geller, Carson, Ghebre, Jonson, and Downs, 2011

Judson et al. (2011) conducted a prospective, randomized controlled pilot study of 43 women with ovarian cancer requiring chemotherapy. Intervention consisted of 20 women in the control arm receiving treatment as usual (TAU), and 23 women in the treatment arm that

received HT with massage and clinical hypnosis. Each patient received HT during chemotherapy treatment after massage therapy for 30 minutes. Inclusion criteria consisted of having newly diagnosed ovarian cancer and scheduled to receive six or more sessions of chemotherapy. Exclusion criteria consisted of having no prior cancers other than non-melanoma skin cancer, being pregnant or lactating, active substance abuse, schizophrenia, or receiving chemotherapy in the past. Quality of life, chemo toxicity levels, and immunological profiles were measured multiple times during the intervention phase. Laboratory data measured were CD4, CD8, salivary IgA, and natural killer cell (NK) counts. Quality of life was assessed using FACT-O and Mental Health Inventory before chemotherapy sessions one, three, and six. Patients were reassessed after six months. Outcome of interest to this practice inquiry is quality of life changes from intervention as some impact on mental health may be present. Sample size of this study was (n=43), and no power analysis was performed. Results found that women in the treatment group had consistently higher CD4, CD8, and NK cells, but this level did not reach statistical significance. The treatment was well tolerated and found not to interfere with chemotherapy.

The homogenous sample suggests a selection bias. One confounding variable is that the type of cancer the participant was experiencing was not addressed. Additionally, medications such as narcotics and antiemetics that may have been taken during the intervention were not accounted for. There was no blinding and no placebo in the control arm. No one withdrew from the study. Because of all these variables this study has an overall quality of poor (EPHPP, 2009).

Limitations of this study include combined therapies so establishing efficacy of single therapy was not demonstrated. Recommendations are that HT and massage are feasible for adjunct care in women with gynecological cancers (Djulgovic et al., 2009). This is a weak

recommendation because of the quality of evidence presented and because the intervention was mixed therapies.

Weze, Leathard, and Grange, 2007

The research team of Weze, Leathard, and Grange (2007) conducted a survey based, qualitative and quantitative study with 147 participants that had symptoms of depression and/or anxiety. The intervention consisted of four one-hour treatments of gentle touch. This study is included with biofield studies because the nature of touch was not described as HT, TT, or Reiki. Inclusion criteria were willingness and ability to complete four sessions and fill out a survey, be older than 16 years old, and have a diagnosis of anxiety, depression, or other mental health disorder. Exclusion criteria were having previous treatment at location, failure to complete the four sessions, and failure to complete the survey. The sample size was 147 participants. This study had a significant selection bias as all participants were recruited from the same facility. No demographic or population data other than a diagnosis of mental illness is identified in the study so it is difficult to assess for confounding variables.

Because this study is qualitative in nature the quality assessment tool described by Cessario, Morin, and Santa-Donato (2002) was used. The methodological congruence is not clearly documented, nor is procedural and ethical rigor clearly defined in the study. In addition, analytical preciseness and confirmability are not clearly defined which contribute to an overall poor quality of evidence (Cessario, Morin, & Santa-Donato, 2002).

Findings report that the participants with the worst symptoms were helped the most and recommend further studies specifically for biofield therapy in the mental health setting. No specific results of the study are reported. This is an extremely weak recommendation and therefore has minimal to no application to the clinical setting (Djulgovic et al., 2009).

Collinge, Wentworth, and Sabo, 2005

In 2005 researchers Collinge, Wentworth, and Sabo conducted a non-controlled pilot study with 25 participants who were already getting psychotherapy. The intervention was massage therapy (n=19), and Healing Touch (n=1). The intervention consisted of one of these biofield therapies in conjunction with psychotherapy in a mental health clinic. Clients were assigned to a biofield therapy based on the judgment of the researchers, who were also clinicians at the mental health facility. The mean number of sessions was five per person. Each person completed at least two sessions. Therapies used in study were Reiki (n=2), acupuncture (n=3), massage therapy (n=19), and Healing Touch (n=1). All patients had a history of trauma, and outcome indicators were based on patient satisfaction with treatment and improved trauma symptoms. Interview data were collected prior to intervention, and self-report instruments were completed post intervention via an investigator-generated Likert scale. The sample size was 25 participants with a mean age of 42 and mean mental health treatment of 7.4 years. Diagnoses of the sample included PTSD (n=10), depression (n=9), anxiety disorder (n=3), or a dual diagnoses (n=3). Perceived helpfulness of therapy was significantly associated with the number of sessions received ($r=0.46$, $p=0.02$ two tailed).

A selection bias existed because the population was 80% women. No confounders reported but the homogenous sample and non-equal diagnostic groups suggest confounders existed. The study design is of poor quality. Limitations of this study include arbitrary quantitative data and inconsistent interventions across the groups. All of these variables contribute to an overall poor quality of evidence (EPHPP, 2009).

All patients were satisfied with treatment and no adverse reactions were reported. A recommendation is made for integrating CAM into mental health care. However, because this

recommendation is based on poor evidence quality it is a weak recommendation (Djulbegovic et al., 2009).

Conclusion

In summary, many studies have evaluated HT in a variety of modalities, but there are no conclusive studies treating psychiatric symptoms with biofield therapies in a primary care setting. However, symptoms such as depression and anxiety have been improved through HT and other biofield therapies as evidenced by current research. We know that depression and anxiety are major morbidity concerns in the United States, and patients frequently seek help for their symptoms in a primary care setting.

