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The Effect of Nutritional Supplementation and Exercise on Subjective Pain and Function in People with Osteoarthritis of the Knee

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THE EFFECT OF NUTRITIONAL SUPPLEMENTATION AND EXERCISE ON SUBJECTIVE PAIN AND FUNCTION IN PEOPLE WITH OSTEOARTHRITIS OF THE KNEE

By

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Dan Scheffer

THESIS

Submitted to the Physical Therapy Department at Grand Valley State University
Allendale, Michigan
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE IN PHYSICAL THERAPY

1999

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THE EFFECT OF NUTRITIONAL SUPPLEMENTATION AND EXERCISE ON SUBJECTIVE PAIN AND FUNCTION IN PEOPLE WITH OSTEOARTHRITIS OF THE KNEE

ABSTRACT

Nutritional Supplementation of glucosamine sulfate and chondroitin sulfate are being promoted in the treatment of osteoarthritis. Recent research has indicated that gelatin was found effective. Moderate exercise is also being advocated. The purpose of this eight week double blind study was to examine the effects of the inexpensive nutritional supplement gelatin, in the form of Knox Nutrajoint, and exercise on pain and functional activity in 49 subjects with osteoarthritis in one or both knees. Subjects were randomly assigned to one of four groups: placebo, placebo plus exercise, gelatin supplement plus exercise and exercise. Exercise consisted of a progressive walking program. Results were assessed via ANOVA and ANCOVA. No significant difference (p≤.05) was found for any group on perceived functional ability or pain as measured by the Arthritis Index Measurement Tool. Both exercise groups did show a significant improvement in mood level. The result of this study could not support the use of gelatin supplementation or a non supervised walking program for the treatment of OA.
ACKNOWLEDGEMENTS

The researchers of this study would like to extend their appreciation to Mark Dreyer, Heather Herron and Arthur Schwarcz. Without these people, this research would not have been possible.
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CHAPTER 1
INTRODUCTION

Background to Problem

Osteoarthritis (OA) is a major cause of disabilities among the aging population in the United States. This disease is not only painful but also has a significant impact on function and quality of life.

As one ages, there are several changes in the body that have an effect on joints. There is a reduction in the number of chondrocytes in cartilage. Cartilage is broken down at a faster rate than it is being formed (Heft, 1995). Increased age is also correlated with decreased absorption of dietary nutrients (Heuther, 1994). Therefore, people may not be absorbing enough of the required nutrients to maintain healthy cartilage even if their diet has not changed. Also, the level of activity tends to decrease quite significantly in many individuals as they get older. Decreased physical activity has a negative effect on joint cartilage secondary to the decrease in nutritional exchange (Hallet, 1994).

Many researchers have correlated moderate exercise programs with increased function and reduced pain in people with OA (Fisher, 1993, Schilke, 1996, Minor, 1989, Ettinger, 1997). Exercise increases general circulation in the body. It increases the metabolic rate of the involved tissues which promotes a stronger, healthier tissue and an increased healing rate after injury (Simkin, 1990).
Intermittent compression and decompression along with gliding of articular cartilage during moderate exercise activities allows synovial fluid to nourish the joint and remove waste products (Hallet, 1994). This movement can also lead to thickening and increased resilience in the cartilage. Exercise also leads to increased muscle and ligamentous strength that provides stability to the joint (Altman, 1990).

**Context and Background to Problem**

Research is accumulating that dietary supplements such as Glucosamine sulfate and chondroitin sulfate (Tapadinhas, 1982, Drovolanti, 1980, Vas, 1982, D'Ambrosio, 1981), Vitamin C (Kipp, 1996, New, 1997, McAlindon, 1996a) and Calcium (New, 1997, McAlindon, 1996b) may decrease pain, improve function and even promote regeneration of articular cartilage. A recently published book, *The Arthritis Cure* (1997) examines the benefits of glucosamine sulfate and chondroitin sulfate. This has lead to a surge in sales of these non-prescription nutritional supplements. However, these supplements can be expensive and often fail to contain the listed “amount of ingredient” (Schart, 1998). There is another nutritional supplement, gelatin, that contains the basic amino acid components of cartilage, it is cheaper and consistently high in quality.

Gelatin hydrosylate, a dietary supplement, is composed of glycine, proline, and other amino acids. These are the components for the biochemical matrix of human cartilage. In a double-blinded study by Adam (1991) 10 grams of gelatin hydrosylate was administered to 52 patients with a diagnosis of OA. All patients were given the gelatin for a period of 2 months. The results indicated a significant
decrease in subjective pain as well as a decrease in the amount of analgesics that were consumed. There was no reported change in the patients that received a placebo.

The Nabisco Company produces a gelatin product called Nutrajoint® that claims to maintain joint and bone health. Knox Nutrajoint® contains gelatin hydrosylate, 100% of RDA for Vitamin C, and 15% of RDA for Calcium. This nutritional supplement is sold in powder form and can easily be dissolved into a beverage for consumption.

In addition to nutritional supplementation, exercise has also been shown to have a positive effect on joint health. Recent research regarding the treatment of OA has focused on increasing the strength of the knee musculature with resistance exercises and/or aerobic exercise programs (Ettinger, 1997, Schilke, 1996, Hallet, 1994, Fisher, 1993, Minor, 1989). Since most individuals are not aware of the appropriate exercise programs, referral to Physical Therapy is becoming an important treatment approach to reduce pain and increase function in people with OA.

Problem Statement

Increasing numbers of people are being referred to physical therapy for treatment of OA. However, the number of treatment visits that insurance will cover for each patient is decreasing. Studies have shown that moderate exercise creates the proper conditions for cartilage to regenerate. However, excessive exercise can cause the degeneration of cartilage (Hallet, 1994). Other studies
have shown that nutritional supplementation can decrease pain and increase function in patients with OA. Conversely, a lack of exercise and or proper nutrition can cause a degeneration of articular cartilage (McDonough, 1981). There are no known studies that compare the effects of exercise and nutritional supplementation. There are only two studies that have looked at the effects of supplementation with gelatin hydrosylate on OA (Adams, 1995, Oberschelp, 1985).

Aims and Purpose
The purpose of this study was to compare the effects of a placebo supplement to 1) exercise alone, 2) a nutritional supplementation of Knox Nutrajoint® (which contains gelatin hydrosylate, Vitamin C, and Calcium), and 3) a nutritional supplementation of Knox Nutrajoint in combination with exercise in the reduction of pain and subjective increase of function in patients with OA of the knee.

Hypothesis/Research Question
The first hypothesis was that nutritional supplementation of Knox Nutrajoint® in combination with a moderate exercise program will be superior to the effects of either exercise alone or Knox Nutrajoint alone when compared to a placebo supplement in the reduction of pain and subjective increase in function in subjects with OA of the knee(s).
The second hypothesis was that the treatment groups receiving nutritional supplementation or exercise would report greater relief of symptoms than the group receiving only a placebo.

**Significance of Problem**

In light of recent changes within health care regarding finance and time constraints, it is integral that physical therapists research the most efficient and cost effective treatments. If researchers can demonstrate that an inexpensive nutritional supplementation in combination with exercise is superior to exercise alone or nutritional supplementation alone in relieving pain and dysfunction caused by OA then it is in the patient’s best interest and that of the Physical Therapy profession to study and promote such discoveries. Not only can this have an effect on the efficacy of treatment but it can also reduce the number of Physical Therapy treatments. This could reduce the overall cost of treatment and improve the quality of life for people suffering from OA. Ultimately there could be a reduction in the number of joint replacements for OA sufferers which would save time and money for patients, and third party payers, in addition to reducing unnecessary pain and dysfunction that patients must endure.
CHAPTER 2
LITERATURE AND CONCEPTUAL FRAMEWORK

Introduction

In the last several years there has been much research done on the cause, management and prevention of Osteoarthritis. Recently there has been a push towards the use of nutrition or nutritional supplements in the management and prevention of OA. This chapter will review the pertinent literature related to articular cartilage structure, age-related changes with articular cartilage, the pathology of Osteoarthritis and current treatments for this disease.

Conceptual Framework

The Matrix of Hyaline Cartilage

Hyaline cartilage covers the surface of bones that form synovial joints. A synovial joint is one in which the articulating bones are covered with hyaline cartilage and are joined together with ligaments and a capsule lined by a synovial membrane that secretes a lubricant into the joint. The hyaline cartilage allows for a smooth low friction surface for the articulation between bones. The cartilage is composed of a large extracellular matrix that includes both fibrous and nonfibrous components as well as a relatively small cellular component. The fibrous component of the extracellular matrix is made of elastin and types II, IX, and XI collagens (Jimenez, 1988). Collagen fibers are composed of the amino acids proline, lysine and glycine. These fibrous components provide support and elasticity to the matrix. The non-fibrous component of the extracellular matrix is
made of glycoproteins and proteoglycans consisting of dermatin sulfate, chondroitin 4 and 6 sulfate and hyaluronic acid. The glycoproteins and proteoglycans attract water and chains of glycosaminoglycans which hydrate the cartilage and provide support for the cellular components (Walker, 1996).

Hyaline cartilage is avascular and aneural. It relies heavily on synovial fluid to provide nutrition and remove waste products. As the joint moves the compressive force that develops between joint surfaces pushes the fluid out of the cartilage into the joint space. When the compressive forces are removed the fluid is reabsorbed into the cartilage. Joint sliding which occurs during joint movement may help distribute the synovial fluid and improve its penetration into the cartilage. During immobilization of a joint the synovial fluid can not adequately nourish cartilage (McDonough, 1981). Thus, a joint must function and move in order to prevent degeneration.

Review of Literature

Pathophysiology of OA

Osteoarthritis is a progressive degenerative disease that slowly destroys the articular cartilage and adjacent periosteal bone in weight bearing joints and frequently used upper extremity joints. Adam (1995) stated that 90% of the population is affected by Osteoarthritis by the age of 70 years. With aging there is a significant loss in the amount of proteoglycan within articular cartilage. This makes the cartilage less smooth and more susceptible to erosion and deformation, decreasing the shock absorption capabilities. The loss of the proteoglycans also decreases the ability of the cartilage to absorb the nutrient rich synovial fluid. As
the connective tissue matrix continues to weaken the cartilage surface becomes irregular and rough. This causes tiny bits of cartilage to break off and settle in the gravity side of the joint and cause irritation to the capsular lining. Formation of new type II hyaline collagen is impaired by the aging process due to the altered activity of the chondrocytes. Chondrocytes instead begin synthesizing type I and type III collagens. The replacement type I and III collagens are fibrous in nature and do not displace and absorb the forces in the joint the same as the normal type II collagen. This change in fiber composition has a significant effect on the biomechanical properties of the joint. Due to the abnormal stresses and the formation of osteophytes around the joint margin, which stretch the joint capsule, the synovial membrane can become inflamed and get increasingly painful over time. As the disease progresses, the articular cartilage can erode down to the periosteum and cause bony changes and deformation.

The number of type II muscle fibers, phasic muscle fibers, also decrease with aging. This causes a decrease in muscle strength around joints. Proper muscular and ligamentous support around a joint can minimize the stresses that are placed on the articular cartilage. The loss of muscle mass due to either disuse or aging further increases the stress on weight bearing joints leading to further progression of OA (Semble, 1990).

