# COMPARATIVE EFFICACY OF SIX-WEEK SELF-MANAGEMENT EDUCATION AND QUADRICEPS STRENGTHENING PROGRAMMES ON PAIN, PHYSICAL FUNCTION, AND QUALITY OF LIFE OF INDIVIDUALS WITH KNEE OSTEOARTHRITIS

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# COMPARATIVE EFFICACY OF SIX-WEEK SELF-MANAGEMENT EDUCATION AND QUADRICEPS STRENGTHENING PROGRAMMES ON PAIN, PHYSICAL FUNCTION, AND QUALITY OF LIFE OF INDIVIDUALS WITH KNEE OSTEOARTHRITIS

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## CERTIFICATION

We certify that this research work was carried out by Mrs Funmilayo Roseline Egwu, in the Department of Physiotherapy, College of Medicine, University of Ibadan, Nigeria, under our supervision.

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## DEDICATION

This thesis is dedicated to my husband and children without whose support I would have abandoned this work.

## ABSTRACT

Osteoarthritis (OA) of the knee is a common musculoskeletal disorder accompanied by pain, functional disability and reduced quality of life. Self-Management Education (SME) and Quadriceps Strengthening Exercises (QSE) have separately been shown to be effective in the management of knee OA. However, it is not clear which of the two techniques is more effective in alleviating pain and improving physical function and Health-Related Quality of Life (HRQoL) associated with knee OA. This study was carried out to compare the efficacy of SME and QSE on pain, physical function and HRQoL of individuals with knee OA.

Seventy-nine (male =13; female =66) individuals with confirmed knee OA participated in this single-blind randomised trial. Participants were consecutively recruited from the outpatient physiotherapy clinic of Barau Dikko Specialist Hospital, Kaduna,and randomly assigned into either the Self-Management Education Group (SMEG; n=42) or the Quadriceps Strengthening Exercise Group (QSEG; n=37). The SMEG had self-management education class (health education on OA, pain management strategies, coping skills for OA and weight control exercises) once weekly for six weeks and they kept a diary of adherence to exercise instructions. The QSEG had quadriceps strengthening exercises thrice weekly for six weeks. Participants' ages were recorded. Other variables: Physical Function (PF), Pain Intensity (PI) and Health-Related Quality of Life (HRQoL), were assessed using the Ibadan Knee/Hip Osteoarthritis Measure (IKHOAM), Visual Analogue Scale (VAS), and Arthritis Impact Measurement Scale Short Form 2 [AIMS-2 (SF)] respectively. Comfortable Pace Walking Time (CPWT) and Fast Pace Walking Time (FPWT) of participants were also measured using a stopwatch. Assessment was carried out at baseline, end of week six and at first, second and third month follow-up. Data were analysed using descriptive statistics, Student t-test and multilevel modelling at $\alpha_{0.05}$.

The ages of participants in the SMEG (53.9±10.4 years) and QSEG (50.1±10.2 years) were comparable. At baseline, no significant between-group difference was observed in PF, PI and HRQoL scores but the SMEG had significantly lower CPWT (14.53±0.24s vs 13.76±0.26s) and FPWT (13.76±0.26s vs 11.52±0.27s). At end of week six, the QSEG had significantly lower PI (2.9±0.3) than the SMEG (3.9±0.3), but the groups were not significantly different in PF (84.3±1.8 vs 88.3±1.9), HRQoL

(21.4±0.7 vs 20.0±0.7), CPWT (12.28±0.25s vs 12.26±0.27s) and FPWT (9.45±0.28s vs 9.08±0.30s). The two groups were not significantly different in all outcomes at first, second and third month follow-up. There was significant within group reduction in PI, increase in PF score and reduction in HRQoL between baseline and the end of the study (3rd month follow- up) for both SMEG and QSEG (PI - 3.8 (0.3) and -2.9 (0.3); PF 11.0 (1.2) and 6.8 (1.4); and HRQoL -2.1 (0.6) and -1.5 (0.7) respectively).

Quadriceps strengthening exercises were more effective in alleviating osteoarthritic knee pain. Self-management education and quadriceps strengthening exercises equally improved physical function and health-related quality of life of individuals with knee osteoarthritis.