CHAPTER 4: DISCUSSION

This chapter describes a synthesis of findings from the critical analysis. Commonalities, strength of recommendations, and limitations are discussed. While there is evidence that Healing Touch (HT) can provide symptom improvement in depression and anxiety, the strength of the recommendations are limited.

Interpretation of Evidence

Commonalities of Studies

Biological markers were sometimes used as outcome measurements. In many cases, the studies using biological outcome measurements such as vital signs, cortisol levels, or other laboratory data (Wilkinson et al., 2002; Judson et al., 2011; Papathanassoglou & Mpouzika, 2012) also demonstrated higher quality of evidence. Studies that reported improvements in biological markers (Judson et al., 2011; Zolfaghari et al., 2012) provided higher strength of recommendations for the benefits of biofield therapy.

Many studies used the State Trait Anxiety Tool as an outcome measure (Rexilius et al., 2012; Hardwick et al., 2012; Maville et al., 2008; Potter, 2007). All studies except Potter (2007) achieved statistically significant changes in anxiety on the STAI across the biofield therapies. Potter (2007) did note an improvement in anxiety symptoms but improvements were not statistically significant. The Hardwick et al. (2012) study has high quality of evidence with strong recommendations for practice. This study used the STAI scale to measure anxiety after HT was given and found a reduction in anxiety ($P=0.045$) evidenced by more relaxed state, and feelings of calmness (Hardwick et al., 2012).

Many other studies used different depression tools as quantitative outcome measures. Potter (2007) did not find any statistically significant findings. Only one high quality study had statistically significant findings for depression using the Beck Depression Inventory II (BDI-II) (Shore, 2004), with outcomes noted such as reportedly less stress and fatigue symptoms that were present a year later. Two moderate quality studies did have statistically significant improvement in depressive symptoms as well (Jain et al., 2012; Rexilius et al., 2012) noted by reduction in stress related to PTSD and improvement in sleep and overall mood. Jain et al. (2012) utilized the BDI-II tool and Rexilius et al. (2012) used the Center for Epidemiological Studies (CES-D) scale for depression measurement.

Strengths of Studies

Studies that were analyzed as having higher quality had several methodological strengths in common. Some of the higher-quality studies (Shore, 2004; Jain et al., 2012) utilized qualified practitioners to deliver the intervention, and some studies (Shore, 2004; Jain et al., 2012) utilized blinded subjects. None of the practitioners in any study were blinded. A few studies utilized appropriate sample sizes based on power analyses, particularly in the randomized control trials (Shiflett et al., 2002; Shore, 2004; Potter, 2007). Finally, nearly all the studies recommended further studies for efficacy of HT and other biofield therapies.

Limitations of Studies

The major limitation among most studies is the lack of robust quality. There were a number of common methodological issues. Most of the studies had strong selection biases such as self-selection for participation (Van Aken & Taylor, 2011). Many studies had confounding variables such as inconsistency with therapies, therapeutic techniques, and inconsistent experience levels among HT practitioners. Even when comparing HT practitioners with the same

educational background and years of experience, the spiritual and personal nature of biofield healing may be difficult to control. Anderson and Taylor identify that many biofield practitioners have no research expertise, therefore the level of scientific rigor cannot be addressed (2011). Without scientific justification, it is difficult to implement biofield therapies into mainstream health care (Anderson & Taylor, 2011).

Benefits of Healing Touch

Through this critical analysis, it appears that HT exerts a positive influence physiologically, as noted by improvements in biomarkers. Furthermore, HT appears to provide some symptom relief of anxiety and depression (Wilkinson et al., 2002; Van Aken & Taylor 2010; Weze et al., 2007; Zolfaghari et al., 2012; Woods, Beck, & Sinha, 2009). Healing touch is cost-effective, non-invasive, relatively easy to incorporate into primary care, is time-effective, and certification is relatively easy to obtain (Healing Touch International, 2012). Although research is limited, no adverse effects were found in implementing HT, or any of the biofield therapies, for a variety of symptoms. Some studies suggest a strong placebo effect for biofield therapies, but regardless of mechanism of action, many people may find relief from symptoms of anxiety or depression through HT and the other biofield therapies (Weze et al., 2007).

Disadvantages of Healing Touch

One of the disadvantages of HT is it requires a good deal of training and commitment on the part of the practitioner (Healing Touch International, 2012). HT is not a common therapeutic modality; hence patients and primary care providers unfamiliar with HT may initially consider it with suspicion. Thirty-minute sessions are recommended for quality care, yet it can be difficult to bill for healing touch in the primary care setting. Although HT has been used for decades and has been studied by researchers, quality evidence of efficacy continues to be lacking.

Limitations of Practice Inquiry

Limitations of this practice inquiry exist. Only 23 studies were found that met inclusion criteria. The possibility exists that some studies were not available in print, or not available in accessed databases exist. The author of this practice inquiry is also a very novice researcher, and this was her first critical analysis of the literature. Although she spent much time in dialogue with her practice inquiry chair, no other researcher verified the results of the critical analysis. As a result of her naïve status more limitations may exist she is not aware of.

Conclusion

In conclusion, HT is an encouraging adjunct to symptoms of depression and anxiety in primary care. A clinical practice protocol can help guide the primary care provider to incorporate HT into practice. Chapter 5 outlines a Clinical Practice Protocol.

