**A Dissertation on**

# EFFICACY OF MASSAGE THERAPY ON PAIN IN PATIENTS WITH OSTEOARTHRITIS OF KNEE: A RANDOMIZED CONTROLLED CLINICAL TRIAL

Submitted by
Dr.R.ARUNTHATHI.

*Submitted to*

***The Tamil Nadu Dr.M.G.R.Medical University,***

*In partial fulfillment of the requirements for*

*the award of Degree of*

**DOCTOR OF MEDICINE**

**Branch – I: M.D. (NATUROPATHY)**

**THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY**

**CHENNAI – 600 032, INDIA**

**2014 - 2018**

**GOVERNMENT YOGA AND NATUROPATHY MEDICAL COLLEGE AND HOSPITAL, CHENNAI, TAMIL NADU**

## ***CERTIFICATE BY THE GUIDE***

**I certify that the dissertation entitled *"Efficacy of Massage Therapy on Pain in Patients with Osteoarthritis of Knee:A Randomized Controlled Clinical Trial"*** is a bonafide work done by the post graduate Dr.ARUNTHATHI.R, Department of Naturopathy, Government Yoga & Naturopathy Medical College and hospital,Chennai – 600 106, under my guidance and supervision, in partial fulfillment of regulations of **The Tamil Nadu Dr.M.G.R.Medical University,** for the award of M.D (NATUROPATHY) Branch – I during the academic period from 2014 – 2017.

Place: Chennai.

Date: DD/MM/2017

**SIGNATURE OF THE GUIDE**

**Dr. N. MANAVALAN**

N.D. (OSM), M.A (G.T), M.SC(Y&N),
M. Phil, P.G.D.Y, P.G.D.H.M, P.G.D.H.H.,
Head of the Department - Department of Naturopathy,
Government Yoga and Naturopathy Medical College,
Chennai – 106.

.

**GOVERNMENT YOGA AND NATUROPATHY MEDICAL COLLEGE AND HOSPITAL, CHENNAI, TAMIL NADU**

## ENDORSEMENT BY THE HEAD OF THE DEPARTMENT

I certify that the dissertation entitled **“**Efficacy of Massage Therapy on Pain in Patients with Osteoarthritis of Knee: A Randomized Controlled Clinical Trial**”** is the record of original research work carried out by Dr.R.ARUNTHATHI in the Department of Naturopathy, Government Yoga & Naturopathy Medical College and hospital**,** Chennai – 600 106 submitted for the degree of **DOCTOR OF MEDICINE (M.D) in Naturopathy** under my guidance and supervision, and that this work has not formed the basis for the award of any degree, diploma, associateship, fellowship or other titles in this University or any other University or Institution of higher learning.

Place: Chennai.

Date: DD/MM/2017

**SIGNATURE OF THE H.O.D**

**Dr. N. MANAVALAN**

N.D. (OSM), M.A (G.T), M.SC(Y&N),

M. Phil, P.G.D.Y, P.G.D.H.M, P.G.D.H.H.,

Head of the Department **-** Department of Naturopathy,

Government Yoga and Naturopathy Medical College,

Chennai – 106.

**GOVERNMENT YOGA AND NATUROPATHY MEDICAL COLLEGE AND HOSPITAL,CHENNAI, TAMIL NADU**

## ENDORSEMENT BY THE PRINCIPAL

I certify that the dissertation entitled **"**Efficacy of Massage Therapy on Pain in Patients with Osteoarthritis of Knee: A Randomized Controlled Clinical Trial**"** is the record of original research work carried out by Dr.R.ARUNTHATHI**,** in the Department of Naturopathy, Government Yoga & Naturopathy Medical College and hospital**,** Chennai – 600 106 submitted for the degree of **DOCTOR OF MEDICINE (M.D) in Naturopathy** under my guidance and supervision, and that this work has not formed the basis for the award of any degree, diploma, associateship, fellowship or other titles in this University or any other University or Institution of higher learning.

Place: Chennai.

Date: DD/MM/2017

**SIGNATURE OF THE PRINCIPAL**

**Dr. N.MANAVALAN**

N.D. (OSM), M.A (G.T), M.SC(Y&N),

M. Phil, P.G.D.Y, P.G.D.H.M, P.G.D.H.H.,

Government Yoga and Naturopathy Medical College,

Chennai – 106.

**INSTITUTIONAL ETHICAL COMMITTEE**

**GOVERNMENT YOGA & NATUROPATHY MEDICAL COLLEGE AND HOSPITAL, CHENNAI – 600 106,**

## CERTIFICATE OF APPROVAL

The Institution Ethical Committee of Government Yoga & Naturopathy Medical College, Chennai reviewed and discussed the application for approval "Efficacy of Massage Therapy on Pain in Patients with Osteoarthritis of Knee: A Randomized Controlled Clinical Trial" for Project work submitted by Dr.R.ARUNTHATHI 2nd yr M.D.Naturopathy, Post graduate, Government Yoga & Naturopathy Medical College, Chennai.

The proposal is **APPROVED**.

The Institution Ethical Committee expects to be informed about the progress of the study and adverse drug reaction during the course of the study and any change in the protocol and patient information / informed consent and asks to be provided a copy of the final report.

**GOVERNMENT YOGA AND NATUROPATHY MEDICAL COLLEGE AND HOSPITAL, CHENNAI, TAMIL NADU.**

## DECLARATION BY THE CANDIDATE

I, Dr.R.ARUNTHATHI solemnly declare that dissertation titled "Efficacy of Massage Therapy on Pain in Patients with Osteoarthritis of Knee: A Randomized Controlled Clinical Trial**"** is a bonafide and genuine research work carried by me at Government Yoga and Naturopathy Medical College and hospital, Chennai from July 2016 - June 2017 under the guidance and supervision of Dr.N.MANAVALAN N.D. (OSM), M.A (G.T), M.SC(Y&N), M. Phil, P.G.D.Y, P.G.D.H.M, P.G.D.H.H, Head of the Department **-** Department of Naturopathy .This dissertation is submitted to The Tamilnadu DR.M.G.R. Medical University towards partial fulfillment of requirement for the award of M.D. Degree (Branch – I) in Naturopathy.

Place: Chennai　　　　　　　　　　Signature of the candidate

Date:　　　　　　　　　　　　　　Dr.R.ARUNTHATHI

## *ACKNOWLEDGEMENTS*

***Creating a dissertation is not an individual experience; rather it is a true societal setting and includes several persons whom I would like to thank sincerely.***

*Foremost, I want to offer this endeavour to our* **GOD** *ALMIGHTY for the wisdom he bestowed upon me, the strength, peace of my mind and good health in order to finish this research.*

*I wish to express my gratitude for the guidance of* ***Dr.N.Manavalan .,****N.D(OSM), M.A (G.T), M.SC(Y&N), M. Phil, Head of the Department – Department of Naturopathy, Government Yoga and Naturopathy Medical College, a true thinker, who leads by example, be it academic or personal for his sparkling reinforcement, creative suggestion, thought-provoking discussions, moral support and methodical analysis which had helped me in completing my dissertation. His own zeal for perfection, passion, unflinching courage and conviction has always inspired me to do more. He has taught me another aspect of life, that, "goodness can never be defied and good human beings can never be denied". For all these, I sincerely thank him from bottom of my heart and will be truly indebted to him throughout my life time.*

*I am also thankful to my Doctoral Committee member* ***Dr.R.S.HIMESWARI,*** *H.O.D – Department of Acupuncture for her valuable advice and suggestions during the course of my research tenure.*

*I express my sincere and utmost gratitude to my Doctoral Committee member* ***Dr. S.T.VENKATESWARAN,*** *H.O.D – Department of Yoga , for his real constructive criticism, suggestions, encouragements and unfailing help during the course of my research tenure. Apart from academic activities ethics and pursuit for quality will intrigue me to replicate.*

*I acknowledge my sincere thanks to our* **PRINCIPAL** *for permitting me to use the facilities in the Institute and for their support during the tenure of my research.*

*I also acknowledge the distinguished members of the panel for approval of my work and exemplary recognition.*

*I would like to record my heartfelt thanks to* ***Dr.K.Kahlil Subramanian., BNYS, Dr.Bharathimaran., BNYS, PhD, Dr.Ganesh Lakshmanan., BHMS, MS(ANATOMY), PhD, Dr.A.M.Chandrasekaran., BNYS, MPH,*** *for being a beacon of knowledge in research and sharing superior teaching skills with me as a student.*

*I take this opportunity to record my sincere thanks to all the faculty of this institution who were carefully selected to oversee the successful implementation of this project as well as to all those who are contributing towards the accomplishment of the project objectives.*

*I also appreciate the efforts and collaborative attitudes of all my colleagues who contributed to the success of this project.*

*My sincere thanks and appreciation goes to all the nursing therapeutic assistance who have willingly helped me out with their abilities.*

*It is my pleasure to acknowledge my thanks to our department technical officers for their constant , immediate help during my research period.I also wish to thank our department administrative Officer*, *the newly joined department staff, our department attendants for assisting in departmental works.*

*I would like to express my heartfelt gratitude towards my family for the encouragement which helped me in completion of this paper. My beloved and supportive husband Dr.N.Kathiresan who is always by my side when times I needed him most and helped me a lot. He was always beside me during the happy and hard moments to push me and motivate me. Also I appreciate my little ones, my little boy K.A.Adhitya Raj and my little girl K.A.Aaradhana for abiding my ignorance, and the patience they showed during my work. Words would never say how grateful I am to all of you. I consider myself the luckiest in the world to have such a lovely and caring family standing beside me with their love and unconditional support.*

*Finally, I acknowledge the people who mean a lot to me, my parents, dear appa R.Rangaraj and my dear amma R.Suseela for sharing faith in me and giving me liberty to choose what I desired. I salute you for the selfless love, care, pain, and sacrifice you did to shape my life. Although you hardly understood what I researched on, you were willing to support any decision I made. I would never be able to pay back the love and affection showered upon by my parents. Also I express my thanks to my brother R.Aravindhan.*

*My heartfelt regard goes to my father-in-law N.P.Natarajan, mother-in-law N.Leelavathi for their unconditional love and support.*

# LIST OF CONTENTS

## LIST OF ABBREVIATION

ACR – American College of Rheumatology

ADL – Activities of Daily Living

AMI – Arthrogenous Muscle Inhibition

BMI – Body Mass Index

CAM - Complementary and Alternative system of Medicine

CDC – Center of Disease Control

CNS – Central Nervous System

CRF – Case Report Form

DNA - Deoxy Ribose Nucleic Acid

EULAR – European League Against Rheumatism

IGA – Instrumented Gait Analysis

KIL – Kellgren I Lawrence

KOOS – Knee injury and Osteoarthritis Outcome Score

LEFS – Lower Extremity Functional Scale

MRI – Magnetic Resonance Imaging

MVC – Maximum Voluntary Contraction

NSAID – Non – Steriodal Anti – Inflammatory Drug

OGA – Observational Gait Analysis

OHE – Optimal Healing Environment

QOL – Quality Of Life

ROM – Range Of Motion

ROS – Reactive Oxygen Species

SMT – Swedish Massage Therapy

TKA – Total Knee Arthroscopy

TUG – Timed Up and Go test

VA – Voluntary Activation

WOMAC – Western Ontario McMaster Universities Osteoarthritis Index

# ABSTRACT

**EFFICACY OF MASSAGE THERAPY ON PAIN IN PATIENTS WITH OSTEOARTHRITIS OF KNEE: A RANDOMIZED CONTROLLED CLINICAL TRIAL**

**INTRODUCTION**:
There are sufficient studies to demonstrate that massage is safe, feasible, and can be used as a therapy. In this study we hypothesis that massage therapy would reduce pain, stiffness, function and improve range of motion and physical function in individuals with osteoarthritis of knee.

**OBJECTIVE**:
To determine whether Swedish Massage Therapy (SMT) of 25-30 Minutes duration for 15 days may reduce pain in OA knees patients and improve the Range of Motion (RoM).

**METHODS**:
A total of 80 participants with age group of 40 – 60 years were randomized into intervention and control group. Intervention group received Swedish massage therapy while control group was under usual care. Intervention lasted for 15 days. Outcomes were assessed using WOMAC INDEX and goniometry at 3$^{rd}$ day, 7$^{th}$ day and 15$^{th}$ day of intervention and compared with baseline data

**RESULT**:
All changes in pain, stiffness, function and ROM for the treatment group were statistically-significantly different from baseline. For the control group there were no statistically-significant changes from baseline as all *P* values were greater than 5%.

**CONCLUSION:**
The study results showed that participants who have OA of the knee may benefit from the Swedish massage intervention therapy and consistent massage therapy may equate to more improved results. Further studies are needed to clarify the long-term effects of Swedish-massage on the progression and symptoms of OA of the knee.



**Keywords**: massage, Swedish massage, knee osteoarthritis, musculoskeletal, chronic pain.

# INTRODUCTION

## BACKGROUND OF THE PROBLEM

Osteoarthritis (OA), also known as degenerative joint disease, is the most prevalent form of arthritis. It is a common disease of aging for which no specific cure, treatment, or means of prevention has been identified. It affects adults beginning at age 50, with incidence increasing with age. Historically, OA has been described as the “wear and tear” of weight-bearing joints of the body, which causes changes in the joints’ cartilage, lining, and underlying bone.

The knee is the joint most commonly affected by OA. Given projected increases in the aging and obese populations, the incidence of OA of the knee is predicted to rise. Despite earlier research indicating joint cartilage degeneration is a possible primary cause of knee OA—initiating internal joint inflammation, edema, and pain—recent research has investigated the causative role of the quadriceps muscle, which is located on the anterior thigh. In this muscle, impairments in function, and weakness; influence on knee joint loading, and proprioceptive deficits seem to contribute to the development or progression of knee OA. Sufficient quadriceps function is essential to basic activities of daily living, such as rising from a chair, standing, walking, and ascending and descending stairs. Researchers have found correlation among quadriceps weakness, increased pain, and altered walking patterns.

Retired adults comprise an older populace that is vulnerable to physical disability, health problems, and social isolation. In the treatment of OA in members of this population, the priority is symptom management. Conventional healthcare management of knee OA involves nonpharmacological measures—such as patient education, exercise, physiotherapy, braces, and complementary and alternative medicine (CAM) modalities—followed by pharmaceutical management and surgery.For patients with OA, CAM interventions provide practical alternatives to conventional medical treatments. A growing body of research supports the efficacy of CAM modalities in helping this population. Massage therapy, acupuncture, prayer, and chiropractic are among the accepted, established CAM modalities employed for a range of medical problems world-wide.

Applied touch, manual manipulation, manual technique, and soft tissue manipulation are synonyms for massage. The reported benefits of massage include breaking the pain cycle, improving function, reducing edema, promoting relaxation, and facilitating healing in various medical conditions. While a plethora of research has explored the use of massage for lower back pain and other chronic musculoskeletal conditions, a recent study also supports the use of full-body massage therapy for the pain and dysfunction caused by OA of the knee. Additional studies, although few, have found that the use of self-massage has an impact on the symptoms of musculoskeletal pain.

OA of the knee is a chronic degenerative joint disease for which self-management of symptoms is the primary treatment of choice. The present research investigated the use of massage therapy as a safe, economical and therapeutic practice that is much like yoga, meditation, and T'ai Chi, all of which have been recognized in the scientific literature as promising self-care alternative therapies for the self-management of OA. In the present study, the researcher explored the effects of Swedish Massage Therapy (SMT) of 25-30 Minutes duration for 15 days may reduce pain in OA knees patients aged between 40 – 60 years of experimental group when compared to conventional therapy group.The researcher sought to answer the following questions: Does the study's intervention increase the knee's range of motion (ROM) in addition to decreasing pain and dysfunction in the knee? If the intervention has these positive affects, should additional research explore it as a promising self-management strategy for people at risk for, or diagnosed with, OA of the knee?

## STATEMENT OF THE PROBLEM

Symptomatic knee OA has a functional impact on more than 1 in 10 adults. Osteoarthritis (OA) affects over 360 million people worldwide and about 150 million people in India constituting 15 percent of the population. In 2007 October survey shows across 15 major cities in India found that, there is high incidence of osteoarthritis and 75% of OA sufferers are not satisfied with their current treatment .

According to 'TNS Arogya (2006-07), the Health Monitor survey, conducted by an ISO-accredited market research agency said that, osteoarthritis is the second most prevalent disease after diabetes in age group of 25-35 years. Centers for Disease Control and Prevention (2002) say that, 1 of every 3 people is affected by painful arthritis and long term use of Osteoarthritis medication caused side effects.

Among the elderly, chronic musculoskeletal knee pain, which may result in mobility and disability in weight-bearing activities of daily living, is the most common presenting problem of knee OA, for which one quarter of people over 55 seek medical attention. Often, patients with knee OA are fearful of falling because of knee joint instability or buckling when descending stairs or curbs. This fear can promote sedentary habits.The primary goal of conventional treatment for knee OA is self-management of its symptoms; however, such treatment is often hampered by noncompliance. Treatment adherence is the principal predictor of a treatment's long-term outcome. CAM interventions provide a practical alternative to conventional approaches to the disease.The exploration of safe, cost-effective interventions or adjunct therapies to address the chronic physical symptoms of knee OA is the problem addressed in this study.

## PURPOSE OF THE STUDY

The purpose of the study was to examine the benefits of Swedish massage intervention therapy for participants diagnosed with knee OA, as seen in improvements in knee pain, joint stiffness, physical functioning, and knee ROM. The researcher designed the study of Swedish massage techniques, in the hope that any findings emerging from this study would stimulate more rigorous research regarding patient-centered Swedish massage interventions for knee OA.

**Research Questions**

This study was designed to answer two primary questions.

**Research Question 1**

To determine whether Swedish Massage Therapy (SMT) of 25-30 Minutes duration for 15 days may reduce pain in OA knees patients aged between 40 – 60 years of experimental group when compared to conventional therapy group as measured by WOMAC'S Knee Questionnaires.

Null hypothesis: The intervention of SMT will have no advantage on participants with knee OA as demonstrated in their responses to the WOMAC'S Knee Questionnaires when compared to the conventional therapy group.

**Research Question 2**

In the above said two groups, to compare the change in Quality of Life (QoL) as measured by the Range of Motion (RoM) measured by the Goniometry.

A universal goniometer is an instrument used to measure joint ROM. The evaluation of a joint with this instrument includes an assessment of its positioning, stabilization, and alignment. The scales on a half-circle goniometer read from 0 to 180 degrees and from 180 to 0 degrees. Increments on the scales range from 1 to 10 degrees, though one- and five-degree increments are the most common.