**Keywords:** Knee osteoarthritis, Self-management education, Quadriceps strengthening exercises

**Word Count:** 471

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# CHAPTER ONE

# INTRODUCTION

## 1.1 Introduction

Osteoarthritis (OA) is the most common type of arthritis.It is characterised by slow degradation of cartilage, pain, and increasing chronic disability. Osteoarthritis is a frequent cause of morbidity, functional limitations, and loss of autonomy in the second half of human life (Douglas et al, 2008; Cubukcu et al, 2012). Epidemiological studies have been based on radiological evidence (Cooper et al, 2000), clinical evidence (Altman, 1991) and/or self-reported diagnoses (Thomas et al, 2014) and a modest agreement has been reported among these three methods of diagnosis (Parsons et al, 2015). Knee OA is probably the fourth most important cause of disability in women and the eighth most important cause of disability in men (Murray and Lopez, 1997). Internationally, OA has been estimated to affect 24% of the general population, with symptomatic OA affecting 9.6% of men and 18% of women 60 years and above. Further, 80% of people over 65 years in high-income countries are affected (Teres et al, 2015). The prevalence of knee OA is rising in the adult population of the United States (Nguyen et al, 2011). About 25% of adults aged over 45 years have previously experienced knee pain lasting over a month or had an episode of knee pain in the last year, and the prevalence increases with age. More than 90% of general practitioners manage at least one patient with severe knee pain over a two-week period (Cottrell et al, 2010). Knee OA is reported to be one of the most common forms of OA in black Africa. It is one of the most common causes of pain in the elderly and has a higher prevalence in women than in men (Mijiyawa and Ekoue, 1993; Ndogo et al, 2013). This was demonstrated in a retrospective study of knee OA patients carried out in Togo, in which 82.8% of the studied population were female (Oniankitan et al, 2009).

Currently, there is dearth of publications on the general epidemiology/prevalence of OA in Nigeria, however some community and hospital based studies have been conducted in some geographical sections of the country. Akinpelu et al (2009) investigated the prevalence and pattern of symptomatic knee OA in Igbo-Ora (a rural community in South Western, Nigeria); and found about 19.6 % of the total surveyed population presenting with symptomatic OA of the knee. A similar study carried out in Northeastern Nigeria by Akinpelu and colleagues in 2011 (Akinpelu et al, 2011b)

showed the point prevalence of symptomatic knee OA to be 16.3% while prevalence of 40.1% and 13.5% were recorded for female and male participants respectively. Obese participants (by BMI and % body fat classifications) had significantly more severe knee OA than their counterparts who were overweight or had normal body weight. Akinpelu et al (2007a) had earlier conducted a 3 -year retrospective study to document the number and pattern of OA cases seen in ten secondary and tertiary Physiotherapy facilities in Lagos and Ibadan (two of Nigerian largest cities) between 1999 and 2002; and reported that patients with OA accounted for 8.9% of all (11574) new patients seen in the clinics during the study period. The knee was found to be the most frequently affected joint while female to male prevalence ratio was 3.5:1.

The majority of patients with osteoarthritis are managed in primary care, and the prevalence of knee osteoarthritis is such that simple interventions which are effective in the community setting are necessary (Roddy et al, 2005). Currently there is no known modality for reversing the progression of knee OA, it can only be managed by ameliorating its symptoms. Treatment of osteoarthritis is aimed at reducing pain and disability to improve function and quality of life (Felson et al, 2000; Baker et al, 2001; Lange et al, 2008; Chaipinyo and Orapin, 2009; Bezalel et al, 2010). Treatment guidelines have recommended a combination of pharmacological and non-pharmacological therapies (Zhang et al, 2007; Zhang, 2008 and McAlindon et al, 2014). If these fail, surgical therapy is recommended (Jordan et al, 2003). Pharmacological therapies include: paracetamol, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), and opioid analgesic drugs.

Drug treatments aimed at relieving pain are often limited by side effects. Traditional NSAIDs have been associated with gastro-intestinal side effects such as dyspepsia, gastric ulcer, haemorrhage and, in severe cases, death (Hippisley-Cox et al, 2005). Cyclo-oxygenase-2 (COX2) inhibitors are a selective type of NSAID developed to achieve the same result as traditional NSAIDs without the associated side effects.However, COX2 drugs are not without serious side effects; they have been associated with adverse cardiovascular incidents such as myocardial infarction (Hippisley-Cox and Coupland, 2005).