CHAPTER 5: HEALING TOUCH CLINICAL PRACTICE PROTOCOL

A clinical practice protocol was the chosen method to disseminate information for this practice inquiry. A clinical guideline is typically developed and agreed upon by recognized authorities and includes diagnostics and screening methods (Singleton & Levin, 2008). In comparison, a clinical practice protocol can be written by nurse practitioners and must represent the best, most current evidence (Singleton & Levin, 2008). A clinical practice protocol may be incorporated into a guideline as an algorithm or decision tree, and both the protocol and guidelines need frequent updates. A clinical practice protocol is specific to one diagnostic situation, such as a patient with mild to moderate depression who needs more intervention than his antidepressant medication (Carr, 2000). For the purpose of this paper, this clinical care protocol is designed to assist the primary care provider in evaluating the patient with depression and anxiety in order to make an evidence-based decision whether or not to recommend Healing Touch (HT) as an adjunct therapy. The clinical practice protocol is presented in Appendix C. A decision tree that can be used in clinical practice by primary care providers is presented in Appendix D.

Purpose

The purpose of this clinical practice protocol is to recommend a best practice model using evidence based practice, suggesting HT to treat symptoms of depression and anxiety in a primary care setting, and to provide a decision tree for implementing HT as an adjunct therapy by primary care providers. The evidence presented in the literature review of this project concludes that although there is mixed results and minimal compelling clinical application of HT, findings are substantial enough to make a recommendation for HT as an adjunct therapy for symptoms of depression and anxiety in the primary care setting. It is not to say that a person with significant

mental illness or a cognitive disorder may not benefit from HT, but this clinical care protocol has been focused to recommend HT for only depression and anxiety as those were the outcomes researched and identified in this project.

Immediate Referral

This clinical practice protocol includes criteria for making an immediate referral for mental health evaluation to the nearest Emergency Department or psychiatrist for the following events: in the case of a suicidal patient (behavior, threats, or gestures), a homicidal patient (behavior, threats, or gestures), psychosis with alterations in thought processes or perceptions (delusions, hallucinations, paranoid thoughts) (Allen, Currier, Carpenter, Ross, & Docherty, 2005).

Clinical Presentation

It is important to gather and/or review a comprehensive history before recommending HT as an adjunct therapy in the primary care setting. The history of present illness should help to elicit physical, emotional, and cognitive symptoms and pertinent negatives. Included in this review should be past medical, family, and social history of the patient (Fortin, Dwamena, & Smith, 2013). A family history of psychiatric illnesses such as depression, anxiety or suicide is pertinent. Personal psychiatric history such as previous anxiety and/or depression, hospitalization for psychiatric reasons, and any psychotropic medication history, should be discussed (Fortin, Dwamena, & Smith, 2013). In addition, risk factors such as recent trauma, illness, or stressors should be evaluated (Trangle et al., 2012). Other information to elicit from the patient includes the chronology of symptoms and how symptoms are affecting the patient's daily functioning (Lyness, 2013). Finally, elicit the patient's previous experiences with complementary or alternative therapies such as biofield, acupuncture, or herbal remedies, and his or her overall

experience with these therapies (Trangle et al., 2012). This will assist the primary care provider in evaluating how open to HT the patient may be. This information from a comprehensive evaluation is helpful when deciding on a treatment trajectory with a patient presenting for depression or anxiety, as the primary care provider will recognize the continuous interaction within the patient's environments and how it contributes to his or her overall health (Fortin, Dwamena, & Smith, 2013).

In addition to a comprehensive history, all medical causes of anxiety or depression should be ruled out before any psychiatric treatment is initiated (Stern, Rosenbaum, Fava, Biederman, & Rauch, 2008). For example, complaints of fatigue or abdominal pain may stem from either a psychiatric or physical etiology (DSM-IV-TR, 2000). Substance use including alcohol, tobacco, and illicit drug use should always be considered (DSM-IV-TR, 2000). A review of systems includes pertinent questions such as fatigue, malaise, difficulty sleeping, weight changes, changes in hearing or vision, respiratory concerns such as shortness of breath or dyspnea, cardiac complaints such as palpitations, discomfort, murmurs, arrhythmias, or dyspnea; any abdominal pain with or without nausea, vomiting, diarrhea, constipation, or GERD symptoms; any genitourinary complaints, arthralgias or myalgias, neurologic concerns such as numbness, tingling, or weakness; and psychiatric complaints including mood changes, suicidal or homicidal thoughts, and hallucinations (Goldman & Schafer, 2012).

The provider should be aware that a mental illness diagnosis is extremely difficult for patients because of the stigma, medication side effects, and symptoms (Fischer & Buchanan, 2013). Furthermore, by establishing a therapeutic, compassionate relationship with the patient, the primary care provider can be a source of education and support. The primary care provider may use a patient-centered interview that helps focus on both chief complaint and emotions

surrounding the patient's concern (Fortin, Dwamena, & Smith, 2013). Additionally, through the therapeutic relationship, the primary care provider will be better positioned to help identify common barriers to mental health care such as lack of finances, inadequate access to care, and polypharmacy (Koch & Scott, 2012).

Described below are subjective and objective presentations of the patient with a depression or anxiety disorder. The purpose of this description is to assist the primary care provider in making an appropriate decision regarding HT if indicated. Included in this section is a discussion of recommended laboratory tests that may be ordered to help rule-out medical etiologies.