Why OA Causes Pain

Several mechanisms have been identified as causes of pain in OA. No nociceptors (pain receptors) have been found in cartilage. Therefore, the pain that people with OA experience originates from other sources. The surrounding
ligamentous capsule and synovial lining are highly vascularized and innervated. If fragments of cartilage are shed on to synovium they can trigger an inflammatory response in the joint capsule. The increased pressure and inflammation will stretch the capsule and result in painful symptoms. Crystals of calcium pyrophosphate dihydrate and calcium hydroxyapatite shed from deeper articular cartilage can also cause an inflammatory response. Enzymes involved in the degradation of cartilage are often present in excess in people with OA and may also stimulate inflammation. Destruction of articular cartilage may allow subchondral bone to become exposed leading to ischemic pain or pain from increased vascular pressure. Muscle spasm, which is common with OA can also cause pain, especially in the low back (Altman, 1990). Muscle atrophy, caused by disuse leads to decreased joint stability, increased biomechanical stress on the joint and therefore a further progression of OA (Altman, 1990, Marks, 1993).

Current treatment of Osteoarthritis

Many interventions and coping strategies are used in the treatment of the progressive disease of Osteoarthritis. These treatments include prevention, symptom reduction, and strategies to halt or even reverse the damage to the joint.

The load that is put on the weight bearing joints plays an important role in the development of OA. Depending on the activity, the hip and knee can absorb forces 3 to 5 times a person's body weight (Walker, 1996). Increased compressive force on the articular cartilage of the knees due to increased body weight has been implicated as a cause of Osteoarthritis (Felson, 1997). Felson also claims that a
weight loss of 10 pounds is correlated with a decrease in 50% of the Osteoarthritis symptoms felt in the knee.

Not only can increased loads predispose a joint to Osteoarthritis but excessive repetitive activity and/or abnormal stresses due to improper body mechanics can also accelerate the degeneration of articular cartilage. Incorrect body alignment such as pronated feet, genu varum, and genu valgum create excessive forces on the knee and can cause or aggravate Osteoarthritis (Brandt, 1997). Many of these mal-alignments can be managed with orthotics.

The emotional and psychological coping mechanisms involved in dealing with this disease can influence a person's subjective rating of pain. Because this disease is not necessarily visible, people may not receive much support from family and friends for the perceived physical pain caused by OA. Psychosocial support has been linked with decreased symptoms of OA. Rene (1982) discovered that if patients with OA of the knee received a phone call from a trained "layperson" once a month, there was a significant decrease in pain in the knee, regardless of their stable medical regime.

The use of non-steroidal anti-inflammatory agents (NSAIDS), or analgesics for the symptom management of patients with OA is very common. One problem with using NSAIDS for symptom management in OA is the potential for serious side effects with long term use. For example NSAID use is associated with increased risk of gastrointestinal complaints, such as ulceration or hemorrhage, with increased age. This is significant because the majority of people with OA are the elderly (Brandt, 1997).
Recent studies have also examined potential negative effects on cartilage with long-term NSAID use. The use of NSAIDs for 24 hours significantly decreases the activity of prolidase and inhibits collagen biosynthesis in vitro (Miltyk, Karna and Patka, 1996). Prolidase is an enzyme that has a crucial role in recycling proline for collagen biosynthesis. However, it is questionable if in vitro results can be generalized to a patient population. Newman and Ling (1985) concluded that long term use of NSAIDs actually accelerates the joint destruction in humans. This study, however, was retrospective and therefore also questionable. The current research suggesting that NSAIDs may be harmful to cartilage, despite their temporary analgesic effects, does not appear conclusive.

Intra-articular corticosteroid injections are another method used to decrease pain in Osteoarthritic joints. Hollander (1953) found that 87% of 231 patients had decreased pain in the knee after these injections. Hollander operationally defined a successful injection as one in which the patient had relief of pain for a minimum of three days. Although the pain is temporarily relieved, other problems occur with excessive use of this therapy. Corticosteroids have been linked with the break down of collagen and can lead to joint failure, such as tendon rupture, with frequent injections (Gray, 1983). In light of this, Hollander (1953) suggests that when this management tool is utilized the injections should be spaced 4 to 6 months apart. Brandt (1997) stated that pain relief after cortisone injection may only be temporary. He also pointed out that blocking of the pain transmission may lead to overuse and further breakdown of the arthritic joint.
In contrast to simply managing pain, treatments have recently emerged that claim to slow, halt or reverse the process of cartilage degeneration. Lequesne, Brandt and Bellamy (1994) demonstrated that the use of Disease Modifying Osteoarthritis Drugs (DMOADs) decreased proteolytic cartilage breakdown and stimulated matrix repair in animals. DMOADs include tissue extracts from animals and also site specific collagenase inhibitors that can attach to the catalytic site of the enzyme. Tissue extracts such as glycosaminoglycan polysulfate, (GAGPS) chondroitin-4-sulfate, and chondroitin-6-sulfate have been shown to stimulate cartilage synthesis. The use of these tissue extracts has also been demonstrated to decrease pain and increase function in patients with OA (Kerzberg, 1987, Lopes, 1982, Drovati, 1980, Tapadinhas, 1982).

Another type of DMOAD that has been investigated is gelatin. Oberschelp (1985) compared three treatments; 1) physical therapy alone, 2) Gerontamin (gelatin and retinal acetate) alone, and 3) a combination of physical therapy and gelatin in 154 subjects diagnosed with chondromalacia patellae, cox and gonarthrosis, or juvenile spine impairment. Subjects consumed the supplement daily for three months. He found that both the Gerontamin alone group and the Gerontamin with physical therapy group had a significant decrease in pain and an increase in mobility. There were no significant differences between these groups. The physical therapy alone group had little effect. He concluded that Gerontamin may be beneficial for people when physical therapy is not indicated. However, the physical therapy employed in this study involved only the use of passive modalities such as iontophoresis, electric current,

In a double blinded study by Adam (1991) 10 grams of gelatin hydrosylate was administered to 52 patients with a diagnosis of OA. The subjects were split in to four groups. Three of these groups received different forms of gelatin (10 grams) and the fourth group received a placebo. Subjects were given the supplements for a period of 2 months. The results indicated a significant decrease in subjective pain as well as a decrease in the amount of analgesics that were consumed among all of the gelatin groups. There was no change in the patients that received a placebo.

A current product that contains the same components as Gerontamine is Knox Nutrajoint®. Knox Nutrajoint® claims to contribute to joint health by providing the nutritional requirements for articular cartilage. The recommended daily amount of Knox Nutrajoint® contains 10 grams of hydrosylated gelatin, 60 milligrams of Vitamin C (100% of RDA), and 300 milligrams of Calcium (30% RDA). It comes in powder form which is mixed into a preferred beverage for consumption.

Physical therapy that combines a balance of strength and aerobic exercise has been shown to decrease the same amount of symptoms as NSAIDs (Minor, 1989). The rational behind the theory of exercise and why it can effectively reduce pain will now be discussed.

Benefits of Exercise in People with Osteoarthritis.
In the last decade, there has been a paradigm shift regarding the role that exercise plays in the management of Osteoarthritis. Previously, researchers noted that arthritis sufferers had decreased muscle strength and physical fitness (Minor, 1989). However, the consensus was that exercise would increase the rate of degeneration of articular cartilage, increasing the likelihood of accelerating the cartilage degeneration (Bland and Cooper, 1984).

Exercise puts biomechanical and physiological stress on articular cartilage. There are chondrocytes, which are living cells within the cartilage, that adapt to the stresses which are imposed on them. These chondrocytes control the breakdown and build-up of components of the cartilage matrix. The stress of static loading on cartilage causes decreased chondrocyte synthesis which leads to a decrease in the density of the cartilage. Cartilage motion without compression, such as passive range of motion, causes thinning of the articular cartilage. However, intermittent compression and decompression of cartilage tends to stimulate chondrocyte growth leading to increased stiffness of the cartilage (Hallet & Andrish, 1994).

In vivo studies, both human and animal, have given researchers insights regarding the effects of exercise on cartilage formation and breakdown. Strenuous levels of exercise tend to cause break down of articular cartilage. In vivo canine studies show a 6 to 11% reduction of Glucosaminoglycogens (GAGS) after strenuous running for 40 weeks (Hallet and Andrish, 1994). The Framingham longitudinal study showed that individuals in the highest quartile of exercise at baseline where 3.3 times more likely to develop knee Osteoarthritis.
(Felson, 1997). However, studies on humans have not been able to demonstrate a progression in articular breakdown associated with running (Kujala, 1995, Lane, 1996, Panush, 1986).

Immobilization also leads to decreased articular cartilage and decreased GAG concentration. In contrast, cyclic loading of articular cartilage increases the movement of higher molecular weight proteins to the joint. These proteins are important building blocks of cartilage (Hallet and Andrish, 1994).

In vivo canine studies with moderate running, 4 km a day for 10 weeks, showed increased GAG content on femoral condyles, and a 10-28% increase in thickness of uncalcified cartilage. Hallet and Andrish (1994) concluded that there may be a critical threshold of exercise in which too little or too much is detrimental to articular cartilage.

Minor, et. al.(1989) compared the effects of either aerobic walking, aerobic aquatic exercise or active range of motion exercises in 120 patients with RA or OA. After 12 weeks, a significant gain was found in aerobic capacity and 50 ft. walking time in both the aerobic walking and aerobic aquatic exercise groups. In addition, these groups also showed decreased depression and anxiety, and increased physical activity. The aerobic walking and range of motion groups reported a significant decrease in pain, however, this was not found with the aquatic group. Fisher, et al. (1993) were pioneers in their attempt to quantitatively measure a three month physical therapy intervention in patients with OA of the knee. The PT program addressed ROM, muscle strength, pain, patient education and functional training. Researchers noted that the muscle
strength and endurance increased significantly in the hamstrings and quadriceps. Functional gains were made in ability to climb stairs, decreased time to walk 50 ft. and rise from a chair. Subjects also reported less pain with activities of daily living.

Recently, a study was conducted by Ettinger, et. al. (1997) to compare the effectiveness of the previous treatment interventions of aerobic exercise and resistance exercise. Based on a self reported disability and pain questionnaire, the effects of structured exercise programs in 365 subjects with OA of the knee were analyzed over a period of 18 months. Subjects included males and females age 60 years or older. A control group was used to account for changes related to health education. Researchers concluded that both aerobic exercise and resisted exercise interventions were related to a decreased score on disability and knee pain questionnaire. Also, the time to complete a 6 minute walk test, ascend and descend stairs, lift and carry 10 pounds and transfer in and out of a car was significantly reduced. These effects were reported across sexes and age groups.

Calcium and Vitamin C

Certain levels of Vitamin C, or ascorbic acid, intake may also be important in the prevention of Osteoarthritis. In a study using Guinea pigs, decreased Vitamin C consumption lead to decreased collagen synthesis in articular cartilage and tendons (Kipp, 1996). In human studies, a 300% reduction in risk of developing OA was found with both moderate and high consumption of Vitamin C. This may be because of the antioxidant effects of the water soluble ascorbic acid on the Reactive Oxygen Species (ROS) which are generated by chondrocytes.
and neutrophils. These ROS can damage hyaluronan, proteoglycans and collagen which are important components of the cartilage matrix. The enzyme used in the hydroxylation of proline to hydroxyproline requires ascorbic acid in order to be effective. Collagen that does not contain the hydroxylated proline is less stable, this is the pathogenesis of connective tissue disorders such as scurvy (Campbell, 1991).

