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Utilization of therapeutic touch in clients diagnosed with chronic pain

Rosa Matonti
University of Nevada, Las Vegas

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UTILIZATION OF THERAPEUTIC TOUCH IN CLIENTS DIAGNOSED WITH CHRONIC PAIN

by

Rosa Matonti

Bachelor of Science
University of New Mexico, Albuquerque
1986

A thesis submitted in partial fullfillment
of the requirements for the degree of

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Rosa Matonti

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Mary Kathan
Examination Committee Chair

Penny Adams
Dean of the Graduate College

Susan R. Nichael
Examination Committee Member

Andrea L. Fyre
Examination Committee Member

Richard D. Tandy
Graduate College Faculty Representative

ABSTRACT

Utilization of Therapeutic Touch in Clients
Diagnosed with Chronic Pain

by

Rosa Matonti

Dr. Mary Koithan, Examination Committee Chair
Professor of Nursing
University of Nevada, Las Vegas

Chronic pain is one of the most pervasive and expensive health care problems in society today. Fibromyalgia and rheumatoid arthritis are chronic disease states which currently have no cure. A common complaint among these patients is constant and unremitting pain, which often worsens with inactivity. At this time treatment for both disease processes is essentially palliative, supportive and aimed at symptom relief.

A quasi experimental design was used to determine if there were any significant differences in pain perception between persons with FM or RA receiving therapeutic touch (TT) and a placebo treatment (PT). Sixty-one subjects served as their own control group. Using a vertical visual analogue scale, pain was measured pre-and post-treatment. It was noted that the data were skewed and had a bimodal distribution. Therefore, the nonparametric tests of Wilcoxon Ranks Tesst and the Chi Square 2X2 Test of Independence were done. The hypothesis, that patients diagnosed with FM and RA would demonstrate significant decreases in pain ($p<.05$) following TT when compared to PT, was not supported ($p=.082$).

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CHAPTER 1

INTRODUCTION

Fibromyalgia (FM) and Rheumatoid Arthritis (RA) are chronic disease states which currently have no cure. Chronic pain is a common complaint among clients with these disease processes. Often the pain is constant and unremitting. Treatment of the pain associated with these two disease processes is palliative and supportive.

Currently the treatment for FM consists of client education, tricyclic antidepressants, nonsteroidal antiinflammatory drugs, exercise, physical therapy, relaxation and stress management, with reassurance and support (Smeltzer, 1987). Treatments for RA consist of conservative medical or surgical interventions. Conservative treatment focuses on hot and cold packs, rest, exercise, physical therapy, antineoplastic medications, a diet high in calories and vitamins, corticosteroids, and antiinflammatory agents. Surgery is done to correct deformities or mechanical deficiency in the intermediate and or late stages (McCance & Heuther, 1994).

Background

FM affects 3.4% of females and 0.5% of males with an average incidence of 2% for the entire United States. The prevalence of the syndrome increases with age, with 7% of the population affected between 60 and 79 years of age. Conservatively, it is estimated

that FM affects three to four million people in the United States. FM can occur at any age, but the average age of onset is in the 40s (Bennett, Smythe & Wolfe, 1992; Simms, 1996).

RA is a chronic systemic inflammatory disease affecting 1% of the population. Rheumatoid arthritis affects women two to four times more often then males. It is most common between the ages of 20-50. (Gallez, 1996; Miller-Blair & Robbins, 1993). RA is the most common rheumatic disorder, the second being osteoarthritis, and the third is FM.

FM is a syndrome of diffuse aching, pain, and stiffness (especially in the morning), accompanied by multiple tender points on physical examination. Concomitant manifestations also present are sleep disturbances; irritable bowel or bladder syndromes; peripheral vascular instability, resembling Reynaud's phenomenon; and sensitivity to weather or temperature changes, with increased stress and activity level. Conventional laboratory tests and radiographic studies are usually normal in the absence of concomitant disease (Bennett, Smythe, & Wolfe, 1992; Simms, 1996; Slotkoff & Clauw, 1996). The most common complaints in those diagnosed with FM are memory loss, poor concentration, forgetfulness, and confusion (Slotkoff & Clauw, 1996).

RA involves an inflammation of the synovium which lines the joints and the tendon sheaths that pass over the joints. It is manifested clinically by malaise and fatigue followed by a symmetric pattern of joint inflammation, most often involving the wrists, hands, elbows, shoulders, cervical spine, hips knees, ankles and joints of the feet. The inflammation is characterized by stiffness and pain, especially in the morning after a

prolonged period of rest, a phenomenon known as "gelling" (Griedinger & Hellmann, 1995; Miller-Blair & Robbins, 1993). Diagnostically, the morning stiffness lasts greater than 30 minutes, and often the affected joint is warm, red, and swollen. Patients often present with flu-like symptoms, decreased energy levels, dry eyes, and mouth.

Currently, the treatment modalities employed for both FM and RA are palliative and supportive, with no known cure. Primary treatment modalities used for FM patients at this time are tricyclic antidepressants, education, exercise, hypnotherapy, electromyography biofeedback (EMG biofeedback), cognitive-behavioral treatment, acupuncture, and electroacupuncture (Simms, 1996). These modalities are not efficacious for all people diagnosed with FM nor are they consistently effective over time. Additionally, the medications often have uncomfortable side effects such as dry mouth, vivid nightmares, and daytime grogginess. Education helps patients understand their syndrome but offers little in the way of pain relief. Exercise has proven effective for many with FM and reduces the need for medications, but often patients do not continue with exercise in the long-term due to post-exercise worsening of symptoms (McCain, Bell, Mai & Halliday, 1988). Studies have shown that EMG biofeedback, cognitive-behavioral treatment, acupuncture, and electroacupuncture offer limited but costly assistance with symptom control in FM.

Treatment for those diagnosed with RA consists of conventional and unconventional therapies. The conventional medications used for this disease are analgesics, nonsteroidal anti-inflammatory drugs (NSAIDs), and disease modifying anti-rheumatoid drugs (DMARDs). Many patients are placed on a combination of all three

therapies (Rankin, 1995). Corticosteroids are also used but are not employed routinely due to their deleterious side effects. All therapeutic regimens in current use have potentially severe toxicity. Similar to FM, RA has no cure, and the goals of treatment are limited to maintaining function, decreasing pain, and minimizing joint damage.

Recent approaches to the treatment of RA have focused on nonconventional therapies such as: exercise, hydrotherapy, acupuncture, heat and cold, relaxation, and distraction (Hall, Skevington, Maddison & Chapman, 1996; Hayes, 1993; Simms, 1996). All of these therapies can be costly and require motivation from the patient. This motivation is often difficult to achieve due to the chronic pain and fatigue associated with RA. Exercise may very well be helpful in long term pain reduction, but exercise is limited due to the immediate pain experienced with exercise.

When treatment modalities of both FM and RA are assessed, it is evident that the side effects of the medications are less than desirable and other suggested therapies can be inconvenient and costly, with many insurance companies refusing reimbursement for unconventional or complementary therapies. Therefore, it is necessary to continue to search for alternative treatments in the care of persons with RA and FM. In particular, it is necessary to find inexpensive, easily used treatment modalities which can offer demonstrable and measurable alleviation of the suffering and pain endured.

Pain is an abstract concept which means different things to different people. Baquie (1989) states, "pain is individual" and that responses to pain depend on a unique combination of nerve fibers, perceptions and emotional makeup. Pain can affect a person emotionally, physically, and spiritually. One might say the person with pain is in a "state

of body, mind, and spirit disequilibrium" (Wright, 1987). Therefore, pain warrants a holistic approach to management, one in which the full spectrum of mind, body, and spirit is addressed. Therefore, modalities of healing which provide a more holistic approach to pain management may be more helpful than the conventional treatment modalities in the treatment of pain associated with FM and RA.

One such modality is therapeutic touch (TT) in which the whole person, mind, and spirit, are assessed and "treated", assisting the person in coping with pain. TT addresses more completely the entire experience of pain and suffering found with RA and FM. Other modalities such as relaxation, biofeedback or guided imagery only focus on one or two aspects of the mind, body, and spirit phenomenon.

TT seeks to offer a treatment for pain and suffering by engaging the energetic body, mind, and spirit in a relationship with self and others, seeking harmony in all of being and living. Quinn and Strelkauskas (1993) state "in TT the recipient and the practitioner are not separate but are interconnected and integral with the total universal energy field."

The mechanism of mind-body-spirit healing in TT is not clearly understood, however studies have illustrated the significant effects of utilizing TT in those with acute pain, anxiety, and psychoneuroimmunology defects.

Research has illustrated the effectiveness of TT for control of the pain experience (Baquie, 1989; Bowman, 1994; Davis, 1996; Owens & Ehrenreich, 1991). A number of studies suggest that TT is useful for those suffering from tension headaches (Keller & Bzdek, 1986; Meehan, 1993) and anxiety states (Gagne & Toye, 1994; Heidt, 1981;

Olson, Sneed, Bonadonna, Ratliff, & Dias, 1992; Parkes, 1985; Quinn, 1984; Simington & Laing, 1993). Four studies have also explored the use of TT in stress reduction (Kreiger, Peper & Ancoli, 1979; Olson, Sneed, Belladonna, Ratliff & Dias, 1992; Wirth & Cram, 1993). Wirth (1990) demonstrated the effectiveness of TT in wound healing, and Quinn and Strelkauskas (1993) illustrated how TT treatments create an increased sense of well-being. TT has also been shown to positively alter certain immunological parameters in both the subjects and practitioners and enhance physical healing (Quinn & Strelkauskas, 1993). It may suggested, therefore, that TT has the potential to alter the pain experience in persons with RA and FM utilizing a method which focuses on mind-body-spirit healing, exploring and enhancing relationships, and decreasing the inflammatory process associated with pain in both conditions. Furthermore, TT offers a potential therapeutic modality which has few documented deleterious side effects and little associated ongoing health care costs.

Problem Statement

Today, patients diagnosed with FM and RA often find themselves in debilitating pain. Treatment of chronic pain associated with FM and RA is generally palliative and supportive and aimed at only symptomatic relief. Additionally, there are numerous deleterious side effects and distracting features associated with current treatment modalities. TT is a noninvasive, nonpharmological treatment modality. TT has been shown through multiple research studies to be effective in chronic pain, depression, and anxiety. It can be administered by a family member for the patient in the privacy of their own home and is not costly, nor does it have deleterious side effects. Additionally, TT

can create an emotional bond between the family member and the patient. TT may well be a viable alternative in the treatment of chronic pain associated with FM and RA, but no study has yet, addressed this modality.

Purpose of the Study

Therefore, the purpose of this study was to determine the effectiveness of TT as a nonpharmological intervention to treat the chronic pain associated with FM and RA. This study evaluated the differences in pain perception in those persons with FM and RA when receiving TT and when receiving a placebo treatment.

Significance of the Study

This study will contribute to a growing body of literature concerning nurses' utilization of TT as a nonpharmalogical treatment and its efficacy in treating those afflicted with the chronic pain of FM and RA. The study attempted to provide beginning validation that TT is an appropriate nursing intervention for those afflicted with chronic pain associated with FM and RA.

TT is an independent nursing intervention used in multiple settings for a variety of purposes. It is noninvasive, inexpensive, and is an energy modality which incorporates the mind-body-spirit healing in its premise. TT offers a holistic alternative to the patient and their families, in that families can easily be taught to do TT for their loved ones for the purpose of the relief of pain and suffering. This provides an opportunity for a special bond to develop between the family member and the patient and also offers a sense of control for the family member in that they are affording pain relief to their loved one. TT increases the treatment options for those affected by FM and RA by adding an alternative

which is safe, easily utilized with no demonstrable side effects, inexpensive, and provides an outcome which strengthens families.

CHAPTER 2

REVIEW OF RELEVANT LITERATURE

Chronic pain is a problem noted among patients with fibromyalgia (FM) and rheumatoid arthritis (RA). Chapter two will examine literature related to FM, RA, chronic pain, and therapeutic touch (TT), a modality commonly used by nurses to alleviate pain and anxiety.

Fibromyalgia

What is known as fibrositis/fibromyalgia has undergone many revisions within the last century. In 1904, "fibrositis" was proposed by William Gowers to describe a supposed inflammatory process of lower back pain. Since then, the term "fibrositis" has been a general term used to describe patients presenting with vague complaints of musculoskeletal pain. Today, the diagnosis fibrositis has been abandoned for the syndrome of symptoms known as fibromyalgia. This syndrome is now known to occur when there is no associated inflammation (Bennett, Smythe & Wolfe, 1992; Krsnish-Shriwise, 1997).

Studies done in the late 1970s provide the current information about FM. These studies identify two reproducible traits for all those suffering from FM: tender points occurring at the same predictable locations and disturbed Stage IV non-rapid-eye-

movement sleep (Bennett, Smythe & Wolfe, 1992). In 1992, the Second World Congress on Myofascial Pain and Fibromyalgia (FM) convened in Copenhagen, Denmark published a position paper and consensus document about FM. This paper summarizes the current position on FM.

> Fibromyalgia is a painful, nonarticular condition predominantly involving muscles; it is the commonest [sic] cause of chronic, widespread musculoskeletal pain. It is typically associated with persistent fatigue, nonrefreshing sleep and generalized stiffness. Women are affected some 10 to 20 times more often than men. Fibromyalgia is often part of a wider syndrome encompassing: headaches, irritable bowel syndrome, irritable bladder, dysmenorrhea, cold sensitivity, Raynaud's phenomenon, restless legs, atypical patterns of numbness and tingling, exercise intolerance and complaints of weakness. A varying proportion (20%-50%) of fibromyalgia patients experience significant depression or anxiety which may contribute to the severity of symptoms or result from having chronic pain. Most fibromyalgia patients experience both diurnal and seasonal variations of symptoms. Typically, symptoms are worse during periods of cold damp weather, at the beginning and end of the day and during periods of emotional stress. (cited in Schneider, 1995, p.401)

These findings led the American College of Rheumatology to develop the currently used criteria for diagnosing FM (Duna & Wilke, 1993). Criteria include widespread pain of at least three months duration with 11 or more of 18 tender points evidenced on physical assessment. This pain is also characteristically continuous, deep, and aching with

diffuse radiation. Patients state the pain is worse with rest and improves with physical activity.

At this time, there is no general consensus on the etiology of FM. Some researchers believe FM is a disorder of the central nociceptive system, while others contend that FM is a neuroendocrinological disorder. Krsnich-Shriwise (1997) state that the etiology is multifactorial and involves, deprivation of restorative sleep, neurobiochemical abnormalities, loss of sympathetic nervous system control, local tissue factors, physical trauma and viruses, and psychological factors.

Other characteristic symptoms that are present in many patients with FM are sleep disturbances, malaise and fatigue, and morning stiffness (Duna & Wilke, 1993; McCain, 1996; Simms, 1996). Other ancillary manifestations are irritable bowel or bladder syndromes; peripheral vascular instability, resembling Reynaud's phenomenon; and sensitivity to weather changes, temperature, or stress and activity level (Bennett, Smythe & Wolfe, 1992). Slotkoff and Clauw (1996) also noted cognitive dysfunction in those with FM. Patients complain of memory loss, poor concentration, forgetfulness, and confusion. Standard laboratory and radiographic studies are usually normal in the absence of concomitant disease.

Current pharmacological treatment for FM includes tricylic antidepressants one hour before bedtime to assist with non-rapid-eye-movement sleep. Tricyclic antidepressants appear to lessen Stage IV sleep disturbance and are thought to increase levels of serotonin and other neurotransmitters in the brain (Duna & Wilke, 1993; Krsnich-Shriwise, 1997; Simms, 1996). Common side effects of tricyclic antidepressants

include: weight gain, nightmares, vivid dreaming, and occasionally, paradoxical insomnia. Rebound insomnia may occur in those that do not taper off the medication (Simms, 1996).

Exercise is another treatment modality employed. It has been illustrated in the literature that exercise helps alleviate the abnormalities of muscle energy metabolism in those with FM. However, several studies have shown that the local hypoxia of the muscle and the muscle's inability to relax between can lead to the pain evidenced by those with FM; this then leads to a paradoxical worsening of pain. In a study conducted by McCain, Bell, Mai, and Halliday (1988), it was noted that patients suffered from post-exercise worsening of symptoms. Therefore, patients are typically disillusioned with exercise as a treatment modality.

With unconventional therapies such as electromyography (EMG) biofeedback, acupuncture, and electroacuptuncture, it is difficult to assess whether the therapies indeed offer some pain relief. EMG biofeedback is a procedure whereby patients receive auditory feedback of ongoing muscle tension in scalp muscles, determined with the use of surface electrodes placed on the forehead. The patients attempt to control their muscle tension in order to obtain relief. Acupuncture utilizes the insertion of microfine needles into specified locations depending on the patient's symptoms and pain pattern. Electroacupuncture is the addition of a weak electrical current. Studies about the use of electromyography (EMG) biofeedback and acupuncture and electroacupuncture contained many limitations, and the instruments used were questionable as to their validity and reliability (Simms, 1996).

Hypnotherapy has shown promise as a treatment modality for those with FM.

Haanen, Hoenderdos & Van Romunde (1991) performed a controlled trial of hypnotherapy with 40 randomized FM patients. Patients in the hypnotherapy group evidenced significantly greater improvement in muscle pain ($p=.004$), fatigue on awakening ($p=.003$), and sleep disturbance ($p<.001$), at both 12 and 24 weeks. Hypnotherapy, therefore, may be an alternative for those diagnosed with FM. However, a drawback to this modality is its cost and the fact that most insurance companies will not reimburse for any treatments.

Rheumatoid Arthritis

RA is a chronic inflammatory autoimmune disease of connective tissue that causes articular inflammation as well as systemic manifestations. Inflammation of the synovium leads to creation of pannus (granulation tissue which usually occurs in the later chronic phases of disease) in the joints, which accounts for most of the disability seen with RA. Persistent synovitis leads to destruction of the cartilage, ligaments and bone. Concomitantly, there is damage to the periarticular structures such as tendon sheaths and bursae, as well as extrarticular involvement of connective tissue of the pleura, lung and heart (Gallez, 1996; Miller-Blair & Robbins, 1993; Rankin, 1995).

Etiology of RA is unknown. The literature illustrates a number of possibilities. Genetic factors, sex hormones, and an infectious agent which may initiate an autoimmune response, culminating in the systemic inflammatory disease may all contribute to the development of RA (Gallez, 1996; Jackson & Ward, 1994).