Subjective Findings

The patient with depression and/or anxiety may present in the primary care setting with symptoms of sadness, fatigue, depressed mood, feeling guilty or worthless, or feeling anxious (DSM-IV-TR, 2000). The patient may also have had traumatic experiences and symptoms of post-traumatic stress disorder as described in Chapter 1 of this paper. Other less specific complaints may arise, and the primary care provider should have a high index of suspicion for depression and anxiety when a patient has vague physical complaints with no known underlying cause, such as abdominal pain (Fortin, Dwamena, & Smith, 2013).

Objective Findings

Next a comprehensive physical exam should consist of pertinent positives and negatives (Bickley & Szilagyi, 2009). Also included in the physical exam is a constitutional assessment that includes first impressions and appropriateness of dress, mood, and physical presentation. The primary care provider will gather information in regards to all major systems (Goldman & Schafer, 2012).

Of particular importance in this care protocol is the psychiatric assessment. Details such as previous psychiatric history, past and current medications, and any alternative treatments used would have been gathered in the history taking piece of the visit (Stern et al., 2008). The patient's appearance should be considered from the perspective of apparent age, posture, nutritional status, personal hygiene, grooming as a reflection of self-esteem, and behaviors such as activity level and mannerisms. Consider the patient's engagement with the practitioner, eye contact, and speech patterns. Additional components of the psychiatric exam should include mental status, mood and affect, memory, thought process and content, judgment and insight. The provider should ask about suicidal thoughts, delusions, or hallucinations (Stern et al., 2008). Performing a detailed psychiatric exam is imperative to obtain an accurate diagnosis (Fisher & Buchanan, 2013).

Laboratory Data

In order to rule out metabolic or medical reasons for psychiatric symptoms, the primary care provider should make an educated decision to order certain lab values when indicated (Lyness, 2013). A complete blood count (CBC) would help to rule out infectious process, hematologic problems, or anemia which could cause altered mental status and fatigue, respectively. Renal and hepatic function and electrolyte imbalances should be considered not only to rule out causes but to ensure safety of medication administration (Lyness, 2013). Low Vitamin D and B12 levels have been implicated in depression and assessing these values may be helpful (Lyness, 2013). Blood alcohol and a urine toxicology screen are important to establish symptoms from illicit drug use or intoxication (Slade, 2007). Finally, screening for hypo- or hyper- thyroidism by obtaining a TSH may be done, as abnormal thyroid function could cause mood disturbances (Lyness, 2013). A list of normal lab values is indexed in Appendix E.

Diagnosis and Evaluation

Once medical causes have been ruled out, a primary care provider should consider a mood disorder in any patient that has repeating complaints, in particular fatigue, pain, feeling overwhelmed, or insomnia (Carey, 2010). As described in Chapter 1, the symptoms of depression vary between patients, but typical symptoms include sadness, anxiety, irritability, or loss of sense of pleasure. Depression is also manifested with physical symptoms such as anorexia, insomnia, or trouble with concentration or libido (Lyness et al., 2009). Signs and symptoms of anxiety also vary, and are a common co-occurring disorder with depression. Full diagnostic criteria is also described in Chapter 1 but can present as symptoms of restlessness, fatigue, difficulty concentrating, irritability, muscle tension, and/or sleep disturbances (DSM-IV-TR, 2000).

As described in Chapter 1 many screening tools exist. Commonly used tools for depression include the Beck Depression Inventory II (BDI-II), the BATHE technique, and Patient Health Questionnaire 9 (PHQ-9). For anxiety common tools utilized include the State Trait Anxiety Inventory (STAI) and the Generalized Anxiety Disorder Scale (GADS) that are also discussed in Chapter 1 under screening tools. However, it is important to consider these screening tools as only one component of the diagnosis. The most significant information and understanding come from the words of the patient, elicited through the interview (Trangle et al., 2012). Once a diagnosis is made and physical causes of symptoms are ruled out, the primary care provider may elect to recommend HT as an adjunct to therapy. As discussed in Chapter 1, depression and anxiety are often co-morbid with other medical illnesses such as cancer, diabetes, asthma, and many more (Carey, 2010). These are not reasons to exclude HT for the patient as HT

may help with other associated symptoms such as pain and stress in these conditions (Hardwick et al., 2012).

Clinical Treatment Guidelines

The most current guidelines should direct the treatment plan for depression and anxiety. A comprehensive treatment plan for depression will include medications such as selective serotonin reuptake inhibitors (SSRI's) or other antidepressants at the discretion of the primary care provider (Trangle et al., 2012). In addition, patient education, self-management, and using a collaborative care model should be initiated (Trangle et al., 2012). Psychotherapy such as cognitive-behavioral therapy is recommended, as well as complementary alternative treatments (Trangle et al., 2012). Finally, close follow-up, including evaluation of the patient's response to treatment is imperative (Trangle et al., 2012). The treatment for anxiety is similar to depression in that a collaborative approach with psychotherapy and medications are recommended (McIntosh et al., 2011).

If a primary care provider elects to recommend HT for a patient, it is recommended to begin 1–2 sessions of at least 30 minutes in length for a minimum of eight weeks to achieve a therapeutic effect. This recommendation is based on recommendations for psychotherapy, which is a minimum of 8-10 weeks (Lyness, 2013). After eight weeks of treatment the primary care provider should re-evaluate symptoms of depression and anxiety by the same tool used for screening. If no change is present in symptoms, the primary care provider, based on discussion with the patient, may elect to either increase frequency or try an alternative adjunctive therapy (Trangle et al., 2012) See decision tree for guidelines, Appendix D.

