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EFFECTS OF OSTEOPATHIC MANIPULATIVE TREATMENT ON OSTEOARTHRITIS

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EFFECTS OF OSTEOPATHIC MANIPULATIVE TREATMENT ON OSTEOARTHRITIS

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TABLE OF CONTENTS

Page

LIST OF TABLES.....iv

LIST OF ILLUSTRATIONS.....v

Chapter

I. INTRODUCTION.....1

II. LITERATURE REVIEW.....4

III. METHODOLOGY.....13

IV. RESULTS.....17

V. DISCUSSION.....26

VI. CONCLUSION.....30

APPENDIX.....33

REFERENCE.....62

LIST OF TABLES

Page

Table 1.....18

LIST OF ILLUSTRATIONS

Page

Figure 1 (Range of Motion Left Knee).....19

Figure 2 (Range of Motion Right Knee).....19

Figure 3 (Up and Go Test).....20

Figure 4 (WOMAC ADL Subscale).....21

Figure 5 (WOMAC Stiffness Subscale).....22

Figure 6 (WOMAC Pain Subscale).....23

Figure 7 (Visual Analog Pain Scale).....24

Figure 8 (NSAID Use).....25

CHAPTER 1

INTRODUCTION

Osteoarthritis (OA) is the most prevalent form of arthritis in the United States. Of those 65 to 74 years old, 18 per 100 women and 8 out of 100 men will experience OA of the knee. (Towheed and Hochberg, 1997) The Center for Disease Control and Prevention (CDC) reported a high prevalence for disability for persons > 65 years. Arthritis or rheumatism accounts for 7.2 million (17.1%) people ranking above back problems and heart disease. (CDC, 1994) The Framingham epidemiologic study of knee osteoarthritis estimated a 27% prevalence for those < 70 years and 44% for those > 80 years. (Nelson, Naimark, Anderson, Kazis, Castell, & Meenan, 1987) This study uses the principles of Osteopathy to treat OA for the elderly as osteopathic manipulative treatment (OMT) specifically addresses the symptoms and signs of OA.

The typical symptom of OA is pain and stiffness "in and around a joint accompanied by limitation of function." (Klippel, 1997) Pain from OA may originate from "periostitis at sites of bony remodeling; subchondral microfractures; irritation of sensory nerve endings in the synovium from osteophytes; periarticular muscle spasm; bony angina due to decreased blood flow and/or elevated intraosseous pressure; and synovial inflammation

accompanied by release of prostaglandins, leukotrienes, and other cytokine." (Klippel, 1997) Other symptoms include morning stiffness, gel phenomenon, buckling/instability. The signs of OA are bony enlargements, limitation of range of motion, crepitus, tenderness on pressure, pain, joint effusion, malalignment and/or joint deformity. (Hazzard, 1999) Most often, pain and limitation of movement from OA cause significant changes in lifestyle for the older adult; functional independence is adversely affected.

Decreased functional independence that affects the quality of life makes this the most debilitating illness in the 65 and older population. Studies have shown that patients with osteoarthritis of the hip and knee have comparable number of days with restricted activity as patients with rheumatoid arthritis. (Towheed, 1997; Holman & Lorig, 1997) Treatment goals for managing osteoarthritic patients is to control pain subsequently minimizing functional limitation and disability. (Hazzard, 1999)

To treat the above dysfunction, current treatments for OA include pharmacologic agents such as NSAIDs, analgesics, intra-articular steroid injections, topical analgesics; glucosamine sulfate and hyaluronic acid; nonpharmacologic measures include weight reduction, therapeutic ultrasound, acupuncture, transcutaneous electrical nerve stimulation (TENS), physical therapy, pulsed electrical stimulation, orthotics, hydrotherapy, self management courses, and support groups. (Wolheim, 1996; Zizic, 1995; Creamer, 1997; & McNoll, 1998) The primary objective of pharmacologic treatments is to decrease

pain resulting in an increased functional capacity and improved quality of life. There are side effects and limitations to pharmacological regimens. For example, the usage of NSAIDs in the treatment of the elderly can result in gastrointestinal bleeding. (McNoll, 1998) Non-pharmacologic treatments are viable alternatives in treating osteoarthritis; osteopathic manipulative treatment is such an alternative.

A primary osteopathic principle dictates that structure and function are reciprocally inter-related. Any change from the "normal" is called a somatic dysfunction. Specifically, somatic dysfunction is the altered or impaired function of related components of the somatic (body framework) system - skeletal, arthrodial, and myofascial structures and related vascular, lymphatic, and neural elements. (Greenman, 1989) OMT is used to return the body to its normal state by increasing symmetry and motion thereby improving body balance and reducing inflammation and pain by increasing fluid flow.

When considering the physiological causes for OA of the knee coupled with the side effects from pharmacological treatment, health care providers must consider alternative treatments. The principles of osteopathy provide a logical spring board to meet that challenge. This present study provides a preliminary understanding of the efficacy of OMT for OA of the knee.

CHAPTER 2

LITERATURE REVIEW

Andrew Taylor Still, M.D. (1828 – 1917) conceptualized osteopathy in June1874 when he "flung to the breeze the banner of osteopathy". (Still, 1908) Anatomy and physiology formed the foundation of osteopathy. The principles include the body is a unit; the body is self regulating and self healing; structure and function are inter-related; and the body systems depend on the integration of the nervous and circulatory system. (DiGiovanna, 1991 & Dodson, 1979) Therefore all restrictions including causes of nerve irritation must be removed for health. Most importantly the fascia must "be free at all parts to receive and discharge all fluids…By its action we live and by its failure we die." (Still, 1902)

Based on Dr. Still's teaching, Osteopathic physicians in the 1900s advocated the use of osteopathic principles to treat diseases. Gibbs postulated that everyone is a "potential victim" of osteoarthritis and old age is the most common predisposing factor. (Gibbs, 1941) The process of aging starts at birth but it is how the body ages that contribute to disease. (Andrews, 1956) Gravity is a destructive force in arthritis especially on a dysfunctional body. (Nelson, 1950)

Factors that predispose person to OA of the knee vary. Nutrition also contributes to arthritis as a rich diet or overeating causing obesity will trigger changes in the somatic system. A history of major knee injury (fracture or use of crutch or cane), chondrocalcinosis, repetitive use, and age > 50 years are additional contributing factors. (Felson, 1990) Externally, environmental stress such as trauma and occupational stress are contributory. Internal factors include structural abnormalities (i.e. flat feet or leg length discrepancy), malfunction of the organic and endocrine systems, emotional or psychic stress, mental or physical fatigue and dietary deficiencies. (Andrews, 1956) A survey of 100 patients at the Ottawa Arthritis Sanatorium found 77% of them had a leg length discrepancy causing un-leveling of the sacroiliac. (Nelson, 1950) Finally the coexistent of degenerative diseases appears to be a contributing factor in OA. (Craske, 1940)

Regardless of these causes, OMT may be used to clear obstruction and increase fluid flow. Osteoarthritis is a syndrome comprising of multiple defects or abnormalities of articular cartilage. (Altman and Dean, 1989) Fischer believed that arthritis is not just disease of the joint but a "constitutional disease that involves the joint." (Fischer, 1945) Those symptoms traditionally surface as "functional disability, restriction of motion, and altered loading of the joints, the secondary effects of connective tissue deterioration..." confirming the osteopathic principle of the inter-relationship of structure and function. (Akeson, Garfin, Amiel, and Woo, 1989) An important cause is a decrease in blood supply

feeding the joints. Any minor alterations in the spinal segments could affect the nervous and circulatory system. In addition any ligamentous injury which causes a joint to be hypermoblie and loss of proprioceptive ability may be a precursor to osteoarthritis. (Fiechtner & Brodeur, 2000) As a result ligaments can elongate and becomes weakened causing joint instability. (Merritt, 1989)

Connective tissue degeneration in and around a joint causes instability and pain. Pain is the body's protective mechanism but its perception varies between individuals. There are two types of pain fibers, fast and slow. Fast pain mediated by the Aδ fibers transmits acute and sharp sensation within 0.1 second. Conversely the slow fibers are mediated by C fibers which provide slow burning, aching, throbbing, nauseating, and chronic pain.

Pain sensation can be caused by either a mechanical, thermal, or chemical stimuli. (Guyton and Hall, 1996) Mechanical irritations of free nerve endings within the joint cause OA pain. Nociceptors in the joint capsule and ligaments, articular fat pads, perivascular sites, bone, periosteum, muscles, and tendons are neural sensors that signal "potentially harmful stimuli or situation to the central nervous system (CNS)." (Zimmerman, 1989) These receptors are sensitive to mechanical strain and joint movements beyond physiological range. Chemical stimuli such as Substance P, bradykinins, prostaglandins, leukotrienes, potassium ions, serotonin, and others are believed to cause chronic excitation of the nociceptors in OA. (Guyton and Hall, 1996) These factors are capable of stimulating mast cells with the release of serotonin and histamine causing

neurogenic inflammation. In addition when C-fibers are stimulated, vasodilation occurs and continues to increase with further stimulation. Both are additive effects causing joint symptoms. As the nerve is chronically stimulated, even light stimulation can elicit an abnormal discharge from the nerve. (Zimmerman, 1989)

In the 1940s, Drs. Korr, Denslow, Wright and others at the American School of Osteopathy studied similar mechanisms for osteopathic lesion (somatic dysfunction). The sympathetic nervous system was implicated as a cause for target tissue damage, either immediate or latent, from prolonged stimulation or inhibition. In the 1950's Korr and Denslow introduced the term "facilitated segment" from research on the relationship of the nervous system (sensory, motor and autonomic) to the osteopathic lesion in osteopathic medical students. The facilitated segments are areas of low resistance to electrical impulse under constant "subliminal excitation." Even at rest, it will be excitable with little stimulation. Consequently over time the individual's reserve is depleted leading to disease. The illness depends on the demands placed on it and the primary target organ. (Korr, 1979) Therefore nociceptive reflexes leading to somatic dysfunction (osteopathic lesion) is evidenced in OA causing motion restriction, pain, and autonomic arousal. (Van Buskirk, 1990)

Not everyone with OA has pain even on radiographic evidence of the disease. The NHANE-I and NHEFS study noted only 44% of their population were symptomatic especially those with more severe disease. This trial also confirms Craske's statement regarding the coexistence of degenerative disease. Subjects

with knee pain had associated hypertension and obesity. (Hochberg, Lawrence, Everett, and Cornoni-Huntley, 1989) The authors concluded that baseline pain is an important predictor of persistent symptoms and development of disabilities. (Zimmerman, 1989)

The most common treatment available for osteoarthritis is pharmacologic treatment using Nonsteroidal Anti-inflammatory Drugs (NSAID) and/or analgesics. Most clinicians will start with an analgesic such as acetaminophen or an NSAID such as ibuprofen. A literature review reveals that 63% of the studies are devoted to NSAID and 5% are non-pharmacologic. (Puett & Griffin, 1994) Rubin estimated > 300 million people on NSAID. (Rubin, 1999) These drugs bring many adverse effects: gastrointestinal (GI), renal and hepatic toxicity, and an increase risk of hypertension. (Ernst, 1997) The most serious complication is GI bleeding in the older adult, the population most affected by osteoarthritis and side effects. Those older than 60 years have 2.5 times the risk of hospitalization and three times the risk of death due to GI complications secondary to age-related physiologic changes in drug metabolism such as absorption, distribution, metabolism, and excretion of the drug. In addition older adults experience polypharmacy which potentially cause more drug to drug interaction. (Adelizzi, 1994) Even the new class of NSAIDS, the COX-2 inhibitor, such as celecoxib, has a potential for gastric bleeding. (Panel Book, Celebrex) Currently medications provide only symptomatic relief.