The joint erosion that takes place with RA leads to "gelling" of the synovial joints (pools of inflammatory mediators). This creates increased pain after prolonged periods of

rest, especially in the morning. Stiffness which lasts greater than 30 minutes, is usually diagnostic for RA (Griedinger & Hellmann, 1995). Clinically, the patient with RA presents with increased malaise and fatigue, stiffness, anemia, and weight loss. This is followed by a symmetrical pattern of joint inflammation, redness, warmth, and tenderness with motion or palpation of the joint. Extrarticular features are: (1) nodules surrounding the joint area associated with high titers of IgM Immunoglobulin; (2) vasculitis, a serious consequence of RA which is an inflammation of the walls of blood vessels; and (3) Sjogren's syndrome, characterized by a reduction of naturally occurring secretions in the eyes, mouth, and vagina (Gallez, 1996).

Diagnosis of RA is done via a number of laboratory tests and radiographic studies. Rheumatoid factor (RF) is a class M Immunoglobulin (IgM). Patients with RA may be seropositive to this antibody, although only 80% of those patients with classical RA have a seropositive titer. RF is also present in approximately 5% of the general population who do not have RA (Gallez, 1996). The erythrocyte sedimentation rate (ESR) is another laboratory study done. An increased ESR is evidence of an inflammatory process but alone cannot be used as a diagnostic tool for RA but may be used as an indicator of disease severity. The higher the ESR, the more active the inflammatory process. Plasma viscosity (PV) is also used to detect an inflammatory process. Today, it is more frequently utilized than the ESR because the specimen can be stored, and the result is independent of a person's age. Finally, x-rays are used to determine the amount of erosion of a joint. Erosions usually first occur in the metatarsal heads of the feet before they are seen in the metacarpophalangeal joints of the hands (Gallez, 1996; Miller-Blair & Robbins,

1993).

There is currently no cure for RA, and management of the disease process revolves around rest, exercise, joint protection, and drug therapy. Davis (1996) viewed education of the disease process as the primary step in managing RA. Comprehension of the disease and compliance with regimens is tantamount for optimum care. Exercise is also an important component of RA. Failure to use joints can lead to immobility and joint stiffening, but physical activity needs to be counterbalanced with periods of rest. A good night's sleep and a period of rest during the day help to alleviate the fatigue and malaise encountered with RA (Davis, 1996). Assistive and adaptive devices are often brought in by the occupational therapist in order to protect the joint, while the physical therapist works with the RA patient to instruct them on proper body positioning and maintaining range of motion to effective joints (Gallez, 1996; Pigg, 1995).

Drug therapy provides a major treatment modality in RA. Nonsteroidal anti-inflammatory drugs (NSAIDs) are used as first-line drug management. However, various NSAIDs, require multiple daily doses which can lead to increased cost, inconvenience of taking so many medications, gastric upset which often leads to ulcers, and possible liver and kidney involvement.

Corticosteriods are also utilized in patients with rheumatoid arthritis (RA). Corticosteroids are employed when patients have a history of severe gastric upset with NSAIDs. Glucocorticosteroids are utilized when NSAIDs are unable to achieve symptom control. They result in short-term clinical benefit and may decrease early erosions of bone. This is why corticosteroids have been utilized in RA management since 1948.

However, these drugs do not modify the pathophysiological process and have toxic side effects (Jackson & Ward, 1994). These include bone loss with increased susceptibility to fractures, increased risk of infection, skin fragility and thinning, ecchymoses, a cushingoid appearance, hypertension, diabetes, and cataracts. The most serious side effect is corticosteroid- induced osteopenia (Kumar & Pope, 1996).

Disease modifying anti-rheumatoid drugs (DMARDs) have long been employed as second-line agents in the treatment of RA. The most commonly prescribed DMARD today is methotrexate (MTX). It is more efficacious than the other DMARDs due to its more rapid action (within six weeks as compared to two months with conventional DMARDs). Until recently, DMARDs were only employed when there was a clear diagnosis of RA. The new theory surrounding these medications is that the early use (at the time of diagnosis) of DMARDs can halt the erosive progression of RA in many patients (Kremer, 1996; Wilens, 1995). However, toxicity is the most common reason for discontinuing DMARD therapy. DMARDs affect the liver and the kidney function, because they are eliminated primarily by the kidney and undergo hepatic metabolism (Miller-Blair & Robbins, 1993).

While there are multiple treatments which seek to address pathophysiological changes, associated with RA, patients diagnosed with RA, like FM, have limited number of therapies that can be employed to control pain a major symptom in both diseases (Clark, 1994; Davis, 1996; Dimmock, Troughton & Bird, 1996; Hayes, 1993; Jackson & Ward, 1994; Kenyon, 1994; Krsnich-Sgruwusem 1997; Simms, 1996).

Currently, patients diagnosed with RA have a limited number of treatment options.

They are routinely started on an oral agent. Often doctors and practitioners refer patients to warm water therapy which offers some relief from the stiffness and pain for some. Other treatment modalites used, have been heat and cold management, and the use of complementary modalities such as acupunture, dietary modifications, and homeopathy (Davis, 1996; Hayes, 1993; Jackson & Ward, 1994; Kenyon, 1994).

The Pain Response

Davis (1996) defined pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"(p.72). Acute pain serves the purpose of warning the body of a harmful stimuli and is usually self-limiting. If acute pain is not resolved, it can become chronic pain.

Segatore (1994) defined chronic pain as that which "persists beyond the usual course of an acute disease...or [that] is associated with a chronic pathological process that causes continuous pain" (p.230). Chronic pain is a complex phenomenon with physical, social, and psychological components. It is estimated that approximately 35% of Americans experience chronic pain in one form or another, and more than 50 million are partially or completely disabled by their chronic pain (Bonica, 1980).

Wallace (1992) described the pathophysiology of pain as nocioception, which is the transmission of noxious stimuli to the spinal cord and then to the thalamus. After these noxious stimuli are perceived in the thalamus, the stimuli are then interpreted as pain. Davis (1996) noted that once nocioception has occurred, it is the unmyelinated C fibers and myelinated A delta fibers which transmit the painful stimuli from the periphery to the central nervous system. The A fibers react immediately and produce the sharper

pain sensation. This type of pain is known as first pain or protopathic pain. The C fibers are slow conducting fibers and transmit a burning or dull pain. This has been called second pain or epicritic pain. Davis states that the C fibers are associated with chronic pain, but that acute pain can turn into chronic pain as a result of C fiber transmission.

Once the stimuli is perceived, both physiological (the physical sensation of pain) and psychological (the cognition of pain) processes come into play. As pain lingers, it affects not only the individual's day-to-day functioning but it also affects their mental state as well. Often patients will attempt several different treatment modalities, from medications to complementary therapies to homeopathy, in order to decrease the effects of chronic pain (Dimmock & Troughton, 1996; Kenyon, 1994). Many people cannot keep their jobs and are unable to maintain current social or familial roles. This can lead to family difficulties and a sense of isolation and hopelessness. The chronic pain sufferer often will withdraw from daily activities, family and friends, becoming more and more depressed and isolated. Chronic pain and depression present simultaneously in many, making it difficult to assess which came first.

Wallace (1992) claimed that " if individuals are not attending to the pain because of purposive distraction or other events occurring in the environment, fewer signals will be transmitted to the thalamus, limbic system, and the cortex" (p.8). Therefore, behavioral interventions such as relaxation, distraction and visual imagery may all reduce the input to these higher centers and ultimately inhibit the full realization of pain. Davis (1996) also stated there is a relationship between anxiety, muscle tension and pain, in that once pain is perceived, a stress response is elicited which leads to physiologic reactions such as muscle

tension and autonomic responses such as blood vessel constriction. Once these stress responses have occurred, the pain increases and the cycle continues. The cycle of pain can be broken with the use of relaxation or distraction, because of the effect they have on the limbic system. These modalities allow for fewer signals to be sent to the thalamus, limbic system, and cortex which leads to decreased pain perception.

Intervention Strategies for Pain Management

Pain can be managed with many modalities such as: physiologic, psychological, and spiritual. Examples of physiologic interventions are modalities such as exercise, complementary therapies, prescribed medications which are usually employed as first or second-line agents, and hot and cold packs. The psychological interventions noted in the literature are education, meditation, relaxation and hypnotherapy. The only intervention that incorporates all three parameters is TT.

Clark (1994) examined the use of exercise to alleviate pain in those diagnosed with FM. Krsnich-Shriwise (1997) also recommended the use of exercise, in the form of aquatic therapy. However, Clark noted that the pain and fatigue associated with FM made beginning or continuing an exercise program difficult if not impossible.

Medication management, includes psychotropic agents, tricyclic antidepressants, anti-inflammatory agents, and other central nervous system-active medications, i.e., the combination of carisprodol, acetaminophen, and caffeine (Simms, 1996). Non-medication treatments include exercise, electromyograhy (EMG) biofeedback, electroacupuncture and hypnotherapy.

Dimmock and Troughton (1996) examined the use of complementary therapies in

patients diagnosed with FM. They noted that 71% of FM patients had used or were currently using a complementary modality. The most commonly used modalities were oral supplementation (78%), special diets (38%), acupuncture (38%), aromatherapy (33%) and osteopathy (30%). The authors did not elaborate on the types of oral supplements or special diets that were employed by the subjects in the study. Kenyon (1994) described the most effective complementary modalities for those diagnosed with RA. Among those included were, acupuncture, food sensitivities, and homeopathies. Kenyon found that dietary manipulation granted the patient their own personal control over their illness. The author further felt that homeopathy had few adverse effects than conventional medicine. Lastly, Kenyon notes that acupuncture should be used for pain control rather than as an anti-inflammatory.

Hayes (1993) discusses the use of heat and cold in the management of RA. In this study, Hayes found that heat and cold improves pain, muscle guarding, stiffness, and limitation of motion, but not to tenderness or swelling. Jackson and Ward (1994) developed a "therapeutic pyramid" for the treatment of RA, and advocated early intervention to decrease pain and debilitation. At the bottom of the pyramid, treatment begins with patient education, physical therapy, and occupational therapy. At the next level, salicylates and nonsteroidal anti-inflammatory drugs, are used to manage the disease and its symptoms. Subsequently, anti-malarial, oral gold and sulfasalazine, are begun with disease modifying antiarthritic drugs, following at the next stage. Finally, corticosteroids are initiated as a last attempt to control RA.

Davis (1996) focused on education and exercise as early nonpharmological

management of RA. Davis proposed the concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) and corticosteroids to reduce active inflammation and its accompanying pain. Disease modifying anti-rheumatoid drugs were recommended in the trajectory of those patients clearly diagnosed with RA.

Success is limited with the use of these medications and only serve to decrease the inflammatory process. Most authors acknowledge that a cure is not evoked with the use of any of these medications, and the potential for uncomfortable and harmful side-effects and ongoing patient symptoms is common. Many of the recommended therapies are costly and inconvenient, while others have extremely deleterious side effects. Research is ongoing for intervention strategies which may treat both the physiological changes of these diseases and its accompanying chronic pain syndrome. Therapeutic success, however, has been sporadic, poorly documented and not without problems. This suggests that TT may be a cost saving, efficacious alternative for these two populations. Clearly, ongoing research into pain management techniques is warranted in both of these disease processes.

Owens and Ehrenreich (1991) agreed that relaxation decreases stress and anxiety, ergo relaxation decreases pain perception. They further claimed that TT was one means of producing relaxation , thereby decreasing stress and associated pain (Gagne & Toye, 1994; Heidt, 1981; Keller & Bzdek, 1986; Randolph, 1984). Owens and Ehrenreich (1991) noted that TT was an effective adjunct to the treatment of chronic pain, in that it elicited a holistic relaxation state. Addressing factors which incorporate the mind-body-spirit healing. Therefore, TT may be one method which facilitates relaxation and a

treatment strategy for the management of chronic pain that has not been historically examined in the research literature.

Therapeutic Touch

Since Dolores Kreiger introduced TT in the 1970s, interest and commitment to TT has grown rapidly amongst practitioners. TT is a healing modality derived from the ancient practice of laying-on of hands (Schmidt, 1995). Quinn (1988) stated, "Therapeutic Touch is a derivative of the laying on of hands but does not take place within a religious context. It is viewed as a natural human potential which can be actualized by the intention of one who wishes to help or to heal" (p.79). Snyder, Egan and Burns (1995) concurred with Quinn, stating, " TT is the process whereby energy is transmitted from one person to another for the purpose of potentiating the healing process."

TT is based on the premise that all individuals have a physical body that is made up of many layers or fields of energy. Steckel and King (1996) explained this phenomenon by stating,

> "The earth has an energy field of gravity that becomes more intense around a planet. Similarly, people have a human energy field that is more concentrated around their bodies. Originally, known as an 'aura', this energy field is now understood as an electromagnetic field throughout nature" (p.52).

This energy field can be felt by anyone in the form of someone entering a room and all those around "feel" his or her presence. Another example of this concept is that of phantom limb pain, whereby the person senses the presence of pain in a lost limb, much like the presence of someone who is dead, and the sense that the person is alive and with

you.

Owens and Ehrenreich (1991) stated that humans extend beyond the skin in the form of energy. Kirlian photography further demonstrates support for the existence of an electrical field around the body. The balanced energy field is symmetrical while disruption in the energy field creates a sense of asymmetry (Owens & Ehrenreich, 1991). It is proposed that this manifestation is what has been identified and is perceived by people as health or human well-being. Therefore, a disturbance in the field is perceived as a disturbance in health. Once the field is balanced, or in "right relationship" a greater state of "health and wellness" will be experienced (Quinn, 1993). The nonpharmalogical intervention of TT has been supported in affecting change in the energy field and thus may also affect a person's perception of health and wellbeing.

Relevant Research

There have been multiple studies examining the effects of TT in the treatment of a variety of conditions ranging from tension headaches (Keller & Bzdek, 1986; Meehan, 1993) to anxiety (Heidt, 1981; Olson, Sneed, Bonadonna, Ratliff & Dias, 1992; Parkes, 1985; Quinn, 1984). Wirth (1990) illustrated the effectiveness of utilizing TT to promote wound healing. Quinn and Strelkauskas (1993) also showed how TT treatments created an increased sense of well-being, altering certain immunological parameters both in the subjects and the practitioners. Landmark studies performed utilizing TT treatments will be discussed further. Due to the number of landmark studies that have utilized TT and the cumulative nature of the research, the studies will be depicted in chronological order.

Delores Kreiger

In 1974, Kreiger performed a quasi experimental design utilizing pre and post hemoglobin testing in subjects receiving TT. Kreiger utilized a group of registered nurses who had taken a TT class. Each trained nurse chose one patient to receive a TT treatment and a second patient to receive routine care. Therefore, 34 hospitalized patients were treated with TT and 34 patients received routine care. Pre-test hemoglobin levels were drawn for all 64 subjects prior to the interventions. No significant difference between groups was noted in the pre-test mean, but post-test mean results showed a significant difference ($p < .01$). The increase in the post-test group treated with TT was significant ($p < .01$) whereas, no significance was noted in the post-test mean of those receiving the routine care. While there are difficulties with the generalizability of this study and the causal relationship between the TT treatment and the apparent change in hemoglobin due to the absence of operational definitions, random assignment to groups and the Hawthorne effect, it was clear that further study of TT was needed.

Delores Kreiger, Erik Peper and Sonia Ancoli

In 1979, Kreiger, Peper and Ancoli wanted to assess the relaxation response that TT elicits and responses of the practitioner during the two days of treatments. The study consisted of three volunteer subjects with chronic pain from a Pain and Stress Control Outpatient Department of a hospital in California. Kreiger, who delivered the TT, was studied for two consecutive days while she was attached to electroencephalographic (EEG), electromyographic (EMG), and electro-oculographic leads (EOG).

On day one, baseline data were recorded on Kreiger while she was doing TT on a patient and while she was alone. Data was collected while Kreiger stood and sat during a

treatment. Data were also collected with eyes open and eyes closed, while Kreiger was sitting and standing. Patients were allowed to sit or lie down, whichever was more comfortable.

The most significant finding in the study was Kreiger's EEG and EOG data. In all the experimental conditions, her record shows a significant amount of fast beta EEG activity. The frontalis muscle activity (EMG) were recorded to determine excessive muscle tension. The EEG illustrated that even when the action of the frontalis muscle subsided, the rapid beta activity continued. Therefore, it was concluded that the rapid beta activity was not an artifact of muscle action.

The records of all three patients showed that they were in a relaxed state with a high abundance of large-amplitude alpha activity in both the eyes-open and eyes-closed states. During this period, no changes were noted in the subjects' EEG, EOG, EMG, temperature or heart rate.

Upon data analysis, it was apparent that Kreiger had increased beta activity during wake state, reflecting a deep mediational state. During TT, patients were noted to be in an alpha state with their eyes open, although most alpha states are normally achieved in the closed eye state. It was concluded that this was due to the increased sense of well being and relaxation that the patients were sensing.

The researchers stated that at the end of the study all of the subjects had improved conditions. This was gleaned from a qualitative description of perceptions by the subjects; no statistical data were collected to defend this conclusion by the authors. Some limitations to this study are: (1) there was no control group; (2) the sample size was small,

therefore, generazibility is impossible; (3) qualitative data are not generalizable; and (4) there was no report as to whether the study was reviewed by a human subject's rights committee. Therefore, the results of this study need to be assessed cautiously. However, this study does lay the groundwork for more stringently controlled experimental studies evaluating the effects of TT and relaxation.

Patricia Heidt

Subsequently, a study was done by Heidt (1979,1981) on the effects of TT on the state of anxiety of hospitalized cardiovascular patients. Heidt built on Kreiger's (1974) initial study, postulating that TT could influence levels of physiologic relaxation which could alter a person's subjective experience of anxiety. Heidt, utilized three groups of 30 hospitalized cardiovascular patients or a total of 90 subjects. All of the subjects completed the A- State Self Evaluation Questionnaire, and were then assigned to treatment group A, B, or C. In group A, the subjects received a treatment of TT. Group B received intervention by Casual Touch (CT), which consisted of the nurse taking an apical pulse, radial pulse, and a left and right pedal pulse each for a period of one minute. Group C received No Touch, which consisted of the nurse sitting beside the patient and talking with him for a period of five minutes.

Following the interventions, the A- State Self Evaluation Questionnaire was readministered, and the pre and post-test means were computed. Subjects who received TT experienced a highly significant ($p < .001$) decrease in state anxiety as compared to pre and post-test means. Furthermore, patients who received TT had a significantly ($p < .01$) greater reduction in post-test anxiety scores than those subjects who received intervention

by CT or No Touch. Therefore, Heidt's hypothesis that subjects treated with TT would exhibit a reduction in state anxiety was supported. There was no significant decrease in state anxiety for either of the two other groups.