Health Promotion and Education

Health promotion and education are important pieces of treatment planning for patients. In the case of anxiety the patient must be educated that his or her symptoms are not due to a medical condition, and treatment expectations should be clear (Ebell, 2008). In the case of depressive disorders the following health promotion should be emphasized: lifestyle modification to reduce stressful activities and promote physical and mental health, development of problem-solving skills, planning social and physical activities, and exploring self-efficacy (Gelenburg et al., 2010).

Collaborative planning with the patient and family of the patient is important to prevent relapse of symptoms, and to increase treatment compliance (Gelenburg et al., 2010). Education for the patient should include the key point that HT is an adjunct therapy and should be used in combination with other prescribed therapies by their primary care provider. Like antidepressant medications, therapeutic effects of HT may take at least four to six weeks (Healing Touch International, 2012). Not all symptoms of mental illness will respond to medications or to HT. Depression can be a chronic illness, therefore a specific plan of action on how to deal with relapse should be discussed, in writing, with patient and primary care provider (Gelenburg et al., 2010). Suicidal thoughts and worsening symptoms of both depression and anxiety should be addressed at each visit, as well as efficacy of both treatment as usual and HT interventions (Gelenburg et al., 2010).

Conclusion

In conclusion, HT can be an appropriate adjunct to treatment of depression and anxiety in the primary care setting. A primary care provider can make this recommendation when the

patient is appropriately managed based on current guidelines. In addition, a patient is an excellent candidate if he or she is open to biofield therapies.

APPENDIX A:
HEALING TOUCH SYNTHESIS TABLE

Appendix A

	First Author, year	Design	Data collection method	Sample size	Statistical significance	Outcomes	Polit & Beck level of evidence	EPHPP strength
Healing Touch Studies	Hersch 2009	SR	LR	22	none reported	counseling most beneficial, HT least beneficial	1	High
	Anderson 2011	SR	LR	5	none reported	moderate studies found	1	Moderate
	Hardwick 2012	QE	VAS, STAI	41	Statistically significant decrease in anxiety ($p = 0.045$)	HT recommended as adjunct for pain and anxiety	4	Poor
	Maville 2008	QE	physiologic measures, STAI	30	HR and Temp decreased significantly ($t[25] = 5.19, P < .001$ and $Z = 3.08, P = .002$), state anxiety decreased ($t[29] = 7.85, P < .001$).	HT contributes to decreased anxiety and positive physiological changes	4	Poor
	Wilkinson 2002	MM	sIgA concentrations in saliva, qualitative questionnaires	22	Statistically significant decrease in stress reduction ($p = 0.003$), and IgA levels	HT is clinically significant	4	Poor
	Tang 2010	QE	visual analog scales and heart rate variability	22	SS decrease in negative symptoms ($p=0.01$) and improvement in positive symptoms ($p=0.004$).	HT lowers stress levels	4	Poor
	Rexilius 2002	QE	DDF, BAI, CES-D, MFI-20, SBS, PSQ	36	statistically significant decrease in anxiety ($p= 0.004$) & depression ($p=0.002$) for massage not HT.	adjunct therapies are feasible in oncology settings	4	Poor
	Van Aken 2010	CS	case studies, HEALTH tool	15	none reported	HT on self can decrease recurrence of depression	6	Poor
	Wardell 2006	MM	pain inventory & profile of mood states, DSLS, VAS, CES-D, interviews	12	none found	some improvement in QoL and depression but not statistically significant	4	Poor

Therapeutic Touch Studies	First Author, year	Design	Data collection method	Sample size	Statistical significance	Outcomes	Polit & Beck level of evidence	EPHPP strength
	Woods 2009	RCT	mABRS, ELISA	64	significant decrease in restlessness ($p=0.03$), & variability of salivary cortisol levels (<0.0001) across time periods	agitation and stress secondary to dementia can be reduced with TT	2	High
	Zolfaghari 2012	RCT/QE	physiologic measures	69	significant decrease in average VS ($p<0.001$) and cardiac dysrhythmias ($p<0.05$)	more studies warranted	2	High
	Papathanassoglou 2012	LR	LR	11	none reported	no concrete conclusion to efficacy based on discrepancies between studies	5	Moderate

Reiki Studies	First Author, year	Design	Data collection method	Sample size	Statistical significance	Outcomes	Polit & Beck level of evidence	EPHPP strength
	Shore 2004	RCT	BDI, Beck Hopelessness, and Perceived Stress	46	1 vs 3, p=0.004. 2 vs 3, p=0.005. 1 vs 2 no significance. Results similar in all measures	Effects of Reiki remained after 1 year	2	High
	Shiflett 2002	RCT	FIM, CES-D	50	none found	No clinically useful findings	2	High
	Lee 2008	SR	LR	9	none reported	Reiki safe, no adverse reactions. No compelling evidence	1	Moderate
	Potter 2007	RCT	STAI, CES-D, HADS	35	none found	Possible improvement in depression and anxiety but not statistically significant	2	Moderate
	Birocco 2012	MM	VAS and description of physical feelings	118	Significant decrease in anxiety (P <.000001)	Recommended in hospital setting for adjunct therapy	4	Poor