Normal knee flexion for males and females between the ages of 25 and 74 is 132 degrees, and extension is zero degrees according to a study by Roach and Miles.

Null hypothesis: The SMT intervention will have no effect on QoLmeasured by WOMACS Knee Questionnaires and knee ROM in terms of flexion or extension as assessed using a goniometer.

**SIGNIFICANCE OF THE STUDY**

The use of CAM therapies is on the rise. The use of CAM therapies such as deep breathing, meditation, massage, and yoga increased significantly. Specifically, the use of massage therapy for health- and illness-related issues increased from 5.0 percent in 2002 to 8.3 percent in 2015. Research studies have found CAM therapies to be beneficial for arthritis and other musculoskeletal conditions. Further, for arthritic patients, the chronicity of the illness, lack of a cure, costs, and side effects of medications and treatments—as well as a sense of helplessness—make CAM therapies attractive.This original investigation into the field of mind–body research focused on a fresh, cost-effective, participatory single or adjunct self-care intervention with the potential to modify disease progression and to affect the symptoms of chronic musculoskeletal disease and other illnesses. There is a clear need for research addressing the body's innate ability to heal itself that focuses on disease prevention and health promotion.

## Scope of the Study

The scope of this study included research associated with the cause, prevalence, symptoms, and treatment of knee OA, a common form of OA that leads to chronic pain and physical limitations for a rising population of older adults. This study also examined massage therapy as a mind-body, safe, economical, and beneficial alternative to traditional nonpharmacological management therapies for knee OA. The study examined the benefits of the SMT intervention therapy on knee pain, joint stiffness, physical functioning, and ROM for participants diagnosed with knee OA.

# OBJECTIVE OF THE STUDY

Literature review provides sufficient rationalization for the initiation of this study. The present study was intended to determine the efficacy of Swedish massage therapy on reducing pain in patients with knee osteoarthritis.

- **Objective 1:**
  - To determine whether Swedish Massage Therapy (SMT) of 25-30 Minutes duration for 15 days may reduce pain in OA knees patients aged between 40 – 60 years of experimental group when compared to conventional therapy group as measured by WOMAC'S Knee Questionnaires.

- **Objective 2:**
  - In the above said two groups, to compare the Range of Motion (RoM) measured by the Goniometry.

# REVIEW OF THE LITERATURE

Osteoarthritis is the most common form of arthritis among adults 45 and older in the world (Hunter, McDougall, & Keefe, 2009). It is a non systemic disease primarily affecting the weight bearing joints of the lower extremity. Primary risk factors for knee OA include gender, congenital malformations, and age. Secondary risk factors include obesity, inactivity, muscle weakness, and heavy physical activity (occupation or recreational) trauma, and rnalalignment (Felson, 2006). Individuals with a history of injury to their anterior cruciate ligament or menisci were shown to develop knee OA 10 to 20 years post injury (Lohmander, Englund, Dahl, &Roos, 2007). Mechanical trauma can result in arthrological factors, such as varus/valgus deformities, leading to biomechanical modifications. Varus alignment is associated with an increase in adductor moment that is responsible for disease progression (Adriacchi, 1994; Mundermann, Dyrby, &Andriacchi, 2005).

Of the afore mentioned factors, secondary risk factors are modifiable.Although difficult to determine which are factors for the development and progression of the disease, researchers agree that obesity is considered the primary risk factor in the progression of knee OA(Taylor, Heller, Bergmann, &Duda, 2004). Weight control, proper body mechanics and regular activity may minimize or at least diminish pain and disability (AGS panel on exercise &osteoarthritis, 2010; Blagojevic, Jinks, & Jordan, 2009).

## Diagnosis and Pathophysiology of the Disease

Recent research suggests the nature of knee OA to be a metabolically active process rather than a condition simply characterized by "wear and tear" of the joint (Velasquez & Katz, 201 0). Currently, researchers regard OA as a metabolic or biochemical phenomenon that involves destruction and remodeling of joints. C- reactive protein, an inflammatory marker, which is evident in early knee OA, can lead to its progression (Spector et al., 1997). Progression of the disease includes the appearance of synovial hyperplasia, osteophyte formation, and capsular thickening (Osteoarthritis, 2001). Osteophyte formation often occurs at the margin of the hyaline cartilage and synovium in response to changes in knee joint loading (Jewell, Watt, & Doherty, 1998). Therefore, osteophyte formation may be the body's attempt at self-repair and redistribution of forces across the joint. This appears to represent an effort by these joint components to reform the joint and surrounding tissues in response to the histochemical changes in cartilage.

Although OA was originally thought to involve the articular cartilage, it is now considered a disease of the entire joint, affecting the whole body as a functional unit (McGibbon, 2002). In addition to the breakdown of articular cartilage, there is subchondral bone remodeling with cyst formation, sclerosis, synovial inflammation, muscle atrophy, spasm and ligamentous involvement. Chondrocytes, synovial leukocytes and bone osteoblasts osteoclasts produce cytokines, the inflammatory mediators associated with inflammation. Inadequate repair of cartilage results from the imbalance of the catabolic and anabolic processes that drive these inflammatory cytokines. Ultimately, these changes in the biomechanical properties of cartilage result in an abnormal increase in pressure on both the cartilage and subchondral bone (Martell-Pelletier, Boileau, Pelletier, &Roughley, 2008).

Mechanoreceptors no longer provide adequate information to muscles, ligaments, tendons and jointcapsules regarding cartilage load (Felson, 2006). As insult occurs to the joint, the body's response is to lay down additional bone to contend with compressional and functional forces placed on the joint. A decrease in cartilage volume accompanies a decrease in joint space, which may result in ligament laxity. As a result, loading rates are 21 % greater than those in normal individuals(Fischer, White, Yack, Smolinsky&Pendergast, 1997).

These physical and histological changes along with capsular thickening, for joint stability, may mark the beginning of the disease.Confirmation of the structural and mechanical changes in the joint can be viewed radiographically. Physicians employ radiographs to establish the diagnosis and rule out other pathological processes. In 1963, the American College of Rheumatology adopted the KellgrenILawrence (KIL) classification based on radiographic evidence as the standard for grading OA severity. The KIL scale correlates with MRl's in detecting osteophytes, cartilage defects and joint effusion (Hayes et al., 2005).

Grades for Severity of Knee OA According to the KellgrenILawrence Scale(Kellgren et al., 1963).

Grade 1 **-** Doubtful joint space narrowing and possible osteophyte lipping

Grade 2 **-** Definite osteophytes and possible joint space narrowing

Grade 3 **-** Moderate multiple osteophytes, definite joint space narrowing and some sclerosis, and possible deformity of bone ends

Grade 4 **-** Large osteophytes, marked joint space narrowing, severe sclerosis,and definite deformity of bone ends

Positive findings associated with knee OA may include asymmetric jointspace, loss of articular cartilage, subchondral sclerosis and cysts, and osteophytic formation (Altman et al., 2008; Blagojevicy, Jinksy, Jeffery, Jordan,2010). Although radiographs are used to confirm the diagnosis, the correlation between radiographs and symptoms is not always consistent (Leslie, 2000). The apparent progression in radiographic change does not always correspond to the degree of pain or to the level of functional ability (Blagojevic et al**.,** 2010; Hunteret al., 2008; McAlindon et al., 1993). Thus, despite radiographic evidence, the individual may be asymptomatic (Osteoarthritis, 2001). The results of a survey administered by Peat, McCarney, and Croft (2001) demonstrate that in a population of individuals (mean age, 55 years), 50% had knee pain without radiographic evidence while the other 50% had radiographic evidence without knee pain. Additionally, the presence and extent of radiographic OA does not predict its progression to a symptomatic state (Kim, Richard, Jones

&Hegab,2003).Although radiographs are currently used to confirm a diagnosis of knee OA**,** Magnetic Resonance Imaging (MRI) may be superior in that it allows for direct visualization of the joint (Racunica et al., 2007**),** and may pick up early OA changes not viewed with radiographs (Watt & Doherty, 2003). To date, radiographs combined with clinical criteria prove to be an excellent and more cost effective alternative in the diagnosis of knee OA (Altman et al., 1986; Flores& Hochberg, 2003; Toivanen, 2007).

This clinical classification criterion for idiopathic knee OA includes the presence of knee pain on most days of the month and at least one of the following: age over 50 years, morning stiffness less than 30 minutes in duration, crepitus on active joint motion. Furthermore, there should be radiographic evidence of osteophytes at joint margins. The combination of clinical and radiographic results increases the sensitivity (91 %) and specificity (86%) of reaching a diagnosis of knee OA (Altman et al., 1986).

According to the Center of Disease Control (CDC), the prevalence of OA is dramatically increasing, and will continue to increase from previously reported numbers of 43 million to 60 million in the year 2020. The disease affects approximately 27 million people in the United States, 33% of whom are over the age of 65 (Lawrence et al., 2008; Sisto, &Malanga, 2006**),** and it is estimated that the number of individuals aged 65 and over will double in the next 20 years (Adelman & Daly, 2001). Sixty percent of adults over the age of 50 are afflicted with this disease (Vad et al., 2002). The incidence of knee OA has risen by 22% from 1990 to 2005 (Flegal, Carroll, Ogden, Curtin, 2010). Ten percent of men and

13 percent of women over the age of 60 have symptomatic knee OA (Zhang& Jordan, 2010) and women have a 1.8 times greater likelihood of developing knee OA (Felson, 1997). Although knee OA is prevalent in the elderly, its presence is increasing steadily in middle-aged individuals (40 and over), and is the most frequently reported reason for orthopedic visits (Leslie, 2000).

When compared to cardiovascular disease, knee OA is the most frequently encountered disability (Doherty, 2001) and is the primary reason for visits to a primary care physician in individuals over the age of 55 (Peat et al., 2001).Inactivity associated with the disease results in greater impairments and activity limitations which ultimately result in an increase in health care costs (Dunlop etal., 2010). In 2008, the annual cost for treating arthritis and its complications was almost 65 billion dollars in the United States (Zhang, 2008).

# Contributing Factors

## *OBESITY*

Obesity is a major health problem in our country. Statistics indicate obesity has doubled between 1971 and 1994 (Fiegel, Carroll, Kuczmarski& Johnson, 1998). Individuals with a body mass index (BMI) greater than 30 are considered overweight, except in those individuals with a low percentage of fatty tissue (Bray, York & Delaney, 1992). Knee OA is more common in obese individuals than in those of normal body weight (Cooper et al., 2000; Murphy et al., 2008.) Obesity is considered the primary risk factor in the incidence of and progression of knee OA (Messier, et al., 2009; Taylor, Heller, Bergmann, & Duda, 2004).

Astephen, Deluzio, Caldwell,and Dunbar (2008) suggest that two thirds of the world population is at risk fordeveloping knee OA in their lifetime.An obese woman and man with a BMI of 30-35 kg/m2 have a four times greater, and 4.8times greater, respectively, risk of developing knee OA when compared to lean individuals. After a knee injury, this risk increases three fold for women, and five to six fold for men (Spector et al., 1994). Additionally, a higher body mass index (BMI) correlates with a larger concentration of inflammatory mediators, which is associated with functional decline and disease progression (Wolfe, 1997).

During walking, ground reaction forces are exerted by the contact surface on the joints. These forces are augmented in obese individuals, resulting in an increase in knee joint load. Greater muscle force is required to withstand this additional load (Browning &Kram, 2007). As a consequence, obese individuals may chose to walk slower, since walking slower minimizes ground reaction forces and knee joint load. When compared to lean individuals, obese individuals walk with less knee flexion and generate less ankle and knee torque and power when walking at self-selected speeds (DeVita&Hortobagyi, 2003).

This suggests that obese individuals may alter their gait to minimize forces associated with a larger mass, and these alterations may result in compensatory motions at other joints (Bejek, Paroczai, Illyes, & Kiss, 2005).In 2000, Cooper et al. conducted a prospective radiographic study involving 354men and women with and without knee pain. In conjunction with radiographs, the subjects completed questionnaires regarding lifestyle, riskfactors, medical history and leisure activities. The authors found that both obesity and knee trauma were strong predictors of incidence, as evidenced by a decrease in joint space, and that obesity is a significant variable in disease progression as these individuals demonstrated greater radiographic evidence.

To determine the effect of knee OA over time, the Framingham study followed 1420 individuals with knee OA over a 30-year period (Felson et al., 1997).Radiographs were obtained before and after the study which demonstrated there was a higher prevalence of radiographic changes in women and that overweight individuals are at higher risk for symptomatic and radiographic knee OA (Felsonet al., 1997).

## *MALALIGNMENT*

At the impairment level, malalignment increases the risk and progression of knee OA (Sharrna et al., 2001; Sharma, Dunlop, Cahue, Song & Hayes, 2003);however, the association of incidence and malalignment continues to be investigated (Tanamas et al., 2009). Radiographs are utilized to assess mechanical knee joint alignment by locating the anatomic axis of the knee via the intersection of two lines, which identify the femoral and tibia1 axis. A varus angle of 1-2 degrees constitutes neutral alignment (Peat, Mallen, Wood, Lacey,Duncan, 2008).

In the elderly, malalignment greater than 5 degrees is associated with greater functional deterioration (Sharma et al., 2001). Varus malalignment is associated with radiographic evidence of decreased tibiofemoral joint space width and an increased external knee adductor moment, which is a marker of OA progression (Andriacchi, 1994; Mundermann, 2005). External knee adduction moments have been linked to an increase in medial knee joint load in individuals with knee varus deformities (Hurwitz,, Sharma, &Andriacchi, 1999; Sharma, et al., 2001). Varus and valgus deformities increase the risk of medial and lateral OA progression respectively, which is augmented if an individual is overweight (Sharma, Cahue, & Dunlop, 2000).

In the literature, a direct relationship between quadriceps strength and OA has been noted (Sharma etal., 2000; Sharma et al., 2003). An 18-month longitudinal study examining quadriceps strength and OA progression in individuals with malaligned and or lax knees utilized baseline isokinetic strength testing and radiographs to determine the presence or absence of malalignment in 237 participants. Additional radiographs were taken 18 months later to assess the progression of the disease. Those individuals with malalignment or highly lax knees showed greater predictability of OA progression. Sharma et al. (2003) conclude that quadriceps-strengthening exercises may produce negative effects on this population. Since their study did not include any strengthening intervention, the negative impact of quadriceps strengthening on knee OA progression in this population is questionable (Sharma et al., 2003).

A subsequent 12-week study investigated the effects of varus malalignment (measured by using 3D motion analysis during gait) on pain and function in individuals with knee OA (Lim, Hinman, Wrigley, Sharrna, &Bennell,2008). Measures of knee varus/valgus laxity were assessed as well as isometric quadriceps and hamstring torque measures. Each participant completed the

Western Ontario and McMaster Osteoarthritis Index **(**WOMAC**),** which is a 24-question self - assessment questionnaire regarding pain, stiffness and function.Bellamy, Buchanan, Goldsmith, Campbell and Stitt (1988) reported this test to be highly valid and reliable (lCC=.88--93)for individuals with hip or knee OA.Performance measures included the step test, stair climb test and walking speed.Quadriceps exercises were performed over a 12-week period, which consisted of seated knee extension, short arc quads, straight leg raises and isometric knee flexion exercises with ankle weights and the raybands. In this study, the severity of the disease was significantly associated with the degree of malalignment.

Both the groups with neutral and malaligned knees had an increase in quadriceps strength and functional measures; however, the increase in quadriceps strength was not associated with an increase in the knee adduction moment in the group with malaligned knees, which may suggest that quadriceps strength may be indicated in this population.

In fact, dynamic optimization (i.e. mathematical formulae) utilizing a 3Dmodel for gait analysis demonstrates that during stance, the knee is stabilized in the frontal plane by the quadriceps and gastrocnemius muscles. This muscular stabilization of the knee serves as a mechanism to control the knee adduction moment (Shelbourne, Torry&Pandy, 2006).

## *PAIN*

Pain is the primary reason and most significant impairment for physician's visits as well as the ultimate cause for total knee replacements (O'Reilly &Doherty, 2003). Pain is the most common symptom in patients with knee OA and contributes to decline in functional activities such as rising from a chair,climbing stairs, and completing activities of daily living (ADL's) (Sharma et al.,2003). Individuals with knee OA usually describe their pain as a deep dull ache that is aggravated with weight bearing activities such as walking. By the year 2020, an estimated three million people in the United States will have a total knee replacement procedure performed secondary to end stage knee OA (Pivaet al., 2010).

Clinicians employ the use of self-report questionnaires in the assessment of pain and function in individuals with knee OA. These include the Medical Outcome Study 36-Item Health Survey Questionnaire (SF-36), the Lower-Extremrty Functional Scale (LEFS), the Knee Injury and Osteoarthritis Outcome Score (KOOS) and the Western Ontario and McMasters UniversitiesOsteoarthritis Index WOMAC). The SF-36, LEFS and KOOS have been reported to be highly valid and reliable tools (Binkley, StratFord, Lott, Riddle, & The NorthAmerican rehabilitation network, 1999; Roos&Toksvig-Larsen, 2003; Ware &Sherboume, 1992).

Current research implicates either a nociceptive or neuropathic mechanism as causative agent of OA pain (Kidd, Langford, & Wodehouse,2007). Central sensitization, the neuropathic mechanism, is thought to result in modification of the central pain transmitting neurons arising from chronic nociceptor stimulation (Woolf & Salter, 2000).

Chronic pain is associated with this central sensitization, which may lead to a hypersensitivity modulating pain transmission resulting in an active process of transmission in both the periphery and the cortex. This "plasticity" can result in excitatory inputs to nociceptive neurons, resulting in additional pain. This may explain why some individuals with OA experience pain in the absence of noxious stimuli (Woolf et al., 2000). Pain characteristics may provide some insights regarding the mechanism of pain.

During one-on-one interviews with 52 individuals with hip OA and 92 individuals with knee OA, participants described their pain intensity, duration, and predictability. Many of the participants described their pain as having "pins and needles" and burning, indicating that the pain may be neuropathic in nature (Hawker, et al., 2008). Individuals with neuropathic pain have hypersensitivity to pressure, cold, heat and light touch (Bennett, Attal, &Backonja, 2007). Intrusive night pain is evident in the later stages of the disease (Woolhead, Gooberman,Hill, Dieppe & Hawker, 2010).