Calcium supplementation has also been implicated in the prevention of OA. One theory is that Osteoarthritis is inversely related to bone mineral density (osteoporosis). As bone loses mineral content and becomes softer it may become more deformed leading to pain and inflammation. According to McAlindon (1996b): “the quality of periarticular bone and its capacity to respond to various stresses, including changes in loading force caused by altered biomechanics, may influence whether Osteoarthritis stabilizes or progresses.”

It has been well documented that increased calcium supplementation is correlated with decreased risk of osteoporosis (Compston, 1990). Researchers using guinea pigs have also correlated decreased vitamin C supplementation with decreased bone density (Kipp, 1996).

Nutrition and Aging

With aging there is a relative decrease in the ability to absorb nutrients. Vitamin deficiencies have been reported in relatively healthy elderly individuals. These include Vitamins B-6, B-12, D, Calcium and Zinc. Decreased dietary intake of fat, protein and calories have also been shown with increased age (Heuther, 1994). McAlindon (1996b) demonstrated that low blood levels of
Vitamin D were correlated with decreased joint space and increased osteophyte growth. However, no studies could be found that investigate the effect of decreased intake or absorption of basic collagen components, such as proline, lysine and glycine, and their relation to Osteoarthritis.

**Functional Tests/Outcome Measures**

The Arthritis Impact Measurement Scale 2 (AIMS2) is a 78 item self-report questionnaire (Appendix B). It is composed of three factors including pain, psychological status, and physical health status. Scales include mobility, walking and bending, hand function, arm function, self-care, household, social, family support, pain, work, tension, mood, satisfaction, perception of health, and impact of arthritis (Meenan, 1992). This tool was designed specifically for individuals with rheumatic diseases. There are between 2 and 6 responses for each question, depending on the wording. These are raw scores that are then converted to a scale of 0-10 for statistical purposes (Meenan, Gertman, Mason, and Dunaif, 1982). Test-retest reliability for this measurement tool ranged from .78-.96, and internal consistency ranged from .74-.96 (Meenan, 1992).

**Summary and Implications for Study**

Arthritis is a condition of excessive breakdown of articular cartilage. Bioavailability of components for collagen synthesis is an important factor in the formation of healthy cartilage. Appropriate building blocks including amino acids; glycine, proline and hydroxyproline, and lysine are necessary to maintain and repair articular cartilage. Gelatin contains hydroxyproline, hydroxylysine and arginine (Adams, 1991). Vitamin C is an important cofactor in collagen synthesis
and is involved in the hydroxylation of Type II collagen which promotes the stability of collagen (Altman, 1990). Calcium supplementation may help maintain bone mineral density (Compston, 1990). Nutritional supplementation has been shown to improve the quality of cartilage by increasing the amount of essential nutrients required to maintain healthy cartilage and to repair damaged cartilage.

Moderate levels of exercise have also been found to decrease pain and increase function in people with Osteoarthritis. The intermittent compression, decompression and gliding associated with moderate exercise has been shown to build and maintain healthy cartilage. It allows for an increased flow of synovial fluid into the joint and into the cartilage. Exercise also provides increased stability to the joint and stimulates the chondrocytes causing increased synthesis of articular cartilage in response to the increased stress demands.

By combining a nutritional supplementation, Knox Nutrajoint, with moderate exercise, the authors of this study hoped to provide optimal conditions to allow nutrients to diffuse into the joint. Theoretically, this combination of treatments should outweigh the benefits of either nutritional supplementation or exercise alone.
CHAPTER 3

METODOLOGY

Design

This experimental study utilized a 2 x 2 factorial design to determine the efficacy of moderate exercise and nutritional supplementation in the treatment of people with Osteoarthritis of the knee. The study was double blinded for nutritional supplementation only. Subjects were randomly assigned to one of four treatment groups for a period of 8 weeks. One group of subjects was put on a progressive walking program and consumed a placebo nutritional supplement (maltodextrin). A second group of subjects consumed a nutritional supplement, Knox Nutrajoint®. A third group of subjects consumed Knox Nutrajoint and was put on a progressive walking program. The fourth group of subjects consumed only a placebo nutritional supplement (maltodextrin). Each subject completed the Arthritis Impact Measurement Scale 2 (Appendix A) before and after the treatment program. The pre-test and post-test scores were evaluated to measure treatment effects. This design was chosen to determine if there is a significant statistical difference between treatment groups and to identify if there is an interaction between the independent variables; moderate exercise and the nutritional supplementation.
Population and Sample

Voluntary subjects were recruited from southeast and southwest Michigan. Subjects were obtained from churches, assisted living centers, University faculty and staff, through newspaper articles, news and radio broadcasts, ads in Michigan newspapers and community postings (Appendix B). After approval was attained from the Human Subjects Review Board at Grand Valley University, letters were sent out to prospective sites of subject acquisition to ask for permission to give a group presentation. Potential subjects who were interested in addressing knee pain secondary to Osteoarthritis were asked to volunteer for this study.

There were 49 participants in this study. Subjects were men (15) and women (34) between the ages of 40 and 85, with a mean age of 58.9 years and a standard deviation of 11.7 years. The subjects had been diagnosed with Osteoarthritis between zero and 30 years. The average years with diagnosis of OA in one or both knees was 9.8 with a standard deviation of 8.21 years.

Potential subjects were given the inclusion/exclusion questionnaire (Appendix C) to determine if they were eligible to participate in the study. Subjects were excluded if they had been diagnosed with Diabetes, Rheumatoid Arthritis, or Peripheral Vascular Disease, if they were consuming supplements of chondroitin sulfate, glucosamine sulfate or gelatin supplements, if they could not walk for 20 minutes at a time or had sensory loss in their lower extremities, had compromised cognitive status, or other unresolved pathology in the knee that would prevent them from taking part in a walking program. Subjects were also excluded if they were currently involved in any type of lower extremity exercise
program three or more times per week with each session lasting 15 minutes or longer in duration.

**Instruments/Materials**

All of the subjects were evaluated before and after treatment with the Arthritis Impact Measurement Scale 2 (AIMS2). This instrument was a subjective self-report questionnaire that addressed many issues such as pain and functional status. As well as completing the AIMS2, each subject was given log sheets to record information on a daily basis (Appendix D). The log sheets measured compliance with nutritional supplement consumption and the walking program.

The placebo treatment was maltodextrin and the nutritional supplementation was Knox Nutrajoint® which contains 10 grams of hydrosylated gelatin, 60 milligrams of Vitamin C (100% of RDA), and 300 milligrams of Calcium (30% RDA). Both the placebo and the Knox Nutrajoint came in powder form that was mixed into a preferred beverage for consumption.

The Nabisco Corporation for the purpose of this study donated the Knox Nutrajoint and the placebo (maltodextrin). Nabisco packaged the Nutrajoint and the placebo in identical single serving envelopes. Envelopes were coded either “A” or “B” to conceal the identity of the contents to both the researchers and the subjects until the results of the study were analyzed. The Nabisco Company gave a gift of $7,500 to Grand Valley State University to help defray the costs involved in conducting this study. Funding allowed the researchers to increase the number
of subjects that could be managed in this study by hiring part time research assistants and for advertising for potential subjects.

**Procedures**

Subject recruitment began on June 1, 1998 and ended January 15, 1999. Researchers recruited subjects in two major ways. The first method of subject recruitment involved going to various senior centers to meet with groups of potential subjects for the study. At the initial meeting, a description of the study was provided. Participants were asked to volunteer for the study. All potential subjects were given or asked the inclusion/exclusion questionnaire. From the results of this questionnaire the researchers determined who was eligible for the study. Those volunteers who were not eligible for the study were given an arthritis information sheet (Appendix E).

The second method of subject recruitment involved advertising through flyers, newspapers, television news broadcasts and a radio interview. Volunteers who called in response to the aforementioned advertisements were read the subject questionnaire. Qualified subjects were then asked to participate in the study. An initial meeting was then scheduled at a convenient location.

All initial meetings were conducted by researchers; Daniel Scheffer and Anna Power. At this meeting, the subjects were given an informed consent form (Appendix F) that was read and signed. The researchers reviewed the consent form with each subject and answered all questions. A medical release form with a letter explaining the study (Appendix G) as sent to each subject's physician to confirm that they had a diagnosis of OA in one or both knees. A stamped
envelope, addressed to the researchers, was enclosed for the physician's office to mail back the diagnosis. Documentation of a diagnosis of Osteoarthritis in one or both knees was obtained for each participant in the study.

Subjects then completed the AIMS2. Each subject was randomly assigned to one of the four treatment groups by choosing an envelope that contained information for that group. An instruction sheet (Appendix H) describing what was expected of their group for the next eight weeks was given to subjects. They were asked not to change their diets or take any new supplements for the next eight weeks. The first group of subjects were put on a progressive walking program and consumed 10 grams (1 packet) of a placebo nutritional supplement (maltodextrin) by mixing it into eight ounces or more of their favorite juice beverage. The second group of subjects consumed 10 grams of Knox Nutrajoint (1 packet) with eight ounces or more of their favorite juice beverage. The third group of subjects consumed a mixture 10 grams (1 packet) of Knox Nutrajoint with eight ounces or more of their favorite juice beverage as well as being put on the progressive walking program. The fourth group of subjects consumed a mixture of 10 grams (1 packet) of a placebo nutritional supplement (maltodextrin) with eight ounces or more of their favorite juice. Each subject also received log sheets at this time to record their compliance over the course of the study. A second copy of the AIMS2 was given to each subject which was to be completed immediately at the end of their eight-week participation in the study. The AIMS2 and the completed log sheets were returned in another stamped envelope addressed to the researchers.
At the end of the initial meeting the researchers supplied the subjects with enough Nutrajoint or placebo (maltodextrin) for eight weeks of consumption. If at anytime the subjects ran out of product they contacted the researchers to be resupplied immediately. This happened two times during the course of the study. One time, a subject moved and lost 2 boxes. Another time, a subject complained that one box of envelopes mixed differently than the rest.

A research assistant phoned participants during weeks 1, 4 and 8. The assistant was blinded to the identity of the nutritional supplement. She used a protocol (Appendix I) to ask participants specific questions and remind them to fill out their log sheets. If a subject had concerns or questions, the researchers would call them back to answer their questions. At the conclusion of the study, the participants were phoned by another research assistant and informed of the identity of the nutritional supplementation they had been consuming during the study. This allowed subjects to continue with the therapeutic intervention if they decided to. After the data was compiled and analyzed, subjects received a mailing letting them know the outcomes of this study.

The walking program that the exercise groups followed consisted of three sessions per week spread out through the week (Table 3.1). Each subject was instructed to walk at a comfortable pace. During the first week each session was 15 minutes long. Five additional minutes were added each week from the second through the fourth week for a total of 30 minutes of walking per session by the fourth week. Thirty-minute sessions were maintained for the remaining four weeks.
### Table 3.1 Eight Week Walking Program for Groups 1 and 3

<table>
<thead>
<tr>
<th>Week #</th>
<th># of days a wk*</th>
<th>walking time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>25</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>7</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>8</td>
<td>3</td>
<td>30</td>
</tr>
</tbody>
</table>

*the three weekly walking sessions should be spread out through the week*
Chapter 4

Data Analysis

Techniques of Data Analysis

All data was entered into a computer text file by a research assistant who was blinded to the type of nutritional supplementation. The SPSS 6.1 Statistics Package was used to assess all data. The data underwent ANOVA to determine main effects and interactions within and between groups. Alpha levels were set at <.05.