Other Biofield Studies	First Author, year	Design	Data collection method	Sample size	Statistical significance	Outcomes	Polit & Beck level of evidence	EPHPP strength
	Jain 2012	RCT	PCL, BDI-II	123	statistically significant decrease in both PTSD symptoms: Cohen's $d=0.85$ & depression symptoms: Cohen's $d=0.70$	Marked decline in PTSD & depression symptoms	2	High
	Jain 2010	SR	LR	66	none reported	strong evidence pain is decreased with BT, moderate evidence anxiety is decreased	3	Moderate
	Bardia 2006	SR	LR	18	none reported	future research should focus on methodology, no adverse events reported	1	Moderate
	Judson 2011	RCT	lab measures, QOL, mental health inventory	43	none found	HT recommended as adjunct for gynecological cancer therapy	2	Poor
	Weze 2007	QE	VAS, EuroQoL	146	stress, anxiety, depression decreased $p<0.0004$	gentle touch ad adjunct for psychiatric disorders	4	Poor
	Collinge 2005	QI	investigator generated instrument & interview data	25	number of therapies improved feeling helped ($r=0.46$, $p=0.02$ two tailed)	CAM in mental health may be a helpful adjunct	6	Poor

KEY

BAI: Beck Anxiety Inventory
BDI: Beck Depression Inventory
BDI-II: Beck Depression Inventory-II (revised)
BT: biofield therapies
CAM: Complementary Alternative Medicine
CES-D: center for epidemiological studies scale
CS: Case Study
DDF: Demographic Data Form
DSL: Diener Satisfaction with Life Scale
ELISA: Enzyme-linked immuno sorbent assay
FIM: functional independence measure
HADS: hospital anxiety and depression scale
HR: Heart Rate
HT: healing touch
LR: literature review
mABRS: modified aggression behavior scale
MFI-20: Multidimensional Fatigue Inventory-20
MM: mixed method design
PCL: Military PTSD checklist
PSQ: Post-study questionnaire
QE: quasi-experimental design
QI: qualitative interview
RCT: randomized control trial
SBS: Subjective Burden Scale
sIgA: secretory immunoglobulin-A
SR: systematic review of randomized control trial
STAI: state-trait anxiety inventory
TT: therapeutic touch
VAS: Visual Analog Scale

APPENDIX B:
QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

Very likely

Somewhat likely

Not likely

Can't tell

(Q2) What percentage of selected individuals agreed to participate?

80 - 100% agreement

60 – 79% agreement

less than 60% agreement

Not applicable

Can't tell

B) STUDY DESIGN

Indicate the study design

Randomized controlled trial

Controlled clinical trial

Cohort analytic (two group pre + post)

Case-control

Cohort (one group pre + post (before and after))

Interrupted time series

Other specify _____

Can't tell

Was the study described as randomized? If NO, go to Component C.

No

Yes

If Yes, was the method of randomization described? (See dictionary)

No

Yes

If Yes, was the method appropriate? (See dictionary)

C) CONFOUNDERS**(Q1) Were there important differences between groups prior to the intervention?**

- Yes
- No
- Can't tell

The following are examples of confounders:

- Race
- Sex
- Marital status/family
- Age
- SES (income or class)
- Education
- Health status
- Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design [e.g., stratification, matching] or analysis)?

- 80 – 100% (most)
- 60 – 79% (some)
- Less than 60% (few or none)
- Can't Tell

D) BLINDING**(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?**

- Yes
- No
- Can't tell

(Q2) Were the study participants aware of the research question?

- Yes
- No
- Can't tell

E) DATA COLLECTION METHODS**(Q1) Were data collection tools shown to be valid?**

- Yes
- No
- Can't tell

(Q2) Were data collection tools shown to be reliable?

- Yes
- No
- Can't tell

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

- Yes
- No
- Can't tell
- Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

- 80 -100%
- 60 - 79%
- less than 60%
- Can't tell
- Not Applicable (i.e., Retrospective case-control)

Adapted from <http://www.ehphp.ca/Tools.html>

APPENDIX C:
HEALING TOUCH CLINICAL PRACTICE PROTOCOL

Healing Touch Clinical Practice Protocol

INTRODUCTION

Title

Healing Touch for adjunct therapy for symptoms of depression and anxiety in primary care.

Bibliography

Harlow, C., & Sheppard, K. (2013). A critical analysis of healing touch for depression and anxiety. *Unpublished manuscript for The University of Arizona College of Nursing.*

Status

This is the first release of this protocol.

Purpose

The purpose of this protocol is to recommend a best practice model using evidence based practice, suggesting Healing Touch to treat symptoms of depression and anxiety in a primary care setting, and to provide a decision tree for implementing Healing Touch as an adjunct therapy.

Policy

This protocol will be reviewed annually to ensure the most current evidence is being practiced in the primary care setting.

Immediate Referral

Immediate referral for mental health evaluation to the nearest Emergency Department or psychiatrist for the following events:

In the case of a suicidal patient (behavior, threats, or gestures)

Homicidal patient (behavior, threats, or gestures)

Psychosis with alterations in thought processes or perceptions (delusions, hallucinations, paranoid thoughts).

Symptoms of severe depression.