Beyond pharmacologic therapy, exercise has been considered for OA treatment although studies show conflicting results. Van Baar did not find conclusive evidence that exercise brings benefits however self report of disability and walking showed a small benefit. (Van Baar, Assendelft, Dekker, Oostendorp, and Bulsma, 1999) However in another study, Van Baar et al found a moderate reduction of pain for the exercise group. (Van Baar, Dekker, Oostendorp, Bijl, Voorn, Lemmens, and Bulsma, 1998) Regular exercise and attention to nutrition will partially preserve muscle mass, strength, and function as the body age. Deyle et al found a statistically significant improvement for a 6-minute walk and the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) score for the physical therapy and exercise group and maintained for one year. (Deyle, Henderson, Matekel, Ryder, Garber, and Allison, 2000) The Fitness Arthritis and Seniors Trial (FAST) results showed an improvement in measures of disability, physical performance, and pain in the aerobic and resistant exercise groups compared to health education program. (Ettinger, Burns, Messier, Applegate, Rejeski, Morgan et al, 1997) Another study on muscle rehabilitation program for improvement on muscle strength, endurance, speed, and function for men with OA resulted in an improvement of 35% for strength and endurance, and 50% for speed. As a result, patients had less dependency, difficulty, and pain. These improvements lasted for eight months after rehab. (Fisher, Pendergast, Gresham, and Calkins, 1991) Overall the authors concluded that exercise is

good for arthritics done "gently and on an individual basis" balanced with rest. (Panush & Holtz, 1994 and Daly & Berman, 1993)

People with OA need to start or continue some type of exercise program to maintain range of motion, flexibility, and strength. Loss of knee extension will reduce walking efficiency and loss of knee flexion to 90° will interfere with stair climbing and transferring resulting in an increased risk for injuries and falls. One study revealed that those who exercised had better control of pain, physical activity, walking distance and with no increase in medication. (Minor, 1999)

Besides exercise therapy for osteoarthritis, alternative modalities include acupuncture, vitamin and mineral, estrogen, and manipulation. A randomized trial of acupuncture as an adjunctive therapy demonstrated an improvement in the WOMAC and Lequesne scores, both were maintained post treatment. (Berman, Singh, Lao, Langenberg, Li, Hadhazy, Bareta, & Hochberg, 1999) Ernst systematically reviewed the literature for controlled trials of acupuncture from 1966 – 1997. Seven of the studies reported a positive result for the acupuncture treatment group. (Ernst, 1997)

Herbal remedies such as glucosamine are aggressively marketed to older adults but not regulated by the Food and Drug Administration. As a result dosages are not uniform. A recent double blind randomized control study at the VA regarding the effectiveness of glucosamine 1500 mg daily did not show statistical significance. (Rindone, Hiller, Collacott, Nordhaugen, & Arriola, 2000) Another trial did not reveal statistical significance in favor of glucosamine use but

did show a decreased score for the WOMAC subscale for pain. (Houpt, McMillan, Wein, & Paget-Dellio, 1999)

Aside from herbals, vitamin supplementation is thought to be helpful in osteoarthritis. The Framingham Study looked at the relationship between dietary intake and serum level of vitamin D in relation to the progression of knee OA. Results indicate a three to four-fold increased risk for progression of OA for subjects in the lower and middle tertile for vitamin D intake. Low serum levels of vitamin D predicted loss of cartilage and osteophyte growth. (McAlindon, Felson, Zhang, Hannan, Aliabadi, Weissman, Rush, Wilson, and Jacques, 1996) McCalindon and Felson reviewed the literature to examine the relationship of Vitamin C intake and knee pain. They found a decreased risk of developing knee pain and a three-fold decrease in the progression of knee OA in the Vitamin C user group. In this study β carotene usage was also associated with a slower progression of OA. (McCalindon & Felson, 1997) Finally the Framingham Study observed a 60% decreased risk of radiographic progression of OA in women who are currently on estrogen compared to those who never use hormone. (Zhang, McAlindon, Hannan, Chaisson, Klein, Wilson, and Felson, 1998)

Osteopathic manipulation is believed to be helpful for disease prevention. "Osteopathic manipulative treatment is absolutely essential in preventing further mechanical strain; it aids in restoring good body mechanics and in building up normal health and resistance to prevent further advances of the disease." (Gibbs, 1941) It is imperative for clinicians to know body mechanics to locate and

remove infection, manipulate to normalize joint mechanics and prevent deformity, and restoration of "normal health and prevention of recurrence." (Gibbs, 1941During treatment, efforts need to be directed toward metabolism rather than the joints specifically. (Nelson, 1950) All doctors "need to know the anatomy and physiology" for effective treatment. (Northup, 1936) In 1969 a British orthopedic surgeon advocated the use of self-manipulation for osteoarthritis as a conservative therapy to "restore the length of the muscles so that their flexibility and extensibility return to normal; break down capsular thickenings and adhesions; and improve articular cartilage and bony incongruity and joint circulation."(Tucker, 1969)

Few studies today specifically address somatic dysfunction in relation to functional status. A recent animal trial used a rat model to illustrate osteopathic treatment principle and arthritis. Rats with induced arthritis were treated with OMT and exercise for 23 sessions. Results showed a statistical significant increase in the OMT treated rat's stride length. (Hallas et al., 1997) Knebl and Gamber demonstrated efficacy of OMT for osteoarthritis of the shoulder. (Knebl, Submitted 2000) Finally Wells et al improved gait performance in Parkinson's patient with OMT. (Wells, 1999) This present study hopes to increase quality of life and functional status with OMT in subjects with OA.

CHAPTER 3

METHODOLOGY

A single-blind randomized study was designed to determine the degree to which osteopathic manipulative treatment (OMT) can improve the quality of life for osteoarthritis (OA) patients over the age of 55. The objectives were to decrease the use of Nonsteroidal Anti-Inflammatory Drug (NSAID) by 30%, reduce pain by 30%, and increase functional status by decreasing pain and increasing range of motion (ROM). The subjects were community dwelling seniors with a diagnosis of knee osteoarthritis from their primary care physicians. The recruitment of subjects included a list of potential subjects from the University of North Texas Health Science Center at Fort Worth Office of Clinical Trials, the Gerontology Assessment and Planning Program, the general medicine and family practice clinics, and the Tarrant County community.

Approximately 768 patients were screened by phone calls. From this group 77 subjects were identified. Twenty- two subjects withdrew without an appointment and 55 patients were scheduled. Thirty-four patients completed the study and seven withdrew after several visits for medical and non-medical reasons. The subjects were assigned into a control, sham, or treatment group by

a list of computer-generated random numbers. A clinical criterion from the College of Rheumatology for knee osteoarthritis was used to identify potential subjects (see inclusion criteria.) Following the protocol approval by the IRB, the following inclusion and exclusion criteria were used:

Inclusion Criteria:

- Knee pain with at least three of the following:
  - age > 55 years
  - stiffness < 30 minutes
  - crepitus
  - bony tenderness
  - bony enlargement
  - no palpable warmth
- non-demented (The Folstein Mini Mental State Exam (MMSE) was administered to all subjects to determine the presence of cognitive impairment.)

Exclusion criteria:

- lack of a diagnosis of knee osteoarthritis
- hip fracture in the last year or vertebral fracture in the last 6 months
- OMT in the last 6 months for the knees
- hip or knee arthroplasty
- knee range of motion < 30 degrees
- inability to rise from a chair.

The study lasted five months. All subjects were seen once a week for the first 4 weeks, once every two weeks for the next three months, and finally four weeks after visit 10 (Appendix A). Objective and subjective data were collected for everyone. Objective data points included the "Up and Go", a timed performance test, with the usual walking aid and a ROM of the knee measurement were obtained using a goniometer with patients in a lateral recumbent position. Subjective data were collected using the visual analogue pain scale (Appendix B) and the Western Ontario and McMaster University Arthritis index questionnaire, a validated questionnaire designed to assess function in osteoarthritis. A blinded assessor collected the data. At each visit subjects self reported the number of pills consumed (analgesic and/or NSAID) since the previous visit (Appendix C).

All groups received an osteopathic structural exam. In addition, the sham group had ROM and the treatment group received OMT using the following modalities: muscle energy, strain-counter strain, myofascial release, cranial-sacral release and unwinding to tolerance. The application of specific modalities is subject-specific based on the investigator's exam. Throughout the entire study, one osteopathic physician examined and treated the subjects eliminating inter-rater reliability variability.

Statistical analyses set at a 0.05 significance level were completed on the total population with appropriate breakdowns by groups: control, sham, and treatment. These include descriptive statistics, Chi-Square for significance levels by categories, and multivariate analysis. The Statistical Package for the Social

Sciences (SPSS) 9.0 software and 0.05 level of significance were used in hypothesis testing.

CHAPTER 4

RESULTS

Forty- two subjects were randomized to a treatment, sham, or control group. Thirty-four subjects completed the study. There was no statistical difference between the three groups for age, gender, ethnicity, marital status, education, or type of occupation (Table 1).

Functional measurements include ROM of the right and left knee using a goniometer, Up and Go Test, and the Western Ontario and McMaster University Osteoarthritis Index (WOMAC). The ROM for both knees was increased but did not achieve statistical significance (p=0.919 for the left knee and p=0.982 for the right knee.) (Figure 1 and 2) The left knee had a more consistent increase for all groups (control, sham, and treatment.) Although 70% of the population had bilateral knee OA, subjects usually experience more restriction in one knee causing gait imbalance. Therefore it was important to review each knee separately.