Gretchen Randolph

Randolph (1979) studied the physiologic responses of female college students to a stressful stimuli while receiving TT treatments. Randolph hypothesized that TT is a "healing meditation" which produces a relaxation response in individuals, and that those persons exhibiting a relaxation response would react in a less stressful manner to stressful stimuli.

Randolph utilized two groups of 30 female college students, who were to view the film entitled, "Subincision", which had been validated as a stress-producing stimulus. The students were monitored simultaneously for skin conductance level, muscle tension and skin temperature. One group received TT while watching the film, and the second group received CT (casual touch) while viewing the same film. CT consisted of a nurse imitating the hand movements of TT without the benefit of knowing or training in TT.

One-way analysis of covariance was used to test the hypotheses. The analysis of data revealed no significant difference between groups on any of three hypotheses. None of the hypotheses were confirmed as no significant differences were noted.

Additional t-tests were performed on stressor stimulus (skin conductance, muscle tension and skin temperature) used to detect a physiologic stress response ($t=5.02$, $p= .001$; $t=5.02$, $p= .001$; $t= 1.19$, $p= 0.24$, respectively). Thus, it was noted that in both the TT and the PMR (passive muscle relaxation) group a significant increase in

physiologic stress responses to the film occurred.

Randolph (1979) offered several reasons for this. Randolph stated that the nurse giving the TT did not do an assessment of the patient prior to the treatment. Secondly, the college students were a healthy population. Since the goal of TT is to help individuals towards optimum wellness, one would expect to see little change in already healthy population that is ultimately healthy. She also claimed that the stress response is not always an unwanted response. Often the stress response offers a means of protection for the individual from an external threat.

Therefore, it was concluded that TT would not alter this potentially helpful response, suggesting that TT connects with the person at a level of intelligence beyond the control of the healer or the recipient of TT. It may be that the healer offers TT to a field, that the field interprets this energy, and makes a decision as to its appropriateness within an overall "universal health plan" (Chopra, 1993).

Janet Quinn

In 1982, Quinn replicated Heidt's (1979) study, theorizing that the effects of TT were due to an energy exchange. Quinn introduced the notion that "If the effects of TT were due to some sort of energy exchange, then TT without physical contact should have the same effect as TT with physical contact" (p. 44). Quinn utilized state anxiety as a measure of efficacy of TT without physical contact. Quinn, hypothesized that there would be a greater decrease in post-test state anxiety scores in those subjects treated with TT than those treated with Non-Contact (NCTT) (Quinn).

A random sample of 60 males and females, hospitalized on a cardiovascular unit in

a metropolitan medical center, were assigned to the experimental group receiving TT or the control group receiving NCTT. In the NCTT group, the nurse mimicked the movements of the nurse actually giving the TT treatment. The nurse in this NCTT group did not center herself nor did she utilize intent to assist the client to optimum wellness, but rather the nurse in the NCTT focused her attention on mentally subtracting from 100 by sevens. Five minute treatments were given to both groups.

State anxiety was measured by the Self-Evaluation Questionnaire, STAI form X-1, developed by Spielberger, Gorsuch, and Lushene (Quinn, 1982). All of the subjects completed a STAI pre and post treatment.

Analysis of the data revealed a significant negative decrease in post-test state anxiety ($t = -4.341$, $p = .0005$), among those who were in the experimental group and received the TT treatment. Therefore, the hypothesis that there would be a significant decrease in post-test anxiety scores by those treated with NCTT than those treated with NC was supported at the .0005 level of significance.

Therese Meehan

Meehan (1985) completed a doctoral dissertation on the effect of TT on the experience of acute pain in the postoperative patient. Meehan, tested the hypothesis that "there will be a greater decrease in post-test acute pain experience scores in subjects treated by TT than in subjects treated by Mimic TT"(p. 11). Meehan also asked the research question: "Is there a difference in post-test acute pain experience scores between subjects treated by TT and subjects treated by Standard Treatment?" (pp. 11-12).

Meehan (1985) used an experimental design and randomly divided 108

postoperative patients into one of three groups. One group received TT, another received Mimic TT, and the third groups received a Standard Treatment (i.e., injection of a narcotic). To measure their pain, the subjects were asked to use a Visual Analogue Scale (VAS). Post-test scores were taken one hour post-treatment, and if anyone requested pain medication prior to this one hour, their post-test scores were recorded as being equal to their pre-test score.

The hypothesis was not supported, with the study revealing the difference between the TT and MT means was 8.98 ($.05<p<.06$), indicating that TT was more effective than the MTT but the statistical significance is just above the .05 level. Further, the difference between the TT and the ST means was 16.11 ($p<.001$) indicating that the ST was more effective than TT. Meehan also noted that within the first hour and beyond the first hour after treatment with an analgesic, the subjects in the TT group waited a significantly longer time before requesting further analgesia compared with subjects in the MTT group ($x^2=4.49$, $p<.05$).

Meehan (1985) offered several explanations for these results. She speculated the rigorous post-hoc testing employed may have been too conservative, and that if a less conservative post-hoc had been used, there would have been statistical significance to support the hypothesis.

Another problem Meehan (1985) noted was in the treatment times. All treatments were kept to five minutes to be consistent with previous studies, and this may not have been long enough for the analgesic effect of TT to take place. Quinn (1982) had already stated that TT typically takes at least 15 minutes or longer for pain relief to be achieved.

Meehan also noted a problem with the Standard Treatment group in that the type of analgesic (a narcotic) may have been too strong a standard by which to compare the effectiveness of TT.

Elizabeth Keller and Virginia Bzdek

Keller (1983) and Keller and Bzdek 1986) examined the effects of TT on tension headache pain. Keller postulated, that anxiety was known to play a role in tension headaches, and that TT decreases anxiety. Therefore, Keller believed that TT should be effective in reducing pain associated with tension headaches. Keller and Bzdek (1986) hypothesized that those receiving TT would experience pain relief; that they would experience greater pain relief than a placebo TT group; and that their pain reduction would last for hours after the treatment.

They utilized an experimental design with 60 female and male tension headache sufferers recruited from a university health service. The subjects were randomly assigned to either a TT group or a "placebo simulation of TT" (Keller & Bzdek, 1986). Then, five minute treatments of the different TT types were used with each group. Subjects were asked to complete three scales from the McGill Melzack Pain Questionnaire (MMPQ) (1975) prior to the treatments and five minutes post-treatment. Each subject also completed the MMPQ four hours posttreatment.

Upon data analysis, it was evident that the TT group revealed a highly significant ($p<.0001$) decrease in pain scores. Pain scores dropped an average of 70% in the TT group while pain scores only decreased 37% in the control group. The study further showed that four hours post-treatment, the experimental groups pain scores dropped an

additional 7% from immediate post-test scores, while the control group scores were 19% lower than their post-test scores. Initially these percentages did not show any differences significant, but the researcher noted that 50% of those in the placebo group had done something else to relieve their pain while only 16% of TT subjects used another intervention. When the subjects who had chosen an intervention within the four hours post-treatment were removed from the analysis, significant differences was found between those treated with TT and those given the placebo treatment.

Therese Meehan and colleagues

Meehan, Mersmann, Wiseman, Wolff, and Malgady (1990) investigated the effects of TT on postoperative pain in 159 subjects who underwent abdominal or pelvic surgery. Subjects were randomly assigned to one of three groups: an experimental group receiving TT, another group receiving a Mimic treatment, and a third receiving standard nursing care. The subjects received their assigned treatment the night prior to surgery and seven times during the postoperative period. The number of doses of analgesics that were requested was documented over the postoperative period. Pain was measured before and at four intervals following each treatment administered with, " as needed analgesics" on the first postoperative day. The study measured the time lapsed between each requested analgesic, using the Visual Analogue Scale (VAS) as the pain measurement tool.

The authors noted a significance difference in the use of analgesics in the group which received the TT treatments. It was also noted that this group waited a much longer period before requesting further medication ($p<.01$). No significant differences were noted in the pain intensity scores between the three groups. Those subjects receiving TT

requested their medications less often and also received smaller doses of medication over the entire postoperative period than the control groups, but the decrease was not significant. It was also noted that the analgesic effect from TT was greater in females.

The authors thus concluded that TT as a combination therapy with narcotic analgesics can offer an alternative to narcotic analgesics alone. This finding replicates Meehan's first study (1985), proposing that TT may have a potential beyond the placebo effect in the treatment of postoperative pain.

Douglas Wirth

Wirth (1990) studied the effectiveness of TT on the healing rate of full thickness dermal wounds in human subjects. A physician using local anesthesia and a skin punch biopsy instrument incised full-thickness dermal wounds in the lateral deltoid region of the arm of healthy male subjects. The 44 male university subjects volunteered for the study and were randomly assigned to either an experimental group that received a five minute TT treatment from an experienced TT practitioner or to a control group that received no treatment. Subjects in the control group merely sat for five minutes. The students did not know whether they were receiving a treatment or not. The students were asked to sit with their hands through a modified door. The subjects were unable to see a practitioner on the other side. Subjects in both groups were asked to put their hands through the opening, and once their hands were through the opening they were instructed to rest their hands on a platform and position themselves comfortably for five minutes.

This double-blind study was done to control for the placebo effect and the potentially confounding effects of belief, caring and compassion. Therefore, subjects and

the physician were kept blind to both group assignment and to the nature of the treatment modality. In fact, both were kept unaware as to that fact that healing was the experimental focus of the study until the end.

Data analysis revealed that those subjects treated with TT experienced a substantial acceleration in the rate of wound healing ($p = .001$). Complete healing occurred in 13 of 23 treated subjects versus 0 of the 21 control subjects by day 16.

A number of methodological issues confound the results of this study. TT was only administered to one of the subject's arms. This treatment method varied vastly from the standardized method that Delores Kreiger describes. Also, Wirth (1990) did not describe whether the nurses utilized aspects of TT such as centering and assessment prior to beginning the treatment. Lastly, there is a question whether Wirth's study was reviewed by a human subject's rights committee. At the same time, this study specifically illustrated, as had no other, the effectiveness of TT. Wirth, had a randomized, placebo-controlled study with unprecedented rigor. This study eliminated any suggestion of the placebo effect or the expectation of healing which most often confounds TT research.

Melodie Olson and colleagues.

Olson, Sneed, Bonadonna, Ratliff and Dias (1992) used a repeated measures analysis to explore the effectiveness of TT in reducing stress in 23 adults following the natural disaster of Hurricane Hugo. The subjects received two TT treatments and one placebo treatment which served as the control. This placebo treatment consisted of sitting quietly with the patient for 20 minutes. Measures of physiologic and psychologic stress were collected before, during and after each session. Physiologic measures assessed were

heart rate, skin temperature, blood pressure, and respiratory rate. Psychologic measures were assessed utilizing two visual analogue scales, one each for state and trait anxiety.

Data analysis illustrated a significant main effect in state anxiety for time ($F=98.63$, $p < .05$) and session ($F=8.52$, $p < .05$). Anxiety scores decreased significantly from before to after the TT intervention and also when the TT sessions were compared with the NT group. It was also noted that state anxiety was significantly correlated with session length for each session (Session 1, $r=.4754$, one-tailed p-value $<.02$; Session 2, $r=.4626$, one-tailed p-value $<.03$). Physiologic measures were not significantly different, but did show some trends towards the relaxation response in those receiving TT.

This study had a number of constraints in that: (1) of the 23 participants who started with the study, only 18 returned for the second treatment and only 8 returned for the third session; and (2) due to the disaster, environmental conditions affecting physiological measures were difficult to control for.

Janet Quinn & Anthony Strelkauskas

In 1993, Quinn and Strelkauskas conducted a pilot study investigating the effectiveness of TT on anxiety, mood, and immune function of TT practitioners and recently bereaved patients. The investigators utilized a descriptive design. The purpose of this study was to " analyze whether the emotions of an individual can have a beneficial effect upon the individual" (p. 14). The authors theorized that, "at the core of the TT process is the intent of the practitioner to help the recipient; that is, the practitioner attempts to focus completely on the well-being of the recipient in an act of unconditional love and compassion. For this reason TT has been called a 'healing meditation'" (p. 14).

Furthermore, the authors believed that, "positive emotions can have a beneficial effect on the health of the individual" (p. 14). The authors cited a study by McClelland (1985) wherein feelings of compassion and unconditional love may increase the effectiveness of the immune system in the experiencer. Therefore, if this hypothesis, is correct then the practice of TT should enhance or support the immune system of both practitioner and recipient.

The study included two practitioners and four recently bereaved subjects. The practitioners had been trained by Delores Kreiger, and they had all practiced the modality for greater than five years. Unlike other TT research where the practitioners were only allowed to treat the subject with a predetermined amount, this study allowed the practitioner the latitude to treat the subject as long as they deemed necessary.

This was a descriptive study, therefore, statistical data were not generated. All of the subjects and the practitioners were asked to complete questionnaires designed to measure baseline anxiety and affect. Blood from subjects and practitioner was also drawn for baseline immunologic examination. These measures were again completed post-treatment on all of the participants and practitioners. It was noted in the study that anxiety scores for the practitioners pre and post-treatment were near zero, however the anxiety scores of the bereaved subjects was 29 % lower post-treatment. The study further illustrated that the affective mood improved for all recipients. Post-treatment blood analysis revealed no consistent variation in subsets identified by the markers Leu-16, OKT1, OKT3, and OKT4 (helper T cell) across recipients. It was noted, however, that there was a consistent decrease in the percentage of OKT8 cells (suppressor T cell) from

the initial baseline blood sample to the last sample in all four recipients.

In the study, both practitioners had a lower percentage of OKT8 cells than recipients prior to TT. The more experienced practitioner was 47% lower than the highest bereaved recipient and 35% lower than the lowest bereaved recipient. These differences were noted throughout the study, even though the recipients experienced a decrease in OTK8 percentages following treatment. The second practitioner began the study with 30% lower OKT8 cells than the highest recipient and 13% lower that in the lowest recipient. It was noted that by the end of the first treatment she was virtually identical in OKT8 to the more experience practitioner, who had remained stable throughout the study. At the conclusion of the study, the more experienced practitioner had a 16% decrease in OKT8 cells, and the second practitioner had a 23% decrease. In summary, these results validated the positive alterations in the immune response of those practitioners that utilize TT, in that there was a decrease in the number of OKT8 (suppressor cells) in the immune system.

This study was a pilot, but the data seemed to indicate that something about the treatment of TT actually influences the lymphocyte subset composition. While this conclusion will need to be explored in further studies, the investigators believed that TT enhances the immunologic function by the inhibition of immune suppression.

Jane Simington and Gail Laing

Simington and Laing (1993) studied the effects of therapeutic touch on state anxiety in the institutionalized elderly. Three hypotheses were proposed by the authors.

1. There will be a significantly lower post-intervention state anxiety level for

subjects receiving TT as compared to those receiving a back rub by a registered nurse unfamiliar with TT (Control Group 2).

2. There will be a significantly lowered post-intervention state anxiety level for subjects receiving intervention by TT as compared to those subjects receiving a back rub from a nurse trained in TT but purposefully preventing centering, not doing assessment, and without the intent to help or heal (Control Group 1).
3. There will be no significant difference between the post-intervention state anxiety level between Control Groups 1 and 2. (Simington & Laing, p. 441)

The authors utilized the Spielberger Stait-Trait Anxiety Inventory (STAI) only on post-intervention. The authors gave the STAI post-intervention because a previous study reported that the elderly participants attempted to replicate answers from the pre-test on to the post-test. Therefore, trying to control for a testing bias, only a post-intervention STAI was employed for this study.

The study utilized a random sample of 105 institutionalized elderly who were cognitively capable of participating. A blind, three group, experimental design was used. The subjects were randomly assigned to either the TT group, Control Group 1 or Control Group 2. In the TT group, the subjects received TT in the form of a back rub by the primary investigator. In Control Group 1, the subjects received a back rub from the investigator who made a conscious effort not to center. In Control Group 2, the subjects received a back rub from an experienced registered mental health nurse who had no knowledge of TT.

A one-way analysis of variance (ANOVA) was done to determine if significant

differences were noted in groups. The only significance noted between groups was the amount of time the subject spent in the institution. According to the authors, this would not have an effect on the STAI scores. To test the hypothesis, an ANOVA was done on post-intervention STAI scores. The mean score for the TT group (27.09) was lower than the mean score obtained for Control Group 1 (32.54) or for Control Group 2 (36.53 ($F=1.06$, $p=.001$). A post-hoc Scheffe test, determined that at the .05 level of significance the TT group was significantly different from Control Group 2. There was no significant difference between the TT group and Control Group 1 or between Control Groups 1 and 2.

The post-hoc Scheffe confirmed that those who had received the TT along with the back rub had lower than the mean state anxiety scores. Hypothesis 1 was therefore supported. Additionally, no significant differences was noted between Control Group 1 or 2, this supported hypothesis 2. Hypothesis 3 predicted that there was no statistical difference between the two groups receiving a back rub, this too was supported.

Some limitations noted within this study are: (1) the primary investigator gave the TT touch treatment as well as attempting to give the Control Group 1 treatment; (2) the authors state that due to the use of two control groups they were able to control for the placebo effect; and (3) no pre-intervention STAI scores were taken. Without a known pre-test anxiety state, it is difficult to assess significance of the scores post-intervention. Pre-intervention STAI testing would have provided a stronger statement in justification of the post-intervention scores.

The study confirmed that it is difficult to not create bias when the researcher is also

giving the treatments. It was suggested that subsequent studies employ TT practitioners who are not the principal investigators in order to address this issue. It was also further documented in this study that the TT practitioner can not truly block the healing intent when giving a placebo treatment. It was suggested that subsequent studies employ different practitioners for each of the treatment types.

Mariah Snyder, Ellen Egan, and Kenneth Burns

Snyder, Egan and Burns (1995) did a pilot study utilizing TT to decrease agitation behaviors in persons with dementia. The purpose of the pilot study was to explore the efficacy of hand massage, therapeutic touch, and presence (control group) in producing relaxation and decreasing agitation behaviors in persons with dementia. The hypotheses studied were:

1. Subjects will have a greater level of relaxation and fewer anxious behaviors following the administration of hand massage and therapeutic touch than prior to administration of the interventions.
2. Subjects will have a decrease in targeted agitation behaviors following the administration of these interventions.
3. Greater changes in the level of relaxation will occur with the use of hand massage or therapeutic touch than with the use of presence. (Snyder, et. al.,p.35)

An experimental crossover design was utilized to study the effects of the these interventions on 17 residents on one Alzeihmer's Care Unit. Subjects ranged in ages from 66 to 90 years of age. Six groups of three subjects each were formed, with data collected

on one group at a time. The order of the interventions was alternated between the six groups.