Background and Definition

According to the National Center for Complementary and Alternative Medicine, complementary alternative medicine (CAM) is defined as, “a group of diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine” (USDHHS, 2012). CAM includes many different types of healing therapies, including the biofield therapies (USDHHS, 2012). The term biofield describes the concept that humans are surrounded by energy fields and this energy can be manipulated or changed for the purpose of healing. Healing Touch is one of the biofield therapies. Healing Touch is a treatment modality used by specially trained practitioners who are often nurses. Healing Touch therapy consists of either light touch or near touch and the practitioner uses mindful meditation often during sessions (Healing Touch International, 2012).

Patients seek complementary and alternative remedies for a variety of ailments, including mental health. (Shattell, Donnelly, Scheyett, & Cuddeback, 2011). Nearly 20 % of people who

used an alternative therapy in the past year also had one or more psychiatric disorders. Both anecdotal and research evidence has found that using Healing Touch for patients can not only reduce anxiety and stress, it can help support the life transition process, promote self-empowerment, and enhance spiritual development (Van Aken & Taylor, 2010). When compared to the high cost of treating mental illness, Healing Touch and other energy therapies are cost effective and have evidence supporting that treatment is effective enough to be inclusive (Vickers, 2008).

Pathogenesis

The pathogenesis of anxiety disorders, including PTSD, are unknown. However, theories exist that the mechanism has to do with modulation disruption in the central nervous system causing heightened sympathetic arousal. Different neurotransmitters have been implicated including gamma-aminobutyric acid (GABA), and serotonin. Other theories about anxiety disorders suggest environmental stressors are a causal agent, particularly in PTSD (Carey, 2010). Anxiety is a naturally occurring reaction to stress in humans, but can become out of hand when it is excessive and uncontrollable, deeming it a pathological disorder (Carey, 2010).

The pathogenesis of depression is also not completely understood, but emerging theories suggest stress, early life experiences, and genetic pre-disposition increase lifetime risk of developing major depressive disorder (Carey, 2010). Different parts of the brain that are thought to be involved with depression are the prefrontal cortex, hippocampus, hypothalamus, and amygdala. Like anxiety, neurotransmitters, such as serotonin and norepinephrine, also play a role (Carey, 2010).

CLINICAL PRESENTATION

A primary care provider needs to suspect a mood disorder in any patient that voices repeating complaints, in particular fatigue, pain, feeling overwhelmed, or insomnia (Carey, 2010).

Depression: The symptoms of depression vary between patients, but typical symptoms include sadness, anxiety, irritability, or loss of sense of pleasure. Depression is also manifested with physical symptoms such as anorexia, insomnia, or trouble with concentration or libido (Lyness et al., 2009).

Major Depressive Disorder, as outlined in the DSM-IV-TR manual, can be confused with other psychiatric and medical diseases so it is imperative the primary care provider is aware of the diagnostic criteria (Carey, 2010).

Diagnosis/Evaluation

One or more of the following screening tools can assist the primary care provider in making a recommendation for Healing Touch based on findings but should only be used in conjunction with a thorough history and physical including laboratory data. They are helpful in verifying a clinical assessment (Carey, 2010).

1. BATHE technique as described by Stuart and Libermann, 1993.

- Asking pointed questions about Background, Affect, Trouble, Handling, and Empathy to get patient to discuss emotions (Stuart & Libermann, 1993). Effective for assessing anxiety related conditions (Carey, 2010).
2. Beck Depression Inventory (BDI-II)
 - Score of 10 - 23 would be a candidate for Healing Touch (mild to moderate).
 3. Center for Epidemiologic Studies Depression Scale (CES-D)
 - Score of 16 or greater is diagnostic of depression according to DSM-IV-TR manual
 4. Patient Health Questionnaire 9 (PHQ-9)
 - Often used in primary care to evaluate depression.
 5. Generalize Anxiety Disorder Scale (GADS)
 - 7 point questionnaire
 6. Hamilton Anxiety Scale (HAS)

DIAGNOSTIC AND LABORATORY FINDINGS

Depression

Diagnostic Criteria for Major Depressive Episode (DSM-IV-TR, 2000): A diagnosis of major depressive episode can be given when: 5+ of the following symptoms have been present for at least two weeks, and at least one of the symptoms includes depressed mood or anhedonia.

- Feeling depressed, most of the day and most days over a two week period
- Marked anhedonia
- Anorexia or significant weight changes
- Insomnia or hypersomnia
- Psychomotor agitation or retardation
- Difficulty concentrating or making decision
- Fatigue and/or loss of energy
- Feeling worthless, excessively guilty, or loss of hope
- Thoughts of death or suicidal ideation

Some patients may not fit the diagnostic criteria for major depression, but may have a different type of depression. These types include:

- Seasonal affective disorder
- Postpartum depression
- Dysthymia (meets two or more criteria but not five)

Anxiety

Diagnostic Criteria according to DSM –IV-TR for Generalized Anxiety Disorder (Carey, 2010)
The focus of anxiety and worry is not confined to cognitive disorders, phobias, somatization disorders, or more extreme anxiety disorders such as eating disorders. The disturbance does not

occur exclusively during a mood disorder, a psychotic disorder, pervasive developmental disorder, substance use, or general medical condition. The anxiety, worry, or physical symptoms cause clinically significant distress or impairment in social or occupational functioning (Carey, 2010).

If a person has anxiety he or she will have excessive anxieties about events or activities. Criteria for diagnosing anxiety include at least three symptoms (listed below) that persist most days for at least 6 months.