TABLE 1. SOCIODEMOGRAPHIC CHARACTERISTICS BY GROUP OF OSTEOARTHRITIS STUDY 2000			
	GROUP		
	CONTROL n (%)	SHAM n (%)	TREATMENT n (%)
Treatment			
Completed	12 (29.3)	8 (19.5)	14 (34.1)
Withdrew	2 (4.9)	2 (4.9)	3 (7.3)
Age y.			
55-64	6 (14.6)	3 (7.3)	8 (19.5)
65-74	3 (7.3)	6 (14.6)	7 (17.1)
75-84	5 (12.2)	1 (2.4)	2 (4.9)
Gender			
Male	5 (12.2)	5 (12.2)	3 (7.3)
Female	9 (22)	5 (12.2)	14 (34.1)
Ethnicity			
Caucasian	13 (31.7)	9 (22)	14 (34.1)
African-American	1 (2.4)	1 (2.4)	2 (4.9)
Hispanic	----	----	1 (2.4)
Marital Status			
Married	9 (22)	6 (14.6)	11 (26.8)
Widowed	3 (7.3)	2 (4.9)	3 (7.3)
Divorced	1 (2.4)	2 (4.9)	2 (4.9)
Single	1 (2.4)	----	1 (2.4)
Living Status			
Alone	6 (14.6)	1 (2.4)	5 (12.2)
With someone	8 (19.5)	9 (22)	12 (29.3)
Education			
< High School	3 (7.3)	----	2 (4.9)
High School	3 (7.3)	3 (7.3)	4 (9.8)
College	7 (17.5)	7 (17.5)	10 (25)
Education	1 (2.4)		1 (2.4)
Masters Degree			
Type of Job	7 (17.5)	7 (17.5)	7 (17.5)
Non-physical	7 (17.5)	3 (7.3)	10 (25)
Physical			

Figure 1

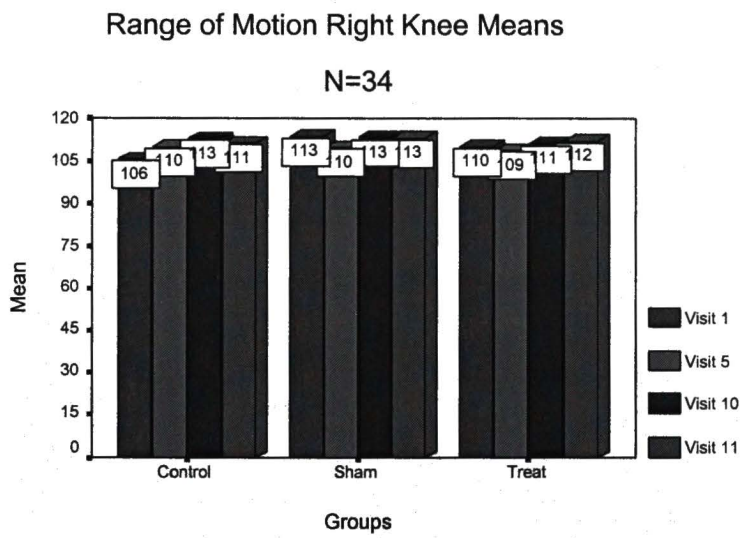


Figure 2

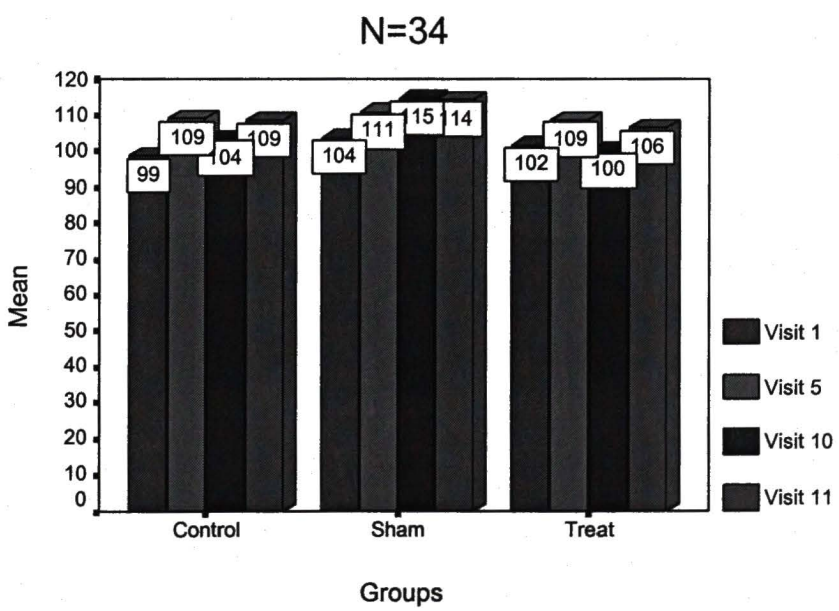


Figure 3 illustrates a downward trend for the Up and Go Test. Statistical significance was not achieved for all groups (p=0.754).

Figure 3

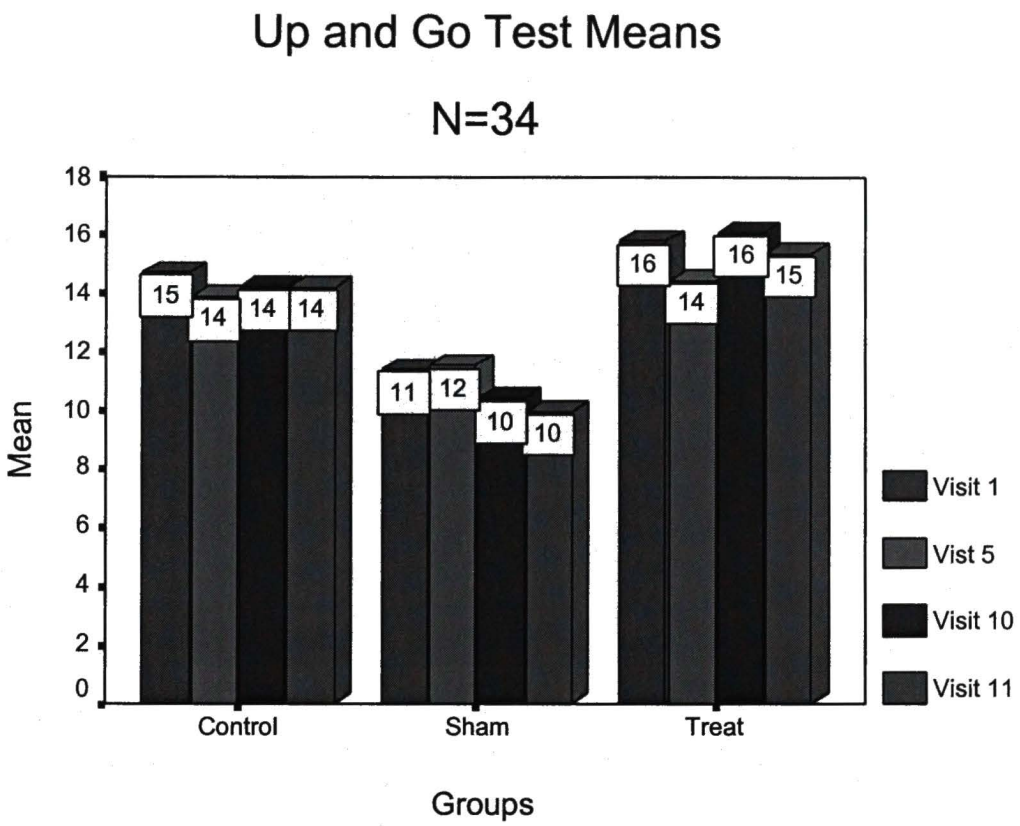


Figure 4 shows a decrease in difficulty for WOMAC Activities of Daily Living (ADL) score for the sham and treatment groups without statistical significance (p=0.721).

Figure 4

WOMAC Difficulty with ADL Means

N=34

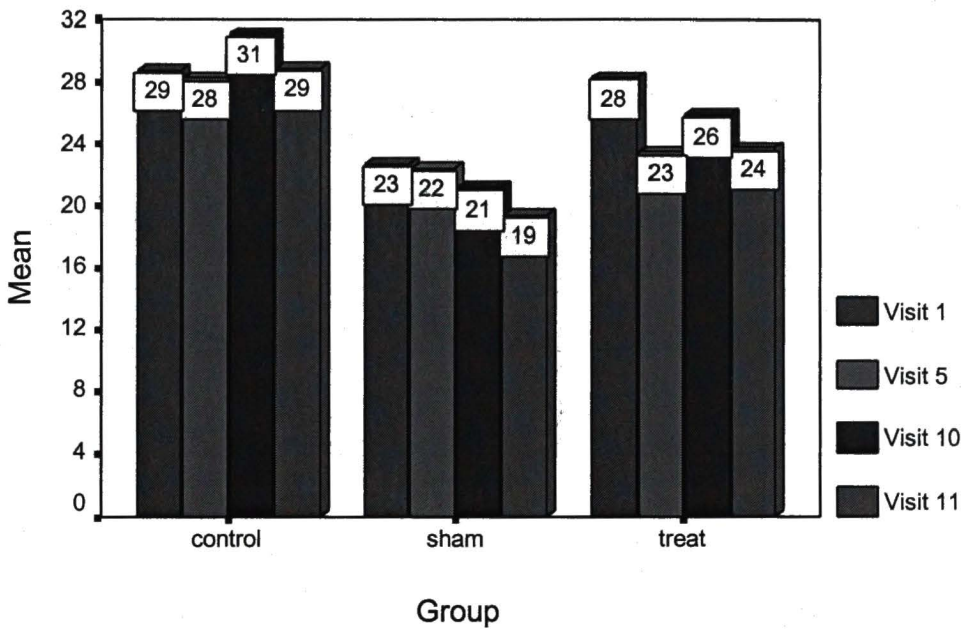
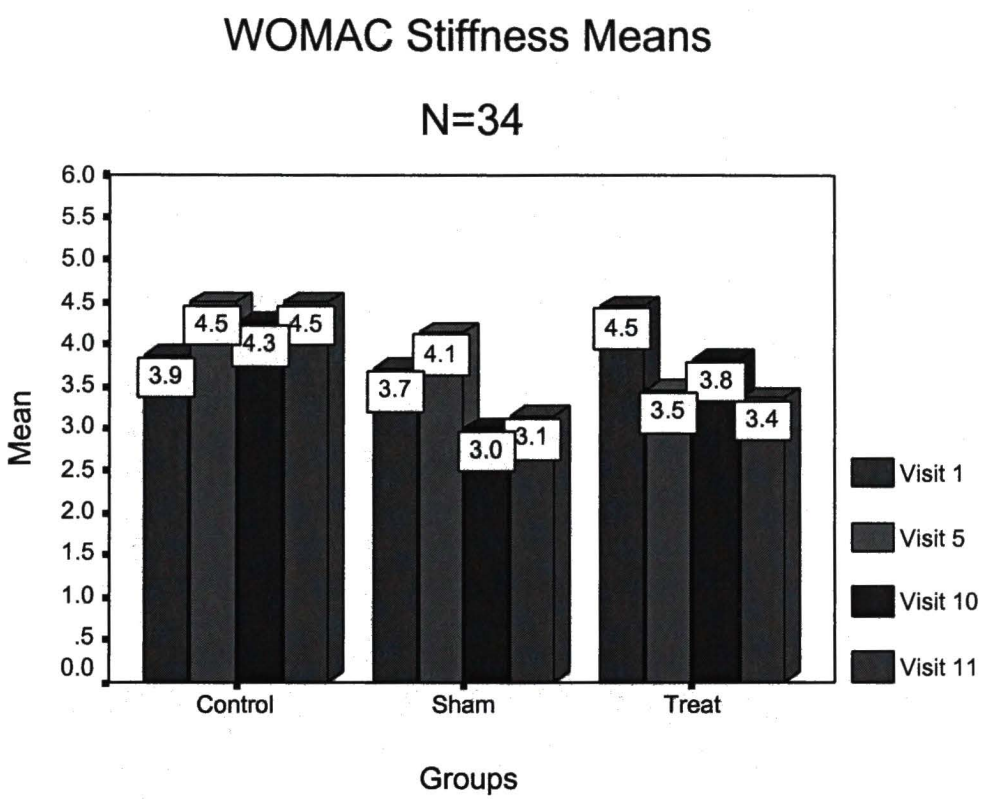


Figure 5 also shows a decline in stiffness for the sham and treatment groups but an increase for the control group (p=0.133).