The client was observed for five days; massage was given for ten days; subject was observed for five days; therapeutic touch was given for ten days; the subject was observed for five days; presence was employed for five days; and the subject was observed for five days. Massage was administered for five minutes, TT was administered for ten minutes, and presence was administered for ten minutes.

The Haycox Rating Scale was used to determine the level of dementia. The authors utilized The Relaxation Checklist to indicate level of relaxation by observing nine areas: forehead, eyes, neck, head arms, hands, legs, feet, and breathing (Luselli, Steinman, Marholin, and Steinman,1982). Behavior and pulse rate were utilized in this study to measure degree of relaxation. Agitated behaviors specific for each subject were recorded on an observation form by the agency staff. Pre and post-test scores were averaged for a five day period.

Repeated measures analysis of variance (ANOVA) and post hoc t-tests were used to analyze changes in the outcomes. Pre-intervention testing revealed no significant differences among all of the indices. Massage and TT resulted in increased level of relaxation as indicated by both measures when compared to pre-intervention level ($t=3.38$, $p=.006$; $t=7.54$, $p=.000$; $t=5.20$, $p=.001$; $t=3.71$, $p=.004$). No statistical significance between pre and post-intervention relaxation behaviors or pulse rate was noted in the presence group ($t=1.30$, $p=.218$). Significant differences also noted between pre and post-intervention scores for anxious behaviors in the massage ($t=4.16$, $p=.001$; $t=6.32$, $p=.001$)

and during the second five days of the TT (t=2.45, p=.027). Again, no significant differences were noted in the presence group. Therefore, hypothesis one was the only one supported by the study. Hand massage and TT produced greater relaxation than presencing.

There are a number of limitations within this study. This sample had difficultly receiving a full treatment in any of the three modalities due to their disease process. Therefore, the efficacy of the treatment modalities is questionable. The author also utilized many agency staff to observe and document behaviors. The author states that interrater reliability was performed, but results were not identified. This then, leads to questions about the reliability of the data collected. The authors did not discuss the credentials of the practitioners who were to give the massage and therapeutic touch treatments. Validity is further threatened by the lack of description of practitioners. It is unclear whether the investigators did the treatments or research assistants were utilized. Therefore, researcher effects, as documented in previous research, can not be assessed in this study.

Susan Peck

Peck (1997) utilized TT to decrease pain in those diagnosed with degenerative arthritis. The purpose of the study was to compare TT and passive muscle relaxation (PMR). Peck hypothesized that if TT reduces anxiety, decreases pain of tension headaches, and promotes well being, then it could be helpful in decreasing the pain associated with degenerative joint disease. The following were the hypotheses that the study tested:

1. Following the administration of noncontact TT, elders will have decreased pain as compared with pain reported during the baseline period.
2. Following the administration of noncontact TT, elders will have greater pain reduction than subjects who received PMR. (Peck, p.178)

The study utilized a two-group longitudinal design, employing repeated measures and repeated treatments. Subjects served as their own control over the four weeks while receiving routine care for arthritis. Routine care served as a baseline control, not a separate treatment group. Routine care consisted of medications, heat or cold applications, prescribed rest and exercise, physical therapy, chiropractic treatment, massage, and steroid infections. A random sample size of 108 subjects began in the study. Of this number, 82 completed the four weeks of treatments.

Pain and distress were both measured by two individual visual analogue scale (VAS). The author utilized a VAS for pain and one for distress. The author chose to use the vertical VAS, because it was more easily understood by elders and it was believed to be more logically consistent with other commonly understood measures, such as temperature and fullness of a container (Peck, 1997). The VAS was administered twice during the baseline period and pre and post-interventions.

The author utilized five different practitioners and herself for the TT treatments. All of the practitioners had a minimum of two years experience administering TT. The PMR intervention was given by seven nurses trained to administer PMR by reading printed information on the intervention. None were certified or trained prior to the study in PMR. Appropriate approvals and consents were obtained.

The subjects were self referred and were randomly assigned to groups. Baseline measures of pain and distress were collected. The subjects received six treatments, each five to seven days apart. The treatments were given in the private practice offices of the practitioners or in the houses of the patients.

A statistically significant difference in the level of distress between the first and sixth pre-treatment measures for pain ($t=4.07$, $p=<.001$) was found. Differences between the first and sixth post-treatment pain test scores were also significant ($t=7.6$, $p=<.001$). Additionally, pain was also significantly different pre- to post-first treatment ($t=5.20$, $p<.001$).

The VAS for distress showed statistical significance differences between the first and sixth pre-treatment VAS measures in the TT group ($t=-3.61$, $p=.001$). The first and sixth post-treatment VAS distress scores were also significantly different ($t=-7.08$, $p=<.001$). The distress scores were significantly different from pre- to post-first treatment ($t=6.5$, $p=<.001$).

In summary, arthritis pain and distress were decreased following the first treatment. Further decreases were also found with subsequent treatments. Therefore, hypothesis one was supported.

In the PMR group, differences in mean scores on the first and sixth pre-treatment VAS for pain were statistically significant ($t=3.11$, $p=.004$). Differences between the first and sixth post-treatment VAS for pain were also statistically significant ($t=6.58$, $p=<.001$). It was noted there was statistical differences between the first and sixth pre-treatment in the PMR group, as well as differences between the first and sixth post-treatment VAS on

the measure for distress ($t=4.01$, $p<.001$). Therefore, Peck (1997) found that arthritis pain and distress were significantly decreased between the first treatment in the PMR group. Further decreases were noted with subsequent treatments in the PMR group, and these differences were statistically significant.

It was noted that both TT treatments and PMR treatments reduced pain and distress in those with degenerative joint disease. Upon further statistical evaluation, the author noted that the PMR post-treatment scores were lower than the TT group, indicating a greater reduction of pain and distress in the PMR group. Hypothesis 2, therefore, was not supported.

There were limitations noted within this study. The author participated in the study which could have led to researcher bias. The author had seven practitioners giving PMR and TT which could lead to differing approaches even if scripting was applied. The setting was also not maintained consistently, The author did not state how long the treatments were. It was also noted that the author started out with 108 subjects and that only 82 finished. This results in mortality bias.

Summary

In summary, the literature illustrates the need for further replication and exploration of the effect of TT with inflammatory disorders. To date, it has been suggested that TT may have the potential to reduce anxiety, reduce autonomic and central nervous system arousal and acute pain and decrease the need for as-needed analgesic medications. It has been further suggested that TT may be a safe and effective modality for healing full thickness dermal wounds, and that TT may potentially have an effect on

the immune system. It may then be extrapolated from the previous research that TT could possibly assist with breaking the cycle of pain, stress and the inflammatory response associated with FM and RA.

In addition, this review of literature identifies the amount of time needed for the relaxation response to occur in different populations and disease states requires further clarification and refinement. The literature is unclear about specific aspects of TT such as: (1) its effectiveness in chronic pain states, (2) the required length of treatment, (3) the effectiveness and biases caused by a mimic or placebo control group, (4) the interaction effect between the subject and the practitioner during TT, and (5) touch versus nontouch methods of TT. Therefore, further research about the effects of TT in chronic pain among populations with inflammatory responses is needed.

CHAPTER 3

FRAME OF REFERENCE

Introduction

The theoretical framework chosen for this study was Martha Rogers' Science of Unitary Human Beings. Rogers published her complex theory in 1970, reflecting knowledge gained from anthropology, psychology, sociology, astronomy, religion, philosophy, history, biology, physics, mathematics and literature (Mariner-Tomey, 1994). Rogers' theory was chosen due to its harmonious nature with concepts associated with TT.

Historical Background

Rogers' (1961), Educational Revolution in Nursing, presented the beginnings for her concepts of man and the universe. In this book, Rogers identified three postulates that provided a conceptualization of man and the universe:

1. Through time and space, man's continuous interaction with the universe moves him toward and away from multiple potential states of equilibrium.
2. Man can initiate change and predict the subsequent series of changes within the limits of his own knowledge and a dynamic universe.
3. Man is uniquely able to unite the past, present, and future in adapting to and

changing with an evolving universe (pp. 18-19).

Rogers' (1964) second book, Reveille in Nursing, identified nursing as a learned profession with its own body of science and abstract principles. Rogers believed that nursing's purpose is "to assist individuals, families, and groups to achieve that maximum level of well-being which lies within the potential of each person" (p. 34). Rogers gave definitions of nursing science and practice, identifying the human being as an open system, a complex electrodynamic field in perpetual interaction with the universe.

In 1970, Rogers wrote An Introduction to the Theoretical Basis of Nursing. In this book, she identified five basic assumptions for nursing:

1. Man is a unified whole possessing his own integrity and manifesting characteristics that are more than and different from the sum of his parts.
2. Man and environment are continuously exchanging matter and energy with one another.
3. The life process evolves irreversibly and unidirectionally along the space-time continuum.
4. Pattern and organization identify many and reflect his innovative wholeness.
5. Man is characterized by the capacity for abstraction and imagery, language and thought, sensation and emotion. (pp. 47, 54, 59, 65, 73)

These original assumptions have been modified and refined over the years by Rogers. In 1980, Rogers identified her work as a conceptual system and identified the four building blocks of nursing science: energy fields, a universe of open systems, pattern and organization, and four dimensionality. At that time, she no longer discussed the

assumptions written in 1970. She presented three principles of homeodynamics which are: helicy, resonancy, and complementarity. These principles of homeodynamics propose a way of perceiving unitary human beings.

In Science of Unitary Man: A Paradigm for Nursing, Rogers (1981) referred to her work as a paradigm rather than a conceptual system. She changed the term "mutual simultaneity" to "continuous, mutual process." By 1986 and 1987, Rogers had eliminated the notion of "organization" and referred to "pattern" alone, defining it as the distinguishing characteristic to the energy field and viewed as a single wave, rather than a "mosaic of waves" (Rogers, 1983, p. 222).

In 1992, Rogers changed four dimensionality to pandimensionality, at this time Rogers believed that pandimensional better portrayed the definition of four dimensionality as a nonlinear domain without spacial or temporal attributes. Pandimensionality connote a universe that has an infinite domain which is nonlinear and continually evolving. This term best describes the Rogerian idea of a unitary whole (Mariner-Tomey, 1994). Rogers' theory proposed a nonlinear, noncausal spontaneous universe, an antithesis to the Newtonian theory of a linear causal world (Reeder, 1993).

Rogers (1992) also identified three relevant theories, the theories of accelerating evolution, paranormal events, and rhythmical correlates of change, emphasizing with the latter that she meant field rhythms. Rogers envisioned a future of nursing practice which included therapeutic touch, imagery, meditation, relaxation, color, taste, sound, fragrance, humor, laughter, mood and attitude therapies.

Theoretical Framework

Rogers believed in an open, nonlinear, noncausal universe of energy which exists in environment and human systems of pattern. The life process of this universe is characterized by wholeness, open systems, unidirectionality, pattern and organization, sentience, and thought (Malinski, 1993; Mariner-Tomey, 1994; Reeder, 1993).

With the passage of time Rogers has revised and updated this conceptual model, citing the change in language and thoughts to the evolution and change within society and technology (Reeder, 1993). In 1983, Rogers changed her wording from "Unitary Man" to "Unitary Human Beings", thus removing the gender bias in the previous term used. She also clarified the term "holistic" as it applies to the theory of Unitary Human Beings. Rogers believed that holistic generally signified a summation of parts, whether few or many. However, she proposed that humans are an indivisible whole which can not be separated into parts or known through examination and summation of those parts (Mariner-Tomey, 1994; Rogers, 1992).

Rogers believed that human and environmental fields are mutual and continuous with one another. The fundamental unit of the living and non-living is the energy field, which is identified by pattern and characterized by a universe of open systems. Rogers viewed energy fields as infinite and irreducible, and the manifestation of pattern as unique to the whole which cannot be predicted from knowledge of the parts. Furthermore, each environmental field is specific to its given human field and both change continuously and creatively. An example of this is aging. Often, aging is viewed as a regressive state, where as one ages they regress to a more infantile state which is less complex. Rogers believes aging to be the opposite process, in that as aging occurs, the pattern becomes

increasingly diverse and complex (Malinski, 1993).

Major Concepts and Definitions

Rogers' conceptual model of nursing was based upon a set of basic assumptions that described the holistic life process of humans. Rogers postulates that human beings are dynamic constantly changing energy fields that are integral with their environmental fields. Both the human and environmental fields are identified by pattern and characterized by a universe of open systems. In describing this system, Rogers postulated four building blocks: energy field, a universe of open systems, pattern and pandimensionality. These concepts can be defined as follows:

Energy field is the fundamental unit to living and nonliving entities. Energy fields are infinite. The human field is an irreducible, indivisible, pandimensional energy field that is identified by pattern and is manifested in ways specific to the whole and which can not be predicted from knowledge of the parts. The environmental field is also an irreducible, pandimensional energy field which is integral with the human field. These fields change continuously and diversify creatively.

Universe of open systems alludes to the fact that the energy fields are open, infinite and integral with one another. It is understood in Rogers model that the human and environmental field are integral with one another and the process is continuous and dynamic.

Pattern is what identifies the energy field. Pattern is what distinguishes the energy field and is viewed as a single wave. The nature

> and manifestation of the pattern is continuously changing and evolving becoming more diversified and unique. The human field is integral with the environmental field and in this way disease, illness or pain are manifested.
>
> Pandimensionality is a nonlinear domain without spatial or temporal attributes. This term provides for an infinite domain without limits. It best describes the idea or the unitary whole. (Mariner-Tomey, 1994, pp. 213-214)

Major Assumptions

Rogers' major assumptions can be examined through her treatment of health, nursing, person, and environment, major concepts of concern to nursing.

Health

Health was abstractly described as a value laden phenomenon, therefore, "health" or "illness" means different things to different people. Rogers believed that "health" and "illness" were both manifestations of pattern to be appreciated and described within the context of a specific human-environmental pattern. Rogers (1993) preferred to use the term well-being or human betterment when discussing health. This description supports her beliefs that the person is sentient and capable of manifesting and evaluating their pattern in ways that are in accord with their individual perceptions of health and illness (Mariner-Tomey, 1994).. When interviewed, Rogers discussed her feelings concerning health and the experiences of health (Koithan, 1993). Rogers stated:

> Everything is a manifestation of field process, including the experiences which we

> call health. Human and environmental fields evolve continuously together, integral to each other. Change within the fields is continuously diverse, creative, and integral in a movement which moves the world forward in a pandimensional sense. (Koithan, pp.89,90)

Health is difficult to describe within the confines of the Science of Unitary Human Beings for the whole of mankind. Rather, health or illness can only be defined by the individual's experience and field patterning. Therefore, health is truly not a goal to be attained and maintained, but rather a personal process of human becoming. Rogers believed that health is uniquely defined by individuals and is experienced by the manifestations of the field pattern. Health defies measurement and health behaviors cannot be specifically observed, but rather experienced by the individual in subjective and objective pattern manifestation, that are recognized through participatory relationships of the individual and the nurse.

The principle of homeodynamics augments Rogers' statements about the nature of health. The principle of resonancy holds that continuous change occurs from lower to higher frequency wave patterns within the human environmental field. An example of this phenomenon in TT is in the fluctuations in energy fields of the subjects from one treatment to another and the corresponding changes in pain perception. Helicy is the continuous innovative probabilistic, increasing diversity of the human and environmental field patterns and is characterized by nonrepeating patterns, this can be viewed in the changes in pain perception during TT. Integrality stresses the continuous, mutual human and environmental field process in the experience known as health, this is evidenced as the

process noted between the practitioners and the subjects' energy field..

Nursing

Rogers believed nursing to be a learned art which entails the creative use of the science of nursing for human betterment (Rogers, 1992). Nursing, when described as a verb, signifies "to do", when it is employed as a noun it signifies " a body of abstract knowledge" (Mariner-Tomey, 1994; Rogers, 1992). Nursing is a profession concerned with the maintenance and promotion of health, however it is conceived by the person, prevention of disease, and caring for and rehabilitating the sick and disabled. Nursing, utilizing the concepts of "Unitary Human Being", is therefore unique, because it is the only science that deals with the entire person. It examines experiences and transactions with the person as an energetic whole rather than as a interconnected system of parts.

Nursing can assist the individual in health promotion by supporting the individual in pattern recognition and interpretation, offering alternative explanations and insights into pattern interpretation, facilitating the individual's active participation and choice, and empowering the individual to maximize the potentials that are inherent in the human and environmental field (Koithan, 1993). As health is a matter of personal perception, "healthy choices, health or illness" outside of the individual experience and field pattern would be difficult for the practitioner to observe or define. Therefore, health can not be measured by the parameters of biology or physics or the social sciences and the like. Rather, health is defined within the human field manifestation by the experiencing individual. Koithan (1993) provided the experience of hypertension as an example.

Hypertension is a label of value that society has placed on the continuous higher

> than average blood pressure reading. It is a biological condition which can be medically treated that has little meaning outside the value given by each individual within their own pattern and field manifestations. Individuals make value judgements about this condition contingent upon the human and environmental field patterning process at any given point in time and space. There is no statement that high blood pressure causes disturbances in a person's health, for health is individually recognized and ordered according to individual pattern recognition. For some, the condition is experienced as negative; for others, it is experienced as positive.(pp. 94, 95)

If one were to view pain from this perspective, a tool would need to be employed that allowed the individual to assess their perception of pain, because the perception of pain, like blood pressure, can not be viewed or assessed by the practitioner. Barrington (1993) stated:

> Studies on pain management have attempted to evaluate what is defined as a human subjective phenomenon. Pain is a unitary, whole person phenomenon involving cognitive and physiologic components which are interpreted through the perception of the person in pain. The person in pain determines the nature, location, and meaning of the pain experience. It is uniquely personal. (p. 201)

Therefore, pain and the manifestation of pattern due to the sensation of pain would be individual and not privy to definition by anyone other than the individual.

Person

Rogers viewed the person as being integral with or inseparable from the

environmental pattern. As previously stated, humans are irreducible; therefore, he or she can not be reduced to parts. People possess their own uniqueness and manifest characteristics that are more than, yet different from the parts (Carboni, 1991; Malinski, 1993; Mariner-Tomey, 1994). Rogers also stated that persons are open systems who are in continuous process with the environment and are sentient, thoughtful beings able to participate creatively in their process. An example of this is the field of patient education. Patients are routinely instructed on health maintenance and promotion activities, it is up to the patient to choose what they are willing to do to maintain what they perceive as "health".