The AIMS2 scale has 15 separate subscales that were assessed. These included mobility, walking and bending, hand function, arm function, self-care, household tasks, social activity, family support, arthritis pain, work related activities, level of tension, mood, satisfaction, health perception and arthritis impact.

Data Analysis

Internal Consistency/Reliability

The internal consistency of each of these scales were calculated using coefficient Alpha. Only nine of the subscales were found to be reliable. The results of the internal consistency calculations are reported in table 4.1.
For the calculation of overall functionality, the mobility, self care and household task subscales were excluded due to little or no variability. The internal consistency of the remaining scales ranged from .63 to .94.

The work related activities subscale was also excluded from the overall functionality calculation due to missing data. This was caused by the AIMS2 scale requiring respondents to skip a section if they were retired, this happened with 20 of the subjects.

Table 4.1: Coefficient Alpha Values for AIMS2 Subscales

<table>
<thead>
<tr>
<th>Scale</th>
<th>Pretest</th>
<th>Post-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility</td>
<td>.56</td>
<td>.33</td>
</tr>
<tr>
<td>Walk/Bend</td>
<td>.73</td>
<td>.79</td>
</tr>
<tr>
<td>Hand</td>
<td>.94</td>
<td>.78</td>
</tr>
<tr>
<td>Arm</td>
<td>.92</td>
<td>.89</td>
</tr>
<tr>
<td>Self Care</td>
<td>-.11</td>
<td>0</td>
</tr>
<tr>
<td>Household</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Social</td>
<td>.80</td>
<td>.62</td>
</tr>
<tr>
<td>Family</td>
<td>.89</td>
<td>.90</td>
</tr>
<tr>
<td>Pain</td>
<td>.82</td>
<td>.68</td>
</tr>
<tr>
<td>Work</td>
<td>.86</td>
<td>.63</td>
</tr>
<tr>
<td>Tension</td>
<td>.93</td>
<td>.85</td>
</tr>
<tr>
<td>Mood</td>
<td>.88</td>
<td>.92</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>.84</td>
<td>.81</td>
</tr>
<tr>
<td>Overall</td>
<td>.78</td>
<td>.82</td>
</tr>
</tbody>
</table>

Analysis of Covariance

ANCOVA, or Analysis of Covariance, were conducted for those subscales demonstrating reliability. Two subscales, Health Perception and Arthritis Impact, that had single response subscales were also analyzed. As each subscale was
analyzed separately, Alpha was set at .05 divided by the number of subscales (13), .004.

Analysis of Covariance indicated no significant effect for walking and bending for the gelatin condition $F(3, 41) = .59$, $p=.448$ or for the walking condition $F(3, 41) = .48$, $p=.494$. The pretest and posttest means for group 1, exercise only, were 5.733, S.D. ± 2.535 and 4.567, S.D. ± 2.597 (See figure 4.1), for group 2, placebo, were 3.35, S.D ± 2.729 and 4.15, S.D ± 2.973, for group 3, gelatin and exercise, were 4.536, S.D. ± 2.545 and 3.607, S.D. ± 2.422, for group 4 were 4.8, S.D ± 1.719, and 4.1, S.D. ± 2.601

![Figure 4.1: Mean Scores for Walking and Bending Subscale.](image)

Analysis of Covariance revealed a significant effect for level of mood in both the exercise groups $F(3,41) = 9.09$, $p=.004$. No significant effect was noted for the gelatin condition $F(3, 41) = 1.25$, $p=.270$. The pretest and posttest means for the exercise only group were 3.033, S.D. ± 2.125 and 2.300, S.D. ± 2.210 (See Figure 4.2), for the placebo group were 2.45, S.D ± 2.034 and 3.10, S.D ± 1.969,
for the exercise and gelatin group were 2.143, S.D. ± 1.447 and 1.786, S.D. ± 1.805, for the gelatin only group were 1.85, S.D ± .937, and 1.700, S.D. ± .919.

![Figure 4.2: Mean Scores for Mood Subscale](image)

Analysis of Covariance revealed no significant effect on pain for the Exercise condition F(3, 41) = 1.18, p=.285. There was no significant effect for the gelatin condition F(3, 41) = 1.68, p = .202. The pretest and posttest means for the exercise group were 5.567, S.D. ± 2.086 and 3.967, S.D. ± 1.968. (See Figure 4.3), for the placebo group were 5.50, S.D ± 2.273 and 4.40, S.D ± 2.633, for the exercise and gelatin group were 4.643, S.D. ± 2.033 and 3.786, S.D. ± 1.862, for the gelatin only group were 5.20, S.D ± 1.829, and 3.500, S.D. ± 1.528.

Analysis of Covariance revealed no significant effect on work related activities for the Exercise condition  F(3, 20) = 0, p=.997. There was no significant effect for the gelatin condition F(3, 20) = .54, p = .473. The pretest and posttest means for the exercise group were 4.306, S.D. ± 4.446 and 2.986, S.D. ± 4.155 (See Figure 4.4), for the placebo group were .714, S.D ± .431 and .714, S.D ± .759, for the exercise and gelatin group were 2.109, S.D. ± 2.692 and 1,250,
S.D. ±1.157. The pretest and posttest means for the gelatin only group were 1.406, S.D ± 1.288, and .625, S.D. ± .510.

![Figure 4.3: Mean Scores for Arthritis Pain Subscale](image)

Analysis of Covariance revealed no significant effect on level of satisfaction for the Exercise condition $F(3, 41) = .42, p=.520$. There was no significant effect for the gelatin condition $F(3, 41) = .61, p = .440$. The pretest and posttest means for the exercise group were 3.583, S.D. ± 2.139 and 2.528, S.D. ± 1.467 (See figure 4.5), for the placebo group were 2.979, S.D ± 2.282 and 2.729, S.D ± 2.392, for the exercise and gelatin group were 2.515, S.D. ± 1.633 and 2.381, S.D. ±1.155, for the gelatin only group were 3.125, S.D ± .977 and .2.625, S.D. ± 1.996.
The Analysis of Covariance for overall Arthritis Impact was not significant for the exercise condition $F(3, 41) = 4.05, p = .325$. The gelatin condition was also not found to be significant $F(3, 41) = 10.68, p = .114$. The reliability Coefficient was found to be .8193 for this subscale. The pretest and
posttest means for the exercise group were 5.000, S.D. ± 2.673 and 3.333, S.D. ± 3.086 (See Figure 4.6), for the placebo group were 5.250, S.D ± 2.189 and 3.500, S.D ± 3.375, for the exercise and gelatin group were 4.107, S.D. ± 2.322 and 3.393, S.D. ± 1.862, for the placebo group were 3.750, S.D ± 2.13 and 3.000, S.D. ± 2.297.

Figure 4.6: Mean Scores for Arthritis impact

The Analysis of Covariance for overall Functional Capacity was not significant for the exercise condition F(3, 41)= .11, p=.662. The gelatin condition was also not found to be significant F(3, 41) = .50, p=.86. The pretest and posttest means for the exercise group were 3.777, S.D. ± 1.023 and 3.116, S.D. ± 1.047 (See Figure 4.7), for the placebo group were 3.168, S.D ± 1.511 and 3.034, S.D ± 1.721, for the exercise and gelatin group were 2.880, S.D. ± 1.041 and 2.672, S.D. ± .897, for the gelatin only group were 2.934, S.D ± .702 and 2.658, S.D. ± 1.056.
Figure 4.7 Mean Scores for Overall functional Capacity Subscale

An analysis of Variance was conducted using the Pain rating scales that subjects filled out on their log sheets. The average pain ratings of week 1, week 4 and week 8 were compared. The average pain rating across all four treatment conditions decreased significantly $F(82,2) = 10.61, p=.000$. However, there was no significant main effects within treatment conditions; gelatin, $F(82, 2) = .83, p=.442$, or exercise $F(82,2)=.62, p=.542$ (See Table 4.2).

Table 4.2 Mean Pain Ratings for Each Group.

<table>
<thead>
<tr>
<th></th>
<th>Week 1 mean</th>
<th>Week 4 mean</th>
<th>Week 8 mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>4.00</td>
<td>3.60</td>
<td>3.20</td>
</tr>
<tr>
<td>Gelatin</td>
<td>4.50</td>
<td>3.917</td>
<td>3.167</td>
</tr>
<tr>
<td>Exercise</td>
<td>4.273</td>
<td>3.636</td>
<td>3.455</td>
</tr>
<tr>
<td>Exercise and Gelatin</td>
<td>3.333</td>
<td>3.250</td>
<td>2.500</td>
</tr>
<tr>
<td>Entire Sample</td>
<td>4.022</td>
<td>3.600</td>
<td>3.067</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>2.190</td>
<td>2.093</td>
<td>1.924</td>
</tr>
</tbody>
</table>
Hypothesis and Research Question Results

The first hypothesis was that nutritional supplementation of Knox Nutrajoint® in combination with a moderate exercise program would be superior to the effects of either exercise alone or Knox Nutrajoint alone when compared to a placebo supplement in the reduction of pain and subjective increase in function in subjects with OA of the knee(s). This was not supported by the results of this study.

The second hypothesis was that the treatment groups receiving nutritional supplementation or exercise would report greater relief of symptoms than the group receiving only a placebo. This was not supported by the results of this study.
Chapter 5
Discussion of Findings

The purpose of this study was to compare the effects of a placebo supplement to 1) exercise alone, 2) a nutritional supplementation of Knox Nutrajoint® (which contains gelatin hydrolysate, Vitamin C, and Calcium), and 3) a nutritional supplementation of Knox Nutrajoint in combination with exercise in the reduction of pain and subjective increase of function in patients with OA of the knee.

It is well documented in the literature that exercise can produce significant improvement on both subjective and objective functional testing in people with OA. The mechanism of cartilage regeneration has also been supported by clinically controlled studies. According to Hallet (1994), articular cartilage and subchondral bone will adapt to increased mechanical stresses by an increase in thickness. However, if the load is excessive, the cartilage will deteriorate instead of regenerate. Therefore, it is important not to exceed the threshold at which cartilage will begin to deteriorate. Theoretically, it is necessary to have the appropriate amount of chondrocytes in the cartilage to assist in regenerating the cartilage matrix when prescribing exercise treatment.

According to previous research on exercise, the authors expected to find a significant effect on the reduction of pain and increase in function with those
individuals in the exercise conditions of this study. All of the other exercise studies demonstrating an increase in functional variables had physical therapists or assistants supervise the exercise program (Kovar, 1992; Fisher, 1993; Fisher, 1989). Unlike other studies that looked at the effects of exercise on OA, this study had no formal supervision of the subjects' exercise program to determine if participants reaching a therapeutic level. Compliance was based on self-report only. The lack of significant findings in functional variables could be attributed to a lack of supervision.

Another possibility was that eight weeks was not a long enough time period to see significant effects of a non supervised home walking program or nutritional supplementation. Previous research investigating exercise on OA of the knee has been 3 to 18 months in duration (Minor, 1989, Fisher, 1993, Ettinger, 1997). Oberschelp (1985) investigated gelatin supplementation for 3 months.