Figure 5



Functional status requires a decrease in pain. Evaluation of this subjective measure used the WOMAC subscale for pain (maximum score for this subsection is 20) and the visual analog scale. Figure 6 indicates the trend for the WOMAC pain score. There was a decrease in pain between visits 1 and 11 for the sham and treatment groups without statistical significance (p=0.338).

Figure 6

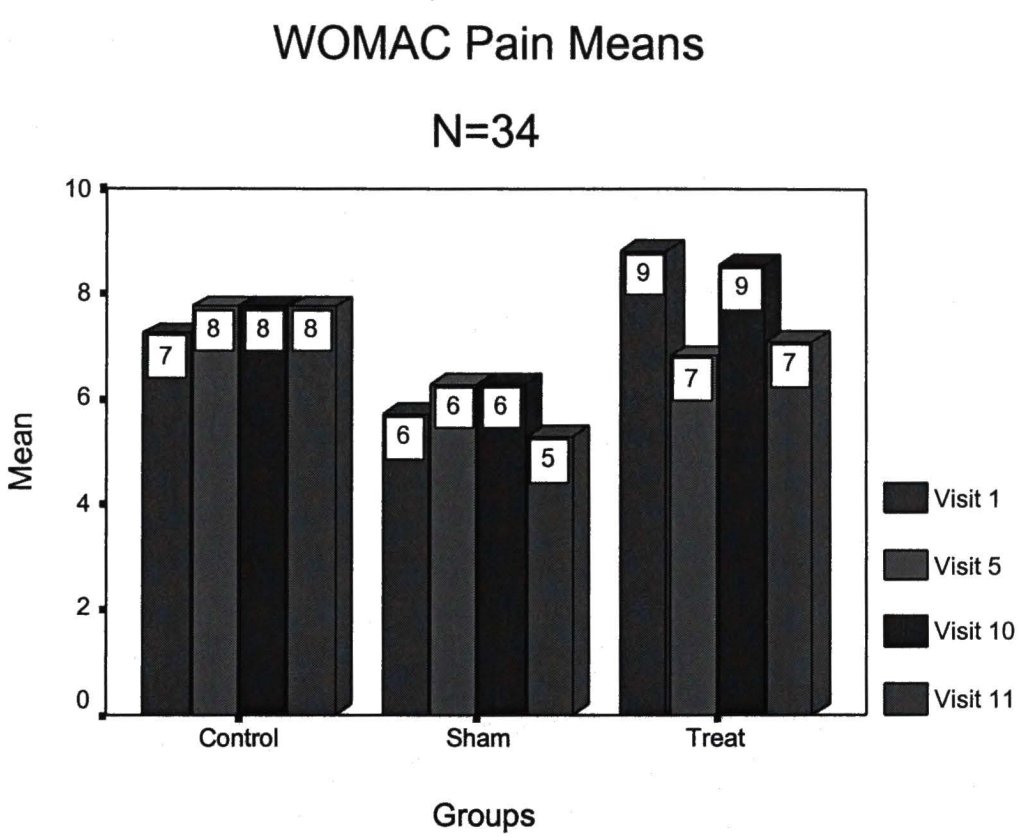

WOMAC Pain Means
N=34
Mean
10
8
6
4
2
0
7
8
8
8
6
6
6
5
9
7
9
7
Control
Sham
Treat
Groups
Visit 1
Visit 5
Visit 10
Visit 11

Figure 7 illustrates the decreased trend in pain for the treatment group (p=0.240) for the visual analog scale. The graph does not show a consistent decline. This may be due to weather, activities, emotional upset or others.

Figure 7

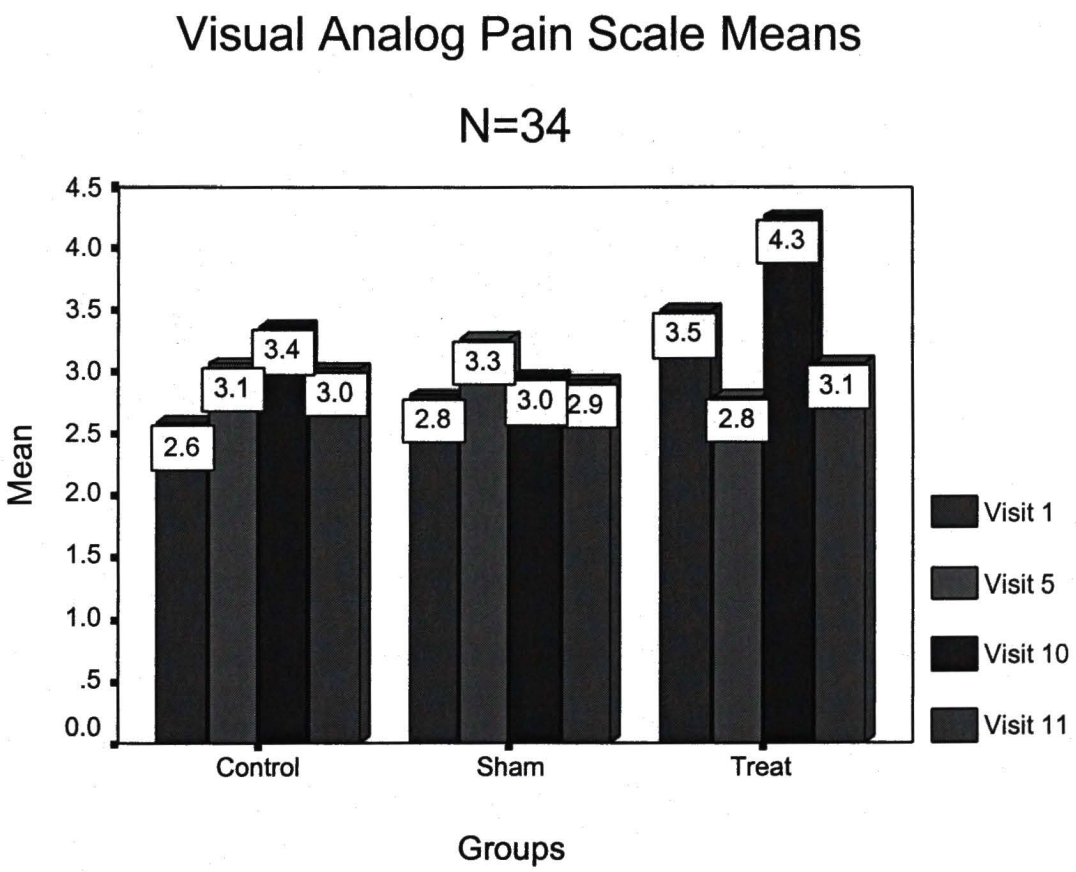
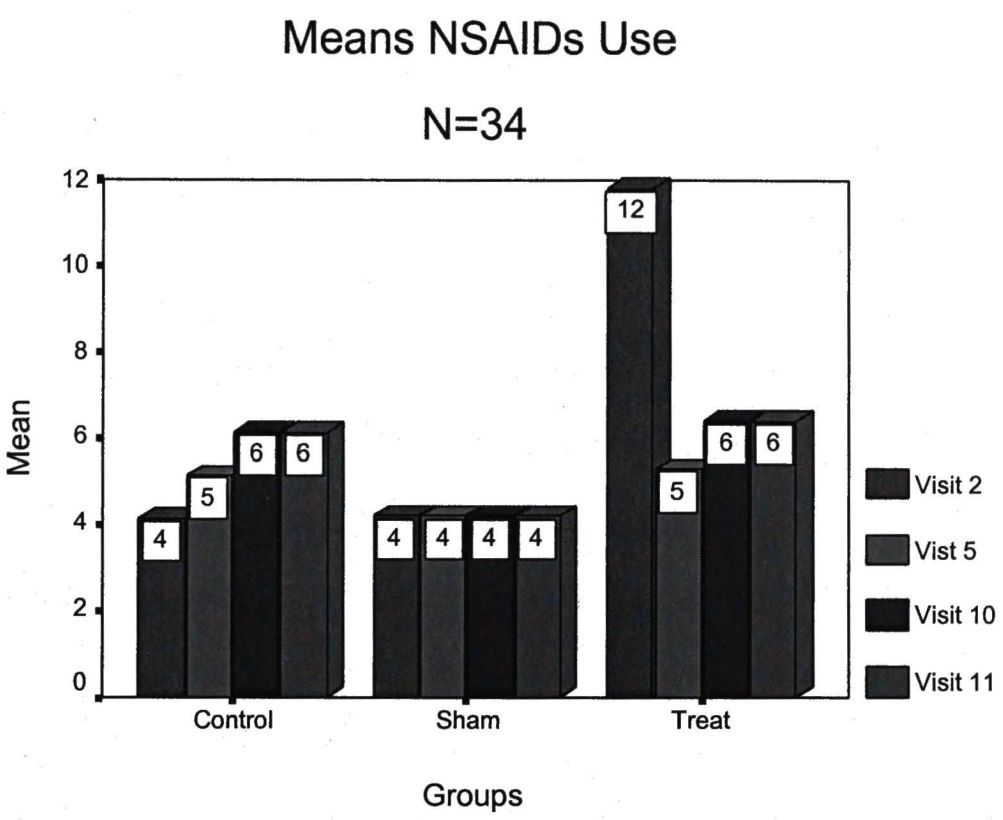


Figure 8



As a result of decreasing pain, NSAID use also declined 50% (Figure 8). A comparison of all groups achieved statistical significance for visits 2, 5, 10, and 11 ($p=0.047$). When groups were analyzed separately, the treatment group showed statistical significance between visits 2 and 11 ($p=0.049$) attaining the study's objective to reduce NSAID usage by 30% is met.