Environment

Rogers defined environment as a single wave perceived by people as a single, unbroken event (Rogers, 1992). Therefore, the principles and characteristics of the human field are identical to those ascribed to in the environmental field. An example of this is the human-environmental field noted in TT, whereby the practitioner interacts with the subjects energy field. The practitioner is an integral part of the subjects energy field.

Theoretical Congruence

The congruence of TT and Rogerian science revolve around several key issues. The energy field is the central and fundamental unit of the human-environmental field. Rogers (1970) theoretical framework postulates that the universe is an open system with individuals and their environment as energy fields that are in constant flux and moving towards increasing diversity. The energy field characteristics of openness, mutual process, diversity, and the ability to manifest pattern are fundamental to the human-environmental

process. The nature of this process is specified by the principles of resonancy, helicy and integrality. Resonancy depicts the change between field manifestations from lower to higher frequencies. Integrality is the relationship that is established in TT between the subject and the practitioner and helicy is the nonrepetative manner of change associated with TT. Until recently TT was viewed as an energy transfer between practitioner and client (Heidt, 1990; Quinn, 1984; Wright; 1987). It is evident that there is no energy exchange, but rather a mutual process of the human and environmental field patterning.

Summary

In summary, Rogers' Science of Unitary Human Beings offers a conceptual framework which focuses on nursing's commitment to human betterment. Health is defined as the individual's manifestations of the field pattern.. Health, according to Rogers, is a value-laden term which defies measurement by the biological, sociocultural, and psychological means. Health behaviors can not be viewed from an objective manner by the practitioner, but rather through subjective and objective pattern manifestation recognition through participatory relationships between the practitioner and the individual. TT is a nursing therapeutic medium congruent with the basic premises of Rogerian human-environmental energy fields and pattern manifestation and evaluation.

Hypothesis

The purpose of this study was to determine the effectiveness of TT as a nonpharmalogical intervention in decreasing the perception of chronic pain associated with FM and RA. It was hypothesized that patients diagnosed with FM and RA would demonstrate significant decreases in pain ($p<.05$) following TT treatment when compared

to placebo treatment.

A repeated measures quasi-experimental design was utilized to test this prediction. Subjects were all treated with a TT treatment one week and a placebo treatment the next week. Therefore, subjects served as their own control.

Major Variables

The major variables in this study were the independent variables of touch treatments either TT or the Placebo treatment (PT) and the dependent variable of pain perception. A PT was given to control for a placebo effect.

Conceptual Definitions of the Variables

Therapeutic Touch

TT is a mutual field process and participatory relationship of energy field relationship between the practitioner and the subject. The two fields move together to assess the patterning of energy based on shared perceptions and relationship. The practitioner centers, assesses the subject, and then by using intent, calls the energy into mutual processing and expansion of field. Quinn and Strelkauskas (1993) illustrate this concept as:

> More recently, it has been postulated that the TT practitioner, knowingly participating in the mutual human and environment process by shifting consciousness into a state that may be thought of as a "healing meditation", facilitates patterning of the recipient's energy field through a process of resonance, rather than "energy exchange or transfer". (p.14)

TT also includes intentional resonating with the participant's energy field

manifestations which allows the free flow of energy between the practitioner patient and universal human environmental energy fields, thus expanding the manifestation of energy patterns and consciousness.

Placebo Treatment

Placebo touch therapy is a state of intentional non-relationship, wherein there will be no attempt to perceive mutual pattern manifestations nor enter into a knowing relationship with the other.

Pain Response

Pain is an individual's perception and evaluation of pattern manifestation. Therefore, the state of pain can not objectively evaluated by anyone. Rather, pain is a subjective experience which can be subjectively quantified by the person experiencing the pain.

Operational Definitions of the Variables

Therapeutic Touch

Five phases of TT intervention were used, including centering, assessment and scanning, unruffling or clearing, relationship and resonating, and evaluation (McRae,1987).

Centering was the most critical phase and occurred throughout the process. The practitioner sustained a centered state of awareness, such as "a meditation in motion". Centering is achieved by using quite meditation, such as deep breathing, relaxation, and imagery.

Assessment involved scanning the field by moving the hands in a rhythmical,

symmetrical manner about two to six four inches from the head to the feet. Through energetic assessment, the practitioner and participant perceive the quality of the flow of energy within each others fields looking for sensory cues and differences in energy manifestation. When the field is open and receptive to co-participation in energy patterning, the field may be perceived as having a soft warmth, smoothness, or gentle vibration. Conversely, fields which are less receptive and closed to others maybe perceived as feelings of congestion, pressure, warmth, coolness, blockage, pulling or drawing, static or tingling.

Unruffling and clearing is a process of calling into relationship and facilitates the movement in synchronous harmonious flow between field patterns. The practitioner uses long downward strokes through the field over the entire body, from head to toe, inviting the pattern of the participant to resonate with their own.

Resonating is directing and modulating energy to establish similarity and mutuality between the two field manifestations. This is the least structured phase of TT as it is determined by the needs of the participants. During this phase, practitioners use hands both on and off the body to facilitate energy flow and integrality of fields. Imagery often helps the practitioner and participant conceptualize the process of energy flow.

Evaluation involves the continual reassessment of the field as changes occur. At the end of a treatment, ideally the two field manifestations will feel synchronous and energy will be flowing harmoniously between practitioner and participants (Mulloney & Wells-Federman, 1996).

Placebo Treatment

PT was administered by a nurse with no training or knowledge in TT. The nurse resembled the TT practitioner in years of age, nursing experience and demeanor. The PT practitioner will neither center herself nor will she utilize "intent" to enter into a relationship with the participant's field pattern. Rather, the PT practitioner will only be moving her hands two to four inches away from the subject's body using a scripted performance process. The intent of the PT was to mimic the motion of the TT practitioner (Appendix A).

Pain Response

The personal perception of pain was measured by a vertical Visual Analogue Scale (v-VAS). The line was 10 cm in length with no anchors on either end. The low end of the scale was on the bottom and it stated, "NO PAIN" and at the top of the scale was the term, "PAIN AS BAD AS IT CAN BE". There were written instructions in large print on the scale to further assist the subject in filling out the tool properly. The tool was generated via computer and measured by hand using a standard ruler in millimeters. The results were measured in one-half centimeter intervals.

Extraneous Variables

Extraneous variables are potential modifying factors, identified by previous studies, related to the perception of pain (Table 1). A demographic questionnaire designed by the researcher provided this information.

Table 1

Demographic Questionnaire

Extraneous Variable	Definition
Age	Age in years
Gender	Identified as male or female
Marital status	Identified as single, married, divorced, or widowed
Education	Highest level achieved in years
Ethnicity	Identified using Caucasian/White, African American/Black, Hispanic, Native American, Other
Diagnosis	Identified as fibromyalgia or rheumatoid arthritis
Year of diagnosis	Identified in months and years
Current medications	Identified in narrative form
Last time medication was taken	Identified in hour of day
Medications not prescribed	Identified by any medication not prescribed by doctor, in narrative form
Last time a non-prescribed medication was taken	Identified in hour of day
Does anything help the pain	Identified by yes or no
What other measures relieve pain	Identified by checking all that apply: relaxation, exercise, acupressure, acupuncture, chelation therapy, reflexology, chiropractor, heat, cold, paraffin, splints, magnets, other.

Summary

Rogerian science is harmonious with the basic premise of TT and the concept of mutual process, relationship and energy patterning. Rogerian theory provides the basis for the hypothesis tested and the theoretical and operational definitions of the variables.

CHAPTER 4

METHODS AND PROCEDURES

Introduction

The purpose of this study was to determine if the utilization of TT would help decrease pain in those diagnosed with FM and RA. It was hypothesized that subjects would exhibit diminished pain perception post-treatment when receiving TT while they would experience no change in pain perception when receiving the PT. Pain was measured pre and post-treatment in both treatment instances utilizing the vertical Visual Analogue Scale (v-VAS).

Research Design

The effectiveness of TT in the treatment of chronic pain was studied using a repeated measures, quasi-experimental design. This design controls for many of the extraneous variables identified historically by researchers of this nursing intervention. In this design, the subjects serve as their own control, decreasing the effect of sample and design biases. Subjects were exposed to both TT (experimental treatment) and to PT (control treatment) during separate sessions three days to one week apart. The order of exposure was determined randomly by drawing names from a hat. Pre-measures and post-measures were conducted during each session. Subjects were blind to the treatment type

used during each session. Only the researcher and the treatment nurses knew the treatment type. Order of the procedure was kept in a logbook by the investigator.

Sample

The study sample was comprised of 61 subjects who had a self identified diagnosis of either FM or RA. Thus, the subjects were self-referred for participation in this study. All information was self-reported. This convenience sample was limited to literate, English speaking men and women. All subjects were of legal age and in pain at the time of the study. A sample size of 61 was chosen for a power of .8 and an alpha of .05. Subjects were recruited from advertisements posted at the Arthritis Foundation and the Rheumatology Clinic, in two major metropolitan Midwest hospital, as well as from support groups, word of mouth, and an advertisement in the daily newspaper that generated over 250 willing participants (Appendix 2). The subjects were randomly chosen from the 250 volunteers by drawing names from a hat.

Subjects were randomly assigned to receive either the TT treatment or the PT for the first visit and the opposite treatment was given on the second visit (three days to one week later). The randomization was accomplished by alternating patients to either the treatment group or the mimic group during their first visit. The second treatment was simply the opposite of the first treatment. The subject's last name, their assigned code number and the first treatment type were logged into a study notebook to decrease the possibility of a scheduling error. All data will be destroyed one year after the study is completed. Until that time, data will be kept in the possession of the investigator in a locked file cabinet.

The subjects were not told which treatment they were receiving. They were only instructed that they were to receive some type of treatment which addresses their pain. The two practitioners and the research assistant were also instructed not to inform the subjects as to which treatment they received.

Setting

The data collection site was located in a large metropolitan city. This city has three major hospitals as well as an academic medical center. The three major hospitals in this city have Health Maintenance Organizations (HMOs). Each hospital has greater than 250 beds. There is cultural diversity in the population served by these hospitals. The ethnicity of the population served by these hospitals is comprised of Hispanic, White and Native American groups. The three hospitals and the academic medical center serve the 800,000 citizens of this city. All of the volunteers responding to the advertisements were from this population group.

Data Collection Procedure

The medical director and nursing director were asked for permission to use their clinic for the present study, following appropriate approvals by the Human Subjects Rights Committees at the University of Nevada, Las Vegas, the medical clinic, and hospital. Volunteers were recruited for eight weeks. From these volunteer respondents, 70 subjects were randomly selected. The selected volunteers were then contacted by the investigator and the pre-screening tool (Appendix 3) was completed through a phone interview by the investigator. This was done to assure that the volunteer met the study criteria. If the subject met the criteria, the informational letter (Appendix 4) was mailed to the subject

explaining the study. Simultaneously, subjects were given an internal code number which served as their identification code throughout the study. The pre-screening tool and identifying information have remained secured with the investigator throughout the study in a locked file.

One week after receipt of the letter, the investigator contacted the subject by phone to schedule their two appointment times, one week apart. The investigator randomly determined the order of the two treatments (TT and PT) by picking the treatment out of a hat. These data were recorded in the logbook, TT identified as Treatment A and PT identified as Treatment B, and secured with the investigator. Subjects were scheduled for a total of 45 minutes for each session. Fifteen minutes was required for the pre-testing session; 15 minutes for the treatment session (TT or PT); and five minutes was needed for the post-testing session. Ten minutes were allotted to prepare the subject, move between the testing and treatment room, and answer any questions that arose.

At the time of the first appointment, subjects were escorted into the pre-treatment room and given a testing packet which included the informed consent, the demographic questionnaire, and the pre-VAS (Appendix 5,6,7) coded with their subject number. Instructions, purpose, and information were again shared verbally with the subjects, and they were offered the option to withdraw from the study. Subjects were also told that all participation was voluntary and could be discontinued at any time with no effect on their medical treatment. They were informed of the confidentiality of all collected data. The investigator was present during the pre-testing period for questions and item clarification.

The investigator did not interact with any of the participants unless a question was posed by a participant and the investigator was needed to provide additional information. Participants answered only the items they chose. Following completion, packets were then inserted into their envelopes and deposited in a locked "Pre-treatment" box.

Once the pre-testing was completed, subjects were taken to the treatment room by the research assistant where they met either the TT practitioner or the PT practitioner to receive the treatment scheduled for that day. The two practitioners were employed to administer the treatments. This addresses the issues identified in previous studies concerning researcher bias and it also decreased the chances of researcher effect.

The TT practitioner has been a certified practitioner for six years and a nurse for greater than 20 years. The PT practitioner has had over 20 years of nursing practice and has had no experience in the practice of TT.

The TT practitioner asked the subject to sit or recline, whichever was more comfortable. At this time, the TT practitioner centered herself and assessed the subject. This was completed by having the TT practitioner move her hands two to four inches away from the subject's body, assessing and learning the subject's manifestations and patterning of energy. After the assessment phase, the TT practitioner then utilized "intent" to enter into a mutual patterning with the subject's energy field in order to change and decrease their pain manifestations and pain interpretation. The PT practitioner also had the subject sit or recline in a comfortable position.

At this time, the PT practitioner neither centered herself nor did she utilize "intent" to relate to the patterning of the subject's energy field. Rather, the PT practitioner only

moved her hands two to four inches away from the subject's body simulating the motions found in TT. The PT practitioner followed a script, created by the investigator and the TT practitioner (Appendix 1). A script was created to decrease the possibility of design bias and to maintain the studies rigor.

Post-treatment, the subject was escorted to the post-treatment room to complete the post-VAS (Appendix 8). The completed test was placed in their coded envelopes and dropped into the locked "Post-treatment" box. Data boxes were kept locked and in the possession of the investigator until the data were coded.

Data Collection Method

The dependent variable of perceived pain was measured by the v-VAS, a sensitive tool for pain measurement which can be easily scored for statistical use (Gift, 1989; Flagherty, 1996). The v-VAS is not anchored on either end, and the use of "NO PAIN" and "PAIN AS BAD AS IT CAN BE" were the descriptors used at each end of the scale (Appendix 7,8).

The scoring of the v-VAS was completed by using a premarked measurement tool with millimeter markings. This type of measurement yields interval level data. All scoring of the v-VAS was completed by one person, minimizing the chance for interrater error and increased reliability of the data retrieved from the instruments. Validity has been established for the v-VAS by a number of researchers and reported in the literature.

Development of the VAS

Precursors of the current v-VAS were found as early as the 1920s (Wewers & Lowe, 1990). In 1923, Freyd described utilizing a tool similar to the VAS, but called it

the Graphic Rating Scale (GRS). Freyd used the GRS to evaluate aspects of personality such as self-consciousness. Freyd noted many advantages of GRS, including the ease of scoring and completion, its provision of multiple options in subject evaluation, and its universality. Later, the VAS in its current form began to appear in the literature in the 1960s.

The v-VAS has been used to measure a number of subjective phenomena such as mood (Folstein and Luria, 1973; Hart, Hill, Bye, Wilkinson & Peck, 1976; Little & McPhail, 1973; Luria, 1975, 1979; Zealley & Aitkin, 1969), anxiety (Brodie, McGhie, O'Hara, Valle-Jones & Schiff, 1975; Giffre, 1983; Kellner & Sheffield, 1968; Lowe & Holm, 1988) and alertness (Aitken & Gedge, 1968; Hart et. al., 1976; Luria, 1979). The VAS has been used in pain management research since 1966 (Bond & Pitowsky) to measure both acute (Gaston-Johansson, Fridh & Turner-Novell, 1988) and chronic pain (Joyce, Zutski, Hurbes & Mason, 1975; McMillian et. al. 1988).

Reliability and Validity of the VAS

Reliability of the VAS has been done utilizing test-retest methods. In one study, by Seymour (1982) subjects were asked to describe the intensity of dental pain within a few minutes and then to describe the distant pain event after 5 minutes and 24 hours. Correlations between those repeated measurements ranged from 0.95 to 0.99.

Revill, Robinson, Rosen and Hogg (1976) assessed the reliability of the VAS also utilizing a test re-test method. In this study, women in labor were divided into two groups evenly. One group was given pethidine and asked to rate a specific pain, approximately half an hour after receiving pethidine. The rating was repeated again in five minutes. The

control group received no pethidine but did complete the VAS. There was a highly significant correlation between each subject's initial score and at five minutes ($r=0.994$) and the memory of pain ($r=0.95$).

Joyce, Zutshi, Hrubes and Mason (1975) compared the VAS and a four point scale (FOPS) for rating chronic pain in those with chronic inflammatory or degenerative joint disease. Patients participated for four weeks and rated pain intensity every day immediately before taking oral analgesic and every hour thereafter for four hours. According to Joyce et.al., the VAS was more accurate and more sensitive than the FOPS in registering the intensity of pain. Joyce et. al. (1975) illustrated discriminant validity in their study by comparing the VAS pain rating scale between patients expected to have pain and those receiving analgesics.

Ohnhaus and Adler (1975) compared a verbal rating scale (VRS) and a visual analogue scale (VAS). However, the researchers believed that the VAS more appropriately assesses what a patient is actually experiencing with respect to changing pain intensities. The correlation between the two scales was highly significant ($r=0.81$, $p < 0.001$).

The validity of the VAS has been tested in a number of ways, including assessment for construct, discriminant, and criterion-related validity. Construct validity was evaluated by Seymour in 1982. Seymour found that the VAS was more precise in discerning a decrease in dental pain after analgesia. In addition, the author felt that the VAS was more sensitive to fine changes in pain as compared to both numerical and four-point rating scales.

Grossman et. al.(1992) demonstrated criterion-related validity, comparing the HPRI instrument to the more traditional VAS and the VDS. On initial and repeat testing, there were high correlations between the HPRI and the VAS ($r=0.99$, $p < 0.0001$).

The Vertical VAS

The VAS is a straight line, with no anchors at the end. The vertical visual analogue (v-VAS) scale was chosen for this study because it has been shown to be more sensitive than the horizontal visual analogue scale (h-VAS), producing higher scores in an user-friendly format (Flaherty, 1996). The advantages of the v-VAS are its simplicity of construction and ease of use. It avoids confounding language, and those with sight impairments can easily see the vertical line. The v-VAS also requires little manual dexterity within which to complete it, a consideration important to those with rheumatoid changes.

Herr and Mobily (1993) documented the effectiveness of the vertical visual analogue scale (v-VAS) in an adult population. They tested subjects between the ages of 45 to 65 years of age and concluded "that the v-VAS was seen more positively than the horizontal visual analogue scale (h-VAS) in ease of completion and in best describing pain" (p.45).