Paracetamol has been the usual first line recommendation for pharmacological management of OA due to its safety profile (Zhang et al, 2004),however some clinical studies(Towheed et al, 2006) have shown that it is not as effective in reducing pain as NSAIDs. Paracetamol has also been known for its hepatotoxic side effect (Scarpignato et al, 2015). Opioids and tramadol constitute a class of analgesics that have been shown to be moderately effective in reducing osteoarthritic pain, however the risk of adverse side effects outweighs its benefits (Fibel et al, 2015). Furthermore, the evidence supporting disease-modifying OA drugs such as glucosamine and chondrointin are inconclusive or weak and this has contributed to increased interest in non-pharmacologic treatments for OA (Thomas et al, 2002; Farr et al, 2010).

Non-pharmacological approaches to of knee OA managementinclude; education, self-management, exercise, appliances (walking sticks, insoles and knee bracing), acupuncture, telephone contact, physical therapy and weight reduction (Jordan et al, 2003, Zhang et al, 2005; Zhang et al, 2007; Zhang 2008 and McAlindon et al, 2014). There has been remarkable advances in physical therapy modalities and equipment (such as ultrasound, short-wave and micro-wave diathermies, electromyographic biofeedback, interferential current, electrical stimulators, transcutaneous electrical nerve stimulators, and LASER) in the management of OA have been witnessed over the years (Porter, 2003),however these modalities are expensive and hence largely unaffordable in most developing countries, while their treatment effects remain elusive and unsatisfactory from available evidences in literature (Adegoke and Gbeminiyi, 2004; Awotidebe et al, 2011). Modalities such as self-management, education, strengthening and aerobic fitness exercises (land or water based) and weight management have been listed as core aspects of managing OA (NICE, 2008; McAlindon et al, 2014). Following the systematic review of a number of randomized controlled trials, these core modalities have been shown to be appropriate for all individuals with OA irrespective of co-morbidity, severity or age (McAlindon et al, 2014). Futhermore these core modalities could easily be adapted for self care, considering the chronic nature of knee osteoarthritis.

Exercise is considered to be one of the most important treatments for patients with mild to moderate knee osteoarthritis (Altman et al, 2000; Jordan et al, 2003; Roos et al, 2005 andIversen, 2010). It is considered as a core aspect of knee osteoarthritis management (Alnahdi et al, 2012) and positive effects on pain and function, as well as

cost-effectiveness have been reported with this form of treatment (Fransen et al, 2003; Segal et al, 2004 and Iversen, 2010). The relationship between quadriceps muscle strength and pain, physical function and quality of life has been well documented in the literature (Pietrosimone et al, 2010; Pietrosimone et al, 2014; Van der Esch et al, 2014; Anwer and Alghadir, 2014). Quadriceps muscle weakness has been said to increase joint stress due to lesser ability to reduce load across the knee joint and thus may play a role in the aetiology and progression of knee OA (O'Reiley et al, 1999; Anwer and Alghadir, 2014). Based on this premise, a number of therapeutic exercises for knee OA have targeted strengthening the quadriceps muscle and reduction in pain as well as improvement in function and health related quality of life (Juhl et al, 2014) have been reported, hence the consistent recommendation of strengthening exercises in themanagement of knee OA (Zhang et al, 2007; Zhang et al, 2008; Zhang et al 2010; McAllindon et al,2014).

Self-management has become a popular component of management in several chronic conditions including arthritis. Self-Management Education (SME) has been listed alongside therapeutic exercises (resistance training exercise programmes, aerobic exercise programmes) as the mainstay of non-pharmacologic treatment of OA knee (Baker et al, 2001: Lange et al, 2008; Kawasaki et al, 2009 and Bezalel et al, 2010).Self-management programmes aim to achieve more than just the provision of information to increase knowledge, which makes them different from the traditional patient education programmes. They aim to change health behaviour and health status by teaching patients to identify and solve problems, set goals and plan actions (Lorig, 2002).Numerous self-management programmes have been developed for different health conditions. Various models have been employed including individual and group-based programmes that may be disease specific or generic (Warsi et al, 2004). Some researchers have evaluated self- management programmes and reviews and meta-analyses of such studies(Mullen et al, 1987; Supero-Cabuslay et al, 1996) have shown that patient self-management education programmes can significantly improve knowledge, compliance behaviours, and health outcomes; however, the effectiveness differs between programmes and disease states. The systematic review of self-management interventions for a number of chronic diseases by Warsi et al (2004) indicated a trend towards a small benefit from arthritis programmes (Coleman et al, 2008a). The small benefit from self-management education for arthritis programmes was attributed to the design of the programme, which puts all forms of arthritis