CHAPTER 5

DISCUSSION

Osteopathic manipulative treatment (OMT) is used to treat not only musculoskeletal ailments but also systemic illness e.g. pneumonia by mobilizing fluids (blood, lymph, cerebrospinal fluid) and removing restriction. Patients with arthritis experience stiffness and pain resulting in decreased motion and impedance of fluid flow. Additionally the body loses muscle mass and strength in normal aging compounding the already compromised system. This study concentrated on removing restriction to increase function by decreasing pain and increasing range of motion (ROM) of the arthritic knee using OMT.

Seventy percent of the subjects in this study had bilateral knee OA and 22.5% had OA of the left knee. Results indicated an increase in ROM for both knees but it was more consistent for the left knee. The reason may be due to the pathology in each knee. Motion even just a small amount, may be beneficial for the stiff joint since the control group also experienced increased motion without receiving additional treatment. The only motion received by the control group was during the ROM measurement. The sham group had ROM of the knee therefore they were expected to increase. The treatment group's restriction was

removed with OMT allowing an increased motion and positively affecting function.

With increased range of motion, the timed Up and Go was expected to improve. There was an improvement but only for one second in all groups. The mean walking time for the control, sham, and treatment group on the first visit were 15, 11, and 16 seconds; and for visit 11 it was 14, 10, and 15 seconds respectively. The lower time predicts better function. If the time is less than 20 seconds then the individual is independent for all basic transfers (bed to toilet.) If the time is greater than 30 seconds then the person is more likely to be dependent. (Podsiadlo and Richardson, 1991) Time may not be affected as much in this study since subjects ambulated independently without assistive device except for two subjects who used canes. Additionally the walking time depends on other factors beside range of motion. If subjects were not feeling well from other co-morbid conditions, they will not walk faster. Activities and stress engaged by subjects may also affect the outcome.

As the osteopathic principle indicated, increased motion improves function. During the course of the study both ROM and walking time improved. Consequently the WOMAC ADL subscale score (maximum score is 68) also improved for the sham and treatment groups. When subjects ambulate with greater ease, difficulty doing daily activities decreases. The ability to perform ADLs decrease morbidity and mortality in the older adults.

Another marker of functional status is stiffness. When subjects do not move secondary to pain, joints will become stiff. The cycle of stiffness, pain, and lack of motion continues until there is intervention. In this study stiffness decreased for subjects in the sham and treatment groups illustrating the osteopathic belief that OMT provided to a stiff joint will decrease stiffness.

Stiffness also reduces the ability to flex the knee joint. In order to flex efficiently, pain must be at a minimum or tolerable to subjects. Results for this study indicated a decline of pain perception for the sham and treatment groups on the WOMAC scale for pain (maximum score is 20). On the visual analog pain scale only the treatment group showed a reduction while the control and sham groups had a small increase in pain. The paradoxical increase in pain for the sham group was unexpected since there was improvement in the ROM. The reason may be that motion in a stiff joint will cause pain. The ability to function does not correlate well with pain and severity of disease. Subjects with severe changes on x-ray may not experience pain while others may perceive pain with little radiographic change. (Zimmerman, 1989)

Although pain is subjective, it is an important measure since subjects base the severity of disease on the magnitude of their symptoms. When pain is decreased, there will be a reduction in NSAID use resulting in a decrease of adverse events such as gastrointestinal (GI) bleed. The OMT group showed a 50% decrease in the use of NSAID. The study's objective of decreasing the use of NSAID by 30% was achieved with statistical significance. A closer

examination of Figure 8 indicates subjects in the treatment group began with more NSAID use either from a more severe disease or other co-morbid conditions causing chronic pain. The dramatic decrease may be due to improving motion with OMT. Other reason for the reduction in NSAID may be secondary to wanting to please the investigator since subjects were aware of the decreased NSAID goal. Overall the goal for reducing NSAID and pain was achieved.

CHAPTER 6

CONCLUSION

This pilot study attempted to look at the effectiveness of osteopathic manipulative treatment for knee arthritis. Both objective and subjective outcome measures were used for evaluation. The only statistically significant outcome was the 50% decreased use in NSAID for the treatment group. Other measures such as the Western Ontario and McMaster University Osteoarthritis Index (WOMAC), Up and Go Test, range of motion (ROM), and visual analog had a downward trend without achieving statistical significance. The problems encountered included the study design and subject's compliance.

In spite of recruitment efforts only 34 subjects (12 in the control, 8 in the sham, and 14 in the treatment group) finished the study. Having a larger sample size would increase the probability of attaining statistical significance. Selection bias may have occurred during the recruitment phase. Most patients were recruited from a list of previous or potential participants from the UNT-HSC Office of Clinical Research. Subjects on this list have an interest in clinical trials enrollment compared to those who are not on this list. Additionally subjects in this study may be dissatisfied with their current treatment and want to learn another treatment plan. Those who are satisfied with their present drug regimen

or are skeptical of alternative treatment will most likely not take part in this study. Other reasons for non-participation include illnesses, lack of transportation, residing in a nursing homes, family/caregiver constraints, or debilitation. Also there was no tangible incentive except that subjects may feel better from OMT and socialization since many older adults are isolated.

Subjects screening criteria need to be improved. Most subjects were ambulatory but one subject used a wheelchair since she has difficulty walking long distance but was able to ambulate with two canes for the required Up and Go Test. Another subject withdrew when he had knee arthroplasty. As a result the population was not uniform causing data to be skewed.

The WOMAC is a self-administered questionnaire regarding pain, stiffness, and difficulty performing ADLs. In this study a blinded assistant administered the test to subjects because some had trouble reading. This may be a potential source for bias since subjects may want to please the administrator.

As a result of having one treating physician, there was no inter-rater reliability problem for this pilot study. However there is a question of whether the subjects were blinded. It is difficult to blind subjects in a manual therapy trial especially if they had manipulative treatment previously. This will probably be an inherent bias for manipulative trials.

Subjects' compliance is another factor. The investigator did not have control over medication dosages or the use of other manual treatment. As a

result several subjects had other therapy. One person went to a chiropractor for his low back pain for one visit. Another went to the chiropractor when she had chest pain post vacation. One had trigger point injection for the upper extremity and thorax. This may have caused some discrepancy in the data.

Requesting subjects to recall pharmaceutical treatment continues to be a challenge. Subjects were asked to keep a record of pills (analgesic or NSAID) consumed since the previous visit. Some recorded weekly and others relied on their memory. A pre-printed daily pill count diary and random telephone follow up by an assistant may improve compliance.

An increase number of subjects for future studies will likely increase reliability in data analysis while increasing the probability of achieving statistical significance. To decrease selection bias, the general public needs to be targeted for recruitment by advertising in newspaper, newsletter, or lectures. A radiograph screen for OA will help limit disease severity. OMT is more viable for mild to moderate disease.

APPENDIX A

WEEKLY SCHEDULE

Table 1: Time Table and Tasks

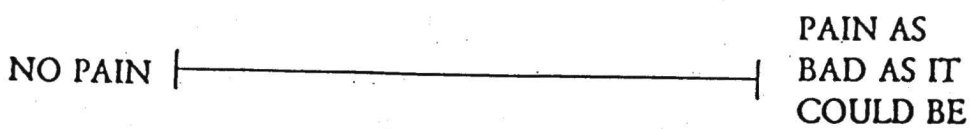
TASK	PERSONNEL	SUBJECTS (N=34)															
		Weekly Visits				Every 2 Weeks											
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	20
Informed Consent	Principal Investigator	X																
History & Physical	Principal Investigator	X																
Folstein MMSE	Principal Investigator	X																
WOMAC	Blinded Assessor	X	X	X	X		X		X		X		X		X		X	X
Visual Analog Scale	Blinded Assessor	X	X	X	X		X		X		X		X		X		X	X
Goniometer	Blinded Assessor	X	X	X	X		X		X		X		X		X		X	X
Get Up & Go Test	Blinded Assessor	X	X	X	X		X				X		X		X		X	X
Medication Review	Principal Investigator	X	X	X	X		X		X		X		X		X		X	X
Structural Exam	Principal Investigator	X	X	X	X		X		X		X		X		X		X	X
OMT/ROM/Control *	Principal Investigator	X	X	X	X		X		X		X		X		X		X	

*Treatment group will receive OMT (N=14)
Sham group will receive ROM only (N=8)
Control group will receive neither OMT nor ROM (N=12)

APPENDIX B

VISUAL ANALOG SCALE

VISUAL ANALOG SCALE FOR PAIN



APPENDIX C

WEEKLY PILL COUNT

NSAID RECORD												
MEDS	PILLS (Number)	VISITS										
		1	2	3	4	5	6	7	8	9	10	11
Nsaidd	NSAID: 0=None, 1= <14, 2=14 to 28, 3=29 to 42, 4=43 to 56, 5=57 to 70, 6=>70											
Anald	**Analgesic Dosage: 0=None, 1=≤7,** 2=7 to 14, 3=15 to 28, 4=28 to 42, 5=43 to 56, 6=57 to 63, 7=>63											
herb	**Types of Herbs for arthritis (Number):** 0=None, 1=One, 2=Two, 3=Three, 4=Four, 5= >four											

WEEKS	DRUGS DOSE & FREQUENCY
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	

APPENDIX D

INFORMED CONSENT

INFORMED CONSENT AUTHORIZATION TO PARTICIPATE IN A RESEARCH PROJECT

TITLE: *EFFECTS OF OSTEOPATHIC MANIPULATIVE TREATMENT ON OSTEOARTHRITIS*

INSTITUTION: University of North Texas Health Science Center at Fort Worth

SUBJECT NAME:_____

LEGAL GUARDIAN NAME:_____

I. STUDY PURPOSE: The purpose of this study is to determine the degree to which osteopathic manipulative treatment (OMT) used on osteoarthritis of the knee can improve your quality of life. OMT includes different types of treatment the doctor uses to release tension in different parts of your body, relax different joints and muscles, and increase the distance muscles can move. The doctor will use her hands to work different parts of your body. We hope to make you feel less pain and discomfort caused by the swelling in your knee. We will be doing this by:

A. Reducing the amount of medicine you take to discomfort you feel in your stomach from using medicines that reduce the swelling in your knee.
B. Giving OMT treatment to reduce the pain you feel.
C. Hoping to increase the amount of movement you can have in your knee because your pain is less.

Subject Initials:_____
Date:_____

II. STUDY PROCEDURE:

This study is being done at the Geriatrics Clinic, Gerontology Assessment and Planning Program (GAP) at 3500 Camp Bowie Boulevard, Fort Worth, TX. Your participation may last up to 20 weeks. You will be requested to make eleven (11) visits to see a doctor at Geriatrics (GAP) Clinic. If you are selected for the study, you will be randomly assigned to one of three following groups (like the flip of a coin).

Group 1: The control group will not receive any formal treatment of the knee.

Group 2: The touch group will have the physician studying the changes in how far your knee can move at each visit.

Group 3: The treatment group will receive 10 Osteopathic Manipulative Treatments over the 5 months of the study.

The following things will happen at each visit

Visit 1: You will be asked to sign this "Informed Consent" form.