Another factor that may have contributed to the lack of significant improvement of the exercising groups over non exercise groups was the variation in stage of arthritic degeneration in each subjects' knees. Because there was no control for the stage or level of arthritis, there was no way to determine if a subject had enough chondrocytes remaining in their knee for effective regeneration of the cartilage.

Neither the gelatin condition nor the exercise condition demonstrated any statistical significance in the comparative reduction of pain or increase in function. Previous studies that were done on gelatin have demonstrated some significant results in mobility and pain status (Adams, 1991, Oberschelp, 1985).
However, most of these studies lacked appropriate controls and used poor measurement tools. The only double blind placebo study that reported significant effects of gelatin on the reduction of pain was by Adams (1991). This study relied on subjective ordinal data and utilized only a chi-square analysis for their statistics.

The results of this study did not support the findings reported in the above gelatin studies. Previous gelatin studies utilized chi-squared tests whereas this study used the more statistically powerful ANOVA and ANCOVA. The results of this study, coupled with the use of parametric statistics, may imply that a type I error could have occurred in the previous studies.

All subjects, regardless of the group they were in, demonstrated an equal decrease in perceived pain scores between weeks one and eight of the study. These results could be attributed to the placebo effect since the subjects were blinded to the type of nutritional supplement that they received.

Rene (1982) discovered that if patients with OA of the knee received a phone call from a trained "layperson" once a month, there was a significant decrease in pain in the knee, regardless of their stable medical regime. This phenomenon could explain why all of the treatment groups had a decrease in pain, as they were called in week one, week four and week eight during their participation in this study.

The exercise group did exhibit a statistically significant increase in mood compared to the non exercise groups. The increase in wellness and overall well
being scores had been found to increase in exercise groups in other studies as well (Minor, 1989; Kovar, 1992).

**Application of practice**

There is an abundance of research using ANOVA and measures with strong validity and reliability that demonstrate the efficacy of a well controlled and supervised exercise program on the treatment of OA (Minor, 1989, Ettinger, 1997, Fischer, 1993). There is also some evidence to recommend gelatin supplementation (Adams, 1991, Oberschelp, 1985). However, the results of this study could not support the recommended use of gelatin supplementation or an unsupervised walking program for the treatment of osteoarthritis of the knee.

**Limitations**

This study did not control for the stage or the severity of arthritic degeneration that each subject had. Nor was the diagnosis of Osteoarthritis classified as to the specific type patellofemoral, tricompartmental or unicompartmental. The stage of arthritis has been shown in other studies to be an important indicator of success of nutritional intervention. Incident arthritis, or arthritis caused by trauma was only controlled for by excluding individuals under 40 years of age as they seem to have a higher incidence of this form of arthritis.

One of the most significant limitations of this study was the lack of control for the subject’s diet. Other than documenting estimated calcium and caffeine intake in the logbook, there were no regulations on each subject’s diet. This could have effected the results if any of the subjects radically change their diet during
the course of the study. Subjects that began to consume high amounts of Vitamin C or products containing gelatin, would have changed the controlled amount of supplementation that they were receiving each day. The authors of this study attempted to control for this by asking subjects to maintain their current diet and to refrain from adding any additional supplements for eight weeks. There were also no baseline diet requirements or inclusion/exclusion criteria before the intervention. This may have been relevant since the researchers were basing the theoretical need for supplementation on the lack of proper amounts within the person’s diet.

This study did not control for the occupations and day to day physical demands of each of the subjects. Determining the correct amount of physical activity to promote joint healing is important in managing OA. Because the subjects were not being asked to control the amount of physical activity outside the treatment protocol, some may have exceeded the amount of physical activity that would foster improvement and produced some degree of pain and inflammation. Others may not have had an adequate amount of activity to stimulate sufficient improvement in the cartilage matrix to show any significant change in pain or function. This could also have affected the outcome of this study.

Although the amount of pain medication was monitored, it could have been a confounding variable with respect to pain reduction. Other orthopedic dysfunction at the ankle or hip was not controlled for as the only requirement was walking time of 15 minutes or more and no previous surgery within 6 months.
Another limitation to this study was the use of only subjective self-report measurement outcomes. Also, there was no formal cognitive measure, which may have been important for a purely subjective outcome measure which required completion of a detailed questionnaire. The results were subject to self-report honestly and compliance.

The length of the study was only eight weeks, which is generally accepted to be the minimal amount of time to report subjective change in pain and function with gelatin supplementation. It may have proved more significant had the length of the study been increased to 6 months or more to allow for a plateau effect.

Another factor that might have affected some subjects' responses to Nutrajoint was that they were not excluded if they had tried chondroitin sulfate, glucosamine sulfate or gelatin in the recent past. It is estimated that 20-50% of the population does not respond to chondroitin sulfate or glucosamine sulfate (Schardt, 1998). It is unknown if this applies to gelatin supplementation with the small sample sizes in this study, 11 to 12 subjects per group, a 20-50% non response level to gelatin supplementation could dramatically effect the results.

Familial disposition for arthritis was not investigated. There may be a genetic component to arthritis that responds differently to nutritional intervention. And last of all, by limiting the focus of this research to the knee, the results of this intervention may not be applicable to other arthritic joints, especially non weight bearing joints.
Suggestions for Further Research/Modifications

Modifications to this study should include the use of a shorter subjective measurement test. The AIMS2 took up to an hour to complete in several cases. Advising patients to consume the supplementation after eating a meal may have reduced stomach discomfort experienced by a few of the volunteers. Also, the diagnosis of renal dysfunction should have been added to the exclusion criteria due to the inability to tolerate higher levels of protein that gelatin contains.

More research needs to be done in the investigation of gelatin and exercise on arthritis. Suggestions for future research include comparing the effect of glucosamine sulfate to that of gelatin on arthritis. The stage of the arthritis should also be controlled for in order to determine the most effective or least effective time in the progression of OA for nutritional intervention. The exercise component should be treated as one of the controlled variables but not as an imposed control as it limited the amount of subjects that qualified for this study by 50%. Larger sample sizes should also be investigated. Also, the response of other arthritic joints to exercise and nutritional supplementation should be examined. The duration of this type of study should be increased and the type of exercise could be tailored towards the current activity level of each subject to insure that therapeutic levels are attained. A follow up study should be considered as well to examine any long-term benefits of nutritional supplementation.
Conclusion/Summary

Despite significant findings in the literature that support the benefits of gelatin supplementation and exercise in the treatment of OA, the results of this study did not support the beneficial effects of either gelatin supplementation or of an unsupervised walking program in the treatment of OA of the knee in people over the age of 40 years. The data indicted that there was a significant improvement in the self reported mood level in the exercise groups when compared to non exercise groups. There was a significant reduction in the perceived pain scores across all four treatment groups. Further study involving more subjects, better supervision of exercise, a longer time interval and a less time consuming subject self assessment tool is recommended.
References


Appendix A

The AIMS2
ARTHritis IMPACT MEASUREMENT SCALES 2
(AIMS2)

Instructions: Please answer the following questions about your health. Most questions ask about your health during the past month. There are no right or wrong answers to the questions and most can be answered with a simple check (✓). Please answer every question.

Please begin by providing the following information about yourself.

NAME:__________________________

ADDRESS:______________________________
Number Street Apt#

City State Zip Code

PHONE:_____________ DATE:________________
Area Code Number Month Day Year

AIMS2 Copyright 1990 Boston University
Please check (√) the most appropriate answer for each question. These questions refer to **MOBILITY LEVEL**.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH ...</th>
<th>All Days (1)</th>
<th>Most Days (2)</th>
<th>Some Days (3)</th>
<th>Few Days (4)</th>
<th>No Days (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How often were you physical able to drive a car or use public transportation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8/</td>
</tr>
<tr>
<td>2. How often were you out of the house for at least part of the day?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9/</td>
</tr>
<tr>
<td>3. How often were you able to do errands in the neighborhood?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10/</td>
</tr>
<tr>
<td>4. How often did someone have to assist you to get around outside your home.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>11/</td>
</tr>
<tr>
<td>5. How often were you in a bed or chair for most or all of the day?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12/</td>
</tr>
</tbody>
</table>

These questions refer to **WALKING AND BENDING**.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH ...</th>
<th>All Days (1)</th>
<th>Most Days (2)</th>
<th>Some Days (3)</th>
<th>Few Days (4)</th>
<th>No Days (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Did you have trouble doing vigorous activities such as running, lifting heavy objects, or participating in strenuous sports?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>13/</td>
</tr>
<tr>
<td>7. Did you have trouble either walking several blocks or climbing a few flights of stairs?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>14/</td>
</tr>
<tr>
<td>8. Did you have trouble bending, lifting or stooping?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15/</td>
</tr>
<tr>
<td>9. Did you have trouble either walking one block or climbing one flight of stairs?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>16/</td>
</tr>
<tr>
<td>10. Were you unable to walk unless assisted by another person or by a cane, crutches, or walker?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>17/</td>
</tr>
</tbody>
</table>
Please check (√) the most appropriate answer for each question.

These questions refer to **HAND AND FINGER FUNCTION**.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH ...</th>
<th>All Days (1)</th>
<th>Most Days (2)</th>
<th>Some Days (3)</th>
<th>Few Days (4)</th>
<th>No Days (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Could you easily write with a pen or pencil?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>18/</td>
</tr>
<tr>
<td>12. Could you easily button a shirt or blouse?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>19/</td>
</tr>
<tr>
<td>13. Could you easily turn a key in a lock?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>20/</td>
</tr>
<tr>
<td>14. Could you easily tie a knot or a bow?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>21/</td>
</tr>
<tr>
<td>15. Could you easily open a new jar of food?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>22/</td>
</tr>
</tbody>
</table>

These questions refer to **ARM FUNCTION**.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH ...</th>
<th>All Days (1)</th>
<th>Most Days (2)</th>
<th>Some Days (3)</th>
<th>Few Days (4)</th>
<th>No Days (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16. Could you easily wipe your mouth with a napkin?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>23/</td>
</tr>
<tr>
<td>17. Could you easily put on a pullover sweater?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>24/</td>
</tr>
<tr>
<td>18. Could you easily comb or brush your hair?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>25/</td>
</tr>
<tr>
<td>19. Could you easily scratch your low back with your hand?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>26/</td>
</tr>
<tr>
<td>20. Could you easily reach shelves that were above your head?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>27/</td>
</tr>
</tbody>
</table>
Please check (✓) the most appropriate answer for each question.

These questions refer to **SELF-CARE TASKS**.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH</th>
<th>Always (1)</th>
<th>Very Often (2)</th>
<th>Sometimes (3)</th>
<th>Almost Never (4)</th>
<th>Never (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>21. Did you need help to take a bath or a shower?</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>28/</td>
</tr>
<tr>
<td>22. Did you need help to get dressed?</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>29/</td>
</tr>
<tr>
<td>23. Did you need help to use the toilet?</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>30/</td>
</tr>
<tr>
<td>24. Did you need help to get in or out of bed?</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>31/</td>
</tr>
</tbody>
</table>

These questions refer to **HOUSEHOLD TASKS**.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH</th>
<th>Always (1)</th>
<th>Very Often (2)</th>
<th>Sometimes (3)</th>
<th>Almost Never (4)</th>
<th>Never (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25. If you had the necessary transportation, could you go shopping for groceries without help?</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>32/</td>
</tr>
<tr>
<td>26. If you had kitchen facilities, could you prepare your own meals without help?</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>33/</td>
</tr>
<tr>
<td>27. If you had household tools and appliances, could you do your own housework without help?</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>34/</td>
</tr>
<tr>
<td>28. If you had laundry facilities, could you do your own laundry without help?</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>35/</td>
</tr>
</tbody>
</table>
Please check (%) the most appropriate answer for each question.