together and uses lay tutors to deliver the programme (Coleman et al, 2008). Example of this approach are the Chronic Diseases and Arthritis Self-Management Programmes (ASMP) developed at Stanford University (Lorig et al, 1993 and Lorig et al, 2001). Hence the development of a self-management education programme specific for knee osteoarthritis (Coleman et al, 2008b) and which was found to be effective in reducing pain, disability and improving the health-related quality of life of patients with knee osteoarthritis (Coleman et al, 2008b; Coleman et al, 2012). Disease and joint specific arthritis self-management education programme such as the Osteoarthritis Knee (OAK) programme has been shown to be moderately effective in ameliorating knee osteoarthritis symptoms (Coleman et al, 2012).

Managing the growing population of OA sufferers in the face of decreasing resources has been a challenge to governments, researchers and health care practitioners (WHO, 2002;Imison et al, 2011; Brosseau et al, 2012; Losina et al, 2014) Self- management education has been advocated as the cure-all for managing chronic diseases including arthritis (Hochberg et al, 2012). Despite this, it was concluded from a recent systematic review of self- management that there is little or no benefit on OA (Kroon et al, 2014). The studies reviewed however were not specific for knee OA. However, self-management education programme specifically designed for knee OA has been shown to have moderate beneficial effects on pain, function and health related quality of life of individuals with knee OA (Coleman et al, 2012). The programme was however delivered with just six contacts with the health care professional hence having a relatively low consumption of healthcare resources. Evidence abound on the effectiveness of quadriceps strengthening exercises in reducing pain, and improving function and health related quality of life in individuals with knee OA (McKnigth et al, 2010; Farr et al, 2010; Bennel and Hinman, 2011; Imoto et al, 2012; Pietrosimone, et al, 2014; Anwer and Alghadir, 2014; Knoop et al,2014) hence exercise therapy has been the first line recommendation for non- pharmacological management of knee OA (Fransen et al, 2015). A recent systematic review and meta-analysis of the impact of various types of exercises on pain and disability on knee OA showed that supervised quadriceps specific exercises produce more reduction in pain and improvement in function than generalized lower limb exercise. It was concluded from the meta-analysis that exercise needs to be performed three times a week for optimal benefit and this benefit is regardless of patient characteristic, radiographic severity and baseline pain (Juhl et al, 2014). Thus, there has been no doubt about the effectiveness of

exercise therapy for the management of OA. However, there is a dearth of studies comparing self-management education and quadriceps strengthening exercise, considering that both have been shown to be effective on knee OA though one consumes more health care resources than the other. Thus, one of the interventions appears to be relatively more expensive than the other in terms of cost of hospital attendance (to the patient) and health care resources (to the government). Furthermore, comparing the efficacy of the two interventions is important in the quest to face the challenge of providing optimal care at the least cost possible for knee OA sufferers, in the face of limited resources (Adegoke and Gbeminiyi, 2004; Brosseau et al, 2012). Comparison of these two treatment modalities might give useful evidence on the relative efficacy of both modalities in order to give an informed appraisal on the choice of therapy for patients with knee OA. This study was therefore designed to compare the effect of a self-management education programme and quadriceps strengthening exercises on pain,physical function and health- related quality of life in individuals with knee OA as well as the short term carry over effect.

## 1.2 STATEMENT OF THE PROBLEM

In several guidelines, self-management education and provision of information about OA and its treatment arepart of the recommendations for the treatment of osteoarthritis of the knee (Zhang et al, 2007; Zhang et al, 2008; National Institute of Health and Clinical Excellence (NICE) 2008; Zhang et al 2010). Self-management education (SME) has been documented to produce positive effects on pain, function and health-related quality of life. In spite of this, there appears to be a dearth of published studies on SME for OA in Africa in general and in Nigeria in particular.