The doctor will ask you questions about your medical history and the medications you take, complete a physical exam that looks at your overall body structure and the specific osteoarthritis of your knee.

A research assistant will use several surveys and instruments to find out how much pain you have, how far your knee can move, and how far you can walk in the shortest period of time.

Subject Initials:_____
Date:_____

Visit 2-10: A research assistant will use several surveys and instruments to find out how much pain you have, how far your knee can move, and how far you can walk in the shortest period of time.

The doctors will go over the medications you take and complete a physical exam that looks at your overall body structure and the osteoarthritis of the knee.

If you are assigned to the treatment group, the physician will give you an osteopathic manipulative treatment for your knee arthritis.

III. RISKS AND DISCOMFORTS OF THE STUDY

If you signed the Informed Consent form, you will be included in the study unless one of the following conditions is found during the medical examination and medical history completed at Visit I:

a. We find that you do not have osteoarthritis of the knee.

b. We find that you received OMT treatment for knees in the past 6 months.

c. We find that you had a hip or knee replacement

d. We find that your osteoarthritis of knee is too advanced for the treatment.

e. We find that you are unable to get up out of a chair.

There may be some pain, soreness (symptoms like a flu) and some tiredness from receiving the osteopathic manipulative treatment

Subject Initials:_____
Date:_____

that may last 24 to 48 hours after treatment. These are temporary. You may also feel some restlessness; this is also temporary. Although there have never been any reported cases, there is a risk of fractures when receiving the osteopathic manipulative treatment.

IV. CONTACTS

If a study related problem should occur, or if you have any questions at any time about the study, you may contact Dr. Chau Pham at 817-735-0291, Dr. Janice Knebl at 817-735-2108 or Dr. Russell Gamber at 817-735-2459. If you have any questions about your rights as a participant in this study, you may contact Dr. Jerry McGill, Chairman, Institutional Review Board, University of North Texas Health Science Center at Fort Worth at 817-735-2561.

V. BENEFITS

By participating in this study, you may find that your osteoarthritis of the knee will not be as painful as in the past. As a result, you will feel better, be able to move around more, and have a better quality of life. The office visits, examinations and study procedures will be at no cost to you.

VI. ALTERNATIVE TREATMENTS

There are alternative treatments, which are available to you for treatment of osteoarthritis of the knee. These generally include the taking of medications that reduce swelling, and therefore pain. These medications, however, can have side effects resulting in stomach and intestinal conditions.

Subject Initials:_____
Date:_____

VII. CONFIDENTIALITY:

Your medical records will be kept as confidential as possible under current local, state and federal laws. However, regulatory agencies and the Institutional Review Board may examine your medical records and study data. In case the final study data should be prepared for publication your name will not appear in any published material.

VIII. COMPENSATION FOR INJURY:

By signing this form, you have not waived any of the legal rights to which you otherwise would have as a participant in this study. The University of North Texas Health Science Center at Fort Worth (UNTHSC) assumes no responsibility for you participation in this study.

IX. LEAVING THE STUDY:

You can choose not to be in the study or to leave it at any time without penalty or loss of benefits that you are otherwise entitled. The doctor may take you out of the study for reason of, but not limited to:

Occurrence of serious side effects
Severe worsening of condition OR
UNTHSC decides to discontinue the study

IRB APPROVED
MAR 1 3 1999
University of North Texas
Health Science Center

Subject Initials:_____
Date:_____

X. CONSENT:

I voluntarily agree to participate in this study. I have had the chance to ask the doctor any questions I have regarding the study.

I have received a copy of this signed Informed Consent Agreement

Subject	Date
Investigator	Date
Co- Investigator	Date
Signature of Witness (Optional)	Date

IRB APPROVED

MAR 1 3 1999

University of North Texas
Health Science Center

Subject Initials:_____
Date:_____

APPENDIX E

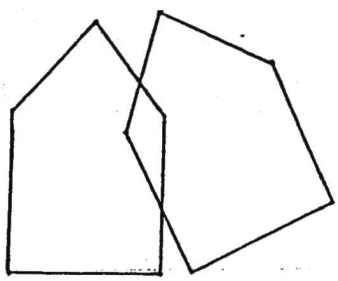
FOLSTEIN MINI MENTAL STATE EXAM

MINI-MENTAL STATE (FOLSTEIN)

	90	ORIENTATION: Please ask each question without providing clues to the answers: Date: _____ 0 = yes 1 = no	
	91	Year: _____ 0 = yes 1 = no	
	92	Month: _____ 0 = yes 1 = no	
	93	Day: _____ 0 = yes 1 = no	
	94	Season: _____ 0 = yes 1 = no	
	95	Address: _____ 0 = yes 1 = no	
	96	Floor: _____ 0 = yes 1 = no	
	97	City: _____ 0 = yes 1 = no	
	98	County: _____ 0 = yes 1 = no	
	99	State: _____ 0 = yes 1 = no	
	100	REGISTRATION: Please ask the resident to repeat the three words. Score the number repeated after the first presentation, but keep saying the words until all are repeated. Rose: _____ 0 = yes 1 = no	
	101	Hat: _____ 0 = yes 1 = no	
	102	Carrot: _____ 0 = yes 1 = no	
	103	ATTENTION AND CALCULATION: Ask the patient to subtract 7 from 100 and to keep subtracting 7 from each figure obtained. Do not re-clue with each substraction. If patient cannot enter or maintain the task, test the ability to spell "world" backwards and score the number of letter in correct order. Test used: _____ 0 = yes 1 = no How far did they count? _____	
	104	RECALL: Ask the patient to recall the three words introduced earlier. Do not provide clues. Rose: _____ 0 = yes 1 = no	
	105	Hat: _____ 0 = yes 1 = no	
	106	Carrot: _____ 0 = yes 1 = no	
	107	LANGUAGE: Naming: Show the two items and ask the patient to name them: Pencil: 0 = yes 1 = no	
	108	Watch: 0 = yes 1 = no	
	109	Repetition: Ask the patient to say "No, ifs, ands, or buts." Score if patient repeats correctly after 1 presentation. 0 = yes 1 = no	
	110	Comprehension: Score 1 point for following each portion of the command. Takes paper in right hand. 0 = yes 1 = no	
	111	Folds paper in half. 0 = yes 1 = no	
	112	Puts paper in lap. 0 = yes 1 = no	

CLOSE YOUR EYES.

WRITE A SENTENCE.



APPENDIX F

DEMOGRAPHIC DATA

OMT: Osteoarthritis of the Knee

1999-2000

Dr. Chau Pham-Principal Investigator IRB No:

Patient's Name: _____ Phone: _____

Address: _____

DEMOGRAPHICS

SPSS	No	Data Element	Value
ssn	1	Social Security Number: (Last four digits) ____/____/____	
sex	2	Gender: 0 = male 1 = female	
		Date of birth: Mon/##/Year (i.e. Jan 1, 1899) ____/____/____	
age	3	Age:	
mstat	4	Marital Status: 0 = Single 1 = Marrried 2 = Divorced 3 = Widowed	
larr	5	Living Status: 0 = alone 1 = with someone	
eth	6	Race/Ethnicity: 0 = Caucasian 1 = African American 2 = Hispanic American 3 = Native American 4 = Asia/Pacific Islander 5 = Other	
edu	7	Highest Educational Attainment: 0 = doctoral degree 1 = Masters degree 2 = Bachelors Degree 3 = Associate degree 4 = Technical/professional school 5 = some college 6 = high school or equivalent 7 = less than high school (enter # of years completed)	
prof	8	Profession: 0 = retired 1 = non-physical profession 2 = physical profession	
		Who is your current family doctor? Name: _____ Address: _____	

Medical Information		
All	Allergy:	
Al2	Allergy:	
Al3	Allergy:	
Al4	Allergy:	
OAK	Chronic Disease: OA of Knees 0=None 1=Left 2=Right 3=Both	
Oah	Chronic Disease: OA of Hip 0=None 1=Left 2=Right 3=Both	
Dm	Chronic Disease: Diabetes mellitus 0=None 1=Yes	
Htn	Chronic Disease: Hypertension 0=None 1=Yes	
Thy	Chronic Disease: Thyroid 0=None 1=Low 2=High	
Pud	Chronic Disease: Peptic Ulcer 0=None 1=Yes	
Dep	Chronic Disease: Depression/psychiatric 0=None 1=Yes	
Hh	Chronic Disease: Hiatal hernia 0=None 1=Yes	
Lu	Chronic Disease: Lung 0=None 1=Yes	
Hrt	Chronic Disease: Heart 0=None 1=Yes	
Arth	Surgery: Arthroscopic of knee 0=None 1=Left 2=Right 3=Both	
Kne	Surgery: Knee (other) 0=None 1=Left 2=Right 3=Both	
Ank	Surgery: Ankle 0=None 1=Left 2=Right 3=Both	
Hip	Surgery: Hip 0=None 1=Left 2=Right 3=Both	
Bac	Surgery: Back 0=None 1=Yes	
Mva	Trauma: motor vehicle accident 0=None 1=One 2=Two 3=Three 4=≥ four	
Lej	Trauma: Lower extremity injury (other) 0=None 1=Yes	
Fal	Trauma: Falls 0=None 1=Injure knee 2=Injure back 3=Injure knee & Back 4=Others	
Psy	Trauma: Psychological/Abuse 0=None 1=Yes	

ps1		Prescription Drug 1: Drug	Dosage	How often taken?	How long taken?	
ps2		Prescription Drug 2: Drug	Dosage	How often taken?	How long taken?	
ps3		Prescription Drug 3: Drug	Dosage	How often taken?	How long taken?	
		Prescription Drug 4: Drug	Dosage	How often taken?	How long taken?	
		Prescription Drug 5: Drug	Dosage	How often taken?	How long taken?	
		Prescription Drug 6: Drug	Dosage	How often taken?	How long taken?	
		Prescription Drug 7: Drug	Dosage	How often taken?	How long taken?	
		Prescription Drug 8: Drug	Dosage	How often taken?	How long taken?	
ps4		Prescription Drug 9: Drug	Dosage	How often taken?	How long taken?	
ps5		Prescription Drug 10: Drug	Dosage	How often taken?	How long taken?	
ot1		Over the counter 1: Drug	Dosage	How often taken?	How long taken?	