These questions refer to **SOCIAL ACTIVITY**.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH ...</th>
<th>All Days (1)</th>
<th>Most Days (2)</th>
<th>Some Days (3)</th>
<th>Few Days (4)</th>
<th>No Days (5)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>29. How often did you get together with friends or relatives?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>36/</td>
<td></td>
</tr>
<tr>
<td>30. How often did you have friends or relatives over to your home?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>37/</td>
<td></td>
</tr>
<tr>
<td>31. How often did you visit friends or relatives at their homes?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>38/</td>
<td></td>
</tr>
<tr>
<td>32. How often were you on the telephone with close friends or relatives?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>39/</td>
<td></td>
</tr>
<tr>
<td>33. How often did you go to a meeting of a church, club, team, or other group?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>40/</td>
<td></td>
</tr>
</tbody>
</table>

These questions refer to **SUPPORT FROM FAMILY AND FRIENDS**.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH ...</th>
<th>Always (1)</th>
<th>Very Often (2)</th>
<th>Sometimes (3)</th>
<th>Almost Never (4)</th>
<th>Never (5)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>34. Did you feel that your family or friends would be around if you needed assistance?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>41/</td>
<td></td>
</tr>
<tr>
<td>35. Did you feel that your family or friends were sensitive to your personal needs?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>42/</td>
<td></td>
</tr>
<tr>
<td>36. Did you feel that your family or friends were interested in helping you solve problems?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>43/</td>
<td></td>
</tr>
<tr>
<td>37. Did you feel that your family or friends understood the affects of your arthritis?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>44/</td>
<td></td>
</tr>
</tbody>
</table>
Please check (✓) the most appropriate answer for each question.

These questions refer to **ARTHRITIS PAIN**.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH ...</th>
<th>Severe (1)</th>
<th>Moderate (2)</th>
<th>Mild (3)</th>
<th>Very Mild (4)</th>
<th>None (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>38. How would you describe the arthritis pain you usually had?</td>
<td>45/</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All Days (1)</td>
<td>Most Days (2)</td>
<td>Some Days (3)</td>
<td>Few Days (4)</td>
<td>No Days (5)</td>
</tr>
<tr>
<td>39. How often did you have severe pain from arthritis?</td>
<td>46/</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All Days (1)</td>
<td>Most Days (2)</td>
<td>Some Days (3)</td>
<td>Few Days (4)</td>
<td>No Days (5)</td>
</tr>
<tr>
<td>40. How often did you have pain in two or more joints at the same time?</td>
<td>47/</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All Days (1)</td>
<td>Most Days (2)</td>
<td>Some Days (3)</td>
<td>Few Days (4)</td>
<td>No Days (5)</td>
</tr>
<tr>
<td>41. How often did your morning stiffness last more than one hour from the time you woke up?</td>
<td>48/</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All Days (1)</td>
<td>Most Days (2)</td>
<td>Some Days (3)</td>
<td>Few Days (4)</td>
<td>No Days (5)</td>
</tr>
<tr>
<td>42. How often did your pain make it difficult for you to sleep?</td>
<td>49/</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All Days (1)</td>
<td>Most Days (2)</td>
<td>Some Days (3)</td>
<td>Few Days (4)</td>
<td>No Days (5)</td>
</tr>
</tbody>
</table>

These questions refer to **Work**.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH ...</th>
<th>Paid Work (1)</th>
<th>House Work (2)</th>
<th>School Work (3)</th>
<th>Unemployed (4)</th>
<th>Disabled (5)</th>
<th>Retired (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>43. What has been your main form of work?</td>
<td>50/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All Days (1)</td>
<td>Most Days (2)</td>
<td>Some Days (3)</td>
<td>Few Days (4)</td>
<td>No Days (5)</td>
<td></td>
</tr>
</tbody>
</table>
| If you answered unemployed, disabled, or retired, please skip the next four questions and go to the next page.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH ...</th>
<th>All Days (1)</th>
<th>Most Days (2)</th>
<th>Some Days (3)</th>
<th>Few Days (4)</th>
<th>No Days (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>44. How often were you able to do any paid work, house work, or school work?</td>
<td>51/</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Most Days (2)</td>
<td>Some Days (3)</td>
<td>Few Days (4)</td>
<td>No Days (5)</td>
</tr>
<tr>
<td>45. On the days that you did work, how often did you have to work a shorter day?</td>
<td>52/</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Some Days (3)</td>
<td>Few Days (4)</td>
<td>No Days (5)</td>
</tr>
<tr>
<td>46. On the days that you did work, how often were you unable to do your work as carefully and accurately as you would like?</td>
<td>53/</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Few Days (4)</td>
<td>No Days (5)</td>
</tr>
<tr>
<td>47. On the days that you did work, how often did you have to change the way your paid work, house work, or school work is usually done?</td>
<td>54/</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No Days (5)</td>
</tr>
</tbody>
</table>
Please check (✓) the most appropriate answer for each question.

These questions refer to **LEVEL OF TENSION**.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH ...</th>
<th>Always (1)</th>
<th>Very Often (2)</th>
<th>Sometimes (3)</th>
<th>Almost Never (4)</th>
<th>Never (5)</th>
</tr>
</thead>
</table>
48. How often have you felt tense or high strung? | [ ]       | [ ]           | [ ]           | [ ]             | 55/       |
49. How often have you been bothered by nervousness or your nerves? | [ ]       | [ ]           | [ ]           | [ ]             | 56/       |
50. How often were you able to relax without difficulty? | [ ]       | [ ]           | [ ]           | [ ]             | 57/       |
51. How often have you felt relaxed and free of tension? | [ ]       | [ ]           | [ ]           | [ ]             | 58/       |
52. How often have you felt calm and peaceful? | [ ]       | [ ]           | [ ]           | [ ]             | 59/       |

These questions refer to **MOOD**.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH ...</th>
<th>Always (1)</th>
<th>Very Often (2)</th>
<th>Sometimes (3)</th>
<th>Almost Never (4)</th>
<th>Never (5)</th>
</tr>
</thead>
</table>
53. How often have you enjoyed the things you do? | [ ]       | [ ]           | [ ]           | [ ]             | 60/       |
54. How often have you been in low or very low spirits? | [ ]       | [ ]           | [ ]           | [ ]             | 61/       |
55. How often did you feel that nothing turned out the way you wanted it to? | [ ]       | [ ]           | [ ]           | [ ]             | 62/       |
56. How often did you feel that others would be better off if you were dead? | [ ]       | [ ]           | [ ]           | [ ]             | 63/       |
57. How often did you feel so down in the dumps that nothing would cheer you up? | [ ]       | [ ]           | [ ]           | [ ]             | 64/       |
Please check (✓) the most appropriate answer for each question.

These questions refer to satisfaction with each health area.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH ...</th>
<th>Very Satisfied (1)</th>
<th>Somewhat Satisfied (2)</th>
<th>Neither Satisfied Nor Dissatisfied (3)</th>
<th>Somewhat Dissatisfied (4)</th>
<th>Very Dissatisfied (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>58. How satisfied have you been with each of these areas of your health?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MOBILITY LEVEL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(example: do errands)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>65/</td>
</tr>
<tr>
<td>WALKING AND BENDING</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(example: climb stairs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>66/</td>
</tr>
<tr>
<td>HAND AND FINGER FUNCTION</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(example: tie a bow)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>67/</td>
</tr>
<tr>
<td>ARM FUNCTION</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(example: comb hair)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>68/</td>
</tr>
<tr>
<td>SELF-CARE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(example: take bath)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>69/</td>
</tr>
<tr>
<td>HOUSEHOLD TASKS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(example: housework)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>70/</td>
</tr>
<tr>
<td>SOCIAL ACTIVITY</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>(example: visit friends)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>71/</td>
</tr>
<tr>
<td>SUPPORT FROM FAMILY</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(example: help with problems)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>72/</td>
</tr>
<tr>
<td>ARTHRITIS PAIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(example: joint pain)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>73/</td>
</tr>
<tr>
<td>WORK</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(example: reduce hours)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>74/</td>
</tr>
<tr>
<td>LEVEL OF TENSION</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>(example: felt tense)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>75/</td>
</tr>
<tr>
<td>MOOD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(example: down in dumps)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>76/</td>
</tr>
</tbody>
</table>
Please check (✓) the most appropriate answer for each question.

These questions refer to arthritis impact on each area of health.

<table>
<thead>
<tr>
<th>DURING THE PAST MONTH ...</th>
<th>Not a Problem For Me (0)</th>
<th>Due Entirely To Other Causes (1)</th>
<th>Due Largely To Other Causes (2)</th>
<th>Due Partly to Arthritis and Partly to Other Causes (3)</th>
<th>Due Largely To My Arthritis (4)</th>
<th>Due Entirely To My Arthritis (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>59. How much of your problem in each area of health was due to your arthritis?</td>
<td>8/</td>
<td>9/</td>
<td>10/</td>
<td>11/</td>
<td>12/</td>
<td>13/</td>
</tr>
<tr>
<td>MOBILITY LEVEL</td>
<td>(example: do errands)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WALKING AND BENDING</td>
<td>(example: climb stairs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HAND AND FINGER FUNCTION</td>
<td>(example: tie a bow)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARM FUNCTION</td>
<td>(example: comb hair)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SELF-CARE</td>
<td>(example: take bath)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HOUSEHOLD TASKS</td>
<td>(example: housework)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SOCIAL ACTIVITY</td>
<td>(example: visit friends)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUPPORT FROM FAMILY</td>
<td>(example: help with problems)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARTHRITIS PAIN</td>
<td>(example: joint pain)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WORK</td>
<td>(example: reduce hours)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LEVEL OF TENSION</td>
<td>(example: felt tense)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MOOD</td>
<td>(example: down in dumps)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
You have now answered questions about different AREAS OF YOUR HEALTH. These areas are listed below. Please check (✓) up to THREE AREAS in which you would MOST LIKE TO SEE IMPROVEMENT. Please read all 12 areas of health choices before making your decision:

<table>
<thead>
<tr>
<th>MOBILITY LEVEL</th>
<th>✓ 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>(example: do errands)</td>
<td></td>
</tr>
<tr>
<td>WALKING AND BENDING</td>
<td>✓ 21</td>
</tr>
<tr>
<td>(example: climb stairs)</td>
<td></td>
</tr>
<tr>
<td>HAND AND FINGER FUNCTION</td>
<td>✓ 22</td>
</tr>
<tr>
<td>(example: tie a bow)</td>
<td></td>
</tr>
<tr>
<td>ARM FUNCTION</td>
<td>✓ 23</td>
</tr>
<tr>
<td>(example: comb hair)</td>
<td></td>
</tr>
<tr>
<td>SELF-CARE</td>
<td>✓ 24</td>
</tr>
<tr>
<td>(example: take bath)</td>
<td></td>
</tr>
<tr>
<td>HOUSEHOLD TASKS</td>
<td>✓ 25</td>
</tr>
<tr>
<td>(example: housework)</td>
<td></td>
</tr>
<tr>
<td>SOCIAL ACTIVITY</td>
<td>✓ 26</td>
</tr>
<tr>
<td>(example: visit friends)</td>
<td></td>
</tr>
<tr>
<td>SUPPORT FROM FAMILY</td>
<td>✓ 27</td>
</tr>
<tr>
<td>(example: help with problems)</td>
<td></td>
</tr>
<tr>
<td>ARTHRITIS PAIN</td>
<td>✓ 28</td>
</tr>
<tr>
<td>(example: joint pain)</td>
<td></td>
</tr>
<tr>
<td>WORK</td>
<td>✓ 29</td>
</tr>
<tr>
<td>(example: reduce hours)</td>
<td></td>
</tr>
<tr>
<td>LEVEL OF TENSION</td>
<td>✓ 30</td>
</tr>
<tr>
<td>(example: felt tense)</td>
<td></td>
</tr>
<tr>
<td>MOOD</td>
<td>✓ 31</td>
</tr>
<tr>
<td>(example: down in dumps)</td>
<td></td>
</tr>
</tbody>
</table>

Please make sure that you have checked no more than THREE AREAS for improvement.
Please check (✓) the most appropriate answer for each question.