Quadriceps Strengthening Exercises (QSE) have also been strongly recommended for the management of knee OA (Zhang 2008; NICE, 2008). Also, nine out of seventeen clinical practice guidelines reviewed by Brosseau et al (2014) recommended strengthening exercises.Strengthening exercises have been shown to improve function, reduce pain and improve health-related quality of life in subjects with knee OA (Roddy et al, 2005, Holden et al, 2008; Fransen and McConnell, 2009). Both SME and QSE have each been shown to be effective treatment modalities in OA management, however there is a dearth of publications on their comparative efficacy. A study comparing SME and strength training showed that both modalities are effective but the

intervention period lasted a long time (9 months), which is not likely to be economically practical in this environment (McKnight 2010).

It is not clear which of these two modalities will produce greater benefits in the management of individuals with knee OA. This study was therefore designed to investigate the comparative efficacy of six weeks of SME and QSE programmes on pain, physical function and quality of life among individuals with knee OA. The study was specifically aimed at answering the following questions:

Will the effects of 6-week self-management education and quadriceps strengthening exercises on pain, physical function and health-related quality of life of individuals with knee osteoarthritis be comparable?

Will the effects of self-management education and quadriceps strengthening exercises on pain intensity, physical function and health-related quality of life of individuals with knee osteoarthritis, be comparable across a three-month follow-up period?

## 1.3 AIMS OF THE STUDY

The aims of this study were to:

1. Investigate and compare the effects of self-management education programme and quadriceps strengthening exercises on pain, physical function and health related quality of life of individuals with knee osteoarthritis.
2. Investigate and compare the carryover effects of self-management education and quadriceps strengthening exercises on pain, physical function and health related quality of life of patients with knee osteoarthritis across a three-month follow-up period.

## 1.4 HYPOTHESIS

### 1.4.1 Major Hypotheses

1. There would be no significant difference between the effects of a 6-week self-management education and 6 weeks of quadriceps strengthening exercises on pain, health-related quality of life, and physical function and walking time at fast and comfortable paces in patients with knee osteoarthritis.

2. There would be no significant difference in the carryover effects of the self-management education and quadriceps strengthening exercise programmes on scores for pain, health related quality of life, physical function and walking time at fast and comfortable paces in patients with knee osteoarthritis over a 3-month follow-up period.

### 1.4.2 Sub Hypotheses

1. There would be no significant difference between the pain intensity (PI) of individuals with knee osteoarthritis in the Self-Management Education Group (SMEG) and Quadriceps Strengthening Exercises Group (QSEG) at baseline, 6th week ofthe intervention phase and atthe1st, 2nd and 3rd month follow-up phase of the study.
2. There would be no significant difference between the health-related quality of life (HRQoL) scores of individuals with knee osteoarthritis in the SMEG and QSEG atbaseline, 6th week of the intervention phase and atthe 1st, 2nd and 3rd month follow-up phase of the study.
3. There would be no significant difference between the physical function (PF) scores of individuals with knee osteoarthritis in the SMEG and QSEG atbaseline, 6th week of the intervention phase and atthe 1st, 2nd and 3rd month follow-up phase of the study.
4. There would be no significant difference between the comfortable pace walking time (CPWT) of individuals with knee osteoarthritis in the SMEG and QSEG at baseline, 6th week of the intervention phase and atthe 1st, 2nd and 3rd month follow-up phase of the study.
5. There would be no significant difference between the fast pace walking time (FPWT) of individuals with knee osteoarthritis in the SMEG and QSEG at baseline, 6th week of the intervention phase andat the 1st, 2nd and 3rd month follow-up phase of the study.
6. There would be no significant difference in the PI of individuals with knee OA in the SMEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2ndand 3rd month follow-up of the study.
7. There would be no significant difference in the HRQoL of individuals with knee OA in the SMEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2ndand 3rd month follow-up of the study.
8. There would be no significant difference in the PF of individuals with knee OA in the SMEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2ndand 3rd month follow-up of the study.

9. There would be no significant difference in the CPWT of individuals with knee OA in the SMEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2ndand 3rd month follow-up of the study.
10. There would be no significant difference in the FPWT of individuals with knee OA in the SMEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2ndand 3rd month follow-up of the study.
11. There would be no significant difference in the PI of individuals with knee OA in the QSEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2ndand 3rd month follow-up of the study.
12. There would be no significant difference in the HRQoL of individuals with knee OA in the QSEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2ndand 3rd month follow-up of the study.
13. There would be no significant difference in the PF of individuals with knee OA in the QSEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2ndand 3rd month follow-up of the study.
14. There would be no significant difference in the CPWT of individuals with knee OA in the QSEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2ndand 3rd month follow-up of the study.
15. There would be no significant difference in the FPWT of patients with knee OA in the QSEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2ndand 3rd month follow-up of the study.