3

ot2		Over the counter 2: Drug _____	Dosage _____	How often taken? _____	How long taken? _____	
ot3		Over the counter 3: Drug _____	Dosage _____	How often taken? _____	How long taken? _____	
ot4		Over the counter 4: Drug _____	Dosage _____	How often taken? _____	How long taken? _____	
ot5		Over the counter 5: Drug _____	Dosage _____	How often taken? _____	How long taken? _____	
mmse		Mini Mental: (Score_____		0 = OK	1 = Demented	

APPENDIX G

OSTEOPATHIC STRUCTURAL EXAM

Examiner: _____

Chief Complaint: _____

Required

Ant./Post. Spinal Curves: I N D

- Cervical Lordosis
- Thoracic Kyphosis
- Lumbar Lordosis

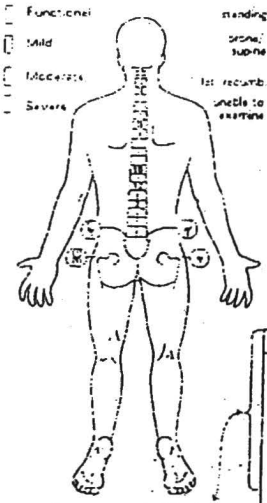
I = increased; N = normal; D = decreased

For Coding Purposes Only

Scoliosis (Lateral Spinal Curves)

- None
- Functional
- Mild
- Moderate
- Severe

sitting
standing
supine
prone
1st recumb.
unable to examine



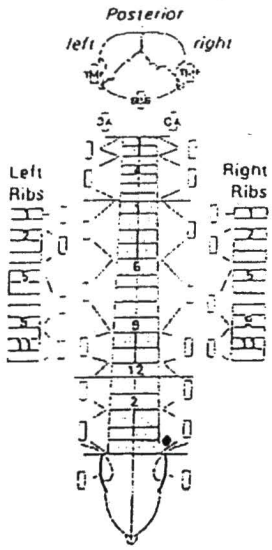
Assessment Tools:

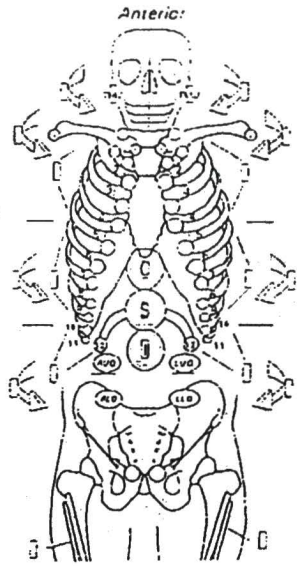
- T – Tenderness
- A – Asymmetry
- R – Restricted Motion
  - Active
  - Passive
- T – Tissue Texture Change

Severity Key:

- 0 – No SD or background (BG) levels
- 1 – Minor TART more than BG levels
- 2 – TART as with 1 & T expl +/- symptoms
- 3 – Symptomatic, R and T very easily found, "Lesion"

Optional Worksheet





Abbreviation Key:

OA Occipitoatlantal joint
Sympathetic ganglia:
C Celiac
S Superior Mesenteric
I Inferior Mesenteric
TMJ Temporo-mandibular Jnt.
TMP Temporal bone
SES Sphenoethmoidal synchondrosis

Region Evaluated	Severity 0	1	2	3	Specific of Major Somatic Dysfunctions
Head					
Neck					
Thoracic T1-4					
T5-9					
T10-12					
Lumbar					
Pelvis/Sacrum					
Pelvis/Innominate					
Extremity (lower) R					
Extremity (lower) L					
Extremity (upper) R					
Extremity (upper) L					
Ribs					
Other / Abdomen					

Major Correlations with:

- Traumatic
- Orthopedic
- Neurological
- Viscero-somatic
- Primary Ms:Skeletal
- Activities of daily living
- Other _____
- Rheumatological
- EENT
- Cardiovascular
- Pulmonary
- Gastrointestinal
- Genitourinary
- Congenital

Other:

Signature of the examiner: _____ Date of Examination: _____

Signature of the examined: _____ Date of Examination: _____

STRUCTURAL EXAM SUMMARY

Region Evaluated	Severity				Range of Motion	Specific of Major Somatic Dysfunction
	0	1	2	3		
Head						
Cervical						
Thoracic 1-4						
5-9						
10-12						
Lumbar						
Pelvis/Sacrum						
Pelvis/Innominate						
Extremity (lower)						
Knees (right)						
Knees (left)						
Extremity (upper)						
right						
left						
Ribs						
Abdomen						
Other						

SEVERITY KEY	
0	No Somatic Dysfunction or Background (BG) Levels
1	Minor TART, more than BG Levels
2	TART obvious (R & T esp.) +/- Symptoms
3	Symptomatic, R and T very easily found, "Key Lesion"

ASSESSMENT TOOLS	
T =	Tenderness
A =	Asymmetry
R =	Restricted Motion
	Active
	Passive
T =	Tissue Texture Change

STRUCTURE EXAM																
			VISIT I-II													
head		Head 0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found														
cer		Cervical 0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found														
		Cervical Range of Motion 0 = non-restricted 1 = restricted 2														
th1		Thoracic 1-4 Severity 0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found														
th2		Thoracic 5-9 Severity 0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found														
th3		Thoracic 10-12 Severity 0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found														
th1r		Thoracic 1-4 Range of Motion 0 = non-restricted 1 = restricted														
th2r		Thoracic 5-9 Range of Motion 0 = non-restricted 1 = restricted 3														
th3r		Thoracic 10-12 Range of Motion 0 = non-restricted 1 = restricted														
l1		Lumbar Severity 0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found														
		Lumbar 0 = non restricted 1 = restricted														
ps1		Sacrum Severity 0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found														
ps2		Sacrum Range of Motion 0 = non-restricted 1 = restricted														
pi1		Pelvis Innominate Severity 0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found														

pi2		Pelvis/Innominate Range of Motion	0 = non-restricted 1 = restricted 4											
exl1		Lower Extremity Severity	0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found											
rkn1		Right Knee Severity	0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found											
rkn2		Right Knee Range of Motion	0 = non restricted 1 = restricted											
lkn1		Left Knee Severity	0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found											
lkn2		Left Knee Range of Motion	0 = non restricted 1 = restricted											
exu1		Upper Extremity Severity	0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found5											
exu2		Upper Extremity Range of Motion	0 = non restricted 1 = restricted											
uexr1		Right Upper Severity	0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found											
uexl1		Left Upper Severity	0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found											
rib1		Ribs Severity	0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found											
rib2		Ribs Range of Motion	0 = non restricted 1 = restricted											
ab1		Abdomen Severity	0=none 1=minor TART 2=obvious TART 3=Symptomatic/easily found											
oth1		Other:												
oth2		Other:												
oth3		Other												

APPENDIX H

WOMAC PROTOCOL & PERMISSION

From: "Prof. N. Bellamy" <nbellamy@medicine.uq.edu.au>
To: "Chau Pham" <cpham@hsc.unt.edu>
Date: 5/29/99 12:08AM
Subject: Re: permission for WOMAC

Dear Chau,
Many thanks for your e-mail. I think you would be considered an academic rather than acommercial user and therefore there would not be a user fee. I will be away for the next two weeks. PLease let me know your final requirements and I will dispatch on my return. I would think the LK version would be best from a community based study. The User Guide 111 is now available. It is copyright protected and should not be photocopied. It costs $25.00 USD per copy + shipping. Plase let me know how many you will need. The recommendation is one/investgator + reference copies. Many thanks for your enquiry.

At 10:37 AM 5/27/99 -0500, you wrote:
>Dear Dr. Bellamy,
>
>Thank you for your prompt reply. I just faxed you a copy of the protocol. Our machine says it was transmitted successfully. The other attepts that were made did not include the international code. Jane Campbell called this morning and gave me the international code. If you do not have it please let me know.
>
>At this time I do not have a grant for this study. However I have submitted an application for a research fellowship grant from the American Osteopathic Association. I will not hear from them until June 1999. This project will fulfill the research requirement for the Fellowship program and my Masters of Public Health degree.
>
>I would need an English version of the WOMAC for this study. I am not sure if I will need a Likert format or the VA format. This is a community based study.
>
>I'm also including the protocol, Effects of Osteopathic Manipulative Treatment on Osteoarthritis, with this E-mail. I hope you get either the faxed copy, E-mail, or both.
>
>Thanks again.
>
>Chau N. Pham
>
>>>> "Prof. N. Bellamy" <nbellamy@medicine.uq.edu.au> 05/26/99 06:13PM >>>
>Dear Chau,
>Many thanks for your e-mail. Please could you send your protocol by e-mail.
>Is your project suppoprted by any industrial/commercial source.? Do you
>reequire English and/or Spanish WOMAC 3.1 for USA? Do you require Likert or
>VA scaled formats. I leave on Sunday for two weeks overseas. If you can
>send info I will try to finalise by end of this week. Many thanks for your
>interest in the WOMAC. Best Personal Reagrds. Nick Bellamy.
>
>

WOMAC 3.0/3.1*/WOMBAT 3.0*/AUSCAN 3.0* INDICES
MEMORANDUM OF UNDERSTANDING (1999)

INVESTIGATOR: _____ **INSTITUTION**_____
PROTOCOL: _____

The following memorandum describes the general conditions under which the WOMAC 3.0/3.1, WOMBAT 3.0 AND AUSCAN 3.0 Indices (including their original, alternate language computerised and special feature versions) are provided for use. The conditions are as follows:

1. Use of the Indices is provided to authorised users and their clinical and research associates and investigators.

2. The Indices should not be provided to unauthorised individuals or agencies without prior notification of the originator (Dr Nicholas Bellamy).

3. All copies of the Indices made for research or clinical purposes must bear my original copyright insignia.

4. Commercialisation and resale of any of the Indices is prohibited.

5. Although the use and publication of data collected on the Indices is not limited in any way, the exact physical form of the Indices may not be published or otherwise displayed in any publication, on the Internet, or any other public access medium.

6. Permission for use is non-exclusive.

7. Only alternate-language forms created by the Health Outcomes Group under my copyright will be used.

8. Approval for use will be confirmed on a protocol by protocol basis. Users should contact Dr Nicholas Bellamy regarding any future use in other protocols.

9. Use of the Indices out with agreed protocols is not permitted.

10. It is strongly recommended that each Investigator be provided with a reference copy of the latest version of the User's Guide.

NICHOLAS BELLAMY August 1999

REFERENCE

Adelizzi, R.A. (1994). Clinical Implications of NSAID pharmacokinetics: special populations, special considerations. JAOA, 94(5), 396-403.

Akeson, W., Garfin, S., Amiel, D. and Woo, S. (1989). Para-articular connective tissue in osteoarthritis. Seminars in Arthritis and Rheumatism, 18(4 Suppl. 2), 41-50.

Altman, R.D. and Dean, D. (1989). Introduction and overview: pain in osteoarthritis. Seminars in Arthritis and Rheumatism, 18(4 Suppl. 2), 1-3.

Berman, B.M., Singh, B.B., Lao, L., Langenberg, P., Li, H., Hadhazy, V., Bareta, J., and Hochberg, M. (1999). A randomized trial of acupuncture as an adjunctive therapy in osteoarthritis of the knee. British Society for Rheumatology, 38, 346-354.

Centers for Disease Control. (1990). Prevalence of disabilities and associated health conditions – United States, 1991 – 1992. JAMA, 272 (22), 1735-1737.