Flaherty (1996) concurred with Herr and Mobily (1993), stating that the v-VAS is more sensitive, produces higher scores, and is easier for subjects to use. Sriwatanakul, Kelvie, Lasagna, Calimlim, Weis and Mehta (1983) noted a preference for the h-VAS in the general population, whereas the adult population preferred the v-VAS. The adult population preferred the v-VAS because of its simplicity and the minimal time required for

the completion of the tool.

In this study, the vertical positioning of the VAS was utilized. This v-VAS was 10 centimeters in length. Each v-VAS utilized was originally generated on a computer to decrease the chances of copier error in size and length of the tool. The subject was asked to respond by making a horizontal line at a position which best describes their pain at the time.

At the extreme boundaries of the v-VAS was inscribed with "PAIN AS BAD AS IT CAN BE" the other end had the descriptor titled, "NO PAIN" (Appendix 7,8). The v-VAS was chosen for this study for a number of reasons. It was noted in the literature that those patients diagnosed with FM were between the ages of 20-50 and those diagnosed with RA were between the ages of 35 to 50. Additionally, it was cited in the literature that the v-VAS was easy to complete and the construction of the line was similar to daily measurements such as an outdoor thermometer.

Several disadvantages of the Visual Analogue Scale (VAS) which may confound the reliability and validity of the instrument have been reported. These include difficulty fitting subjective experience into a straight line continuum, psychomotor problems that preclude marking on a line with a pen or pencil, and the need for the researcher to measure and record the pain score which could lead to inaccuracies in data reporting (Grossman, et. al., 1992; Flaherty, 1996; McMillan et. al., 1988). Flaherty and Grossman et. al. also noted concern that the VAS is difficult to use over the phone. McMillan et. al. reported that the VAS cannot provide information about the location, quality, associated symptoms, pattern or factors that aggravate or relieve pain. Therefore, the h-VAS and v-

VAS are only reliable and valid to assess the quantity of pain perceived at a given point in time.

Ethical Considerations

The subjects participated in this study based on a self referral and voluntary process. This study was approved by the thesis committee, Department of Nursing University of Nevada Las Vegas Human Rights Review Committee, University of Nevada Las Vegas Human Subjects Review Board, and Lovelace Respiratory Review Institute. Letters of approval are included in Appendix 9, 10 and 11. Approval was also received from the department director of the clinic used in the study and the approval letter is in Appendix 12.

An informational letter (Appendix 4) was mailed to each participant prior to the start of the study and a consent form (Appendix 5) was given on the day of the first treatment. Both included:

1. A statement identifying the researcher and her affiliation with the University of Nevada, Las Vegas;
2. An invitation to participate in the study as part of a research project;
3. Criteria for participation in the study;
4. An explanation of the purpose of the research, a description of the procedure to be followed, and the expected length of time to complete the questionnaires and tool;
5. A statement identifying benefits of study;
6. A statement describing maintenance of the subject's anonymity;

7. The names, addresses, and phone numbers of the people to contact for answers to questions about the study and for questions about the rights of research subjects;
8. An assurance that participation in the study was voluntary.

Completion of the questionnaires indicated a consent to participate in the study. The subjects were instructed that their participation or refusal to participate in the study would in no way jeopardize their medical care.

Data Analysis

Descriptive data analysis was performed for all the demographic data. Frequency distributions were tabulated for age, marital status, education, ethnicity, income, and diagnosis of the participants pre-test pain scores for treatment one and treatment two. Correlational analyses were performed to examine associations of selected demographic variables with the dependent variable of the study.

Hypothesis

The hypothesis predicted that patients with FM and RA will demonstrate decreased levels of pain ($p<.05$) post treatment utilizing TT, as measured by a v-VAS, when compared to PT.

A paired t-test was performed to assess for the variance and the differences between the pre and post-test pain scores. A two-way repeated measures ANOVA was done to assess for any significance between the pre and post pain scores and the treatment received. A Wilcoxon Signed Ranks was done due to the multimodal distribution of the pain scores. Lastly, a Chi-Square 2X2 Test of Independence was done to make inferences

about population differences in proportions between the two groups of subjects. The Chi-Square 2X2 Test of Independence was chosen due to the multimodal distribution of the data. The Chi-Square will be contrasting the expected frequencies and the observed frequencies.

Summary

In summary, this study employed a quasi-experimental repeated measures design with pre and post-treatment measure. The vertical visual analogue scale (v-VAS) was used for this study due to its ease in completion and scoring. The v-VAS has established validity and reliability as a tool to measure perceived pain.

All of the appropriate consents were obtained prior to the start of the study, and all questions were answered in a nonthreatening environment by the investigator. All risks and benefits of the study were discussed with the subjects. The investigator also received approval by all appropriate reviewing boards.

CHAPTER 5

RESULTS

This chapter presents results describing the sample of this study. Analyses related to the hypothesis and correlational analyses of selected demographic characteristics with the major variables of the study are presented.

Demographics of the Sample

The sample for this study consisted of 70 subjects with FM or RA. Of the 70 subjects enrolled, 61 had usable data. Forty-five of the subjects had a diagnosis of FM and 17 subjects had the diagnosis of RA. One subject identified that day had been diagnosed with FM and RA, and therefore, did not meet the study criteria. Eight of the subjects either did not complete a pre-treatment or a post-treatment v-VAS. This left a total sample of 61 subjects for the study, giving a study mortality of 13%. This sample is also representative of those diagnosed with FM and RA. The sample is predominately female (90.2%) with a mean age of 55.79 years, and 44% having an income greater than $30,000 per year. It was noted that most of this population was employed which affected the research design. Also, it was noted that 73.8% of the population had the diagnosis of FM and 27.9% had the diagnosis of RA, the lack of RA subjects made further analysis impractical due to the small sample size. The selected characteristics of the subjects are

presented in Table 2.

Table 2

Description of the Sample

Variable	N	% of Sample
Gender		
Female	55	90.2
Male	6	9.8
Marital Status		
Divorced	19	31.1
Married	35	57.4
Single	3	4.9
Widowed	4	6.6
Education		
In High School	1	1.6
High School graduate	21	34.4
College, 1-2 years	18	29.5
College, 3 + years	11	18.0
Graduate, Masters or Ph.D.	10	16.4
Ethnicity		
Caucasian/White	40	65.6
Caucasian/Hispanic	2	3.3
Caucasian/Native American	2	3.3
Hispanic	14	23.0
Native American	1	1.6
African American	2	3.3
Income*		
$0-10,000	5	8.2
$10,000-$15,0000	7	11.5
$15,000-$20,000	2	3.3
$20,000-$25,000	6	9.8
$25,000-$30,000	7	11.5
$30,000-$35,000	8	13.1
$35,000-$40,000	5	8.2
$40,000-$45,000	2	3.3
$45,000-more	12	19.7
Diagnosis**		
Fibromyalgia	45	73.8
Rheumatoid Arthritis	17	26.2

Note. n=61 subjects

*Income-not all subjects responded

**Diagnosis-one person had both Fibromyalgia and Rheumatoid Arthritis

Pain Outcomes Data

In this study, the dependent variable of pain was measured at the interval level utilizing the v-VAS. Scores for the v-VAS had a possible range between 0 to 10 centimeters. In this study, the range of scores in the TT group was 0.50 to 10.00 on pre-test and 0.50 to 9.00 on post-test. Scores ranged between 0.50 and 9.50 on pre-test for the PT group and 0.00 to 10.00 on post-test. In the TT group, the mean score on pre-treatment testing was 5.97 (SD=2.41) and on post-treatment was 4.37 (SD=2.69). The mean scores for the PT group were 5.12 (SD=2.29) for the pre-treatment test and 3.70 (SD=2.69) for the post-treatment test. These frequency data are reported in Table 3.

Table 3

Frequency Data for Pre and Post Treatment v-VAS Pain Scores.

Variable	Mean	SD	Possible Range	Sample's Range	Skewness
TT					
Pre-test	5.97	2.41	0-10.00	.50-10.00	.058
Post-test	4.37	2.69	0-10.00	.50- 9.00	.464
Placebo					
Pre-test	5.12	2.29	0-10.00	.50-9.50	-.694
Post-test	3.70	2.31	0-10.00	.00-9.00	-.106

Further examination of the frequency data revealed that the post-test TT and the pre-test PT scores were significantly skewed (.464 and -.694 respectively). Additionally, the frequency distributions in Figures 1 through 4 showed that the post-test scores for the TT treatment type had a multimodal distribution. Therefore, the data obtained in this study

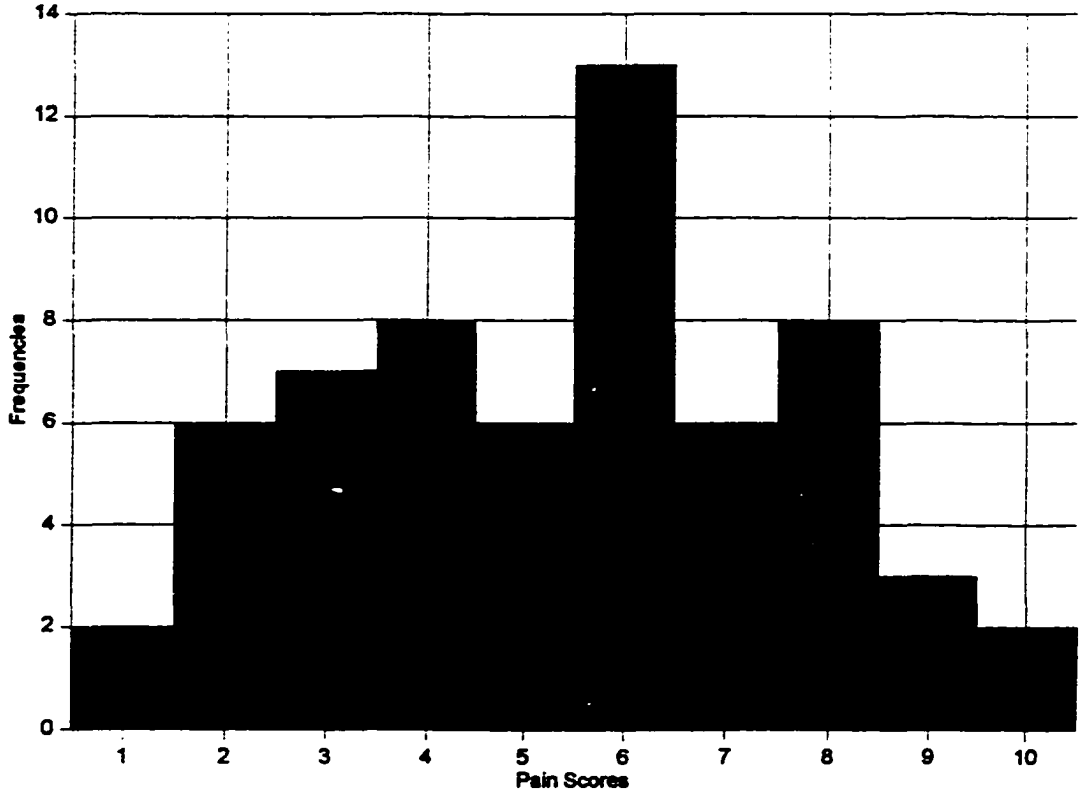

Figure 1. Distribution of VAS pain scores, placebo treatment, pre-score.
Notes. Standard Deviation=2.41
Mean=6.0
N=61

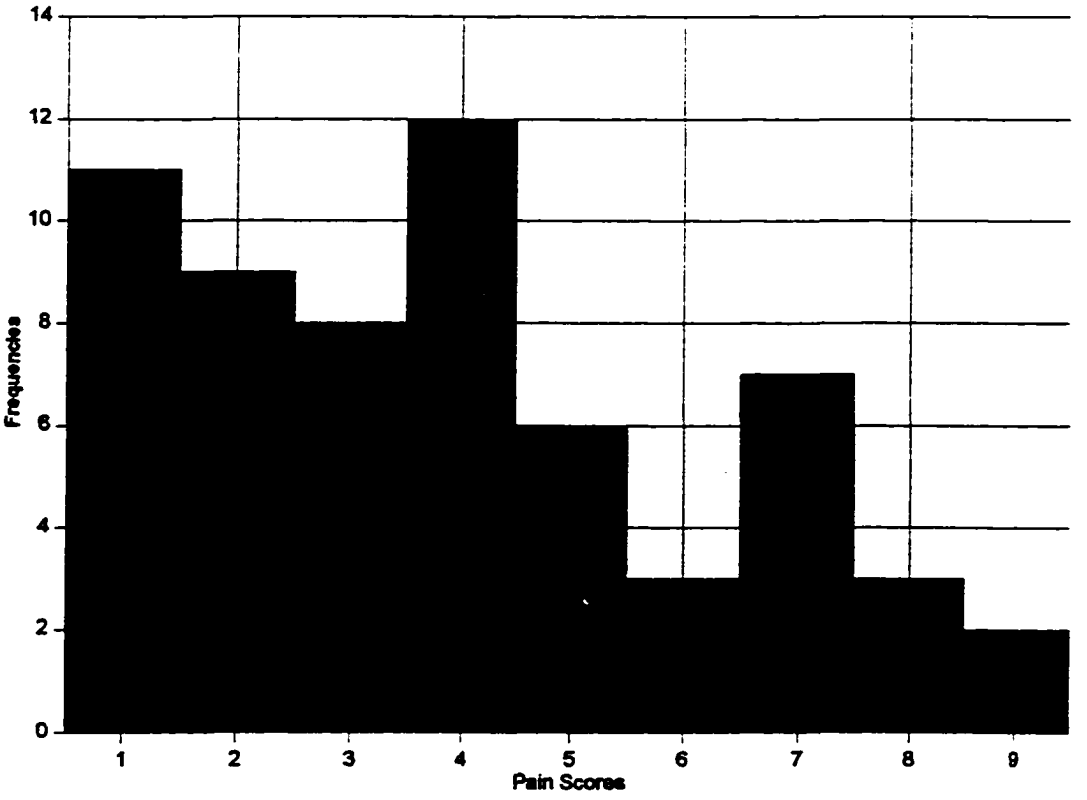

Figure 2. Distribution of VAS pain scores, placebo treatment, post-score.
Note. Standard Deviation=2.69
Mean=4.4
N=61

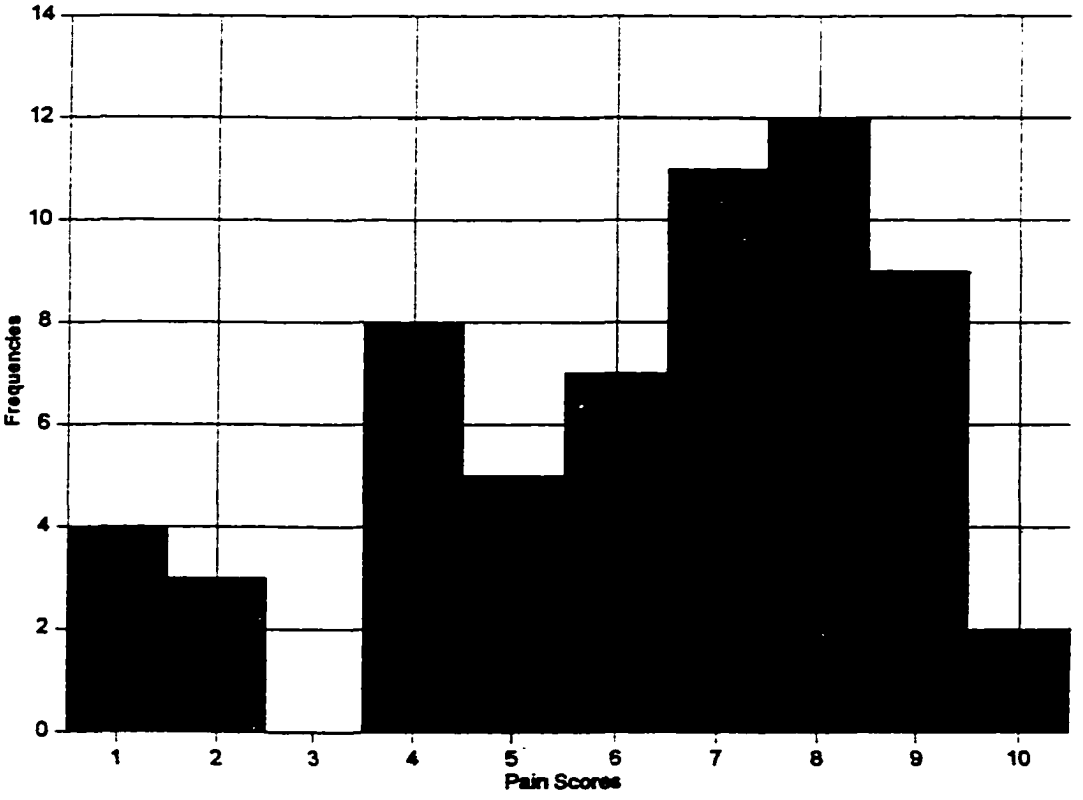

Figure 3. Distribution of VAS pain scores, experimental treatment, pre-score.
Note. Standard Deviation=2.29
Mean=5.1
N=61

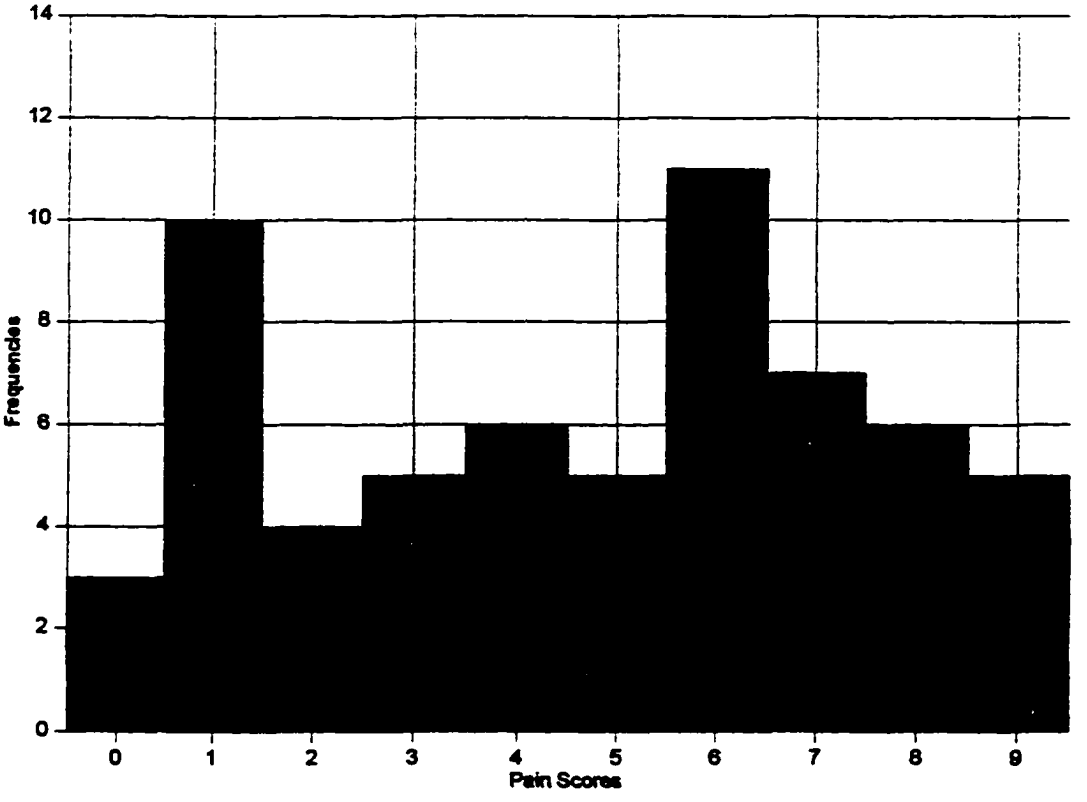

Figure 4. Distribution of VAS pain scores, experimental treatment, post-score.
Note. Standard Deviation=2.31
Mean=3.7
N=61

Table 4

Comparison of Pre and Post Treatment v-VAS scores for the Therapeutic Touch and Placebo Groups

Treatment	Pre-Mean	Post-Mean	t	p*
TT	5.97	4.37	6.856	0.00***
Placebo	5.12	3.70	5.50	0.00***

Note. *Two-tailed p values, df=60
**Pain was rated from 0 (no pain) to 10 (pain as bad as it can be).
***$p<.05$

in Table 5. As this table indicates, there was a significant difference between the two treatment types on pre-treatment pain scores. Before receiving the PT intervention, subjects reported significantly less pain than before receiving the TT intervention. There was also a significant difference in post-test scores. Subjects again reported less pain after receiving PT than after receiving TT. Therefore, although subjects served as their own controls, the pre-test pain scores were non-equivalent for the two treatment types and these differences may have lead to the significant differences observed on the post-test pain scores.