Pain at night can cause sleep disturbances in individuals with OA, which may be associated with fatigue, depression, anxiety and disability (Pawlikowska et al., 1994). Night pain is associated with a greater subjective report of fatigue and a reduced sense of well being in these individuals (O'Reilly et al., 2003).Understanding OA pain from the patient's perspective may be beneficial in determining the appropriate treatments for pain.

However, since pain is subjective, individuals may have different descriptors of their pain. Due to these variations, pain is difficult to measure (Woolhead, et al., 2010). Yet, an inverse relationship between pain and both strength and function has been reported in the literature (Fitzgerald, Childs, Ridge, &Irrgang, 2002). Additionally, self reports of physical function may be interpreted by the person as the pain experienced with these activities rather than the ability to actually perform the activities. Since individuals tend to report a decrease in physical function when having pain, performance-based measures should be utilized to assess physical function (Stratford et al., 2006), as these measures are more sensitive to change and less influenced by pain than self-reported measures (Piva et al., 2010).Subject-reported measures of pain and disability do not always correlate with functional performance tests. Therefore, performance measures combined with self-reported measures will yield a more accurate outcome (Stratford et al.,2006).

Medication is often utilized to diminish pain experienced in advanced stages of knee OA**.** It has been reported that administration of NSAIDS to minimize pain can result in "analgesic arthropathy" due to excessive knee joint loading. Given the noted inverse relationship between pain, adductor moments and external knee flexion moments (Huwitz, Sharma, &Andriacci, 1999), an excess of medication can disguise the body's recognition and response to pain.

Normal cartilage homeostasis is a balance between degeneration and repair. It is well demonstrated that NSAIDS tip the balance in favor of the destructive activities, and in doing so, exacerbate the very condition for which they have been prescribed (Hauser, 2010). Although pain medication is utilized to promote wellbeing, caution is advised in that over use may result in progression of joint degeneration. Since pain is inherently a protective mechanism, excess use of analgesics may have short comings. Exercises based on improving strength and decreasing activity limitations may prove to be an alternative treatment and minimize the use of this medication in the knee OA population.

## MECHANICS / PATHOMECHANICS

### *GAIT*

Gait is an automatic phenomenon requiring an intact neuromuscular and musculoskeletal system to coordinate and integrate the kinematic, kinetic, kinesthetic factors associated with it. Pain-free walking is a basic task required for normal locomotion and is an essential component for maintaining an independent life style (Bejek, Paroczai, Illyes, Kocsis& Kiss, 2006). Individuals with OA have difficulty with walking secondary to pain, stiffness and decreased flexibility (Van Baar, Assendelft, Dekker, Oostendorp&Bijlsma, 1999; Dixon etal., 2010). Their altered gait patterns, muscle atrophy, decreased range of motion, decreased strength, loss of function, and knee joint stiffness can lead to activity limitations (Slemenda, Brandt, Heilman, Mazzuca, &Braunstein, 1997;Gingac et al., 2006).

Ultimately, painful walking may cause individuals to limit not only their level of activity but also their participation level in the community.Any pathological process affecting changes in flexibility, stability, strength, power or neural input may produce alterations in temporal-distance parameters that quantify gait including velocity, cadence, step length and stride length (Perry,1992; Perry &Burnfield, 2010).

In the past, clinicians relied on observational gait analysis (OGA) to report on gait characteristics, which can be subjective as personal bias, and or clinical experience may influence this assessment (Sisto, 1998). Technological advances remove the subjectivity from gait observation by utilizing instrumented gait analysis (IGA), which provides spatiotemporal information on individual gait patterns. Quantitative gait analyses have demonstrated significant gait discrepancies in patients with knee OA (Lafuente, Sanchez-Lacuesta, Soler, Poveda&Prat, 2000).

During normal walking, adults ambulate at a speed that minimizes excessive energy expenditure. Healthy 40-60 year old women and men walk between 1.35mls and 1.41 mls respectively when ambulating at a comfortable speed. These values can increase to 1.94 and 2.19 mls when individuals walk as fast as they can without running (Bohannon, 1992).Individuals with knee OA ambulate with significantly reduced walking speed, lower cadence, shorter stride length, and with a more prolonged stance phase of the gait cycle compared to age-matched controls (Adriacchi et al., 1982; Baliunaset al, 2002; Gok et al., 2002; Hurwitz et al., 2000). These adaptations may be attributed to limb avoidance secondary to pain (Al-Zahrani&Bakheit, 2002; Andriachhi, Galante, &Fermier, 1982; Baliunas et al., 2002).

People with knee OA employ a re-programming mechanism of the neuromuscular system which alters normal patterns that may result in minimizing joint loading forces during gait (Robon, Perell, Fang &Guererro, 2000). Walking slower is also associated with a reduction in these joint forces. Values of approximately 25% less or greater, dependent on the parameter measured, have been reported for knee OA individuals when compared to controls (England &Granata, 2007). As the disease progresses, gait speed can be reduced as much as .55m/sec in some individuals (Zoltan et al., 2006). Gait speed has been found to be directly proportional to single stance time and inversely proportional to double support time (Perry, 1992). Most importantly, a decrease in gait speed is associated with activity limitations (Edmund, 1997) and accounts for individual gait variations as well as force attenuation (Perry, 1992).

During normal walking, the knee encounters compressive forces that are equal to three to six times an individual's body weight (Grainger &Cicuttini, 2004). This increase produces an augmented contact force at the knee joint (Kaufman, Hughes, Murray, Kai-Nan 2000). An increase in walking speed requires augmented force and duration of the knee musculature to accommodate the increase in ground reaction force associated with faster walking speeds (Andriacchi et al., 1977). Thus, muscle activation is an important contributor to all joint forces about the lower extremity throughout the gait cycle.

The gait cycle constitutes both the stance and swing phase. The stance and swing phase, periods during which one (single support) or both feet (double support) are in contact with the floor, account for 62% and 38% of the gait cycle respectively when an individual walks at a rate of 80m/min (Perry, 1992). When the foot strikes the floor during load phase, external ground reaction forces are directed vertically through the ankle, knee and hip, causing the knee to flex. To counterbalance the external moment and minimize joint forces, the quadriceps must produce an internal moment large enough to balance the external moment to resist knee buckling and absorb the forces associated with these knee joint loads (Winter, 1991). Quadriceps weakness during this weight bearing phase may result in increased activity of the hip extensors and ankle plantar flexors to contribute to the net support moment (Oatis, 1994).

It is interesting that while some individuals with knee OA may reduce their knee flexion at heel strike to minimize these ground reaction forces (Childs, Sparto, Fitzgerald, Bizzini, &Irrgang, 2004; Mundermann et al., 2005), others demonstrate an increase in knee flexion during the loading phase (Heiden et al., 2009), which requires a greater net internal moment to accommodate for this increased joint angle. Also, an increase in knee flexion (Baliunas et al. 2002, Childs et al., 2004) as well as extension (Munderman, 2005) has been reported in the literature and further contributes to the knee instability seen in the individual with OA**.**

Knee instability (buckling, shifting, or giving out) in the OA population is associated with factors that include muscular weakness, ligament laxity,proprioception deficits, malalignment and pain (Fitzgerald, Irrgang, Piva, Irrgang,&Bouzubar, et al., 2004). These individuals adopt a "quadriceps avoidance gait"which limits the quadriceps eccentric muscle control at knee flexion, resulting in an increased knee joint load (Taylor, Bergmann, Heller, &Duda, 2004). In the event that this loss of stability is caused by the inability of the hamstrings or quadriceps muscles to generate adequate torque (Kannus&Jarvinen, 1997), muscular co-contractions stabilize the joint (Lewek, Rudolph &Synder-Mackler,2003a). This increased muscle activity around the joint results in a "stiffness" that compensates for joint instability, but these co-contractions increase the energy expenditure associated with walking (Kuo et al., 2010). Furthermore, these contractions can increase the adductor moment (Heiden et al., 2009). In the normal knee joint, loads are disproportionately transmitted to the medial compartment (Morrison, 1968). Forces attenuated at the medial joint during gait constitute 60-80% of the total force transmitted across the knee joint, and are 2.5times greater than lateral forces (Baliunas, Hurwitz, Ryals, Karrar, Case, Block et al., 2002). As the ground reaction force passes medial to the knee, the knee joint attenuates 70% of the load (Andriacchi, 1994). There is an increase in the external knee adductor moment, in both early and late stance, which results in medial compartment load distribution across the tibia1 plateau (Andriacchi, 1994**;**Teichtahl, Wluka, &Cicuttini, 2003; Lim et al., 2008). As this external ground reaction force passes medial to the knee, In the OA population there is a larger and more variable external knee adductor moment associated with walking when compared to normals, at terminal stance (Hurwitz, Ryals, Case, Block & Andriacchi, 2002), resulting in an increase in pain as the forces are augmented.Therefore, co-activation augments these forces and contributes to the progression of OA in the already compromised joint **(**Leweket al, 2005) and can result in an increase in energy expenditure (Kuo&Donelan, 2010) in an individual who may already be experiencing fatigue (Bouzubar, &Fawzi, 2003).

Forces become greater during single limb support as the center of gravity(COG) shifts to the support leg with the trunk, and the hip adducts to maintain the center of mass over the stance foot (Oatis, 2004). A correlation has been noted between the severity of disease and single limb adduction moment during gait (Kim et al., 2003). These moments are further augmented as an individual walks faster; (Andriacchi, Ogle, &Garante, 1977; Thorp, Sumner, Block, Moisio, Schott,&Wimmer, 2006); therefore, individuals with knee OA decrease their walking speed to decrease these external forces (Thorpe et al., 2006). Since these external knee adduction moments are greater in magnitude than those in the sagittal plane, individuals with knee OA utilize compensatory mechanisms to decrease joint loading (Al-Zahran et al., 2002; Bejek et al., 2006; Hutwitzet et al.,1999). Subjects with medial joint compartment involvement may reduce the load by turning their foot outward, decreasing stride length and/or leaning their trunk toward the affected extremity. This allows the load to be distributed across the entire joint for attenuation of ground reaction forces **(**Hurwitz**,** et al., 1999).

These forces increase proportionally with overweight individuals. Body mass index (BMI) is linked with medial compartment OA and both are related to varus deformities (Sharma, et al. 2000). Since body mass is proportional to joint loading, overweight individuals may demonstrate even larger adaptations during gait (DeVita et al., 2003).

Finally, the ankle and/or hip can compensate for mechanical changes that result from knee pathology (Levangie&Norkin, 2002). Robon et al. (2000) found that subjects decreased plantar flexion moments during terminal stance to prevent anterior tibia1 advancement. The increase in dorsiflexion causes the tibia to displace anteriorally, therefore decreasing the in-line knee joint reaction force, thus preventing large compressive forces at the knee. Gait velocity can also be amplified by increasing the hip flexion moment during terrninal stance in these individuals (Fisher et al., 1997; Robon et al., 2000). The increased hip flex or moment results in picking up rather than pushing off the foot to initiate initial swing. In both circumstances, these compensatory strategies serve to decrease knee joint forces and shorten stride length (Robon et al., 2000).

Although stair climbing is similar to walking, the biomechanical demands are greater in this activity. A stair climbing task requires greater sagittal plane control as the moments increase threefold when walking up and down stairs (Levangie&Norkin, 2005) with greater knee extensor torque and power required to perform this task (Mizner& Snyder-Mackler, 2005). Thus, the ability to efficiently ascend/descend stairs is dependent on both joint mobility and muscle strength (Perry et al., 2010). Negotiating stairs can be very challenging for individuals with knee OA (Whatling ). Individuals with knee OA often report the need for a hand rail to get up from a chair or climb a set of stairs.Women demonstrate greater knee flexion angles and larger knee external moments during both stair ascent and descent (Hughes, Kaufman, Morrey, Morrey & An, 2000), which may explain the increased incidence of OA in this gender (Felson, 1997).When compared to level walking, the knee sustains a 12-25% greater joint load when climbing stairs (Whatling et al., 2008). Forces in single leg stance increase threefold for every one pound of body weight, therefore, obesity may adversely affect load distribution when climbing stairs (Felson, Reva, Dieppe,Hirsh &Helmich, 2003).

Emphasis is placed on the knee and lower extremity muscles to advance the body forward against gravity while clearing the contralateral leg. As the body advances forward, the weight-bearing limb accepts the body weight from the contralateral limb as well as advancing the head, neck and trunk (HAT) over the limb. This requires the hip and knee extensors to load concentrically while the hip abductors maintain a level pelvis.Greater range of motion and larger internal moments are required with this activity at these joints (Kaufman, Hughes, Morrey, Morrey, &An, 2001).

During weight acceptance at load phase, there are increased demands for the quadriceps muscles to absorb shock and maintain stability when accepting the body weight. Individuals with advanced knee OA ascend stairs by decreasing peak external knee flexion moments while increasing the peak hip external moments (Asay et al., 2008**),** which results in a lateral trunk lean while ascending/descending stairs. This adaptive mechanism assists in unloading the medial joint compartment (Hunt, Wrigley, Hinman, &Benell, 2010). Advancing the leg during stair ascent is accompanied by a foward trunk lean, which appears to be a compensatory strategy to decrease knee joint load as it correlates with a reduction in net quadriceps moment (Asay et al., 2008).

Although this strategy is effective for reducing joint forces, these compensations can alter lumbar spine biomechanics (Whatling et al., 2008).Descending stairs places a greater demand on the knee. During weight acceptance at the load phase, there are increased demands for the quadriceps muscles to absorb shock and maintain stability when accepting the body weight in order to advance the swing limb. These eccentric quadriceps muscle contractions are associated with greater muscular control which, in turn, increases compressive forces on the knee joint (Radin, Paul, Rose, & 1972). It comes as no surprise that these individuals report more difficulty with this activity,as external knee flexion moments are six times greater with stair descent (Hughes et al., 2001).

## MUSCULAR WEAKNESS

Arthrogenous muscle inhibition is a phenomenon described as muscle inhibition secondary to altered afferent input from a diseased joint. This results in a reduction in efferent motor neuron stimulation of the quadriceps (Hurley et al.,1998).In individuals with knee OA, joint effusion may prevent full voluntary activation of muscles that cross the joint. This phenomenon has been termed arthrogenous muscle inhibition (AMI), which results from abnormal afferent information elicited from the damaged joint (Hurley &Newham, 1993). AMI reduces the number of motor units supplying the major muscle group crossing the knee, i.e., quadriceps. This decrease in full muscular activation has a direct contribution to quadriceps muscle weakness and resultant muscle atrophy(Hurley etat., 1993; Stevens, Mizner, & Snyder-Mackler, 2003).

Lewek, Rudolphand Synder-Mackler (2003b) report that the failure of the central nervous system (CNS) to activate the quadriceps muscle suggests that abnormal afferent information is sent to the motor neuron pool. The literature identifies investigative methods for activation failure. These include twitch inter polation and burst superimposition techniques. The former represents a single supplemental stimulus (delivered via electrical stimulation) applied to a voluntary maximally contracted muscle where the latter is delivered by a stream of supplemental stimuli (delivered in the same fashion). If there is additional recruitment greater than 5% elicited after the application of the electrical stimulus, the percent deficit is proportional to the degree of activation failure. A mathematical ratio that results in 1.0 implies full activation of a muscle (Lewek et al., 2003b).

Hurleyand Scott (1 998) believe AMI may be part of the pathogenesis of degenerative joint diseases. As these muscles become weaker, the joint's ability to withstand load diminishes. This added joint stress results in knee pain and subsequent gait alterations. Individuals modify their gait pattern by decreasing walking speed,lowering cadence, decreasing stride length and increasing stance phase to compensate for knee pain and/or instability.Both normal (experimentally effused) and pathological knee joints (witheffusion) exhibit full volitional quadriceps activation failure (Hurley et al., 1993). In a group of knee OA participants (mean age of 61) who reported little to no pain or joint effusion, maximal voluntary contraction (MVC), quadriceps activation or voluntary activation (VA) were 72.5% when compared to 93% in an age matched control group (Hurley et al., 1997).

In the elderly, peak torque relative to bodyweight, was 20% less in individuals with symptomatic or radiographic evidence of knee OA (Slemenda et al., 1997). Quadriceps activation failure has been linked to a decline in physical function in individuals 45years and older with knee OA(Fitzgerald, Piva, Irrgang, Bouzubar, & Starz, 2004), and is found to be the greatest single predictor of lower limb functional limitations, exceeding that of knee pain (Felson, 2006; Kijowski, Blakenbaker, Stanton, Fine & De Smet,2006). These functional activity limitations are compounded in the elderly, as there is a 40 % decrease in strength of these muscles with advancing age (Jahagirdar&Kendre, 2010). Addressing deficits associated with knee OA in the middle-aged population may delay or lessen the development of these activity limitations.

In 2002, Berth, Urhuch and Awiszus examined maximal voluntary contractions in knee OA patients before and after a total knee arthroscopy (TKA) and found similar results; however, after surgery, strength deficits persisted. In addition, the non-operational leg demonstrated a decrease in strength as compared to age-matched controls. After a three-year period, these investigators re-evaluated strength in the study participants. They found that although MVC's improved, quadriceps strength was still considerably lower when compared to controls. Other investigators examining this population found similar results in strength deficits (Fitzgerald, 2005; Stevens et al., 2003).

Interestingly,Berth et al. (2002) found that even after an exercise intervention, their subjects employed compensatory mechanics in performing a sit-stand task one year post surgery, suggesting the need to incorporate functional training in an exercise program (Farquhar, Reisman, & Snyder-Mackier, 2008). Diminished quadriceps muscle strength has been associated with progression of the disease and may represent the initiation of knee OA on the quadrilateral limb (Zeni& Snyder-Mackler, 201 0). The results of the "Chingford knee study demonstrate that 50% of 45-64 year old obese females with unilateral OA developed incident changes in their contralateral knee over a two year period (Spector, Hart, &Deyle, 1994).

## REHABILITATION EXERCISES FOR KNEE OA

Several practice guidelines recommend exercise for individuals with knee OA**.** The Ottowa Panel (Brousseau et al., 2005) , European League AgainstRheumatism (EULAR) (Pendleton et al., 2003), American Academy ofOrthopedic Surgeons (Voelker, 2009) and American College of

Rheumatology(Altman, Hochberg, Moskowitz, &Schnitzer, 2000) reviewed numerous randomized controlled studies regarding knee OA and developed exercise recommendations for treatment. Although recommendations vary, they all agree that exercise is an integral component in the treatment of knee OA. However, insufficient data exists to determine the frequency, duration and intensity of the exercise program. To date, only the Ottowa Panel (2005) has evaluated the specific exercises in relation to their outcomes, particularly for the management of pain and improvement in function.