- Restlessness or feeling on edge
- Easily fatigued
- Difficulty concentrating
- Irritability
- Muscle tension
- Sleep disturbances

Co-Morbidities

Patients with chronic illnesses are much more likely to have co-morbid anxiety or depression. Some of the more common associated chronic illnesses are: asthma, diabetes, cancer, heart diseases, multiple sclerosis, chronic obstructive pulmonary disease, and epilepsy.

A patient presenting with depression may also have anxiety symptoms, and these can be secondary to a depressive event or a comorbid anxiety disorder. Careful screening by the primary care provider is paramount.

Clinical Treatment Guidelines

See decision tree for guidelines, Appendix D

Health Promotion and Education

In the case of anxiety, patients must be educated that their symptoms are not because of a medical condition, and treatment expectations should be clear.

In the case of depressive disorders and/or anxiety the following health promotion should be emphasized:

- Lifestyle modification to reduce stressful activities and promote physical and mental health
- Problem-solving: work to develop problem-solving techniques and skills
- Planning social activities
- Planning physical activities
- Explore self-efficacy

Patient education

- Healing Touch is an adjunct therapy and should be used in combination with other prescribed therapies by their primary care provider.
- Therapeutic effects may take at least 4-6 weeks
- Not all symptoms of mental illness will respond to medications or to healing touch

- Depression can be a chronic illness; establish a plan should relapse occur

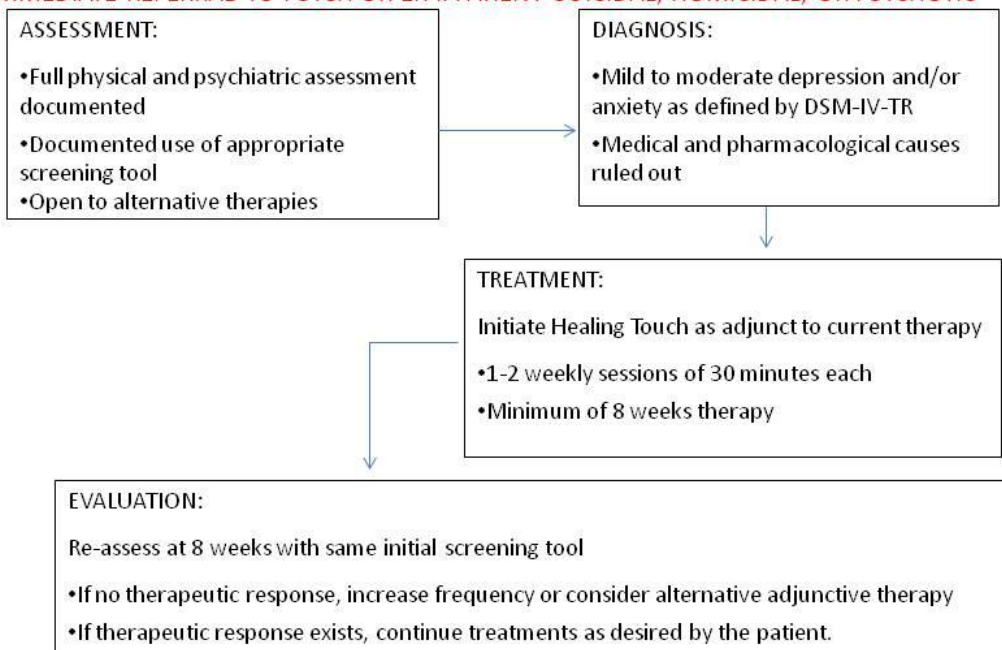
Monitoring and follow-up care

- Establish an agreement with the patient in advance, should symptoms of depression return
- Assess suicidality at every visit
- Assess for psychotic symptoms (delusions, hallucinations, paranoia) at every visit

APPENDIX D:
DECISION TREE FOR USING HEALING TOUCH

Decision Tree for Using Healing Touch

IMMEDIATE REFERRAL TO PSYCH OR ER IF PATIENT SUICIDAL, HOMICIDAL, OR PSYCHOTIC



APPENDIX E:
NORMAL LIMITS OF LABORATORY VALUES

NORMAL LIMITS OF LABORATORY VALUES

- WBCs: 3200 – 9800/mm³
- RBCs: 4.3 – 5.9 10⁶/mm³ for males, 3.5 – 5.0 for females
- Hemoglobin: 13.6 – 17 g/dl for males, 12-15 for females
- Hematocrit: 39% to 49% for males, 33% - 43% for females
- MCV: 76-100 μ m³
- MCH: 27-33 pg
- MCHC: 33-37 g/dl
- Platelet count: 130-400 x 10³/mm³
- TSH: 2-11 uU/ml
- ALT: 10-40 U/L in males, 8-35 U/L in females
- Alkaline phosphatase: 30-120 U/L
- AST: 0-35 U/L
- Creatinine: 0.6 – 1.2 mg/dl
- BUN: 8 to 24 mg/dL in males, and 6 to 21 mg/dL in females
- Glucose: 70 – 110 pg/ml
- Sodium: 135 – 147 (serum) mEq/L
- Potassium: 3.5 – 5 (serum) mEq/L
- Vitamin B12: 200 – 800 pg/ml
- Vitamin D: 16-65 pg/ml

APPENDIX F:
IRB REQUIREMENT DOCUMENTATION

From: Pasvogel, Alice
Sent: Tuesday, March 26, 2013 8:13 AM
To: Gluski, Amanda
Cc: Moon, Christina
Subject: graduation requirements completed

Amanda,
Christina Moon has completed graduation requirements related to human subjects.
Alice

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