These questions refer to your CURRENT and FUTURE HEALTH.

61. In general would you say that your HEALTH NOW is excellent, good, fair, or poor?

   Excellent (1)   Good (2)   Fair (3)   Poor (4)

   ___          ___          ___          ___ 32/

62. How satisfied are you with your HEALTH NOW?

   Very Satisfied (1)   Somewhat Satisfied (2)   Neither Satisfied Nor Dissatisfied (3)   Somewhat Dissatisfied (4)   Very Dissatisfied (5)

   ___          ___          ___          ___          ___ 33/

63. How much of your problem with your HEALTH NOW is due to your arthritis?

   Not a Problem For Me (0)   Due Entirely To Other Causes (1)   Due Largely To Other Causes (2)   Due Partly To Arthritis and Partly To Other Causes (3)   Due Largely To My Arthritis (4)   Due Entirely To My Arthritis (5)

   ___          ___          ___          ___          ___          ___ 34/

64. In general do you expect that your HEALTH 10 YEARS FROM NOW will be excellent, good, fair, or poor?

   Excellent (1)   Good (2)   Fair (3)   Poor (4)

   ___          ___          ___          ___ 35/

65. How big a problem do you expect your arthritis to be 10 YEARS FROM NOW?

   No Problem At All (1)   Minor Problem (2)   Moderate Problem (3)   Major Problem (4)

   ___          ___          ___          ___ 36/
Please check (✓) the most appropriate answer for each question

This question refers to OVERALL ARTHRITIS IMPACT.

<table>
<thead>
<tr>
<th>Very Well (1)</th>
<th>Well (2)</th>
<th>Fair (3)</th>
<th>Poor (4)</th>
<th>Very Poorly (5)</th>
</tr>
</thead>
</table>

66. CONSIDERING ALL THE WAYS THAT YOUR ARTHRITIS AFFECTS YOU, how well are you doing compared to other people your age?

37/

What is the main kind of arthritis that you have?

Check = 1
Blank = 0

- Rheumatoid Arthritis
- Osteoarthritis/Degenerative Arthritis
- Systemic Lupus Erythematosis
- Fibromyalgia
- Scleroderma
- Psoriatic Arthritis
- Reiter’s Syndrome
- Gout
- Low Back Pain
- Tendonitis/Bursitis
- Osteoporosis
- Other

38/ 39/ 40/ 41/ 42/ 43/ 44/ 45/ 46/ 47/ 48/ 49/

68. How many years have you had arthritis?

50-51/

DURING THE PAST MONTH...

<table>
<thead>
<tr>
<th>All Days (1)</th>
<th>Most Days (2)</th>
<th>Some Days (3)</th>
<th>Few Days (4)</th>
<th>No Days (5)</th>
</tr>
</thead>
</table>

69. How often have you had to take MEDICATION for your arthritis?

52/
70. Is your health currently affected by any of the following medical problems?

<table>
<thead>
<tr>
<th>Medical Problem</th>
<th>Yes (1)</th>
<th>No (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental illness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol or drug use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ulcer or other stomach disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anemia or other blood disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>53/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>54/</td>
<td></td>
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<td>55/</td>
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<td>56/</td>
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<tr>
<td>57/</td>
<td></td>
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<td>58/</td>
<td></td>
<td></td>
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<tr>
<td>59/</td>
<td></td>
<td></td>
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<tr>
<td>60/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>61/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>62/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>63/</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

71. Do you take medicine every day for any problem other than your arthritis? 64/

72. Did you see a doctor more than three times last year for any problem other than arthritis? 65/
Please provide the following information about yourself:

73. What is your age at this time? 66-67/

74. What is your sex?
   Male (1) 68/
   Female (2)

75. What is your racial background?
   White (1) 69/
   Black (2)
   Hispanic (3)
   Asian or Pacific Islander (4)
   American Indian or Alaskan Native (5)
   Other (6)

76. What is your Current marital status?
   Married (1) 70/
   Separated (2)
   Divorced (3)
   Widowed (4)
   Never married (5)

77. What is the highest level of education you received?
   Less than seven years of school (1) 71/
   Grades seven through nine (2)
   Grades ten through eleven (3)
   High school graduate (4)
   One to four years of college (5)
   College graduate (6)
   Professional or graduate school (7)

78. What is your approximate family income including wages, disability payment, retirement income, and welfare?
   Less than $10,000 (1) 72/
   $10,000 - $19,999 (2)
   $20,000 - $29,999 (3)
   $30,000 - $39,999 (4)
   $40,000 - $49,999 (5)
   $50,000 - $59,999 (6)
   $60,000 - $69,999 (7)
   More than $70,000 (8)

Thank you for completing this questionnaire.

Appendix B

Attention Arthritis Sufferers

If a physician has diagnosed you with Osteoarthritis in one or both of your knees you may be eligible to participate in an exciting new study that is being conducted through Grand Valley State University.

The purpose of this study is to explore alternative treatments such as nutritional supplementation and exercise on decreasing pain from arthritis of the knee. We are looking for men and women who are over 40 years of age. If you would like more information about this study please call Dan Scheffer and Anna Power at 1-800-797-6046.

Osteoarthritis is a disease that destroys the cartilage in the weight bearing joints of the body such as knees, hips, ankles and back. With Osteoarthritis, the body is not able to rebuild cartilage at the same rate that it is being destroyed. By providing the correct nutrition the body can improve its ability to rebuild cartilage and decrease pain.

Unfortunately you will NOT be eligible if

- You have a diagnosis of Diabetes or Peripheral Vascular Disease
- You are currently consuming nutritional supplementation such as; chondroitin sulfate glucosamine sulfate or gelatin
- If you cannot walk for 20 minutes without stopping
- If you are currently involved in any lower extremity exercise program that you participate in 3 or more times a week for 15 minutes or more at a time. (Walking, Biking, Running)
- Loss of feeling in your legs
Appendix C

Subject Questionnaire

Circle the Appropriate Response

1. Have you been diagnosed by a physician as having Osteoarthritis or Degenerative Joint Disease of one or both knees?  
   YES  NO

2. Have you ever been diagnosed with Diabetes or Peripheral Vascular Disease?  
   YES  NO

3. Do you currently have any numbness or loss of feeling in either of your legs?  
   YES  NO

4. Do you currently have any unresolved problems with your knees other than Osteoarthritis or Degenerative Joint Disease?  
   YES  NO
   If yes, please explain: ________________________________

5. Are you currently taking any nutritional supplements such as vitamins, Glucosamine sulfate, chondroitin sulfate, Nutrajoint or minerals?  
   YES  NO
   If yes, what are you taking? ________________________________

6. Are you able to walk for 15 minutes continuously without difficulty?  
   YES  NO

7. Do you perform any type of exercise including walking on a regular basis. If yes, please describe what exercise you do, how much time it involves per week and the number of times per week that it is performed. ________________________________

Please Print:

Name (first and last) ______________________

Mailing Address ______________________

____________________________________

Social Security Number _____-____-____  Home Phone ( ) ____-____

50
## Appendix D

### Daily Log for Exercise and Nutritional Supplementation Groups

<table>
<thead>
<tr>
<th>Day</th>
<th>Sun</th>
<th>Mon.</th>
<th>Tues.</th>
<th>Wed</th>
<th>Thurs.</th>
<th>Friday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consumed Powder</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walked (record time)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amount of Pain/anti inflammatory Medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># of drinks containing caffeine ++</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain rating (0-10) 0 = no pain 10 = worst pain possible</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium rich foods consumed **</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Calcium rich foods consumed include:**
- 1 c. Milk,
- 1 c. yogurt,
- 1 slice of cheese
- 1 bowl ice cream.

++Caffeine Containing foods include:
- 1 c. Tea
- 1 c. Coffee
- 1 can of coke/Pepsi/mountain dew.
## Daily Log for Nutritional Supplementation only groups

<table>
<thead>
<tr>
<th>Day</th>
<th>Sun</th>
<th>Mon.</th>
<th>Tues.</th>
<th>Wed</th>
<th>Thurs.</th>
<th>Friday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Consumed Powder</td>
<td>Amount of Pain/anti-inflammatory Medication</td>
<td># of drinks containing caffeine ++</td>
<td>Pain rating (0-10) 0 = no pain 10= worst pain possible</td>
<td>Calcium rich foods consumed **</td>
<td></td>
</tr>
</tbody>
</table>

**Calcium rich foods consumed include:**
- 1 c. Milk,
- 1c. yogurt,
- 1 slice of cheese
- 1 bowl ice cream.

++Caffeine Containing foods include:
- 1 c. Tea
- 1 c. Coffee
- 1 can of coke/Pepsi/mountain dew.
Appendix E

Arthritis Information

Thank you for your interest in our study. Although you cannot participate, we would like to share some information that may be helpful for you.

These are some things that you may want to try:

1. **Glucosamine Sulfate**
2. **Chondroitin Sulfate**
These supplements can be found in many health food stores. They are an important component of the cartilage in your joint. Many people have noticed a decrease in pain after using these for at least 2-4 weeks.

3. **Knox Gelatin or Knox Nutrajoint®**
This product can be found in the gelatin aisle of many grocery stores. It contains the amino acids that are used to build Type 2 cartilage, which is important for your joint. Many people have experienced a decrease in pain after taking this daily for 2-4 weeks. The recommended dosage is on the container; one scoop daily.

4. **Vitamin C supplements**
Some people recommend taking Vitamin C because it is used when the body is trying to make type 2 cartilage. If your diet is low in Vitamin C (if you don’t eat many fruits or drink juice often), it may affect the strength of the cartilage in your joint.

5. **Calcium supplements**
Calcium is important for strong bones. If your bones aren’t strong, it could affect how strong your joints are. If you do not consume many dairy products, or if you drink a lot of caffeinated products, you may benefit from calcium supplements.

6. **Antioxidants**
These supplements may help protect the cartilage in your joint from being destroyed by free radicals. Antioxidants include Vitamin A, Vitamin C, Vitamin E, and Selenium.