The goal of an exercise program for knee OA is to minimize pain and improve function; however, systematic reviews of physical therapy interventions suggest this cannot be accomplished utilizing a specific approach (Jamtvedi etal., 2008). The literature supports strengthening, aerobic, flexibility, stability,mobility, proprioceptive and balance exercises in the treatment of individuals with knee OA (Devis-Corn by, Cronan, &Roesch, 2006; Deyle, 2000; Fitzgerald, 2000;Huang et al., 2003; Hurley et al., 2002; Gur et al., 2002; McCarberg& Hers,2001 ; Pendleton, et al., 2000). These types of exercises have been recommended with only moderate noted benefits in decreasing pain and improving function (vanBaar et al., 2001). Additionally, long term beneficial effects have not been extensively studied (Dunlop et al., 2010) and those that have indicate that the positive effects of exercise diminish and ultimately disappear over time (Pisters, Veenhof, deBakker, Schellevis& Dekker, 2007).Given that low levels of physical activity correlate with functional decline in the OA population, it is important that the activities associated with rehabilitation continue long after the completion of the rehabilitation program.Recognizing the need to maintain physical function in this population,Dunlop et al. (2010) examined factors associated with aspects that would improve or control OA over a period of time. They merged initial intake data from the OA initiative study (which included 2274,45-79 year old participants) with data one year post and found that physically active adults had greateperforrnance outcomes in function as evidenced by significant improvements in both the 20 meter walk and chair stand test. These findings suggest a correlation between a healthy active lifestyle and performance maintenance outcomes.Additionally, functional task training, where activities are designed to mimic ADL's may encourage a more active lifestyle, and therefore decrease functional limitations (Pisters et al., 2007).

Rehabilitation exercises that are designed to improve muscle strength are based on exercises that address the individuals' impairment rather than their functional limitations as defined by their activity and participation level. Isotonic,isokinetic and isometric strengthening exercise programs, which address impairments, have been utilized in knee OA protocols with positive significant results in strength gains (Huang et al., 2003); however, ADL's involve the integration of cognitive, perceptual and motor functions influenced by the variability of the individual's dynamic environment. (Mulder, 1991). Thus, impairment-based exercises (e.g. quadriceps strengthening) may not effectively improve functional performance levels. Additionally, the inability to coordinate complex musculoskeletal control must also take into consideration environmental demands for effective performance of the task (Shumway-Cook &Woollacott,1995).

Functional task training, task specificity and functional training have long been utilized in stroke rehabilitation (Carr & Shepherd, 1982). Practicing motor tasks in the context of the environment for which it is to be carried out has been found to promote motor learning. The theoretical framework supporting functional task training suggests that functional improvement necessitates practice of the actual task and that motor neuron pools are organized according to specific tasks, not specific muscles (Platz, 2004). The extent and efficiency of the motor skill transfer is enhanced by the performance of that task-specific activity (Schmidt & Lee, 2005), which increases muscle performance and sensory motor integration, resulting in optimal functional performance (Ageberg&Roos, 2010).

Although the literature is limited for functional task training in knee OA, the available data does support the benefits of functional task training. As previously mentioned, deVreede et al. (2005) found significant improvements in fitness sores of 70 year old women who performed functional task exercises compared with an age-matched group assigned to a traditional strengthening exercises.Whitehurst, Johnson, Parker, Brown, and Ford (2005) found similar results in their 12-week study of functional task exercises with an elderly population. The exercises included wall squats, single leg balance, star exercise, modified push ups and walking over obstacles while carrying bags. The environment was varied by obstacle height, changing directions and walking backward. Outcome measures were significant for the get up and go test (TUG), standing reach, sit and reach and self-report of physical function. In 2008, Milton, Porcari, Foster,Gibson, and Undermann modified the exercise program of Whitehurst et al.(2005) and added a control group to their study who were instructed to carry out their usual exercise regimen. Their results also indicated that the functional task group demonstrated significant improvements in performance tests. In a pilot study of 45-65year old knee OA subjects, who were randomized to either a functional task training or traditional exercise group, Stutz-Doyle (2008) found the functional task training group demonstrated a significant increase in quadriceps muscle strength and gait velocity as well as greater improvements in TUG scores.

An exercise program tailored to the individual's diagnosis, lifestyle, habits and co-morbidities may well provide a rehabilitative program that may be more positively embraced and adhered to for a longer period (Pisters, et al., 2010).Although well documented as initially successful, strengthening exercise programs are often abandoned and the initial successful results are minimized(vanBaar, et al**.,** 2001). Non-compliance with home exercise programs is an issue in people with knee OA secondary to several psychometric variables such as age, culture, fear and motivation (Campbell et al., 2005). Some older adults with knee OA believe that exercise and activity will exacerbate the pain and symptoms associated with this condition (Wilcox et al., 2006). Furthermore, exercise that requires additional equipment and special scheduling constraints may present obstacles in the course of rehabilitation. Activities that are part of a person's lifestyle or personal history may be more readily adopted and adhered to over time (Veenhorf et al., 2006). Since there is limited information regarding the benefit of functional task training programs in the OA population overstrength training exercises , further investigation is warranted in the knee OA population; therefore, the purpose of this study was to investigate whether functional task training would be more effective in decreasing pain, improving strength and increasing functional mobility in this population.

## THE AGING PHYSICAL BODY AND OSTEOARTHRITIS

The literature indicates OA is the most common musculoskeletal condition of aging, with most treatment being palliative in nature with functional capacity as the treatment goal. Osteoarthritis, combined with the natural decline of muscles, bones, and the cardiovascular and digestive systems, not only causes a chain reaction, but may also un mask other subclinical conditions.The effects of aging on the muscular system include a loss of muscle mass as well as the number of muscle fibers. Additionally, reduction of synovial fluid, joint capsule and ligament stiffness, and loss of range of motion can all affect mobility. Finally, the standing posture for these patients, with both knees and hips flexed, creates added compensation and pain when ambulating or performing activities of daily living.These are but a few of the age-related physical changes for which seniors seek relief, changes that impact the physical limitations and quality of life.

The various treatments and nonpharmacological management approaches for knee OA are varied and individualized; for patients who are looking for additional pain relief or improved function, the benefits obtained from CAM interventions can be an effective means of appealing to OA patients. Older citizens between the ages of 54 to 92 have embraced the use of CAM because of its potential to alleviate pain.

## CAM AND OSTEOARTHRITIS

The use of CAM therapies for pain and dysfunction is increasing as the aging population increases. The physiological, psychological and emotional impact of chronic pain combined with the aging process and other medical conditions make CAM therapies more appealing. Of special interest might be those that can be self-administered—i.e., prayer, meditation, Tai Chi, magnet therapy and self-massage. Self-massage can be considered a mind/body approach to self-healing. It is one alternative approach that promotes self-healing and may create a shift from an emphasis on disease and treatment to one of self-management. Alternative therapies have given researchers options but scientific proof for non-ordinary forms of holistic healing—i.e., increased spirituality, self love, feeling whole, or increased energy and movement are being considered.

There is ample evidence to support the therapeutic claims of CAM therapies. However, they are not used enough in the treatment of OA. Often it is due to lack of knowledge on the part of doctor or patient, cost to patient, time constraints with doctor visits, lack of conviction that measures may be helpful, fear of litigation, and increased use of pharmaceuticals for symptom relief. Consequently, there is a vital need for more holistic research that may increase quality of life, which may ensure better control not only of knee OA symptoms, but of other chronic diseases.

## THERAPEUTIC MASSAGE

Massage therapy is considered part of complementary alternative medicine (CAM) and rehabilitation therapy. Massage, a form of applied touch, is one of the oldest healing techniques. It has evolved, primarily because valid research is now available to support its therapeutic value. According to the American Massage Therapy Association, “massage therapy” is a generic term that denotes both (a) the promotion of health and well-being by way of soft tissue manipulation and movement of the body and (b) a health care profession engaged in by massage practitioners.

The primary characteristics of massage are touch and movement. The strokes are combined to form a comprehensive intervention often referred to as Swedish massage, the technique utilized by most published trials on massage therapy. This form of massage is often used in randomized clinical trials.

The terminology, which describes the classic massage movements, is derived from the English and French languages. The following terms describe the classic massage strokes:

- *Effleurage* (gliding);
- *Petrissage* (kneading);
- Friction (pressure from fingertips with circular or transverse movement);
- Tapotement (tapping); and
- Vibration (shaking).

When massage is used for salutary purposes, it is referred to as therapeutic massage, which is the manual application of a technique to the skin, soft tissue, muscles, tendons, ligaments, and/or fascia for beneficial purposes.

Massage therapy is considered part of both complementary and alternative medicine (CAM) and rehabilitation therapy. As stated earlier, a 2002 report from National Health Survey indicated that sixty-two percent of adults in the United States had used some form of CAM therapy, and five percent used massage therapy for pain relief, rehabilitation, stress reduction, relaxation, and depression and as an aid to general wellness. Applied touch, manual manipulation, manual technique or soft tissue manipulation are synonyms for massage. No matter what the terminology, the reported benefits of massage include breaking the pain cycle, improving function, reducing edema, promoting relaxation, and facilitating healing in various medical conditions.

Much of the literature evaluating the use of therapeutic massage for musculoskeletal conditions has provided verifiable objective, evidence for its effectiveness and efficacy.

## EFFECTIVENESS OF MASSAGE THERAPY

Evidence-based studies of massage for musculoskeletal conditions yield potentially useful and beneficial alternative pain control techniques that could act on a combination of muscles. Low back pain is one of the most common musculoskeletal conditions in which the application of massage therapy is effective.

Several randomized controlled studies have demonstrated its benefits for low back pain; Cherkin and colleagues specifically evaluated massage as a CAM therapy for low back pain. In this study, researchers looked at 262 randomly chosen patients with persistent low back pain. The study's participants were randomly assigned to receive therapeutic massage, traditional Chinese medical acupuncture, or self-care educational materials. At the end of a 10-week treatment period, therapeutic massage proved superior to both acupuncture and self-care educational materials. The one-year follow-up determined the continued benefits of massage, indicating that it remained superior to acupuncture, but not to self-care educational materials. The results of this study suggested that "massage is an effective short-term treatment for chronic low back pain, with benefits that persist for a year."

Additionally, massage proved more economical as it relates to cost to provider, pain medication and outpatient Health Maintenance Organizations. Back care services were about 40 percent lower in the massage group. A limitation of this study was the lack of a control group; also, the cause of the back pain was not considered, making replication difficult for future research.

In another study on subacute low back pain and massage therapy, Michele Preyde provided worthwhile insight into the relationship between comprehensive massage therapy, soft tissue manipulation, remedial exercise with posture education, and placebo sham laser therapy. Subjects with low back pain were randomly assigned to one of the four groups; all 107 patients received 6 treatments over one a month period. The comprehensive massage group alone had significantly better scores than the remedial exercise and sham (placebo) laser groups on measures of function, pain intensity, and quality. Thus, “massage was significantly better than exercise for measures of function in the short term.

”Preyde’s research contributed a significant perspective of therapeutic massage as an effective treatment for low back pain; however, better defined research is needed to establish a specific protocol for the massage and soft tissue manipulation with adequate descriptions. Further research is also needed to investigate the effects of specific massage techniques (e.g. *petrissage*, friction, trigger points), rather than an integration of comprehensive massage techniques that would allow for better replication of studies.

Similarly, the authors of a Cochrane Review, which investigated the effects of interventions for prevention, treatment and rehabilitation in a health care setting, also concluded that massage therapy might be beneficial for patients with nonspecific subacute or chronic low back pain, especially when combined with exercise and education. In a clinical comparative study, Maria Hernandez-Reif and colleagues evaluated the treatment effects of massage for reducing pain, depression, anxiety, stress hormones and improving trunk range of motion associated with chronic low back pain.

This study consisted of twenty-four adults with low back pain of at least six months duration who were randomly assigned to either massage therapy ($n$=12) or progressive muscle relaxation ($n$=12). The massage group received two 30-minute massage therapy sessions per week over five weeks by trained massage therapists. By comparison, the superiority of massage therapy over relaxation produced significant improvement in trunk flexion and range of motion, increased serotonin and dopamine levels, reduced depression and anxiety, and improved mood. Subjects receiving relaxation therapy reported less anxiety. Small sample size and lack of follow-up were limitations of this study. Although the findings from the preceding reviews and studies support the effectiveness of massage for a range of musculoskeletal conditions, in an assessment of massage for neck musculoskeletal pain, a systematic review noted "although there has been a marked increase in the number of publications that incorporate massage…the contribution of massage to manage neck pain remains unclear."

In summary, the four preceding studies have provided scientific evidence of the effectiveness of massage therapy for depression and anxiety and musculoskeletal conditions—specifically, low back pain. The trials have reported that massage therapy is superior to acupuncture and exercise, and may constitute the primary intervention or act as an adjunct with other interventions when combined with exercise and education.

Interest in massage therapy has continued for other chronic pain conditions. Jennie Tsao's review focused on the following chronic nonmalignant pain: fibromyalgia, mixed chronic pain, shoulder pain, carpal tunnel, low back pain, and headache pain. This review's examination of its clinical implications concluded that massage therapy has overall beneficial value, but a limitation in the review of massage research is the lack of follow-up assessments. Finally, a meta-analysis review of twenty-seven massage therapy studies, which focused on still other types of pain, concluded that massage therapy did not provide significant effects on pain when assessed immediately following a session; however, lasting benefits were present after a series of massage treatments.

In an opposing view, Geoffrey Harris reviewed guidelines on the effectiveness of therapies for musculoskeletal conditions and reported that massage was ineffective. His report on a panel formulating evidence-based guidelines for rehabilitation intervention in the management of pain in the low back, knee, shoulder, and neck indicated that though massage is considered a part of rehabilitation, the major implication of this analysis as it relates to knee pain is that “there is poor evidence to support the use of several widely used interventions in the treatment of knee pain. The main difficulty in determining the effectiveness of rehabilitation interventions is the lack of well-designed, prospective, randomized controlled trials.”

In conclusion, massage therapy has been considered a part of rehabilitation; however, it can also be integrated with other therapies or used alone in therapy. It is reasonable to believe that if massage can help with low back pain and other chronic musculoskeletal conditions, it can also be therapeutic for pain relief and dysfunction in OA of the knee.

## THE EFFICACY OF MASSAGE THERAPY

Efficacy can provide evidence to support the various claims of massage therapy’s effectiveness on musculoskeletal conditions, and provide a blueprint for the replication of future studies. In an editorial article, authors E. Ernst and M. Pittler discuss the important difference between effectiveness and efficacy in research. They assert “typical efficacy study tests whether the experimental therapy generates specific therapeutic effects, while the typical effectiveness study is aimed at quantifying the sum of specific effects and other contributors to the total therapeutic effect.”The authors also indicate that for the best research value efficacy data studies are needed prior to research on effectiveness in order to ensure the value of treatments.

In a recent, well-designed landmark 2006 pilot study, Perlman and colleagues were the first researchers to investigate the efficacy of massage therapy on both the range of motion and pain in OA of the knee. Researchers measured the clinical significance of massage therapy as a possibly influencing the results, during the initial eight-week delay. It is relevant to mention that the study duration of sixteen weeks allowed the researchers to assess improvement in the eight-week follow-up of the intervention group; however, future studies of OA could benefit from longer follow-up studies. Finally, the authors did an admirable job in providing ample support to suggest that “massage therapy is efficacious in the treatment of OA of the knee, with beneficial effects persisting for weeks following treatment cessation.”This research provided worthwhile insight into the relationship between massage therapy not as an adjunct treatment but as a single modality for the treatment of pain and range of motion associated with OA of the knee.

Massage and consequent decrease in pain may indicate that the pain relief was a result of other tension in muscles and other psychological factors such as the nonspecific effects of attention and touch. Areas of possible study in future investigations could include carefully designed treatment protocols with control groups addressing various other types of OA such as hip, spine, and hand, clarifying the site and extent of the dysfunction and pain as factors in the efficacy of therapeutic massage. To date this is the only research to investigate the efficacy of massage for knee OA. Although the trial revealed significant results, the continued use of therapist-administered massage as a regular treatment to ensure its therapeutic value is often cost-prohibitive in long-term nonpharmacological self-management of knee OA, some patients could have difficulty financing regular massages.

The preceding theories and reviews supporting the significant physiological and or psychological value of massage in many conditions were either based on theoretical reasoning, research material or clinical studies; however, the precise explanatory mechanisms of action in massage therapy needs more research. In summary, the studies in this review identify the application of massage for low back pain, OA and other chronic pain conditions. Its short-term effectiveness as an adjunct therapy in preparation for exercise and other interventions were discussed in Furlan’s study. Similarly, massage proved superior to relaxation, acupuncture and self-care education for low back pain.

Finally, when the study integrated massage therapy into treatments for chronic pain, it was found to be beneficial. In this context, massage has proven to be an effective adjunct, integrative, rehabilitative, and/or therapeutic intervention in the treatment of musculoskeletal and chronic pain conditions, as mentioned previously. The exact mechanisms of action, however, remain unclear, and thus the need for future mechanism studies.

## MECHANISMS OF ACTION

Until now, the focus of this literature review has been the efficacy and effectiveness of massage therapy. The previously discussed studies have validated the possible physiological and psychological benefits of massage therapy. However, the theoretical mechanism by which massage operates gives clarity in the clinical integration and application of massage therapy. Nevertheless, a closer look at the relationship between the direct influence of massage on muscles, circulation, and the soft tissue being manipulated has not been extensively researched. The effects of massage are considered to be produced by more than one mechanism or a combination of mechanical, neural, chemical, physiological, or psychological factors that create the basis for research findings. For example, the Touch Research Institute at the University of Miami has focused their research on various age groups and medical conditions that may benefit from massage therapy. Despite the studies' reported significant effects on the body's serotonin, dopamine, and cortisol levels, the underlying mechanisms of massage therapy's action are not understood.

The benefits of massage therapy have been related to the ability of manual massage to influence the skin, soft tissue, muscle, tendons, ligaments, and/or fascia for therapeutic purposes. Commonly reported effects of massage therapy suggest that massage produces a combination of effects. In his book *Soft Tissue Manipulation,* Leon Chaitow proposes that pressure as applied in deep kneading or stroking along the length of a muscle tendon encourages venous, lymphatic, and tissue drainage, as well as replacement with fresh oxygen. Additionally, the removal of metabolic waste enhances homeostasis and reduces pain.