Craske, D.W., Robuck, S.V., Lindberg, R.F. (1940). Symposium on arthritis. JAOA, 39(5), 239-247

Creamer, P. (1997) Intra-articular corticosteroid injections in osteoarthritis: do they work and if so, how? Annals of the Rheumatic Diseases, 56, 634-636.

Creamer, P. and Hochberg, M.C. (1999). Management of osteoarthritis. In Hazzard, W. R., Blass, J. P., Ettinger, W. H., Halter, F. B., & Ouslander, J. G. (Eds), Principles of Geriatric Medicine and Gerontology (4th Ed.), (p.1155). New York: McGraw Hill.

Daly, M.P. and Berman, B.M. (1993). Rehabilitation of the elderly patient with arthritis. Clinics in Geriatric Medicine, 9(4), 783-801.

Deyle, G.D., Henderson, N.E., Matekel, R.L., Ryder, M.G., Garber, M.B., and Allison, S.C. (2000). Effectiveness of manual physical therapy and exercise in osteoarthritis of the knee. Annals of Internal Medicine, 132(2), 173-181.

DiGiovanna, E.L. & Schiowitz, S. (1991). An Osteopathic Approach to Diagnosis and Treatment (pp. 4-5) New York: J.B. Lippincott Company.

Dodson, D. (1979). Manipulative therapy of the geriatric patient. Osteopathic Annals, 7, 29-33.

Ernst, E. (1997). Acupuncture as a symptomatic treatment of osteoarthritis. Scandinavian Journal of Rheumatology, 26, 444-447.

Ettinger, W.H., Burns, R., Messier, S.P., Applegate, W., Rejeski, W.J., Morgan, T., Shunmaker, S., Berry, M.J., O'Toole, M., Monu, J., and Craven, T. (1997). A randomized trial comparing aerobic exercise and resistance exercise with a health education program in older adults with knee osteoarthritis, the fitness arthritis and seniors trial (FAST). JAMA, 277(1), 25-31.

Felson, D.T. (1990). The epidemiology of knee osteoarthritis: results from the Framingham osteoarthritis study. Seminars in Arthritis and Rheumatism, 20(3, Suppl. 1), 42-50.

Felson, D.T., Naimark, A., Anderson, J., Kazis, L., Castelli, W., & Meenan R. F. (1987) The prevalence of knee osteoarthritis in the elderly: The Framingham osteoarthritis study. Arthritis and Rheumatism, 30(8), 914-918.

Fiechtner, J.J. & Brodeur, R.R. (2000). Manual and manipulation techniques for rheumatic disease. Rheumatic Disease Clinics of North America, 26(1), 83-97.

Fife, R.S. and Hochberg, M.C., (1997). Osteoarthritis. In J. H. Klippel (Ed.), Primer on the Rheumatic Diseases (11th ed.). (pp. 216-221, 464). Atlanta, Ga: Arthritis Foundation.

Fischer, R.L. (1945). Osteopathic lesion in arthritis. JAOA, 44(11), 489-491.

Fisher, N.M., Pendergast, D.R., Gresham, G.E., and Calkins, E. (1991). Muscle rehabilitation: its effect on muscular and functional performance of patients with knee osteoarthritis. Archive of Physical Medicine and Rehabilitation, 72, 367-374.

Gibbs, S.B. (1941) Structural and dietetic consideration of arthritis. JAOA, 40(6), 257-264.

Greenman, P. (1989). Principles of Manual Medicine (p.11). Baltimore: Williams & Wilkins.

Guyton, A., & Hall,. (1996). Somatic sensations II: pain, headache, thermal sensation. In A. Guyton & Hall (Eds.), Textbook of Physiology, 9th Edition (pp. 609-614). Philadelphia, PA: W.B. Saunders Company.

Hallas, B., Lehman, S., Bosak, A., Tierney, S., Galler, R., Jacovina, P., Scandalis, T.A., and Wells, M. (1997). Establishment of behavioral parameters for the evaluation of osteopathic treatment principles in a rat model of arthritis. JAOA, 97(4), 207-214.

Hochberg, M.C, Altman, R.D., Brandt, K.D., Clark, B.M., Dieppe, P.A., Griffin, M.R., Moskowitz, R.W., & Schnitzer, T.J. (1995) Guidelines for the medical management of osteoarthritis. Arthritis and Rheumatism, 38(11), 1535-1545.

Hochberg, M.C., Lawrence, R.C., Everett, D.F., and Cornoni-Huntley, J. (1989). Epidemiologic associations of pain in osteoarthritis of the knee: data from the national health and nutrition examination survey and the national health and nutrition examination-I epidemiologic follow-up survey. Seminars in Arthritis and Rheumatism, 18(4 Suppl. 2), 4-9)

Holman, H.R. and Lorig, K.R. (1997) Overcoming barriers to successful aging: self management of osteoarthritis. West Journal of Medicine, 167, 265-268.

Houpt, J.B., McMillan, R., Wein, C., and Paget-Dellio, D. (1999). Effect of glucosamine hydrochloride in the treatment of pain of osteoarthritis of the knee. The Journal of Rheumatology, 26(11), 2423-2430.

Knebl, J.A. and Gamber, R. (2000). Improving functional ability in the elderly by osteopathic manipulative treatment. Manuscript submitted for publication.

Korr, I.M. (1979). Clinical significance of the facilitated state (1955). In B. Peterson (Ed.), The Collected Papers of Irvin M. Korr (pp. 152-157). Newark, OH: American Academy of Osteopathy.

Korr, I.M. (1979). The concept of facilitation and its origins (1955). In B. Peterson (Ed.), The Collected Papers of Irvin M. Korr (pp. 148-151). Newark, OH: American Academy of Osteopathy.

Korr, I.M. (1979). The neural basis of the osteopathic lesion (1947). In B. Peterson (Ed.), The Collected Papers of Irvin M. Korr (pp. 120-127). Newark, OH: American Academy of Osteopathy.

Lane, N.E. and Thompson, J.M. (1997). Management of osteoarthritis in the primary-care setting: An evidence-based approach to treatment. The American Journal of Medicine, 103(6A), 25S-30S.

McAlindon, T.E., Felson, D.T., Zhang, Y., Hannan, M.T., Aliabadi, P., Weissman, B., Rush, D., Wilson, W.F., and Jacques, P. (1996). Relation of dietary intake and serum levels of vitamin D to progression of osteoarthritis of the knee among participants in the Framingham study. Annals of Internal Medicine, 125, 353-359.

McCalindon, T. and Felson, D.T. (1997). Nutrition: Risk factors for osteoarthritis. Annals of Rheumatic Diseases, 56, 397-402.

McColl, G. (1998) Treating osteoarthritis. Australian Family Physician, 27 (1/2), 32-35.

McDowell, I. (1996). Measuring Health: A Guide to Rating Scales and Questionnaires (2nd ed.), 341-346, 383-391.

Merritt, J.L. (1989). Soft tissue mechanisms of pain in osteoarthritis. Seminars in Arthritis and Rheumatism, 18(4 Suppl. 2), 51-56.

Minor, M.A. (1999). Exercise in the treatment of osteoarthritis. Rheumatic Clinics of North America, 25(2), 397-415.

Northup, T.L. (1936). Possible effects on general arthritis from foot manipulation. JAOA, 35, 304-305.

Panush, R.S. and Holtz, H.A. (1994). Is exercise good or bad for arthritis in the elderly. Southern Medical Journal, 87(5), S74-S78.

Podsiadlo, D. and Richardson, S. (1991). The timed "Up & Go": A test of basic functional mobility for frail elderly person. Journal of the American Geriatric Society, 39, 142-148.

Puett, D.W. & Griffin, M.R. (1994). Published trials of nonmedicinal and noninvasive therapies for hip and knee osteoarthritis. Annals of Internal Medicine, 121(2), 133-140.

Rindone, J.P., Hiller, D., Collacott, E., Nordhaugen, N., & Arriola. (2000). Randomized, controlled trial of glucosamine for treating osteoarthritis of the knee. West Journal of Medicine, 172, 91-94.

Rubin, B. R. (1999). Specific cyclooxygenase-2 (COX-2) inhibitors. JAOA, 99 (6), 322-325.

Searle & Pfizer. (1999, October). Panel Book for Celebrex (Celecoxib) (Issue YCE18121U). Searle & Pfizer.

Still, A.T. (1902). The Philosophy and Mechanical Principles of Osteopathy. (pp. 55-60). Kansas City, MO: Hudson-Kimberly Publishing Company.

Still, A.T. (1908). Autobiography of A.T. Still (Rev ed.). (pp. 85, 94) Kirksville, MO: A.T. Still.

Towhead, T.E. and Hochberg, M.C. (1997). A systematic review of randomized controlled trials of pharmacological therapy in osteoarthritis of the knee, with emphasis on trial methodology. Seminars in Arthritis and Rheumatism, 26(5), 755 – 770.

Tucker, WE. (1969). Treatment of osteoarthritis by manual therapy. The British Journal of Clinical Practice, 23(1), 3-8.

Van Baar, M.E., Assendelft, W. J.J., Dekker, J., Oostendorp, R. A.B., Bulsma J. W.J. (1999). Effectiveness of Exercise therapy in patients with osteoarthritis of the hip or knee. Arthritis and Rheumatism, 42(7), 1361-1369.

Van Baar, M.E., Dekker, J., Oostendorp, R.A.B., Bul, D., Voorn, T.B., Lemmens, J.A.M., Bulsma J. W.J. (1998) The effectiveness of exercise therapy in patients with osteoarthritis of the hip or knee: A randomized clinical trial. The Journal of Rheumatology, 25(12), 2432-2439.

Van Buskirk, R.L. (1990). Nociceptive reflexes and the somatic dysfunction: A model. JAOA, 90(9), 792-809.

Wolheim, FA. (1996) Current pharmacological treatment for osteoarthritis. Drugs, 52(Suppl. 3), 27-38.

Wells, M.R., Giantinoto, S., D'Agate, D., Areman, R.D., Fazzini, E.A., Dowling, and Bosak, A. Standard osteopathic manipulative treatment acutely improves gait performance in patients with parkinson's disease. JAOA, 99(2), 92-98.

Zhang, Y., McAlindon, T.E., Hannan, M.T., Chaisson, C.E., Klein, R., Wilson, P.W., and Felson, D.T. (1998). Estrogen replacement therapy and worsening of radiographic knee osteoarthritis. Arthritis and Rheumatism, 41(10), 1867-1873.

Zimmerman, M. (1989). Pain mechanisms and mediators in osteoarthritis. Seminars in Arthritis and Rheumatism, 18 (4 Suppl. 2), 22-29.

Zizic, T.M., Hoffman, K.C., Holt, P.A., Hungerford, D.S., O'Dell, J.R., Jacobs, M.A., Lewis, C.G., Deal, C.L., Caldwell, J.R., Cholewczynski, J.G., and Free, S.M. (1995) The treatment of osteoarthritis of the knee with pulsed electrical stimulation. The Journal of Rheumatology, 22(9), 1757-1761.