## 1.5 DELIMITATION

This study was delimited as follows:

*Participants*

Individualsdiagnosed with knee OA irrespective of type or severity and residing in Kaduna and its environs.

Individuals with knee OA who are able to perform the physical tests involved in the study.

Individuals with knee OA who understand and read either English or Hausa language.

*Instrument*

Ibadan Knee/ Hip Osteoarthritis Outcome Measure for the assessment of physical function

Visual Analogue Scale (VAS) for assessment of pain intensity.

Arthritis Impact Measurement Scale (short form) (AIMS2 SF) for the assessment of health-related quality of life.

## 1.6 Limitation of study

The researcher was not able to ascertain the extent to which the participants adhered to the instruction that participants should not engage in other vigorous activities such as dancing and excessive walking, jumping, jogging and such like activities during the course; which may cause flare up of the OA symptoms thereby affecting the results. The researcher was also not able to ascertain that there was no interchange of information about the intervention from one group to the other. This may affect the internal validity of the study.

The choice of an index knee for assessment of pain, in participants with bilateral knee OA might have effects on participants' physical function and health-related quality of life and hence threaten the internal validity of the study. Expectedly bilateral knee OA will have more profound influence than unilateral OA on the variables under investigation in this study.

## 1.7 SIGNIFICANCE OF THE STUDY:

1. The outcome of this study could contribute to the formulation of a treatment protocol (guideline) for the management of knee osteoarthritis among Nigerian physiotherapists.
2. This study wouldcontribute to reduction in the patient load on physiotherapists and physiotherapy facilities, since the study showed that a treatment option which involves one contact with the physiotherapist per week is comparatively

as effective as one with three contacts per week on physical function and health-related quality of life.

3. The outcome of this study would make treatment more accessible to patients with knee osteoarthritis who live far away from physiotherapy facilities.
4. The outcome of this study would add to the existing body of knowledge on management of knee osteoarthritis.

## 1.8 DEFINITION OF TERMS

Self-management education: This is an intervention which involves the provision of information to individuals about their condition to improve knowledge, identify and solve problems, set goals and plan actions (Coleman et al, 2012).

Participants: These are people who met the inclusion criteria for the study.

Index knee: the index knee is the worse affected knee in the case of bilateral knee OA

# CHAPTER TWO

# LITERATURE REVIEW

## 2.0 Osteoarthritis of the knee

Osteoarthritis (OA)

Osteoarthritis (OA) is a degenerative disease, considered to be one of the major public health problems (Hannson et al,2010; Cuperus et al, 2013). Itis a type of arthritis that is caused by the breakdown and eventual loss of the cartilage of one or more joints and thus the most common cause of musculoskeletalpain and disability (Felson et al, 2000; Roddy et al, 2004; Zhang et al 2010). Osteoarthritis of the knee is a common condition which contributessignificantly to the burden of physical disability, particularly in the elderly (Creamer et al, 2000; Inje et al, 2010). More disability and clinical symptoms result from OA of the knee than from any other joint (Deyle et al, 2005). The articular cartilage does not contain nerve endings, so cannot generate pain (Doherty, 2002; Porter, 2004); the pain of OA thus arises as an indirect consequence of the damage to the cartilage. The surrounding tissues that have nociceptors give rise to pain when distorted by the presence of osteophytes, the loss of normal joint structures and the development of joint instability (Doherty, 2002).

## 2.1 The knee joint

The knee joint is the largest and possibly the most complex synovial joint in the body. Itis a combination of three articulations; one between the femur and patella and two between the femoral condyles and tibial plateaus (McGinty et al, 2000). It is located between the two longest lever arms of the body and bears the majority of body weight,which exposes the joint to great torques (McGinty et al, 2000). It is primarily a hinge type of synovial joint, allowing flexion and extension; however, the hinge movements are combined with gliding and rolling and with rotation about a vertical axis.Although the knee joint is well constructed, its function is commonly impaired when it is hyperextended (Moore and Dalley, 2006). Also, the supporting bony and soft tissue structure must be able to withstand considerable loads and/or extremely applied torques since the joint allows movement in only one plane (Soderberg, 1997). The stability of the knee joint depends on: (1) the strength and actions of the

surrounding muscles and their tendons and (2) the ligaments that connect the femur and tibia (Moore and Dalley, 2006). The joint is relatively weak mechanically because of the incongruence of its articular surfaces which have been compared to two balls sitting on a warped table top (Moore and Dalley, 2006).