According to Chaitow, the muscle energy technique, which is a type of soft tissue manipulation, when employed in combination with massage, is also capable of relaxing muscles by inhibiting the muscles' capability. Another resource book which supports the use of manual hands-on therapy provides evidence-based theories for professions that incorporate manual therapy in conjunction with other medical therapies. *The Principles of Manual Medicine* by Philip Greenman defines manual medicine's soft-tissue procedure as "the manual application of force directed toward influencing specific tissues of the musculoskeletal system, by peripheral stimulation, enhancing some form of reflex mechanism that alters biologic function. The direct procedures include massage, effleurage and kneading, stretching, friction and so forth...The therapeutic goals are to overcome congestion, reduce muscle spasm, improve tissue mobility, enhance circulation, and 'tonify' the tissue." Greenman states the mechanism of massage is also a soft tissue procedure that "can mechanically stretch the skin, fascia, and muscle tissue of the body to enhance their motion and pliability.

These procedures are useful in encouraging circulation of fluid in and around the soft tissues of the musculoskeletal system, enhancing venous and lymphatic return, and decongesting parts of the body compromised by injury or disease…These same procedures can have a neurologic effect, modifying muscle physiology to overcome hypertonicity, spasm and the relief of musculoskeletal pain."The preceding theories involve the application of manual pressure that focuses on the potential of massage to influence muscle and soft tissue in order to effect therapeutic change within the body. This mechanism of massage has not been widely investigated and the evidence is limited; however, Geoffrey Goats' early investigations into the use of massage to promote healing, relaxation, and decreased pain have provided the foundation for the current mechanism theories.

His research provided significant contributions in the application of massage with various medical conditions. According to Goats' theory, massage dilates superficial blood vessels and increases the rate of blood flow, which can accelerate healing. Similarly, Steven Stanos and others supported Goats' theory in a recent article on "Physical Medicine.

Rehabilitation Approach to Pain," which classified the beneficial effects of massage into two areas: reflexive and mechanical. The stimulation of endogenous opioid release and relaxation were considered reflexive. The mechanical pressure exerted by various massage strokes may prevent, delay, or decrease muscle tightness and improve superficial lymph and venous circulation channels. Previously, Maria Hernandez-Reif and colleagues in a small study reported the increase in range of motion and flexibility created with various massage strokes, but another small study, in which the ability of massage to enhance flexibility of the hamstring muscle group was investigated, yielded different results. This study of eleven healthy males had fifteen minutes of effleurage and petrissage massage applied to the hamstring muscles for two sessions. In a sit and reach performance, measurements pre- and post-massage showed no significant change.

Theories that support massage therapy’s influence on lymph drainage to remove muscle toxins and reduce edema are reflected in anecdotal accounts, however, empirical supportive evidence is currently lacking and more conclusive research is needed. Finally, in 1965, Melzack and Wall’s research, yielded the gate control theory, that suggest pain signals traveling via small nerve fibers are allowed to pass through to the brain signaling pain, while signals sent by large nerve fibers, e.g. touch, are blocked, “closing the gate” to pain. This shed new light on the complexities of understanding acute and chronic pain.Specifically, the gate control theory can be is applied to massage therapy, the pressure receptors, which are longer and more myelinated than pain fibers, are stimulated during massage and travel faster, closing the gate to any pain signals. Thus, massage has therapeutic value especially with chronic pain processing, potentially providing some relief and relaxation.

Even though the underlying mechanisms for massage therapy need further research, its efficacy and effectiveness has stimulated its use by parents for their premature and healthy infants, sick children, and care givers, as well as self-massage as part of self-care for certain chronic conditions.

# RESEARCH METHODS

The researcher's methods, research design and rationale, recruitment and selection of participants; assessment instruments, and intervention protocol are identified to address the following theoretical question. Does this intervention increase the knee's range of motion as well as decrease knee pain, stiffness and dysfunction in individuals with OA of the knee? Also, this chapter provides a description of methods used to collect data, sample-size determination, randomization, data collection and analysis and ethical considerations.

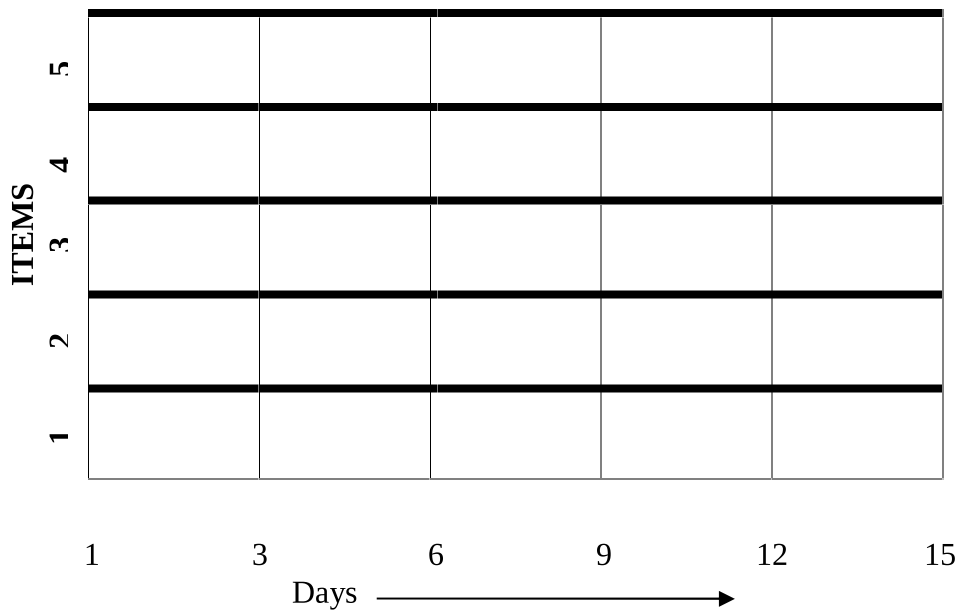
## Research design

This study examined the benefits of Swedish massage therapy intervention on knee pain, joint stiffness, physical functioning and knee range of motion on participants diagnosed with knee osteoarthritis (OA). The study consisted of two treatment groups, an SMT intervention group of 40 supervised and a conventional treatment control group of 40 supervised with no intervention therapies.

The participant patient with the age group of 40 to 60 years will undergo detailed history and examination at baseline according to a pre designed Case Report Form (CRF). Written informed consent will be taken from the patients. Randomization will be done to allocate patients into their respective two groups. During the study, accurate documentation of clinical parameters and outcome measures including pain score measured by WOMAC'S knee questionnaires and

Range of Motion at poppliteal angle measured by goniometry which has been given in Annexure – I will be assessed and duly completed for both groups. Experimental group patients will be explained about the SMT intervention in detail and SMT will be applied following a pre-determined therapy protocol (Figure-2), in a staged manner for an average duration of 25-30 minutes duration of 15 days with monitoring their compliances at the laboratory. Control group patients will receive their usual care management. The control group patients will receive the conventional therapy without SMT, see study flow chart below.

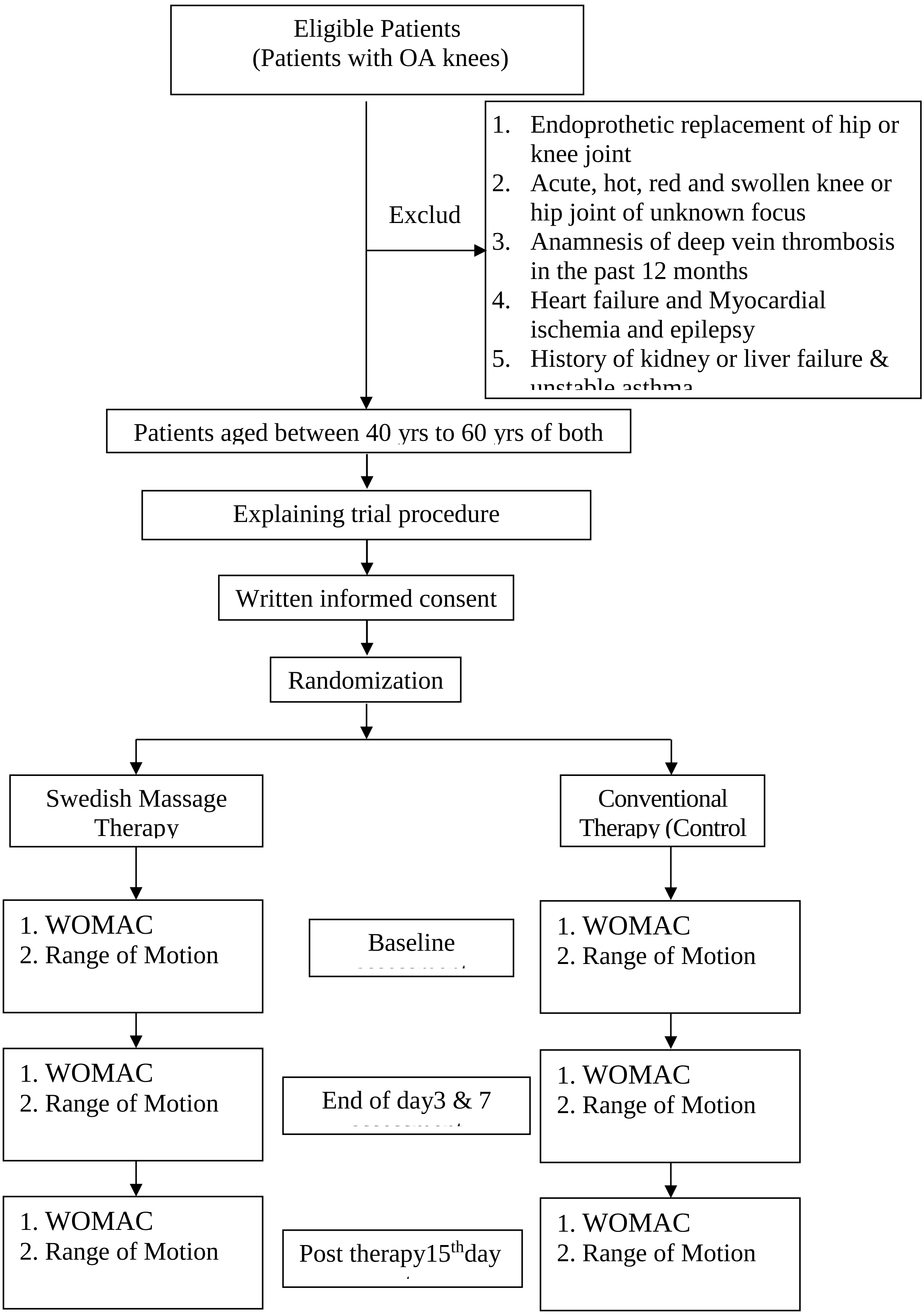
**<u>Pre determined therapy protocol</u> [Figure-2]**




**<u>Items:</u>**

1. Touch + Nerve Compression + stroking
2. Friction + Fulling + petrissage
3. Friction + Rolling + Wringing
4. Friction + Hacking + spatting
5. Friction + beating + clapping + stroking

## Study Design



Patients will be reviewed as outpatients at 0th day, 3rd day, 7th day and at the end of day 15. The primary outcome of efficacy—i.e. change in pain score at the baseline will be compared with that of follow up period. At day 7 and day 15, the clinical data on WOMAC and Range of Motion will be obtained and compared to the baseline values. The changes in these variables will be compared in both the groups.

## Participants

Men and woman aged between 40 to 60 years, who possessed no limitations that prevented mobility of the knee and had a written diagnosis of osteoarthritis (OA) of the knee, were recruited for a period of one year time, April 2016 to April 2017.

The study was carried out at Government Yoga and Naturopathy Medical College Hospital, Chennai – 600 106. The aim of the hospital is to bring a life style change in every patient to over come disease in the aspect of both prevention and rehabilition. The study was presented and approved by the Institutional Ethical Committee.

## Recruitment and Inclusion/Exclusion

The participants were recruited from the already visiting patients of the centre. Interested individuals who qualified for the study were checked for the following inclusion criteria.

1. Both genders
2. Age ≥ 40 years ≤ 60 years
3. Symptomatic osteoarthritis of knee (following the revised criteria of the American College of Rheumatology
4. Radiographically established OA of the knee
5. Willing to sign informed consent form on their own.

Those who qualified fulfilling the inclusion criterias were subjected for the following exclusion criterias.

1. Endoprothetic replacement of hip or knee joint
2. Acute, hot, red and swollen knee or hip joint of unknown focus
3. Anamnesis of deep vein thrombosis in the past 12 months
4. Heart failure and Myocardial ischemia and epilepsy
5. History of kidney or liver failure & unstable asthma
6. A rash or open wound over the knee.
7. Pregnancy

## Dependent Variables

Participants were evaluated for changes in pain, and physical function through the use of, 1) WOMAC'S questionnaires and 2) Range of Motion at poppliteal angle measured by goniometry using a goniometer. The dependent variables consisted of one ROM measurements and fourWOMACS knee questionnaires measurements.

## Sample-Size Determination

The appropriate sample-size for a one-tailed test on paired participants was determined prior to the start of this study by setting the Type I error rate to 5%, the Type II error rate to 20%, and the central tendency (mean or median) difference to 1 variability unit (1 standard deviation or 1 interquartile range), with the goal to test whether range of motion (ROM) of participants in the intervention group improved from baseline to follow-up visits due to SMT, whether range of motion (ROM) of participants in the control group improved from baseline to follow-up visits with no intervention therapy.

It was determined that for the 83 central tendency equal to 1 variability unit the number of participants in each group should be 8 participants or a total of 16 participants. The appropriate sample-size for a two-tailed test on independent participants was determined prior to the start of this study by setting the Type I error rate to 2.5% on each tail, the Type II error rate to 20%, and the central tendency (mean or median) difference to 1 variability unit (1 standard deviation or 1 interquartile range)with the goal to test whether range of motion (ROM) at baseline of participants in the intervention group was the same as range of motion (ROM) at baseline of participants in the control group as compared to range of motion (ROM) at baseline of participants in the intervention group was not the same as range of motion (ROM) at baseline of participants in the control group.

Further the previous study carried out by Juberg et al (2015), reported on a sample size of no 25 in which the SMT was applied the results shows that the baseline VAS score 69.4(13.8) ± 13.8 and the follow up score was 43.0± 25.1 which gives improvement of 23.4% of VAS score. So it was determined that for the central tendency equal to 1 variability unit the number of participants in each group should be 40 participants or a total of 80 participants.

**PROCEDURE OF THE INTERVENTION (MASSAGE):**

## ORDER OF MOVEMENTS:

1. Touch
2. Nerve compression
3. Stroking
4. Friction - centripetal
5. Superficial kneading – fulling
6. Friction
7. Deep kneading – petrissage ,rolling
8. Friction
9. Wringing
10. Friction
11. Percussion - hacking, spatting, beating, clapping
12. Stroking

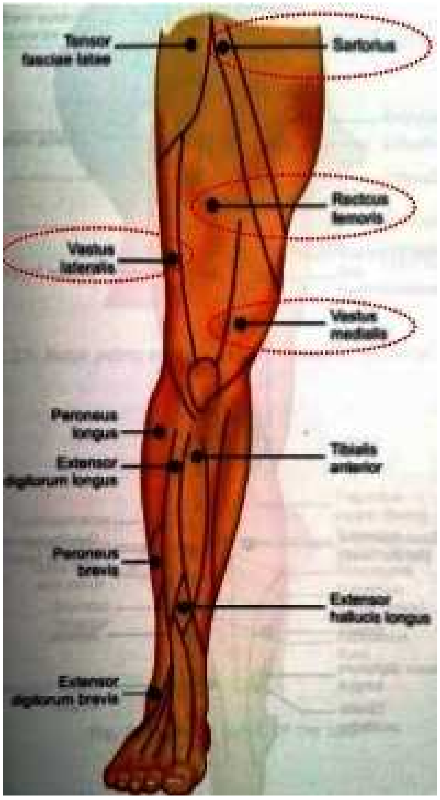
1. TOUCH:

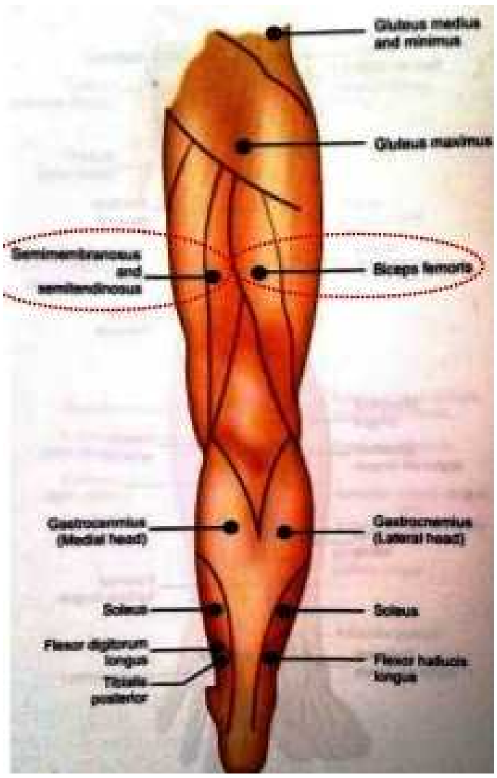
Pressure type of touch is applied, which consists of appliying light pressure with both hands upon the entire legs.

2. NERVE CMPRESSION:

Strong pressure is made upon the motor points of sciatic and femoral nerve.

**MOTOR POINTS OF FEMORAL AND SCIATIC NERVE**



3. STROKING:

Touch with motion using tips of all fingers of both hands gently over the skin from hip downwards to ankles with light contact is given.

4. FRICTION:

Whole hand is moved over the entire surface of leg with a considerable degree of pressure in the direction of venous blood flow above the knee and in the direction of arterial blood flow below the knee.

5. SUPERFICIAL KNEADING: (fulling)

The skin is grasped between terminal phalanges of first and second finger in opposition to the thumb. The two hands are used in alternation all over in a systemic manner.

6. FRICTION:

Same as above in circular and spiral form is given.

7. DEEP KNEADING:

7a.PETRISSAGE:

The muscles of leg are grasped by the palmer surface of the hand, keeping the fingers closure together. Taking care that the fingers only oppose thenar eminence and not thumb. The parts not only squeezed or compressed in hand but lifted from the bone, rolled, stretched, in an upward direction.

7b. ROLLING:

Extended fingers are held close together and rolled by a to and fro movement against deep lying tissue. The limb placed in half flexed position the movements being applied first to thighs and then to legs.