7. **Exercise**
Appendix E, Cont.

Lately, researchers have realized that a certain amount of exercise 3-5x a week may be helpful in maintaining healthy cartilage for your joints. Many people with Arthritis have found that exercise in moderate amounts such as walking or swimming has helped relieve some of their pain. Specific exercises for the joint have also relieved pain in some individuals. It is important that you discuss new exercise programs with your doctor.

8. Weight Loss

If you have arthritis in your legs and you are overweight, your joints are working extra hard. By losing weight, you are decreasing the amount of force that is going through your cartilage. It may be helpful to speak to your doctor if you wish to start a weight loss program.

*These are some things that you may want to try. If your doctor has prescribed something for your arthritis, these things may be tried, but DON'T stop doing what you are already doing without speaking to your doctor. If you are thinking of trying nutritional supplements, talk to your doctor, a certified nutritionist, or your pharmacist about what dosage would be most appropriate for you.*

*It is usually recommended that you try one new thing at a time, so that you can decide what is helpful for you. This is only a partial list, new research is being conducted all the time to find the best way to treat Arthritis.*

*Most of the information found here can be found in the book The Arthritis Cure by Jason Theodosakis and Brenda Adderly (1997) published by St. Martins Paperbacks, NY, NY. If you want more detailed information this may be a good place to start.*

Another great resource is The Arthritis Foundation. In Grand Rapids the number is (616) 774-873
Appendix F

Consent Form

You are invited to participate in a research study entitled The Effects of Nutritional Supplementation and Exercise on Subjective Pain and Function in Osteoarthritis of the Knee. This purpose of this study is to investigate the effects of Knox Nutrajoint®, Maltodextrin and walking on Osteoarthritis. This study is being conducted through the Grand Valley State University Physical Therapy program. Dan Scheffer and Anna Power are the principal investigators for this research and it is being funded by the Nabisco Corporation. Nabisco will provide the Knox Nutrajoint and Maltodextrin as well as all mailing materials free of charge.

In order to be included in this study:

- you must be above 40 years of age
- you must be able to walk for 15 minutes at a time without supervision.
- you must have doctor diagnosis of Osteoarthritis or Degenerative Joint Disease in one or both knees

You will be excluded from this study:

- If you have had joint replacement surgery in both of your Osteoarthritis knees
- If you have had fractures or tendon tears within the last 90 days in your Osteoarthritis knee(s).
- If you have been diagnosed with Diabetes of Peripheral Vascular Disease.
- If you are unable to walk for 15 minutes at a time without supervision
- If you have been exercising your legs at least 3x a week, 15 minutes at a time (such as water aerobics, aerobics, walking, biking).

You will be randomly assigned to one of the following four groups (a process similar to flipping a coin).

A. Walking 3x a week and drinking maltodextrin daily
B. Walking 3x a week and drinking Knox Nutrajoint daily
C. Drinking maltodextrin daily
D. Drinking Knox Nutrajoint daily

You will not be told if you are receiving Maltodextrin or Knox Nutrajoint. Likewise, the researchers will not know which group you are in until the end of the study.

<table>
<thead>
<tr>
<th>Knox Nutrajoint – 40 Calories</th>
<th>Maltodextrin – 40 Calories</th>
</tr>
</thead>
<tbody>
<tr>
<td>10g Gelatin (protein)</td>
<td>10g Maltodextrin (carbohydrate)</td>
</tr>
<tr>
<td>300mg Calcium, 30% RDA</td>
<td>Dietetic Cloud</td>
</tr>
<tr>
<td>60mg Vitamin C, 100%RDA</td>
<td>Artificial Colors</td>
</tr>
</tbody>
</table>
Appendix F-cont.

1. The study will last for 8 consecutive weeks.
2. You will have to complete a 15 minute written questionnaire regarding pain and function before and after the study as well as maintain a daily written log.
3. Your physician will have to confirm your diagnosis of Osteoarthritis or degenerative joint disease of one or both knees by signing a form before you begin participation in this study.
4. The information you provide throughout the course of this study will remain confidential to the extent permitted by law. Dan Scheffer and Anna Power are the only people allowed access to the data pertinent to this study. Your identity will not be disclosed without written consent in any publications resulting from this research project.
5. You may experience a decrease in knee pain during the 8-week study.
6. A very small percentage of people have experienced minor gastrointestinal discomfort (gas, bloating) with the consumption of gelatin due to its protein.
7. By participating in this study there is a possibility that the knee pain may increase temporarily if you are assigned to one of the exercise groups.
8. The results of this study will be made available to you at the end of the study through a mailing.
9. During this study we ask that you not add glucosamine sulfate, chondroitin sulfate to your diet or change your normal eating habits.
10. You are one of at least 100 volunteers participating in this study.
11. Knox Nutrajoint and Maltodextrin as well as other nutritional supplementation are available at any grocery store if you wish to try these instead of participating in this study.
12. Participation in this study is voluntary and you may withdraw at anytime without any repercussions by contacting either Dan Scheffer or Anna Power by phone at 1-800-797-6046.
13. If the researchers feel it necessary for you to discontinue with the program they may do so without your consent. Reasons for discontinuation may include, but are not limited to, gastrointestinal discomfort with Nutrajoint or excessive pain with exercise.
14. You will be informed if significant new findings become available, during this study, that may affect your willingness to continue to participate in this study.
15. A copy of the signed consent form will be given to you.
16. If you are a woman of child bearing age or think that you are pregnant, you should consult with your physician prior to entering this study.
17. You will be phoned at weeks 1, 4, and 8 of the study to ask if you have any questions as you will be going through the program independently.

Please Initial______

56
Appendix F, Cont.

I acknowledge that:

A researcher has personally gone over this consent form with me and given me the opportunity to ask questions about this research study. I also feel that my questions have been answered to my satisfaction. If I have any questions during the study I can phone Dan Scheffer at 1-800-797-6046 or Robert Henderson, chair of Human Subjects review Board at Grand Valley State University at (616) 895-2195.

I hereby authorize the researchers to release the information obtained in this study to scientific literature. I have been informed that my name will not be identified and that all information that I have provided will remain confidential.

I acknowledge that I have read and understand the above information and that I agree to participate in this study.

________________________________________________________________________
(Participant Signature) (Witness)

________________________________________________________________________
Date Date
Appendix G
Physicians Confirmed Diagnosis

Dear Dr. ______________,

I ______________ give Dr. ______________ permission to release information
(patient's signature) (print)
from my medical records pertaining the diagnosis of Osteoarthritis/Degenerative Joint Disease for the purpose of research.

I am currently involved in a study on Osteoarthritis with graduate students and faculty from the Grand Valley State University Physical Therapy program. In order to participate in this study I must have your confirmation that I have Osteoarthritis/ Degenerative Joint Disease of one or both knees. Could you please confirm my diagnosis and send this letter back to the researchers in the stamped envelope that I have provided. This study will last for eight weeks and will look at the effect of a progressive walking program and Nabisco's Knox Nutrajoint on the symptoms of Osteoarthritis. Knox Nutrajoint can be purchased at any large food store and contains 10 grams of gelatin (protein), Calcium, and Vitamin C. Maltodextrin will also be used as a carbohydrate supplement containing corn starch and artificial colors. The data will be collected with the Arthritis Impact Measurement Scale 2 taken both before and after the 8-week protocol. I will be randomly assigned to one of four groups. Group one will walk for up to 30 minutes 3 times per week and consume Knox Nutrajoint. Group two will only consume Knox Nutrajoint. Group three will walk for up to 30 minutes 3 times per week and consume maltodextrin. Group four will only consume maltodextrin. The maltodextrin and Knox Nutrajoint will be in powder form and mixed into a fruit juice for consumption once a day. Thank you for your time.

I ________________ confirm that ________________ was diagnosed with Osteoarthritis
(Physician's Signature) (Patient's Name)
of his or her ______________ knee(s). Date __________
(Left, Right, Both)

If the Doctor has any questions please feel free to call the researchers:

Dan Scheffer 1-800-797-6046
or Robert Hendersen, chair of GVSU Human Subjects Review Board at (616)
895-2195
Appendix H

Instruction sheet for group 1 and 3

1. Fill out and sign the letter to your doctor requesting your diagnosis of Osteoarthritis or Degenerative Joint Disease.

2. Put the doctor’s letter in the large yellow envelope along with the stamped envelope addressed to Dan Scheffer marked “Doctor” on the back.

3. Every day you will be mixing one pouch of the powder given to you into at least 8 ounces of your favorite juice drink. It is important that you consume this think 15 minutes to an hour before you exercise.

4. It is important to walk for the designated amount of time three times a week. Use the table to determine how long you need to walk each week. Try to walk Monday, Wednesday and Friday or Tuesday, Thursday, and Saturday. This way your body will get a day of rest between exercise.

<table>
<thead>
<tr>
<th>Week #</th>
<th># of days a wk</th>
<th>walking time (minutes)</th>
</tr>
</thead>
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   *the three weekly walking sessions should be spread out through the week

5. Every day fill out your logbook.

6. At the end of 8 weeks immediately fill out the Arthritis Impact Measurement Scale 2. **Please make sure that every question is answered, even if it does not seem to apply to your condition.

7. After completing the Arthritis Impact Measurement Scale 2 put it in the large stamped envelope marked “DONE” and mail.

8. If you run out of powder or you have any questions please call Dan Scheffer at 1-800-797-6046.
Appendix H, cont.

Instruction Sheet for Groups 2 and 4

1. Fill out and sign the letter to your doctor requesting your diagnosis of Osteoarthritis or Degenerative Joint Disease.

2. Put the doctor’s letter in the large yellow envelope along with the stamped envelope addressed to Dan Scheffer marked “Doctor” on the back.

3. Every day you will be mixing one pouch of the powder given to you into at least 8 ounces of your favorite juice drink. Try to drink this mixture in the morning.

4. Every day fill out your logbook.

5. At the end of 8 weeks immediately fill out the Arthritis Impact Measurement Scale 2
   **Please make sure that every question is answered, even if it does not seem to apply to your condition.

6. After completing the Arthritis Impact Measurement Scale 2 put it in the large stamped envelope marked “DONE” and mail.

7. If you run out of powder or you have any questions please call Dan Scheffer at 1-800-797-6046
Appendix I
Research Assistant instructions

Phone calls to Subjects

1. Each subject is to be called at weeks 1, 4, and 8.
2. Introduce yourself as an assistant in the arthritis study.
3. Ask the subject if they were mixing their powdered supplement into a liquid and drinking it once per day.
3a. If the subject was in an exercise group, ask how often they were walking.
4. Asked if there are any questions or problems that needed to be addressed.
5. Thank each subject for participating in the study.
6. If the subjects have questions, contacted the primary researchers DS and AP. DS or AP will call the subject and answer any questions and or mail the subject additional supplements if needed.

Week 4
1. Follow above steps 1-6
2. Remind subject to mail in their confirmation of a diagnosis of osteoarthritis if they had not already done so.

Week 8
1. Remind subjects to include their log sheets and AIMS2 surveys in the envelope that they mail back to the primary researchers.

Note: After the log sheets and the tests were received in the mail each subject was called by an unblinded research assistant CS. CS called each subject and revealed which nutritional supplementation group they were in. Each subject was then thanked again for participating in the research study.