As the t-test assumes normal distribution of the dependent variable, the t-test may be invalid in this study (Polit, 1996, p. 130). Therefore, a Wilcoxon matched-pairs signed-ranks test was used to examine the data to determine the effect of the non-normal distribution on the t-test results. Refer to Table 6. Again, there were significant differences found between pre- and post-test pain scores for both types of treatment. There were also significant differences found between the two treatment types on pre-test

pain scores. However, using this non-parametric test there were no significant differences found between the subject's post-test pain based on intervention types. Therefore, previous conclusions were verified.

Table 5

Comparison of Pre and Post Treatment Pain Scores for the Therapeutic Touch and Placebo Groups

Treatment	t	p
TT to PT Pre-test	1.982	.05
TT to PT Post-test	1.46	.15

Table 6

Wilcoxon Signed Ranks Comparing TT and PT Scores

Variable	Z	Asymp. Sig. (2-tailed)
Pre-test-Post-test TT	-4.976	.000*
Pre-test-Post-test PT	-3.434	.000*
Pre-test only TT to PT	-2.869	.004*
Post-test only TT to PT	-1.742	.082

Hypothesis Testing

It was predicted that the subjects would report significantly lower pain when receiving TT when compared to the PT intervention. Because subjects served as their own controls, receiving both levels of the independent variable and the dependent variable was observed in each subject four times, a two-way, repeated measures, Analysis of Variance (ANOVA) would be the preferred method of data analysis (Polit, 1996, pp.169-170).

The basic assumptions of the ANOVA are: (1) two or more nominal-level independent variables, (2) random sampling, (3) dependent variables which are normally distributed, and (4) homogeneity of variance. In repeated measures ANOVA, observations are not assumed to be independent of each other. Rather, a correlation between measures is assumed. This assumption is critical and is tested by the Mauchly's test of sphericity. While this assumption was met ($p=0.000$), the skewed and multimodal distributions of the various pain scores presented significant threats to the ANOVA proposed in this study. Therefore, the Chi-Square Test of Independence was used to test the hypothesis.

The Chi-Square assumes that: (1) data must be frequency data; (2) there must be an adequate sample size; (3) measures must be independent of each other; and (4) variables may be theoretically categorized (Polit, 1996, 195-196). Additionally, the 2X2 chi-square distribution assumes that there will be a frequency of at least 10 subjects per cell. When there are less than 10, the Yates' Correction for Continuity Factor should be applied (Polit, 1996, p. 198).

In order to categorize the data, pain scores were transformed to nominal data. Subjects were assigned to one category if they experienced a negative change in their pain status (pain decreased) and a second category if they reported a positive change in their pain status (pain increased). If pain remained the same, the subjects were excluded in the hypothesis testing.

The frequency data and the chi-square results are reported in Table 7. The results illustrate that 48.4% of subjects had decreased pain scores post-PT versus 51.6% who reported decreased pain scores in the post-TT group. Refer to Table 7. Thirteen subjects

Table 7

Pain Scores by Groups

Result	Group Placebo	Treatment	Total
Increased Pain			
Count	7	7	14
Expected Count	6.8	7.2	14
% within Result	50.0%	50.0%	100%
Decreased Pain			
Count	46	49	95
Expected Count	46.2	48.8	95
% within Result	48.4%	51.6%	100%
Total			
Count	53	56	109
% of Total	48.6%	51.4%	100%

Note. Number of missing observations: 13.

are reported to be missing, as their pain scores did not change. Although both groups had decreased pain scores there, was no statistical support that one treatment was better

than the other (x^2=.012, p=.912). The Yates' Correction Factor was applied in this study, because two of the cells contained only seven subjects. Therefore, the research hypothesis was rejected as there was no statistically significant differences between treatment responses.

The Influence of Demographic Characteristics on Reported Pain Scores

Historically, it has been theorized that responses to pain are related to a variety of personal characteristics. The literature proposes that various ethnic groups perceive pain and cope with pain differently. Age has also been known to affect the perception of pain.. Kodiath (1991) states that the elderly are the largest population suffering with chronic pain, and that this pain is not merely physical, but psychological, social, spiritual, and economic.

In this study, personal demographic data were collected for each subject in order to test for these confounding relationships with the outcome variable of pain. Demographic characteristics were collected as three levels of data. Categorical variables included marital status and ethnicity. Ranked data were collected for education income and gender. Continuous incremental data were collected for age and years diagnosed with either FM or RA. The relationships between each of these variables and pain were considered using the appropriate parametric and nonparametric tests of relationship, dependant on data level. Table 8 demonstrates that there were no statistically significant relationships found in the sample between the demographic characteristics and reports of pre-treatment pain scores. Additional correlational testing of demographic variables was

Table 8

Correlations between Demographics Characteristics and First Pre-Test Pain Scores (n=61)

Variable	r	p
Marital Status	-.033	.800
Education	-.055	.671
Ethnicity	-.090	.489
Income	.066	.613
Gender	.039	.768
Age	.078	.552
Years of Diagnosis	.125	.338

Note. *p<.05

not pursued due to the lack of clinical and statistically significant results and the severe limitation of power found in the initial data analysis.

Methodological Limitations

Limitations noted within the study include: convenience sampling of population; sample size; the use of two different practitioners; the lack of environmental control over lighting and sound; the use of a placebo treatment; the different days utilized for treatments, and the potential for crossover effect due to length of time between treatments.

The population was a convenience sample rather than a randomized sample. All those subjects that self-referred were accepted into the study if they met the criteria.

Sample size was also an issue, Polit (1996) notes that when a multimodal distribution occurs is when there has not been an adequate sampling of the target population. Therefore, the sample size needed to be larger and selection randomized.

The use of two different practitioners who resembled one another so closely may have provided a limitation in this study. Even, under the most rigorous designs, one cannot guarantee that the two treatments were identical. Thus, the potential for the Hawthorne effect increases. The use of such a similar practitioner could have also impacted the study, according to Benner (1984), the PT practitioner could have begun to utilize the principals of TT due to her knowledge and expertise (cited in Marinier-Tomey, 1994).

Environmental control was also difficult in the clinic due to the availability of the treatment room and the heating and cooling system. The hospital is over 70 years old and the heating and cooling systems are antiquated. A few of the subjects complained about the room being too cold or that there was too much light in the room to relax. Lighting was also difficult to control because one treatment room had a window, whereas the other did not. Therefore, lighting was not consistent between rooms.

Two design flaws were also noted in this study. Those subjects receiving TT had to be given their treatment on a Wednesday, and those receiving the PT were treated on Saturdays. Due to time and clinic constraints, the TT was given on a Wednesday and the PT was given on a Saturday when the clinic was closed. This could have made a difference in the level of anxiety and stress in those that came to the study. The group that came on Wednesday had to fight the traffic during a work week, find a

parking space in a busy hospital, and possibly came from a work setting (40% had incomes greater than $30,000/year) which might contribute to the increase in anxiety and pain. This might suggest why the pain scores were notably higher pre-treatment for the intervention type. This also could have negatively impacted the study in that the TT practitioner had a more stressed, anxiety-ridden population. The literature is clear that for both FM and RA, stress and anxiety plays an important role in the escalation of pain.

Secondly, 30% of the two types of treatments were, on several occasions, scheduled only three days apart. Theoretically, this could have caused a crossover effect. Koithan (personal communication, June 22,1998) states, "Quinn, has discussed the speculation that TT lasts for at least one to two weeks, therefore, administering the PT three days post TT could have potentially created a carryover effect." This could theoretically explain why the group on Saturday had lower mean pain scores pre and post-treatment.

Summary of Results

There were no significant differences in post-treatment pain scores between the TT or PT treatment types. It was noted, however, that both groups showed a significant decrease in pain scores post-treatment. Several alternatives are offered as explanations for these results.

CHAPTER 6

DISCUSSION

Major Findings

The present study does not support the hypothesis which predicted that TT would decrease the perception of pain more effectively than PT in those diagnosed with FM and RA. Rather, both TT and PT led to a significant decrease in pain scores post-treatment.

Five alternative explanations regarding the outcomes of this study are offered: (1) The sample size was not large enough; (2) there was the potential for the carryover effect of one treatment to the other; (3) a Hawthorne effect may have been present; (4) there may have been subject-setting interaction effect; and, (5) there may have been a researcher-setting interaction effect, wherein a caring-validating presence creates a healing context which decreases pain perception.

The current sample size was 61 subjects. While initial power analysis prior to the collection of data suggested that a power of .80 would be achieved with a sample of 75, re-analysis of the power with a sample size of 61 revealed a power of only .10. In order to reach a power of .50, a sample of 550 subjects would have been required. This suggestion that the sample size was far too small was further confirmed by a multimodal distribution of the outcome data, also signaling an inadequate sampling of the population (Polit, 1996). While Polit recommends continued sampling of the population when

multimodal distributions are found, additional sampling was limited by the scope and nature of this project.

The carryover effect from one treatment to another could have explained why those receiving the PT three days post-TT had significantly lower pain scores pre and post-treatment. In this study it was noted that 30% of the subjects were given treatments within three days of each other. This occurred due to time constraints and scheduling difficulties. Koithan (personal communication, June 22, 1998) stated, "Quinn (January 15, 1996) has theoretically postulated that the carryover effect of TT could last up to two weeks. Therefore, giving a treatment within a few days of another would lead to lower pain scores on the second treatment. While, this is considered appealing if a PT is not employed; it would absolutely confound the effect if additional treatments are used sequentially". This carryover effect could have created the significantly lower pain scores pre- and post-treatment which were noted in the PT group. Additionally, a strong crossover effect could explain the significantly lower pain scores following PT when compared to post-TT pain scores.

The Hawthorne effect is also a concern in this study. Polit (1994) defines the Hawthorne effect as, "the effect on the dependent variable caused by the subject's awareness that they are participants under study" (p.613). The subjects and researcher in this study were blind to the treatment being administered. The researcher attempted to control for the Hawthorne effect; however, there was the potential that this indeed occurred. When pain is longstanding and intractable, as in both FM and RA, people are desperate for any treatment modality that offers some relief from pain. These populations

are seeking any treatment modality that will ease their pain. This need for pain relief thus may have led to the potential for the Hawthorne effect. Anecdotal comments offered by the subject's indicated that they were searching diligently for pain relief and were prepared to do anything to obtain relief. These findings raise serious concerns about the vulnerability and susceptibility of this population to treatments which have no documented effects. While the current study showed no differences when using TT in the treatment of chronic pain, the issue of alternative and scientifically supported treatments for chronic pain remain a primary concern for nursing and healthcare professionals.

Subject-setting interaction may have also altered the effects of TT and PT. Subjects may have experienced relaxation during the administration of TT and PT, simply because both treatments offered a one hour break from the hassles of life. As such, contributed to the reductions in pain. This, in and of itself, may have helped to break the pain-tension-anxiety cycle (Baquie, 1989; Segatore, 1994; Wallace, 1992) Both treatments required that the subjects lie down or sit down in a comfortable position with their eyes closed in a quiet environment.

Finally, there may have been a researcher-setting interaction. Benner (cited in, Mariner-Tomey, 1994) states that the "expert nurse has an intuitive grasp of the situation and is able to identify the region of the problem without wasting consideration on a range of alternative diagnoses and solutions" (p. 168). Benner believes that nursing needs to be described as a caring relationship which enables the nurse to engage in a relationship with the person, such as the relationship that is created between the patient and the practitioner in the health care setting. Once the patient creates a relationship with the practitioner,

there is a sharing of information. This can affect how the practitioner assesses and treats the subjects' pain. Only in the creation of a relationship can the practitioner truly understand the patient's subjective perception of pain.

The presence of a caring, listening, and validating practitioner may have also affected the level of relaxation for some which led to a decreased perception of pain. This in itself may have lulled the subjects into a feeling of relaxation and calm. Presence is a form of validation and caring that the practitioner extends to the person. Moch and Schaefer (cited in Snyder, 1992) defined presence as, "a process of being available with the whole of oneself and open to the experience of another through a reciprocal interpersonal encounter" (p. 238). Presence within the context of Rogerian theory is viewed as a relationship that is created between the practitioner and the client in which mutual patterning occurs. When this mutual patterning occurs there is a mutual sharing of information and experiences. In this way the practitioner is able to assist the client to a state of human betterment.

In summary, the confounding effects of a small sample size, the potential for a carryover effect, the possibility of a Hawthorne effect, subject-setting interaction and researcher-setting interaction may all have contributed to the outcomes of this study. These alternative explanations need to be assessed further if this study is replicated.

Theoretical Congruence

While the research hypothesis was not supported, the findings from this study suggest areas of potential congruence with Rogers' (1990) theory of Unitary Human Beings. The reduction of pain observed following an energetic transaction between nurse

and client in the form of either TT or PT support the premise of complementarity and integrality. When any caring practitioner enters into a relationship with another person's energy field, Rogers postulates that changes naturally occur through mutual patterning and evolutionary movement. This act of creating a relationship between practitioner and client leads to a mutual re-patterning as fields resonate and interact with each other. The decreases in pain perception whether during TT or PT, could be considered outcomes of the energy field transaction between the patient and the practitioner.

Evidence of the existence of the three principles of Rogerian homeodynamics (resonancy, helicy, and integrality) is suggested by the findings of this study. The fluctuations of the energy fields of the subjects from one treatment to the next and the corresponding changes in pain over time may reflect the process of resonancy. The nature of the changes in pain may be manifestations of helicy and integrality, as viewed in the human-environmental process noted between the practitioner's and the subject's energy field. Stated simply, pain is a subjective phenomenon which can only be described by the subject. Pain also changes over time and this was viewed in the pre and post-treatment pain scores as well as between the TT and PT.

This study may also support the conceptualization of an expert nurse as postulated by Benner (Mariner-Tomey, 1994). Both practitioners possessed experience, skills and knowledge of 20 years and were able to achieve the critical presencing and relational skills of a TT practitioner. Furthermore, the PT practitioner, as the expert nurse, may have been able to recognize patterns based on a deep experiential background and the innate desire to meet the patient's needs of pain relief (Mariner-Tomey, 1994). Thus, the effective

mechanism (pattern recognition) in TT could have been provided by this expert PT practitioner.

Generalizability

Caution is indicated in the interpretation of these findings in that the two disease processes in this study were FM and RA; therefore, generalization of these findings to other groups with chronic pain would not be appropriate. The generalizability of the results of this study are also hampered by the design flaws and sampling error previously discussed.

The sample size was not large enough, further it was a convenience sample which did not allow for a homogenous population. In addition, the multimodal distributions of scores indicated that the data were not representative of the target population being studied. Therefore, generalizability of the findings is impossible. Further studies correcting the biases found here, need to be done in order to validate these findings.

Implications for Nursing

The mechanism of TT is not clear, yet nursing uses TT and claims it works. (Heidt, 1981; Meehan, 1985; Peck, 1996). This study showed that there were no significant differences in post-treatment pain scores between the TT or PT treatment types. Therefore, this study questions the effectiveness of TT in those diagnosed with FM and RA. Caution is suggested in utilizing TT in practice settings for those diagnosed with chronic pain.

Research about TT lends credence to the effect of interpersonal relationships on patient care. It is conceivable that some form of mutual relationship was created in both

TT and PT. Therefore, this study possibly illustrates the need for practitioners to enter into caring relationships and the need for further investigation of presence, caring and validation of the patient's complaints. Further research is needed to determine the effects of a caring relationship on pain perception.

When patients are in longstanding pain, the literature shows that they will attempt anything to alleviate their suffering (Kenyon, 1994). The chronicity of the pain suffered in FM and RA, create a vulnerable population, in need of some pain relief. This can lead to an endless onslaught of "alternative remedies" that can be potentially harmful and costly to patients. Often patients with chronic pain are left to cope with their pain in silence. Those diagnosed with FM and RA have no hope for a cure at this time. A number of medications are often tried but fail to provide pain relief. This is especially true with FM subjects. Outcomes research provides health care professionals an opportunity to validate whether a therapy is worthy. This study showed that both treatments led to a decrease in pain scores post-treatment.

Suggestions for Future Studies

Additional research is needed in the area of chronic pain and treatment modalities. Further studies also need to assess the effects of TT and to evaluate the specific parts of the treatment. Researchable areas include:

1. What are the essential components of TT treatments and at which point does the greatest change occur?
2. When does the effect of TT begin and how long does it last once a treatment has been given?