7c.WRINGING:

Twisting simultaneously either in same or in alternation, executed by the hands. The movements begins at groin and progresses downward to the ankle.

10. PERCUSSION:

10a. HACKING:

The blows are given using ulnar border of the hand and the fingers are held slightly apart, but loosely so that they are made to come successively in contact.

10b. SPATTING:

The blows are given with palmer surface of the extended rigid fingers.

10c.BEATING:

The body is struck by palmar surface of half closed fist.

10d. CLAPPING:

The palmer surface of the whole hand is so shaped as to entrap the air which it comes in contact with the skin producing loud explosive sound. Administered on fleshy parts of the legs.

11. STROKING:  Same as above.

## Randomization

Eighty independent age-eligible women and men with kneeOA were recruited and then assigned equally either to the intervention group or the control group randomly using a uniform distribution. By using the uniform distribution, the assumption holds that all participants are members of the same distribution family and have equal probability of selection to either the intervention group or the control group.

## The Role of the researcher

During the research study, the researcher's role was to recruit participants for the study, obtain a location, preparation of room; maintain regular written and verbal communication with participants, and wellness center staff; organize procedures, and the proper protection and storage of confidential information. In order to minimize bias, the researcher monitored the study, answered questions on procedures; designed data collection forms, and prepared the final report. The intervention and assessments were conducted by the researcher. The researcher also entered all data onto collection forms, submitted data regularly, and the statistician blindly tabulated the statistics.

## Ethical Considerations

The institutional ethical comitee' approved the study. The researcher was also conscious of the participant's well-being and safety. Prior to each massage intervention session safety precautions were recited and physical observations made. Additionally adaptations were made for physical limitations, for example, while seated if the participant felt more comfortable, a stool was provided. Also necessary precautions were taken care of for any unexpected minor injury.

## RESEARCH FINDINGS

### Descriptive Statistics

Baseline demographics along with WOMACS and ROM data comparing the intervention group to the control group are presented in Table below. In addition to descriptive statistics, Table 1 is used to determine if the intervention and control group populations come from the same distribution. The Wilcoxon Rank Sum test was used to compare continuous and ordinal variables and Fisher's Exact test was used to compare discrete variables. There is an insignificant *P* value for all variables at the 5% significance-level, which means that the intervention and control groups come from the same population and are appropriate for comparing results of this study to determine whether participants with OA of the knee have improved pain-level, improved joint stiffness, improved physical functioning, and improved range of motion (ROM) due to self-massage intervention therapy.

The average age of these participants are 54 years of age. The majority of these participants were female (86%). More than half (61%) of these participant's sleep less than 8-hours per night, take medicine (56%) related to OA, and exercise at least one time per week, (64%). More than half of these participant's have been diagnosed with OA of the knee (61%) for more than 4 years. The majority of these participants (83%) does not have an immediate family with history of knee replacement and does not have any inflammatory condition (75%) of the knee.

Most participants (80%) at baseline believed that SMT provides a poor or fair improvement to the muscle pain they experience due to OA of the knee. The pain-level, joint stiffness, and physical functioning of the knees at baseline were moderate. The average range of motion at baseline for right flexion and left flexion was 108 degrees.

**Swedish-Massage Therapy Study Baseline Demographics Intervention Group Compared to Control Group**

| **Intake Questions** | **Statistics** | **Intervention (N=40)** | **Control (N=40)** | **Total (N=80)** | **p_value1** |
|---|---|---|---|---|---|
| Age | Mean (Std) | 54.8 (9.36) | 55.6 (8.33) | 55.2 (8.73) | 0.9124 |
| Pain | Median (IntQ) | 2 (1.00) | 2 (1.00) | 2 (1.00) | 0.6615 |
| Joint Stiffness | Median (IntQ) | 2 (0.00) | 2 (1.00) | 2 (1.00) | 0.5316 |
| Physical Function | Median (IntQ) | 2 (1.00) | 1 (1.00) | 2 (1.00) | 0.2526 |
| Global | Median (IntQ) | 2 (1.00) | 2 (1.00) | 2 (1.00) | 0.8440 |
| Right Flexion | Mean (Std) | 108 (13.6) | 113 (13.0) | 110 (13.4) | 0.2080 |
| Left Flexion | Mean (Std) | 108 (16.2) | 114 (11.5) | 111 (14.2) | 0.2791 |
| Both Flexion | Mean (Std) | 108 (13.8) | 114 (10.2) | 111 (12.3) | 0.2479 |
| Right Extension | Mean (Std) | 6.7 (4.54) | 9.4 (3.79) | 8.1 (4.36) | 0.0711 |
| Left Extension | Mean (Std) | 7.1 (3.46) | 10.3 (5.81) | 8.7 (4.98) | 0.0988 |

| | | | | | |
|---|---|---|---|---|---|
| Both Extension | Mean (Std) | 6.9 (3.75) | 9.9 (3.88) | 8.4 (4.05) | 0.0289 |
| Gender | Female | 14 (77.78%) | 17 (94.44%) | 31 (86.11%) | 0.3377 |
| Male | | 4 (22.22%) | 1 (5.56 %) | 5 (13.89%) | |
| Hours Sleep / Night | 6 hrs. | 2 (11.11%) | 5 (27.78%) | 7 (19.44%) | 0.7685 |
| 7 hrs. | | 8 (44.44%) | 7 (38.89%) | 15 (41.67%) | |
| 8 hrs. | | 7 (38.89%) | 5 (27.78%) | 12 (33.33%) | |
| 10+ hrs. | | 1 (5.56 %) | 1 (5.56 %) | 2 (5.56 %) | |
| Medicine Intake OA | None | 10 (55.56%) | 6 (33.33%) | 16 (44.44%) | 0.3881 |
| | Once | 4 (22.22%) | 6 (33.33%) | 10 (27.78%) | |
| | Twice | 4 (22.22%) | 4 (22.22%) | 8 (22.22%) | |
| | Three+ | 0 (0.00 %) | 2 (11.11%) | 2 (5.56 %) | |
| Exercise / Week | Zero | 7 (38.89%) | 6 (33.33%) | 13 (36.11%) | 0.2119 |
| | Once | 4 (22.22%) | 1 (5.56 %) | 5 (13.89%) | |
| | Twice | 1 (5.56 %) | 5 (27.78%) | 6 (16.67%) | |
| | Three+ | 6 (33.33%) | 6 (33.33%) | 12 (33.33%) | |
| Knee OA | Right | 5 (27.78%) | 2 (11.11%) | 7 (19.44%) | 0.6350 |
| | Left | 3 (16.67%) | 4 (22.22%) | 7 (19.44%) | |
| | Both | 10 (55.56%) | 12 (66.67%) | 22 (61.11%) | |
| Yrs. Diagnosed with OA | < 1 Yr. | 1 (5.56 %) | 3 (16.67%) | 4 (11.11%) | 0.7965 |

| | | | | | |
|---|---|---|---|---|---|
| | 1-3 Yrs. | 5 (27.78%) | 5 (27.78%) | 10 (27.78%) | |
| | 4-9 Yrs. | 7 (38.89%) | 5 (27.78%) | 12 (33.33%) | |
| | 10+ Yrs. | 5 (27.78%) | 5 (27.78%) | 10 (27.78%) | |
| Family History Knee Replacement | Yes | 3 (16.67%) | 3 (16.67%) | 6 (16.67%) | 1.0000 |
| | No | 15 (83.33%) | 15 (83.33%) | 30 (83.33%) | |
| Any Inflammatory Condition | Yes | 4 (22.22%) | 5 (27.78%) | 9 (25.00%) | 1.0000 |
| | No | 14 (77.78%) | 13 (72.22%) | 27 (75.00%) | |
| Non-Professional Massage Last 12 Mo | 0 | 10 (55.56%) | 6 (33.33%) | 16 (44.44%) | 0.4339 |
| | 1 | 6 (33.33%) | 6 (33.33%) | 12 (33.33%) | |
| | 2-4 | 1 (5.56 %) | 4 (22.22%) | 5 (13.89%) | |
| | 5+ | 1 (5.56 %) | 2 (11.11%) | 3 (8.33 %) | |
| Rate Massage Muscle Pain | Poor | 8 (44.44%) | 5 (27.78%) | 13 (36.11%) | 0.1720 |
| | Fair | 5 (27.78%) | 11 (61.11%) | 16 (44.44%) | |
| | Good | 5 (27.78%) | 2 (11.11%) | 7 (19.44%) | |

p_value based on Wilcoxon Rank Sum for ordinal and continuous and Fisher’s Exact for discrete.

**Changes in WOMAC'S and ROM from Baseline to Follow-up**

Participants with OA of the knee completed WOMACS questionnaires and ROM measurements were taken by researchers at Baseline, 3 days, 7 days, and 15 days for both the intervention and control groups.

Table 2A and Table 2B provides a change from baseline to the 3rd day follow-up of the same participant (paired participants) and compares the intervention group to the control group,

Table 3A and Table 3B provides a change from baseline to the 7 daysfollow-up of the same participant (paired participants) and compares the intervention group to the control group, and Table 4A and Table 4B provides a change from baseline to the 15 daysfollow-up of the same participant (paired participants) and compares the intervention group to the control group.

A *P* value based on Student's t Distribution was utilized to determine a 5% significance-level for ROM measurements and the Wilcoxon Signed-Rank test was utilized to determine a 5% significance-level for WOMACS questions. Median differences and interquartile ranges are presented for WOMACS assessments, and mean differences and standard deviations are presented for ROM assessments.

There were twenty-four WOMACS questions that were condensed into 4 groups. Question 1 through Question 5 makes up the assessment of how much pain a participant possesses as a result of osteoarthritis, Question 6 and Question 7 makes up the assessment of the joint stiffness a participant possesses as a result of osteoarthritis, Question 8 through Question 24 makes up the assessment of the physical functioning a participant possesses as a result of osteoarthritis, and all WOMACS questions, Question 1 through Question 24, excluding Question 20 and Question 23, consists of the combined median value of degree of pain, joint stiffness, and physical functioning for each participant as a result of osteoarthritis. Range of motion (ROM) measurements of the right knee bent, left knee bent, right knee straight, and left knee straight were taken by RAs using a goniometer to assess a participant's mobility as a result of OA. Additionally, right and left knee bent (both flexion) measurements were combined into a group by calculating the average for each participant, and right and left knee straight measurements were combined into a group by calculating the average for each participant.

**Three days Follow-Up**

At the 3rd day post-intervention follow-up there were statistically-significant changes observed in the treatment group for: pain (p=0.0010), joint stiffness (p=.0052), physical functioning (p=.0002), global WOMACS (p=.0003), right flexion (p<.0001), left flexion (p<.0001), both flexion (p<.0001), right extension (p<.0001), left extension (p<.0001), and both extension (p<.0001). All changes for the treatment group were statistically-significantly different from baseline. For the control group there were no statistically-significantly changes from baseline as all *P* values were greater than 5%.

**Table 2A: WOMACS Comparisons of Intervention Group to Control Group from Baseline to three day Follow-up**

| | | Intervention (N=40) | | | | Control (N=40) | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Week** | **Variable** | **Before to After** | **Median Diff** | **IQR** | **p_value1** | **Before to After** | **Median Diff** | **IQR** | **p_value** |
| 4 | Pain | 1.5 to 1.0 | -1.0 | 1.000 | 0.0010 | 1.5 to 1.5 | 0.0 | 0.000 | 0.9844 |
| 4 | Joint Stiffness | 2.0 to 1.0 | -0.5 | 1.000 | 0.0052 | 2.3 to 2.0 | 0.0 | 0.500 | 0.2031 |
| 4 | Physical Function | 2.0 to 1.0 | -0.8 | 1.000 | 0.0020 | 1.5 to 1.5 | 0.0 | 0.000 | 0.6250 |
| 4 | Global WOMACS | 2.0 to 1.0 | -1.0 | 1.000 | 0.0107 | 1.5 to 2.0 | 0.0 | 0.000 | 1.0000 |

**p_value is based on Wilcoxon Signed Rank test.**

**Table 2B: ROM Comparisons of Intervention Group to Control Group from Baseline to three day Follow-up**

| Intervention (N=40) | | | | | | Control (N=40) | | | |
|---|---|---|---|---|---|---|---|---|---|
| **day** | **Variable** | **Before to After** | **Mean Diff** | **Std** | **p_value** | **Before to After** | **Mean Diff** | **Std** | **p_value** |
| 3 | Right Flexion | 107.8 to 114.9 | 7.2 | 6.428 | 0.0002 | 113.1 to 116.7 | 3.6 | 9.043 | 0.1085 |
| 3 | Left Flexion | 107.4 to 115.2 | 7.8 | 7.310 | 0.0003 | 113.3 to 117.5 | 4.2 | 10.880 | 0.1226 |
| 3 | Both Flexion | 107.6 to 115.1 | 7.5 | 4.033 | <0.0001 | 113.2 to 117.1 | 3.9 | 9.244 | 0.0922 |
| 3 | Right Extension | 6.7 to 13.4 | 6.7 | 3.908 | <0.0001 | 9.4 to 8.6 | -0.8 | 4.618 | 0.4544 |
| 3 | Left Extension | 7.1 to 12.3 | 5.2 | 3.130 | <0.0001 | 10.6 to 10.8 | 0.3 | 6.524 | 0.8588 |
| 3 | Both Extension | 6.9 to 12.8 | 5.9 | 2.960 | <0.0001 | 10.0 to 9.7 | -0.3 | 4.918 | 0.8135 |

**p_value is based on Student's t Distribution**

**Seven Days Follow-Up**

At the seventh day post-intervention follow-up there were statistically-significant changes observed in the intervention group for: pain (p=0.0002), joint stiffness (p=.0002), physical functioning (p=.0024), global WOMACS (p=.0010), right flexion (p<.0001), left flexion (p<.0001), both flexion (p<.0001), right extension (p<.0001), left extension (p<.0001), and both extension (p<.0001). All changes for the treatment group were statistically-significantly different from baseline. For the control group there were no statistically-significantly changes from baseline as all p_values were greater than 5%.

| | | **Intervention (N=40)** | | | | **Control (N=40)** | | | |
|---|---|---|---|---|---|---|---|---|---|
| **day** | **Variable** | **Before to After** | **Median Diff** | **IQR** | **p_value** | **Before to After** | **Median Diff** | **IQR** | **p_value** |
| 7 | Pain | 1.5 to 0.0 | -1.0 | 1.000 | 0.0002 | 1.5 to 2.0 | 0.0 | 1.000 | 0.7891 |
| 7 | Joint Stiffness | 2.0 to 1.0 | -1.0 | 0.500 | 0.0002 | 2.3 to 2.0 | 0.0 | 0.500 | 0.4805 |
| 7 | Physical Function | 2.0 to 0.5 | -1.0 | 1.500 | 0.0024 | 1.5 to 2.0 | 0.0 | 0.000 | 1.0000 |
| 7 | Global WOMACS | 2.0 to 1.0 | -1.0 | 1.000 | 0.0010 | 1.5 to 2.0 | 0.0 | 0.000 | 1.0000 |

**Table 3B: ROM Comparisons of Intervention Group to Control Group from Baseline to 7th day Follow-up**

| | | **Intervention (N=40)** | | | | **Control (N=40)** | | | |
|---|---|---|---|---|---|---|---|---|---|
| **day** | **Variable** | **Before to After** | **Mean Diff** | **Std** | **p_value** | **Before to After** | **Mean Diff** | **Std** | **p_value** |
| 7 | Right Flexion | 107.8 to 120.4 | 12.6 | 7.064 | <0.0001 | 113.1 to 116.4 | 3.3 | 9.393 | 0.1505 |
| 7 | Left Flexion | 107.4 to 122.6 | 15.2 | 11.547 | <0.0001 | 113.3 to 117.2 | 3.9 | 9.934 | 0.1151 |
| 7 | Both Flexion | 107.6 to 121.5 | 13.9 | 7.638 | <0.0001 | 113.2 to 116.8 | 3.6 | 8.796 | 0.0996 |
| 7 | Right Extension | 6.7 to 18.3 | 11.7 | 4.201 | <0.0001 | 9.4 to 8.4 | -1.1 | 4.412 | 0.3243 |
| 7 | Left Extension | 7.1 to 18.0 | 10.9 | 4.351 | <0.0001 | 10.6 to 10.3 | -0.3 | 6.057 | 0.8480 |
| 7 | Both Extension | 6.9 to 18.2 | 11.3 | 3.813 | <0.0001 | 10.0 to 9.3 | -0.7 | 4.544 | 0.5419 |

**p_value is based on Student's t Distribution.**

## Fifteenth day Follow-Up

At the 15th day post-intervention follow-up there were statistically-significant changes observed in the treatment group for: pain (p<.0001), joint stiffness (p=.0002), physical functioning (p=.0005), global WOMACS (p=.0001), right flexion (p<.0001), left flexion (p<.0001), both flexion (p<.0001), right extension (p<.0001), left extension (p<.0001), and both extension (p<.0001). All changes for the treatment group were statistically-significantly different from baseline. For the control group there were no statistically-significantly changes from baseline as all p_values were greater than 5%.

At the 15th daypost-intervention follow-up, the (absolute median difference=1) is equivalent to the (interquartile range=1) in the treatment group for: joint stiffness and global WOMACS, which agrees with the requirement of 80% power.