3. How does TT affect the practitioner's energy field and does the client's energy field affect the unskilled nurse?
4. Would a longitudinal type study be more efficacious in assessing the effects and duration of TT?
5. Would a novice graduate nurse evoke decreases in pain perception versus an expert nurse versus a seasoned TT practitioner?
6. What is the effect of a caring presence on chronic pain?

Questions such as these begin to direct research into areas that are currently unexplored.

Summary

In summary, TT and PT treatments both provided a decrease in pain perception for people with RA and FM. There were several sampling and design flaws which render these conclusions questionable, at best. However, the data support that there may be an effect created by an expert nurse within a caring relationship. Theoretically, Benner suggests that the observed effects in the study may be due to the subjects ability to evoke the innate desire of the expert nurse to assist them with pain relief, thereby leading to a decrease in pain perception in those subjects treated.

Few conclusions may be drawn may be drawn from this study. However, these findings point to the need to continue to work in the area of chronic pain and treatment modalities. Additionally, this study suggests that a caring presence and its effects on client outcomes needs further exploration.

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APPENDICES

APPENDIX 1

Treatment Script

1. Ask the patient if they would like to sit or recline.
    a. If they chose to lie down put pillows underneath their head and knees to support their back.
    b. If they choose to sit have them sit comfortably in a chair

2. Place your hands for a few moments on the patients:
    a. If reclining, on their upper right arm for 1 minute.
    b. If sitting stand behind the patient with your hands lightly on their shoulders for 1 minute.

3. In a straight sweep move your hands from the top of the patient's head to their feet. Remember to keep you hands two to four inches away from their bodies.

4. Then begin with small sweeps over the entire body, again from head to toe.

5. Next, pick some areas of the body and do additional concentrated sweeps to this area, you may also hold the area or joint for one minute. The sweeping motion needs to be away from the body towards the floor (if sitting) or towards the feet (if reclining).

6. Next, select areas and brace this with your hands and hold for one to two minutes. Randomly choose a number of areas (depending on time).

7. Then do more short sweeps over the entire body.

8. Lastly, do one head to toe sweep and have the patient sit up if lying and if sitting have them just sit for one to two minutes..

9. Thank the patient for their participation and bring them to the front to the research assistant.

10. Go back to your room and come out when you are ready for your next patient.

Some appropriate responses to patient questions are:

1. I cannot divulge which treatment you will be receiving today.
2. Just relax and breathe normally.
3. You may ask to top the treatment at any time.
4. This treatment will take approximately fifteen minutes.
5. You may reposition at any time during the treatment.
6. I am not at liberty to divulge any specifics of the study or treatment you will be receiving.

APPENDIX 2

Attention those diagnosed with Fibromyalgia and Rheumatoid Arthritis

If you are interested in being included in a research study being done at Lovelace Health Systems, utilizing the complementary therapy of ***Therapeutic Touch*** to ***decrease pain***, please contact ***Rosa Matonti RN, BSN, CDE*** at ***(505) 262-3395*** from 8:00 a.m. to 4:00 p.m. you can leave a voice mail at this number. This study is scheduled to ***begin*** in ***February*** and to ***conclude*** by ***April 1998***. You will not be asked to terminate any of your current medications nor any other types of treatments you are currently receiving. The criteria for being in the study is that you are of legal age and that you have been diagnosed with Rheumatoid Arthritis or Fibromyalgia for at least 6 months and be in pain.

Funded by the Lovelace Clinic Foundation

APPENDIX 3

Prescreening Survey

1. Which disease process do you have?
2. Has a doctor told you you have Rheumatoid Arthritis or Fibromyalgia?
3. How long ago were you diagnosed?
4. What is your date of birth?
5. Is English your primary language?
6. Are you currently in pain?
7. How often are you in pain?
   a. always
   b. most days
   c. some days
   d. never
8. Meets study criteria? Yes_____ No _____ If No, do not continue.
9. Name:_____
   Address:_____
   Telephone #: _____
10. Informational Letter sent: Date _____
11. Followup phone call: Date _____ Appointment Date: _____

APPENDIX 4

Informational Letter

Dear_____:

Thank you for inquiring about the research project on chronic pain for those diagnosed with Rheumatoid Arthritis and or Fibromyalgia. I am a registered nurse and I am presently conducting a study of the effects of Therapeutic Touch on chronic pain. This study has been approved by the Lovelace Institutional Review Board and is being funded by the Lovelace Clinic Foundation.

Participation criteria is that one must have the diagnosis of either Rheumatoid Arthritis or Fibromyalgia, and the diagnosis must be at least 6 months ago. The participant must also be at least 21 years of age, be in pain, and be able to read and write in English.

I would like to explain a few details of the study that are important for you to know at this time. You will receive a total of two different treatments on two separate days approximately one week apart. You will not be informed which treatment you are to receive on your scheduled treatment day. All treatments will last approximately 15 minutes. The treatments will be done by registered nurses experienced in the therapies. During the treatments you will be asked to sit or recline in a comfortable position. The nurse will pass her hands over your clothed body during the treatment. The nurse will keep her hands approximately two to four inches away from your skin.

You will be given a questionnaire and a pain scale to complete prior to the treatment. This will take approximately 15 minutes to complete. Immediately after the treatment the pain scale will again be administered to each participant. This will take approximately 5 minutes to complete. after your treatment. Ten minutes will be allotted for preparation time and answering questions. The total time at the clinic should be approximately 45 minutes.

Your participation in this study is completely voluntary. You have the right to refuse to participate at any time during the study without jeopardy to your medical care at Lovelace Health Systems. I believe that your participation in this study will be informative and of benefit to you and future patients.

I assure you of the confidentiality of the information collected in this study. Your answers will not be linked to your name and all information obtained will be reported as group data only. Your name will only be used in compiling individual questionnaires and scheduling appointments. You will be contacted within the following week for an appointment time. You will be informed of the date, time and location of the study, at which time every effort will be made to accomodate your schedule. Thank you!

Sincerely,

Rosa Matonti RN, BSN, CDE
Graduate Student, Department of Nursing
University of Nevada, Las Vegas

Jeremy Gleeson MD
Medical Director Endocrinology/Diabetes

Ben Klein Ph.D.
Pain Management and Behavioral Medicine

APPENDIX 5

Patient Information and Consent Form

Study Title:	Utilization of Therapeutic Touch in Clients with Chronic Pain
Investigators:	Rosa Matonti RN, BSN, CDE Principal Investigator
	Jeremy Gleeson, MD Co-Investigator
	Ben Klein, Ph.D. Co-Investigator
Address:	Lovelace Health Systems 5400 Gibson Southeast Albuquerque, New Mexico 87108

You are being asked to take part in a research study. Please read this consent form carefully and ask as many questions as you like before deciding whether you want to participate.

1. PURPOSE OF THE STUDY:

The purpose of the study is to investigate the effect of Therapeutic Touch on the pain experienced by persons with Fibromyalgia and Rheumatoid Arthritis. Therapeutic Touch has been found to have the potential to relieve tension, decrease acute pain, and help patients to relax. Therefore, it may be helpful in relieving chronic pain. Patients treated with Therapeutic Touch have reported relief from acute pain and little study has been done with persons with chronic pain.

When being treated by the nurse giving the Therapeutic Touch treatment the nurse will focus and direct her intention to help decrease your pain by using her hands. The nurse will move her hands at a distance of two to four inches from the surface of the skin. This allows the nurse to feel for areas of coldness or congestion where energy is not being circulated well within the body, thereby causing pain or discomfort. This treatment will take a maximum of fifteen minutes. It will be done over ones clothing, and the participant will be asked to sit or recline in a comfortable position during the treatment.

When being treated by the nurse giving the Placebo treatment the nurse will repeat all of the movements of the nurse giving the Therapeutic Touch treatment. The treatment will be done over ones clothing, and the participant will be asked to sit or recline in a

centering, the assessment and the intention to heal that is inherent in the Therapeutic Touch treatment. The nurse giving the Placebo treatment will not have any experience or knowledge in the use of Therapeutic Touch. The subject will not be told which treatment they will be receiving.

2. TERMS OF THE STUDY:

To participate in this study you would have had to have the diagnosis of either Fibromyalgia or Rheumatoid arthritis for at least six months and be at least 21 years of age. Participation in this study requires answering questions about your background and usual daily activities as well as describing the level of pain you are having before and after the treatment. You will be asked to come to Lovelace Hospital, located at 5400 Gibson Southeast. The treatments will be given in the Diabetes/Endocrinology Unit on the second floor, located near the East parking area, on two separate occasions, spaced approximately one week apart for each treatment. The treatments will last approximately 15 minutes and the completion of the questionnaire and pain survey will take approximately 20 minutes. Ten minutes will be allotted for answering questions and preparation time. In all the time commitment will be approximately 45 minutes total per session. You will not at any time be asked to stop any of your medications or treatments.

3. RISKS OR DISCOMFORTS TO THE PATIENT:

Therapeutic Touch is used by many nurses as part of their nursing care and many studies of the effects of Therapeutic Touch have been done. No uncomfortable or harmful side effects are known to occur as a result of treatment by Therapeutic Touch.

4. BENEFITS AND COMPENSATION:

There will be no monetary compensation or additional charges to the participant for participating in this research study. The potential benefits of the study will be the identification of a complementary modality, that is noninvasive and nonpharmological in decreasing pain in those diagnosed with Rheumatoid Arthritis and Fibromyalgia.

5. CONFIDENTIALITY OF RECORDS:

Medical records which identify you and the consent form signed by you will be inspected by the Lovelace Institutional Review Board. Because of the need to release information to this party, absolute confidentiality cannot be guaranteed. The results of this research may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations. All data will be converted to a code number and be used for research purposes only.

6. TERMINATION OF STUDY:

Your participation in this study is voluntary. You may refuse to participate, and

you are free to withdraw at any time. Neither of these actions will result in the loss of any benefits to which you are otherwise entitled, nor will it prejudice your doctors against you in any way.

However, if you withdraw from this study, you will be required to contact the investigator immediately. Your participation in this study may also be ended without your consent by the study investigator if: (1) you fail to come to the scheduled treatment appointment or (2) if the study is stopped for any reason. At study termination, you will be given the option of requesting study results, which will be mailed to the you within three months of the termination of the study.

7. AVAILABLE SOURCES OF INFORMATION:

Any questions or concerns may be directed to Rosa Matonti RN, BSN, CDE at (505)262-3395 between 8:00 a.m. and 4:00 p.m., Dr. Mary Koithan at (702) 895-3408 or the University of Nevada, Las Vegas Office of Sponsored Programs at (702) 895-1357.

For information concerning your rights as a research subject, you should contact Lovelace Risk Management at 232-1950.

8. AUTHORIZATION:

Any known risks and potential benefits have been explained to me in this consent form. In addition, any new information concerning this study will be made available to me as it becomes known. I have had adequate chance to ask questions and I may ask them at any time while the study is in progress. I understand that my consent to participate in this research study does not take away any legal rights which I may have in the case of negligence or other legal fault of anyone who is involved in the study.

I voluntarily execute this consent form as my own free act and deed, and am willingly and freely consenting to participate in this study. I will receive a copy of this signed consent form.

Patient Signature	Date
Witness Signature	Date
Investigator's Signature	Date

Patient Initials	Cons TOUCH / 2/3/98 Date

APPENDIX 6

Demographic Questionnaire

Please check the correct answer or fill in the blank

1. How old are you? _____

2. Are you?
   - ❑Male
   - ❑Female

3. Are you?
   - ❑Single
   - ❑Married
   - ❑Divorced
   - ❑Widow

4. What is the highest grade in education you have finished? _____

5. What is your ethnic background?
   - ❑Caucasian/White
   - ❑African-American/Black
   - ❑Hispanic
   - ❑Native American
   - ❑Other (please specify) _____

6. What is your diagnosis?
   - ❑Fibromyalgia
   - ❑Rheumatoid Arthritis

7. How many months/years have you had this diagnosis? _____

8. What are the current medications you are taking? _____
_____
_____
_____
_____

9. What medications have you taken today? _____
_____
_____

10. Do you use any medications not prescribed by a doctor (i.e. herbal products, teas, poultices)?

❑No

❑Yes, If yes what are they? _____

_____

_____

_____

_____

11. Do you do anything else to help with the pain? If yes, proceed to number 12. If no, go to 13.

❑No

❑Yes

12. What other things do you do to relieve the pain?

❑Relaxation

❑Exercise

❑Accupressure

❑Acupuncture

❑Chelation therapy

❑Reflexology

❑Chiropractor

❑Other, please specify _____

13. Please estimate your household income?

❑$0-$10,000

❑$10,001-15,000

❑$15,001-$20,000

❑$20,001-$25,000

❑$25,001-$30,000

❑$30,001-$35,000

❑$35,001-$40,000

❑$40,001-$45,000

❑greater than $45,000

APPENDIX 7

PRETREATMENT
VISUAL ANALOGUE SCALE

This is a line which extends from "no pain" to "pain as bad as it could be." Please place a single mark through the line at a point between the two extremes which best represents the degree of pain you are experiencing now.

PAIN AS BAD AS IT CAN BE

NO PAIN

APPENDIX 8

POSTTREATMENT
VISUAL ANALOGUE SCALE

This is a line which extends from "no pain" to "pain as bad as it could be." Please place a single mark through the line at a point between the two extremes which best represents the degree of pain you are experiencing now.

PAIN AS BAD AS IT CAN BE

NO PAIN

QUESTION:
Do you feel a difference after today's treatment?
❑ No
❑ Yes, If yes, explain briefly:_____

APPENDIX 9

UNLV

PROTOCOL FORM APPROVAL SHEET

FOR RESEARCH INVOLVING HUMAN SUBJECTS

Log Number: ____2-1998_____

Title of Project: _Utilization of therapeutic touch in clients with chronic pain___

Investigator: _____Rosa Matonti, R.N. and Mary Koithan, R.N.,Ph.D.

After reviewing this proposal, the members of the _Department of Nursing, Human Subjects Rights____ **Review Committee have indicated below their approval/disapproval of this proposal.**

Signature of Committee Members	Approve	Disapprove
Susan Kowalski	✓	
Carol Rayfield	✓	
Margaret Lewis	✓	

The above named project is hereby approved/disapproved (circle one).

Date: 23 Jan 1998

Margaret Lewis
Committee Chairperson's Signature

Department of Nursing
4505 Maryland Parkway • Box 453018 • Las Vegas, Nevada 89154-3018
(702) 895-3360 • FAX (702) 895-4807

APPENDIX 10

UNLV

DATE: February 9, 1998

TO: Rosa Matoni (NUR)
M/S: 3018

FROM: Dr. Lawrence Golding
Chairman, Biomedical Sciences Committee
of the UNLV Institutional Review Board

RE: Status of Human Subject Protocol entitled:
"Utilization of Therapeutic Touch in Clients with Chronic Pain"

OSP #501s0198-151b

This memorandum is official notification that the protocol for the project referenced above has been approved by the Biomedical Sciences Committee of the Institutional Review Board. This approval is approved for a period of one year from the date of this notification, and work on the project may proceed.

Should the use of human subjects described in this protocol continue beyond a year from the date of this notification, it will be necessary to request an extension.

If you have any questions or require any assistance, please Marsha Green at 895-1357.

cc: M. Koithan (NUR-3018)
OSP File

Office of Sponsored Programs
4505 Maryland Parkway • Box 451037 • Las Vegas, Nevada 89154-1037
(702) 895-1357 • FAX (702) 895-4242

APPENDIX 11

Institutional Review Board

November 21, 1997

Rosa Matonti, RN
Lovelace Clinic Foundation
5400 Gibson Blvd. SE
Education Bldg. 2nd Flr
Albuquerque, NM 87108

SUBJECT:
IRB# 97-094 **Title: Utilization of Therapeutic Touch in Clients with Chronic Pain**

Dear Ms. Matonti:

The Institutional Review Board has reviewed your protocol for the referenced project. Approval has been granted by Expedited Review on ***November 21, 1997.*** Approved are:

Protocol:	**N/A**
Number of Patients:	**Approximately Sixty-five (65) to Seventy-five (75)**
Consent Form:	**ConsTOUCH/111897**
Period of Review:	**Twelve (12) months**
Advertising:	**Yes**
Investigators:	**Jeremy Gleeson, MD., Ben Klein,PhD**

The IRB must be notified of any problems, which occur, or changes to the protocol or consent form.

Approval will expire at the end of the ***twelve (12) month*** period extending from ***November 21, 1997 to November 21, 1998.*** If the program is to continue beyond the original period of time, you are responsible for submitting a progress report to the IRB prior to the expiration date. Although you will receive a notice and a progress report form from the IRB office approximately ***October 10, 1998,*** please make a note of the renewal date as a safeguard. This will assure sufficient time for processing and review prior to expiration of approval.

If the study ends prior to the expiration date, you should submit an end of study report to the IRB so that the approval may be discontinued.

Sincerely,

Margaret J. Gunter

Margaret J. Gunter, PhD., Chair
Institutional Review Board

APPENDIX 12

LOVELACE HEALTH SYSTEMS

September 30, 1997

To whom it may concern:

This letter allows University of Nevada Las Vegas student Rosa Matonti, RN to utilize the Lovelace Health Systems Endocrinology/Diabetes unit to collect data for her thesis entitled "Utilization of Therapeutic Touch in Clients with Chronic Pain". We have received an abstract of the study including data collection tools and cover/permission letter. She may begin collecting data at this unit after receiving approval from the Human Subjects Rights Committee at the University of Nevada Las Vegas and the Lovelace Institutional Review Board. We look forward to having Rosa conduct this study at our facility.

Sincerely,

Pat Hamilton

Patricia Hamilton RN, MSN
Director of Nurses Endocrinology/Diabetes

5400 Gibson Blvd., S.E.
Albuquerque, New Mexico 87108
(505) 262-7000

VITA

Graduate College
University of Nevada, Las Vegas

Rosa Matonti

Home Address:
9908 Irbid Northeast
Albuquerque, New Mexico 87122

Degrees:
Bachelor of Science, Nursing, 1986
University of New Mexico, Albuquerque

Special Honors and Awards:
Sigma Theta Tau, 1997
Sigma Theta Tau's Poster Presentation Award, 1997

Thesis Title: Utilization of Therapeutic Touch in Clients Diagnosed with Chronic Pain

Thesis Examination Committee:
Chairperson, Dr. Mary Koithan, Ph.D.
Committee Member, Dr. Susan Michael, DNSc.
Committee Member, Andra Fjone, MSN
Committee Member, Dr. Richard Tandy, Ph.D.