**Table 4A: WOMACS Comparisons of Intervention Group to Control Group from Baseline to 15th day Follow-up**

| | | **Intervention (N=40)** | | | | **Control (N=40)** | | | |
|---|---|---|---|---|---|---|---|---|---|
| **day** | **Variable** | **Before to After** | **Median Diff** | **IQR** | **p_value1** | **Before to After** | **Median Diff** | **IQR** | **p_value** |
| 15 | Pain | 1.5 to 0.0 | -1.0 | 0.000 | <0.0001 | 1.5 to 1.0 | 0.0 | 0.000 | 1.0000 |
| 15 | Joint Stiffnes | 2.0 to 1.0 | -1.0 | 0.500 | 0.0002 | 2.3 to 2.0 | 0.0 | 1.000 | 0.6074 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 15 | Physical Function | 2.0 to 0.5 | -1.0 | 1.500 | 0.0005 | 1.5 to 2.0 | 0.0 | 0.500 | 0.1875 |
| 15 | Global WOMACS | 2.0 to 0.0 | -1.0 | 1.000 | 0.0001 | 1.5 to 2.0 | 0.0 | 0.000 | 1.0000 |

**p_value is based on Wilcoxon Rank Sum test.**

**Table 4B: ROM Comparisons of Intervention Group to Control Group from Baseline to 15th day Follow-up**

| | | **Intervention (N=40)** | | | | **Control (N=40)** | | | |
|---|---|---|---|---|---|---|---|---|---|
| **day** | **Variable** | **Before to After** | **Mean Diff** | **Std** | **p_value1** | **Before to After** | **Mean Diff** | **Std** | **p_value1** |
| 15 | Right Flexion | 107.8 to 116.9 | 9.2 | 8.787 | 0.0004 | 113.1 to 115.3 | 2.2 | 9.735 | 0.3464 |
| 15 | Left Flexion | 98.7 to 113.6 | 14.9 | 18.681 | 0.0035 | 113.3 to 116.1 | 2.8 | 9.583 | 0.2355 |
| 15 | Both Flexion | 103.2 to 115.3 | 12.1 | 12.405 | 0.0007 | 113.2 to 115.7 | 2.5 | 8.135 | 0.2097 |
| 15 | Right | 6.7 to | 2.8 | 3.919 | 0.0079 | 9.4 to | -1.1 | 3.234 | 0.1631 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Extension | 9.4 | | | | 8.3 | | | |
| 15 | Left Extension | 7.1 to 11.4 | 4.3 | 4.198 | 0.0005 | 10.6 to 10.3 | -0.3 | 6.057 | 0.8480 |
| 15 | Both Extension | 6.9 to 10.4 | 3.5 | 3.283 | 0.0003 | 10.0 to 9.3 | -0.7 | 4.004 | 0.4719 |

**p_value is based on Student's t Distribution.**

# DISCUSSION

Did Swedish Massage affect the Pain, Stiffness, Function and Knee Range of Motion in Osteoarthritis of the Knee?

In this research, Swedish massage intervention in a sample of community-dwelling adults with a diagnosis of osteoarthritis of the knee significantly affecting pain, joint stiffness, physical function and range of motion. The two dependent variables in this study are 1) WOMACS questionnaire, which evaluates clinically important patient-relevant changes in health status as a result of an intervention; and 2) active range of motion (ROM) of both knees (at full extension and flexion) using a goniometer.

Previous research, described in the Literature Review, has not definitively identified the cause of knee pain and knee OA. However, theories of its possible origin vary from systemic factors, mechanical dysfunction of the knee joint, and the role of the quadriceps femoris muscle. The resulting pain and physical compensation predispose older people to increased disability risks, disease progression and the adoption of sedentary lifestyles. Hence, the significant clinical outcomes as measured by WOMACS scores may indicate the intervention has the potential to affect the disease, and to influence pain and stiffness and physical function. In addition, ROM measurements are affected by the rectus femoris muscle, which is one of the four muscles that make up the quadriceps muscle group. This muscle crosses both the hip and knee and, if shortened, may affect knee flexion in knee OA.

The randomized Swedish massage study used outcome measures assessed at baseline and repeated on 3rd, 7th, 15th post-intervention. There were progressive and statistically significant improvements in pain, stiffness, function and range of motion over eight of the twelve months in the intervention group, compared to no change in the control group. Lastly, following each session, the WOMACS questionnaire and ROM measurement were completed. Swedish massage reduced pain, stiffness, and function over a fifteen days period. Although the underlying mechanism of massage is not well understood, proponents of massage propose that pressure applied in deep kneading or stroking along the length of a muscle tendon encourages venous, lymphatic, and tissue drainage. In addition, the removal of metabolic waste enhances homeostasis and reduces pain.

## SUMMARY

The three, seven and fifteenth day follow-up each shows an improvement over baseline due to Swedish massage intervention therapy. While both the 7th and 15thday showed improvement over the baseline. There was no improvement between the 7th and 15thday period of time.

Figure 3A, seen below, is the 7th day median WOMACS graph indicating changes, joint stiffness gave the highest responsiveness from baseline to 3rd day and baseline to 7th , followed by physical function then, global WOMACS and pain were equal as compared to no change in the median control group's WOMACS results in 3B below.

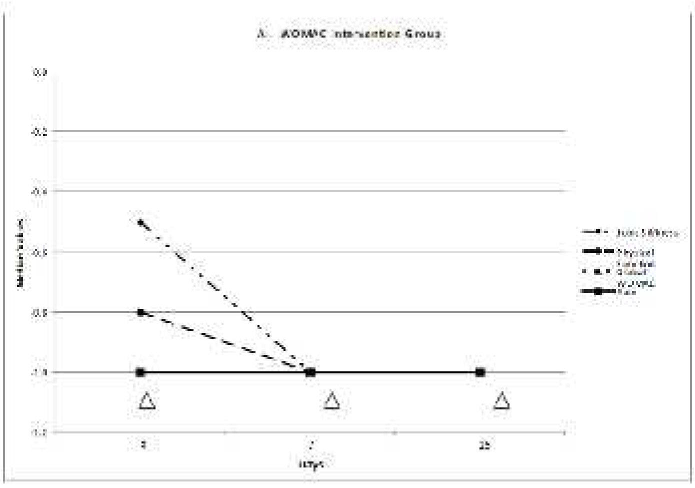



**Figure 3A: WOMAC Median Difference by Treatment Period for Intervention Group**

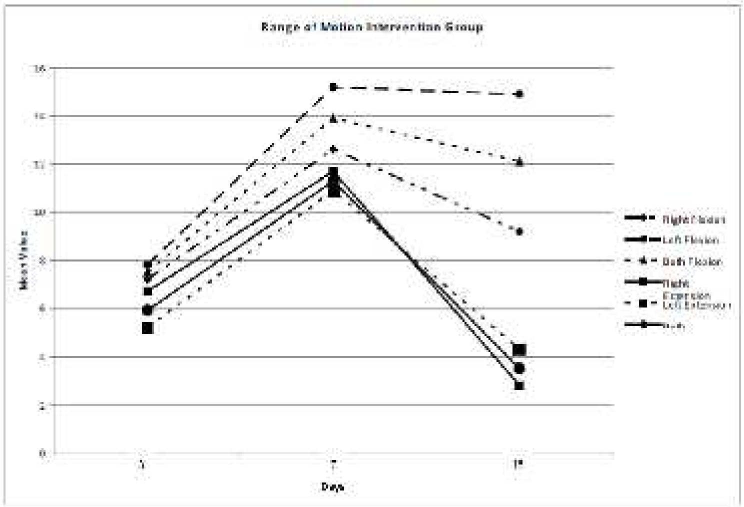



**Figure 4A: ROM Mean Difference by Treatment Period for Intervention Group**

In Figure 4A while this study did not have scientific data to compare flexion to extension of right, left and both knees, it appears that flexion of right, left and both knees demonstrated continued improvement over the extension of right, left and both knees during the 15th day study. Extension decline, while still improved over baseline, reflected the possible direct relationship between SMT of the quadriceps muscle performed during the first seven days of Swedish massage theraphy. The 15 day follow-up of range of motion also shows an improvement as compared to baseline, but is not improved compared to the seven day follow-up. The control group showed no significant changes, patterns are similar and declining.

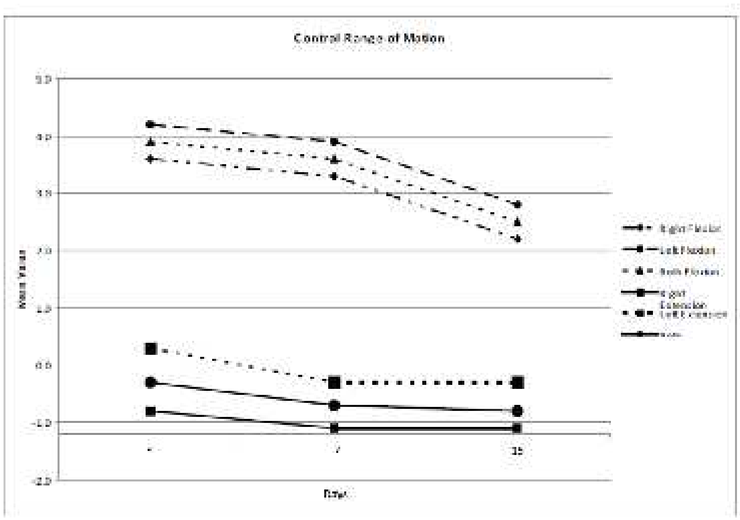



**Figure 4B: ROM Mean-Value by Treatment Period for Control Group**

Although the graphs reflect no improvement after the three days intervention, research has documented that mutipledoses have a significant effect for delayed assessment of pain, especially when massage is applied over a course of treatment. Patients who were assessed days after treatment ended exhibited continued lower levels of pain.

## Implications for Application

This study contributes to an emerging evidence-based massage research category of Swedish massage. This category of massage is patient-centered, benefiting patients who are seeking ongoing solutions for chronic symptoms related to knee OA. The researcher presented evidence-based CAM, mind-body self-care therapies (i.e. yoga, massage, prayer, and T'ai Chi) for OA management. Osteoarthritis researchers predict that the prevalence of OA will increase as the population ages and that the need for economical, participatory therapies aimed at managing the pain and disability caused by loss of joint mobility will also increase. This research study presented evidence-based results that the quadriceps muscle may be a causative factor in the pathogenesis of knee OA. This study provides significant evidence that the application of Swedish massage may have important implications for future research, particularly in terms of managing pain and dysfunction; and affecting knee ROM of knee OA. Moreover, this research showed that massage on the quadriceps muscle may significantly affect the pain, stiffness, physical function and knee range of motion caused by OA of the knee.

## Implications for Future Research

Given the challenges of a healthcare system that focuses on managing physical disease with drugs, surgery and expensive technologies, the optimal healing environments (OHE) solution is to foster health programs that support lifestyle modification and chronic disease management.

Future research with larger samples is needed to determine the efficacy and effectiveness of Swedish massage in the general population.

Future researchers should also test the replicability of this study's findings with other populations, such as people with OA of the ankle or hand.

Long-term follow-up studies of self-massage for knee OA to assess adherence, use of medication, and disease progression are also needed. Moreover, the assessment of the long-term benefits of Swedish massage may lead to its inclusion in clinical guidelines as a safe and therapeutic therapy for the nonpharmacological management of knee OA.

Equally important, Swedish massage may be considered a mind-body or CAM therapy; as such, future explorations of its clinical application and use with other interventions are warranted. Finally, future studies may also investigate the challenges and solutions presented in this work reflecting the trends in OA management, which favors minimally supervised or patient-centered care protocols to examine the efficacy and effectiveness of massage and other adjunct therapies such as exercise or yoga.

# CONCLUSION

This study aimed to understand the effect of massage on pain in patients with osteoarthritis of knee. Though there was not much difference between seventh and fifteenth day there was significant result after intervention.With the above results it can be said that massage can be used as an adjuvant therapy in reducing pain. Also it has effect on increasing range of motion.

The study results showed that participants who have OA of the knee may benefit from the Swedish massage intervention therapy and consistent massage therapy may equate to more improved results. Further studies are needed to clarify the long-term effects of Swedish-massage on the progression and symptoms of OA of the knee.

# REFERENCES


1. Buckwalter JA, Saltzman C, Brown T: The impact of osteoarthritis:implications for research. *Clin Orthop Relat Res 2004:S6-15.*

2. Hand out on Health: osteoarthritis.www.niams.nih.gov.com.

3. Samuel L, Turek's. Orthopaedics, Principles and their application, J.B Lippincott Company, 4th Edition, Vol.1:484.

4. Felson D. Osteoarthritis. Rheum Dis Clin North America 1990; 16: 499 – 512.

5. Lohmander LS, Gerhardsson d V, Rollof J, Nilsson PM, Engstrom G:Incidence of severe knee and hip osteoarthritis in relation to different measures of body mass: a population-based prospective cohort study. *Ann Rheum Dis 2009, 68:490-496.*

6. Meenakshi Sinha ,'30-plus more prone to osteoarthritis now', TNN Sep 22, 2009.

7. Gov US national Library of Medicine, National Institutes of Health, Journal of Korean Academy of Nursing 2011 Dec; 41(6):821-33.

8. Jacobs M. Massage for the relief of pain: anatomical and physiological considerations. Physical Therapy Review 1960; 40:93-8.

9. Kutner JS, Smith MC, Corbin L, Hemphill L, Benton K, Mellis BK, Beaty B, Felton S, Yamashita TE, Bryant LL, Fairclough DL: Massage therapy

versus simple touch to improve pain and mood in patients with advanced cancer: a randomized trial. Ann Intern Med 2008, 149:369–379.

10. Wentworth LJ, Briese LJ, Timimi FK, Sanvick CL, Bartel DC, et al. (2009)Massage therapy reduces tension, anxiety, and pain in patients awaiting invasive cardiovascular procedures. Progress in Cardiovascular Nursing 24: 155–161.

11. Frey Law LA, Evans S, Knudtson J, Nus S, Scholl K, et al. (2008) Massage reduces pain perception and hyperalgesia in experimental muscle pain: a randomized, controlled trial. Journal of Pain 9: 714–721.

# COPYRIGHT

## DECLARATION BY THE CANDIDATE

I hereby declare that the Dr. M. G. R. Medical University, Tamilnadu shall have the rights to preserve, use and disseminate this Dissertation / Thesis in print or electronic format for academic / research purpose.

Place: Chennai

Signature of the candidate,

Date:

Dr.R.ARUNTHATHI

**MSG – OAK trial** **REGISTRATION FROM** **CRF - 001**

Screening ID No: Participant initials: ______

Date of visit (dd/mm/yyyy): ___ / ___ /______

Gender: 1. Female 2. Male ☐ Age in years: ☐☐

Date of birth (dd/mm/yyyy): ___ /___ /______

**SECTION 1: ELIGIBLITY CRITERIA**

**1.1 INCLUSION CRITERIA:**

| | |
|---|---|
| 1. Have you obtained written informed consent from the participant? | 1 – yes ☐ if yes, date of consent<br>2 – no ----/----/------- |
| 2. Is the patient 40yrs – 60yrs. | 1 – yes<br>2 – no |
| 3. Does the patient have pain in the knee?<br>(If yes, three from the following five question must be **yes**) | 1 – yes ☐<br>2 – no |
| 3.1 Is morning stiffness present? | 1 – yes ☐ if yes, go to 3.1.1<br>2 – no |
| 3.1.1 Tick that applies | a. Morning stiffness < 30 mins ☐<br>b. Difficulty raising from bed ☐<br>c. Is stiffness occurring later in the day<br>1.yes ☐ 2. No ☐ |
| 3.2 Is crepitus present on active motion? | 1 – yes ☐<br>2 – no |
| 3.3 Is bony tenderness present on palpation? | 1 – yes ☐<br>2 – no |
| 3.4 Is bony enlargement present on examination? | 1 – yes ☐<br>2 – no |
| 3.5 Is palpable warmth of synovium present? | 1 – yes ☐<br>2 – no |
| 4. Is the patient willing and able to attend all the session of the hospital based program? | 1 – yes ☐<br>2 – no |

If answer to any of the four question (1, 2, 3, 4) is **NO**, then the patient is **not eligible**.

**1.2 EXCLUSION CRITERIA**

| | |
|---|---|
| 1. Does the patient currently participating in any other clinical trial in the same hospital or other site? | 1 – yes ☐<br>2 – no |
| 2. Does the patient have any of the following conditions or other medical conditions that would prevent the participant completing the trial follow up duration?<br>Endoprothetic replacement of hip or knee joint<br>Deep vein thrombosis<br>Heart failure and myocardial ischemia<br>Epilepsy | 1 – yes ☐<br>2 – no |

INVESTIGATORS SIGNATURE DATE ---- /---- /--------

**MSG – OAK TRIAL** **BASELINE ASSESSMENT** **CRF – 002**

Participant ID: Participant Initials: __________

Date of assessment: ___ /___ /______

**SECTION 1: CONTACT DETAILS**

| | |
|---|---|
| 1. Name of the participant | |
| 2. Address<br>Street<br>Postal code<br>Landmark | |
| 3. Telephone number | Home ________________________<br>Mobile ________________________ |
| 4. E – Mail ID | |
| 5. What is your marital status? | Single – 1 Married – 2 Widow / widower – 3 separated / divorced – 4 others – 5 _____________ |

**SECTION 2: DEMOGRAPHICS**

| | | |
|---|---|---|
| 6. Patient's highest educational qualification | None - 1<br>Primary school – 2<br>Secondary school – 3<br>Undergraduate – 4<br>Postgraduate – 5<br>Technical / vocational - 6 | ☐ |
| 7. Employment Status | Employed – 1<br>Unemployed , home duties – 2<br>Retired - 3 | ☐ |
| 8. Occupation<br>If employed indicate resent work classification else, indicate past / lifetime work classification, if any | 1. Professional, big business, landlord, university teacher, class 1 IAS / services officer, lawyer<br>2. Trained, clerical, medium business owner, staff manager, mid – level farmer, teacher<br>3. skilled manual laborer, small business owner, small farmer<br>4. semi – skilled manual laborer, marginal landowner, rickshaw driver, carpenter , fitter<br>5. unskilled, manual labourer, landless labourer<br>6. homemaker<br>7. retired<br>8. unemployed | ☐ |
| 9. Number of members in the household | Adult<br><br>Children | ☐<br>☐ |
| 10. Distance between the clinical site and house of residence (approximately) | In kilometres | ☐ |

**SECTION 3: MEDICAL HISTORY**

| | |
|---|---|
| 1. Did you have any increase in weight within past 1-5yrs? | 1 – yes<br>2 - no ☐ |
| 2. Did you have frequent knee injuries? | 1 – yes<br>2 - no ☐ |

| | |
|---|---|
| 3. How many minutes you kneel or squat in a day? | 1 - < than one hour<br>2 - > than one hour ☐ |
| 4. How often did you take pain killers in the past one year? | 1 – none<br>2 – monthly once ☐<br>3 – weekly once<br>4 - daily |

**SECTION 4: CLINICAL FEATURES**

| | |
|---|---|
| **VITAL SIGNS** | |
| 1.Blood pressure (mm Hg) | |
| 2. Pulse rate (beats / min) | |
| **ANTHROPOMETRIC MEASUREMENTS** | |
| 1.Height (in cms) | |
| 2. Weight (in kg) | |
| 3. BMI | |

**SECTION 5: WOMAC QUESTIONAIRE**

**Pain**

1. Walking 0 1 2 3 4
2. Stair Climbing 0 1 2 3 4
3. Nocturnal 0 1 2 3 4
4. Rest 0 1 2 3 4
5. Weight bearing 0 1 2 3 4

**Stiffness**

1. Morning stiffness 0 1 2 3 4
2. Stiffness occurring later in the day 0 1 2 3 4

**Physical Function**

1. Descending stairs 0 1 2 3 4
2. Ascending stairs 0 1 2 3 4
3. Rising from sitting 0 1 2 3 4
4. Standing 0 1 2 3 4
5. Bending to floor 0 1 2 3 4
6. Walking on flat surface 0 1 2 3 4
7. Getting in / out of car 0 1 2 3 4
8. Going shopping 0 1 2 3 4
9. Putting on socks 0 1 2 3 4
10. Lying in bed 0 1 2 3 4
11. Taking off socks 0 1 2 3 4
12. Rising from bed 0 1 2 3 4
13. Getting in/out of bath 0 1 2 3 4
14. Sitting 0 1 2 3 4
15. Getting on/off toilet 0 1 2 3 4
16. Heavy domestic duties 0 1 2 3 4
17. Light domestic duties 0 1 2 3 4 Total Score: ______ / 96 = _______%

**SECTION 6: RANGE OF MOTION**

| | |
|---|---|
| 1.Right knee | |
| 2.Left knee | |

INVESTIGATOR'S SIGNATURE DATE ____ /____ /_______

MSG – OAK TRIAL **POST- INTERVENTION FOLLOW UP – 3RD DAY** CRF – 003

Participant ID: Participant Initials: __________

Date of assessment: ___ /___ /______

**STATUS OF THE PATIENT**

1. Data obtained yes☐ No ☐

**SECTION 1:**

1. Tick all that applies.
   - Pain increased ☐
   - Difficulty in walking ☐
   - Other serious adverse events ☐

**SECTION 2: CLINICAL FEATURES**

| | |
|---|---|
| **VITAL SIGNS** | |
| 1.Blood pressure (mm Hg) | |
| 2. Pulse rate (beats / min) | |
| **ANTHROPOMETRIC MEASUREMENTS** | |
| 1.Height (in cms) | |
| 2. Weight (in kg) | |
| 3. BMI | |

**SECTION 5: WOMAC QUESTIONAIRE**

**Pain**

1. Walking 0 1 2 3 4
2. Stair Climbing 0 1 2 3 4
3. Nocturnal 0 1 2 3 4
4. Rest 0 1 2 3 4
5. Weight bearing 0 1 2 3 4

**Stiffness**

1. Morning stiffness 0 1 2 3 4
2. Stiffness occurring later in the day 0 1 2 3 4

**Physical Function**

1. Descending stairs 0 1 2 3 4
2. Ascending stairs 0 1 2 3 4
3. Rising from sitting 0 1 2 3 4
4. Standing 0 1 2 3 4
5. Bending to floor 0 1 2 3 4
6. Walking on flat surface 0 1 2 3 4
7. Getting in / out of car 0 1 2 3 4
8. Going shopping 0 1 2 3 4
9. Putting on socks 0 1 2 3 4
10. Lying in bed 0 1 2 3 4
11. Taking off socks 0 1 2 3 4
12. Rising from bed 0 1 2 3 4
13. Getting in/out of bath 0 1 2 3 4
14. Sitting 0 1 2 3 4
15. Getting on/off toilet 0 1 2 3 4
16. Heavy domestic duties 0 1 2 3 4
17. Light domestic duties 0 1 2 3 4 Total Score: ______ / 96 = _______%

**SECTION 6: RANGE OF MOTION**

| | |
|---|---|
| 1.Right knee | |
| 2.Left knee | |

INVESTIGATOR'S SIGNATURE DATE ____ /____ /_______

MSG – OAK TRIAL **POST- INTERVENTION FOLLOW UP – 7TH DAY** CRF – 004

Participant ID: Participant Initials: __________

Date of assessment: ___ /___ /______

**STATUS OF THE PATIENT**

1. Data obtained yes☐ No ☐

**SECTION 1:**

| |
|---|
| 1. Tick all that applies.<br>Pain increased ☐<br>Difficulty in walking ☐<br>Other serious adverse events ☐ |

**SECTION 2: CLINICAL FEATURES**

| | |
|---|---|
| **VITAL SIGNS** | |
| 1.Blood pressure (mm Hg) | |
| 2. Pulse rate (beats / min) | |
| **ANTHROPOMETRIC MEASUREMENTS** | |
| 1.Height (in cms) | |
| 2. Weight (in kg) | |
| 3. BMI | |

**SECTION 5: WOMAC QUESTIONAIRE**

**Pain**

1. Walking 0 1 2 3 4
2. Stair Climbing 0 1 2 3 4
3. Nocturnal 0 1 2 3 4
4. Rest 0 1 2 3 4
5. Weight bearing 0 1 2 3 4

**Stiffness**

1. Morning stiffness 0 1 2 3 4
2. Stiffness occurring later in the day 0 1 2 3 4

**Physical Function**

1. Descending stairs 0 1 2 3 4
2. Ascending stairs 0 1 2 3 4
3. Rising from sitting 0 1 2 3 4
4. Standing 0 1 2 3 4
5. Bending to floor 0 1 2 3 4
6. Walking on flat surface 0 1 2 3 4
7. Getting in / out of car 0 1 2 3 4
8. Going shopping 0 1 2 3 4
9. Putting on socks 0 1 2 3 4
10. Lying in bed 0 1 2 3 4
11. Taking off socks 0 1 2 3 4
12. Rising from bed 0 1 2 3 4
13. Getting in/out of bath 0 1 2 3 4
14. Sitting 0 1 2 3 4
15. Getting on/off toilet 0 1 2 3 4
16. Heavy domestic duties 0 1 2 3 4
17. Light domestic duties 0 1 2 3 4 Total Score: ______ / 96 = _______%

**SECTION 6: RANGE OF MOTION**

| | |
|---|---|
| 1.Right knee | |
| 2.Left knee | |

INVESTIGATOR’S SIGNATURE DATE ____ /____ /_______

MSG – OAK TRIAL **POST- INTERVENTION FOLLOW UP – 15TH DAY** CRF – 005

Participant ID: Participant Initials: __________

Date of assessment: ___ /___ /______

**STATUS OF THE PATIENT**

1. Data obtained yes☐ No ☐

**SECTION 1:**

1. Tick all that applies.
   - Pain increased ☐
   - Difficulty in walking ☐
   - Other serious adverse events ☐

**SECTION 2: CLINICAL FEATURES**

| | |
|---|---|
| **VITAL SIGNS** | |
| 1.Blood pressure (mm Hg) | |
| 2. Pulse rate (beats / min) | |
| **ANTHROPOMETRIC MEASUREMENTS** | |
| 1.Height (in cms) | |
| 2. Weight (in kg) | |
| 3. BMI | |

**SECTION 5: WOMAC QUESTIONAIRE**

**Pain**

1. Walking 0 1 2 3 4
2. Stair Climbing 0 1 2 3 4
3. Nocturnal 0 1 2 3 4
4. Rest 0 1 2 3 4
5. Weight bearing 0 1 2 3 4

**Stiffness**

1. Morning stiffness 0 1 2 3 4
2. Stiffness occurring later in the day 0 1 2 3 4

**Physical Function**

1. Descending stairs 0 1 2 3 4
2. Ascending stairs 0 1 2 3 4
3. Rising from sitting 0 1 2 3 4
4. Standing 0 1 2 3 4
5. Bending to floor 0 1 2 3 4
6. Walking on flat surface 0 1 2 3 4
7. Getting in / out of car 0 1 2 3 4
8. Going shopping 0 1 2 3 4
9. Putting on socks 0 1 2 3 4
10. Lying in bed 0 1 2 3 4
11. Taking off socks 0 1 2 3 4
12. Rising from bed 0 1 2 3 4
13. Getting in/out of bath 0 1 2 3 4
14. Sitting 0 1 2 3 4
15. Getting on/off toilet 0 1 2 3 4
16. Heavy domestic duties 0 1 2 3 4
17. Light domestic duties 0 1 2 3 4 Total Score: ______ / 96 = _______%

**SECTION 6: RANGE OF MOTION**

| | |
|---|---|
| 1.Right knee | |
| 2.Left knee | |

INVESTIGATOR'S SIGNATURE DATE ____ /____ /_______

# INFORMATION SHEET

We are conducting a study **"Efficacy of massage therapy on pain in patients with osteoarthritis of knee: A randomized controlled clinical trial"**

The purpose of this study is to evaluate the effectiveness of massage therapy on reducing pain in patients with osteoarthritis in comparison to control group.

We need your participation in this study. Here we are assessing pain, quality of life, and range of movements.

The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss or benefit to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of investigator                                        Signature of participant

Date:

# INFORMED CONSENT FORM

**Title of the study: "Efficacy of massage therapy on pain in patients with osteoarthritis of knee: A randomized controlled clinical trial"**

**Name of the Participant:**

**Name of the Principal Investigator:** Dr.R.ARUNTHATHI.

**Name of the Institution:**

Government Yoga & Naturopathy Medical College, Chennai – 600 106

**Documentation of the informed consent**

I ______________________________ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in **"Efficacy of massage therapy on pain in patients with osteoarthritis of knee: A randomized controlled clinical trial"**

1. I have read and understood this consent form and the information provided to me.

2. I have had the consent document explained to me.
3. I have been explained about the nature of the study.
4. I have been explained about my rights and responsibilities by the investigator.

5. I have been informed the investigator of all the treatments I am taking or have taken in the past ________ months including any native (alternative) treatment.

6. I have been advised about the risks associated with my participation in this study.

7. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.

8. I have not participated in any research study within the past _________month(s).

9. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.

10. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent.

12. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.

13. I have understood that my identity will be kept confidential if my data are publicly presented.

14. I have had my questions answered to my satisfaction.
15. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

**For adult participants:**

**Name and signature / thumb impression of the participant (or legal representative if participant incompetent**)

Name ___________________________ Signature__________________

Date_________________

**Name and Signature of impartial witness (required for illiterate patients):**

Name ___________________________ Signature__________________

Date_________________

Address and contact number of the impartial witness:

**Name and Signature of the investigator or his representative obtaining consent:**

Name ___________________________ Signature__________________

Date_________________

## INFORMATION TO PARTICIPANTS

**Investigator: Dr.R.ARUNTHATHI..**

**Name of Participant:**

**Title: “Efficacy of massage therapy on pain in patients with osteoarthritis of knee: A randomized controlled clinical trial”**

You are invited to take part in this research/ study /procedures. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns. You are being asked to participate in this study being conducted in Government Yoga & Naturopathy Medical College, Chennai – 600 106

**What is the Purpose of the Research?**

Osteoarthritis being an degenerative disease is the most common form of arthritis. Over time, the joint may lose its normal shape. This causes more pain and damage. People with osteoarthritis usually have joint pain and stiffness. As per World health Organization Osteoarthritis is the fourth leading cause of death. Massage therapy seems to be effective in reducing pain and improves the quality of life in patients with osteoarthritis.

**The Study Design**

Randomized controlled trial.

**Study Procedures**

Swedish massage of 25–30 min daily for15 days.

**Possible Risks to you - nil**

**Possible benefits to you**

Early diagnosis with intervention will be given.

**Possible benefits to other people**

The result of the research may provide benefits to the society in terms of advancement of medical knowledge and/or therapeutic benefits to future patients.

**Confidentiality of the information obtained from you**

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examinations, investigations, and your medical history). By signing this document, you will be allowing the research team investigators, other study personnel, sponsors, IEC and any person or agency required by law like the Drug Controller General of India to view your data, if required.

The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

**How will your decision to not participate in the study affect you?**

Your decisions to not to participate in this research study will not affect your medical care or your relationship with investigator or the institution. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

**Can you decide to stop participating in the study once you start?**

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during course of the study without giving any reasons.

However, it is advisable that you talk to the research team prior to stopping the treatment.

## **ஆராயசசி ஒபபுதல படிவய**

***ஆயவு தலைபபு:***

“மூடடு வாத நோயானால ஏறபடுய வலிககு மசாஜ சிகிசசையால நனமைகள குறிதத மருததுவ ஆராயசசி”

*ஆராயசசியாளர பெயர்:* மரு. அருநததி.ர.

*ஆராயசசி நடககுய இடய:*இயறகை மருததுவததுறை, அரசு யோகா மறறுய இயறகை மருததுவக கலலூரி, அருயபாககய, செனனை –106

*பஙகுபெறுபவரின பெயர்:* *வயது:*

*பாலினய:* ஆண / பெண

*பஙகுபெறுபவரின அடையாள எண:*

இநத ஆராயசசியின விவரஙகளுய அதன நோககமுய முழுமையாக தெளிவாக எனககு விளககபபடடது. எனககு விளககபபடட தகவலகளை புரிநதுகொணடு நான எனது சயமதததைத தெரிவிககிறேன.

நான இவவாராயசசியில பஙகுபெறவுய, ஆராயசசிககு தேவையான அனைததுபரிசோதனை மேறகொளளவுய முழுசயமதய தெரிவிககிறேன.

இநத ஆராயசசியில இருநதுநான எநதநேரமுய விலகலாய எனறுய அதனால எநதபாதிபபுய ஏறபடாது எனபதையுய புரிநதுகொணடேன.

நான எனனுடைய சுயநினைவுடனுய முழுசயமதததுடனுய இநத ஆராயசசியில பஙகேறகக சயமதிககிறேன.

*ஆராயசசியாளர கையொபபய* *பஙகுபெறுபவர்கையொபபய /*

*இடதுகைபெருவிரலரேகை*

*தேதி :* *தேதி :*

# ஆராயசசி தகவலப தாளா

ஆயவு தலைபபு :

“மூடடு வாத நோயானாலப ஏறபடுய வலிககு மசாஜ சிகிசசையாலா நலாமைகளா குறிதத மருததுவ ஆராயசசி”

ஆயவாலா நோககய:

மூடடு வலியை குறைபபதிலப மசாஜ சிகிசசையாலா செயலபதிறனை கலாடறியுய ஓரு மருததுவ ஆயவு.

தஙகளாலா வலியாலா தவாரய, மூடடுஇயககததிலா வரசா, வாழககை தரய முதலியன மதிபபடுசெயதபபாலானரு ஆராயசசிககு உடபடுததபபடுவாரகளா.

உஙகளா அனைதது தகவலபகளாலாஇரகசியய பாதுகாககபபடுய.தஙகளாபெயரையோஅடையாளஙகளையோமுலா அனுமதியாலபலாமலப வெளயிடமாடடோயஎலாபதையுயதெரிவததுககொளாகிறோய.

இநத ஆயவலப பஙகுகொளாவது தஙகளாலா தனாபபடடவிருபபமாகுய. மேலுயநஙகளாஇநதஆராயசசியாலபஇருநதுஎநதநேரமுயபாலாவாஙகலாயஎலாபதைதெரிவா ததுகொளாகிறோய.

இதனாலப நஙகளா பெருய மருததுவ சிகிசசையாலப எலபவாத குறைவோ அலபலது உஙகளை எலபவாததிலோ பாதிககாது எலாறு உறுதி அளாககிலாறோய.

*ஆராயசசியாளரகையொபபய* *பஙகுபெறுபவர கையொபபய /*

*இடதுகைபெருவிரலபரேகை*

தேதி :

தேதி :

**The WOMAC (Western Ontario and McMaster Universities) Index of Osteoarthritis**

Overview:

The WOMAC (Westren Ontario and McMaster Universities) index is used to assess patients with osteoarthritis of the hip or knee using 24 parameters. It can be used to monitor the course of the disease or to determine the effectiveness of anti-rheumatic medications.

Pain:

(1) walking

(2) stair climbing

(3) nocturnal

(4) rest

(5) weight bearing

Stiffness:

(1) morning stiffness

(2) stiffness occurring later in the day

Physical function:

(1) descending stairs

(2) ascending stairs

(3) rising from sitting

(4) standing

(5) bending to floor

(6) walking on flat

(7) getting in or out of car

(8) going shopping

(9) putting on socks

(10) rising from bed

(11) taking off socks

(12) lying in bed

(13) sitting

(14) sitting

(15) getting on or off toilet

(16) heavy domestic duties

(17) light domestic duties

While the index was being developed performance of social functions and the status of emotional function were also included. These were not included in the final instrument.

Social function:

(1) leisure activities

(2) community events

(3) church attendance

(4) with spouse

(5) with family

(6) with friends

(7) with others

Emotional function:

(1) anxiety

(2) irritability

(3) frustration

(4) depression

(5) relaxation

(6) insomnia

(7) boredom

(8) loneliness

(9) stress

(10) well-being

Scoring and Interpretation

| **Response** | **Points** |
|---|---|
| none | 0 |
| slight | 1 |

| | |
|---|---|
| moderate | 2 |
| severe | 3 |
| extreme | 4 |

Alternatively a visual analogue scale (VAS) may be used ranging from 0 to 10.

score =

= SUM(points for relevant items)

average score =

= (total score) / (number of items)

Interpretation:

• minimum total score: 0

• maximum total score: 96

• minimum pain subscore: 0

• maximum pain subscore: 20

• minimum stiffness subscore: 0

• maximum stiffness subscore: 8

• minimum physical function subscore: 0

• maximum physical function subscore: 68

References:

Bellamy N Buchanan WW et al. Validation study of WOMAC: A health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. J Rheumatol. 1988; 15: 1833-1840.

Bellamy N. Pain assessment in osteoarthritis: Experience with the WOMAC osteoarthritis index. Semin Arthritis Rheumatism. 1989; 18 (supplement 2): 14-17.

Bellamy N Kean WF et al. Double blind randomized controlled trial of sodium meclofenamate (Meclomen) and diclofenac soidum (Voltaren): Post validation reapplication of the WOMAC osteoarthritis index. J Rheumatol. 1992; 19: 153-159.

Hawker G Melfi C et al. Comparison of a generic (SF-36) and a disease specific (WOMAC) instrument in the measurement of outcomes after knee replacement surgery. J Rheumatol. 1995; 22: 1193-1196.

Lequesne M. Indices of severity and disease activity for osteoarthritis. Seminars in Arthritis and Rheumatism. 1991; 20 (supplement 2): 48-54.

Stucki G Sangha O et al. Comparison of WOMAC (Western Ontario and McMaster Universities) osteoarthritis index and a self-report format of the self-administered Lequesne-Algofunctional index in patients with knee and hip osteoarthritis. Osteoarthritis and Cartilage. 1998; 6: 79-86.