## 2.2 Epidemiology of osteoarthritis

Osteoarthritis (OA) is the commonest form of arthritis and the most common joint disease worldwide (Hogue and Mersfelder, 2002; Thomas et al,2014), with more than 7 million people in the United States affected by the disease (Deyle et al, 2005). Approximately 25% of adults aged over 45 years have previously experienced knee pain lasting over a month or had an episode of knee pain in the last year, and prevalence increases with age. More than 90% of General Practitioners(GPs) manage at least one patient with severe knee pain over a two-week period (Cottrell et al, 2010). Manek and Lane (2000) submitted that in the Western countries, radiographic evidence of OA is present in the majority of persons by 65 years of age, about 80% of persons more than 75 years of age, while approximately 11% of persons older than 64 years have symptomatic OA of the knee.

In a population survey of nearly 9000 people aged 50 years or over in the United Kingdom, Underwood (2004) found that one in four people had chronic knee pain while 45% of 3757 patients with rheumatic disease in a study carried out in Belgium had OA (Vanhoof et al, 2002). In a study covering rural and urban communities in Bangladesh, OA of the knee also accounted for 7.5% of all diagnosed rheumatic conditions among people aged 15 years and above. A retrospective study at the Rheumatology Clinic of Lome Teaching Hospital, Togo, among 2626 patients seen over a three-year period, also indicated that 232 had appendicular OA with 83% of the females and 17% of the males presenting with knee OA and hip OA accounting for 7.3% of all cases (Mijiyawa and Ekoue, 1993).

Age-standardized prevalence of radiographic knee OA was 27.2% among participants in a study conducted in Framingham(Zhang and Jordan, 2010). Radiographic hip OA was less common than hand or knee OA. For example, about 7% of women older than 65 years in the study of osteoporotic fractures had radiographic hip OA. However, in another study carried out in Johnston County, the prevalence of hip OA was much

higher, with 27% of participants who were at least 45 years old demonstrating radiographic evidence of Kellgren and Lawrence grade 2 or higher OA (Lawrence et al, 2008). Potential explanations for the differences between these studies relate to differences in study populations, definitions of OA, distribution of risk factors for disease, and the experts that interpret the radiographs (Zhang and Jordan, 2010).

Symptomatic OA is generally defined by the presence of pain, aching, or stiffness in a joint with radiographic OA. The age-standardized prevalence of symptomatic hand and knee OA was 6.8% and 4.9% respectively among Framingham participants who were 26 years old and above. However, the prevalence of symptomatic knee OA was much higher (16.7%) among participants older or equal to 45 years of age in the Johnston County Osteoarthritis Project (Zhang and Jordan, 2010). About 9% of participants in the Johnston County study had symptomatic hip OA (Lawrence et al, 2008). There is however a paucity of meaningful data on the cumulative incidence of developing OA as the length of time over which the risk of OA is calculated is critical but not always clearly specified or known. Further, because OA is a chronic disease occurring mostly among the elderly, competing risk or death from other diseases makes direct estimation of the cumulative incidence of OA difficult (Zhang and Jordan, 2010).

Oliveria et al (1995) reported the age- and sex-standardized incidence rates of symptomatic hip, knee, and hand OA to be 88, 240 and 100/100,000 person-years respectively in participants in a Massachusetts Health Maintenance Organization, and that the incidence rates of symptomatic OA of either the hand, knee, or hip increase rapidly around age 50 and then level off after age 70. They estimated the lifetime risk of developing symptomatic knee OA to be about 40% in men and 47% in women. This risk rises to 60% in participants with a body mass index (BMI) of 30 or higher (Murphy et al, 2008).

Graingner and Cicutinni (2004) reported that about 1.2 million people have symptoms of OA in Australia and 13% of the reported population was classified as disabled or handicapped by the disease. Gunther et al (1998) evaluated the radiographic and clinical patterns of advanced hip and knee OA in South West Germany and found that, of the total 809 patients with hip and knee OA (420 hip OA, 389 knee OA) scheduled for total joint replacement in selected hospitals around the region, patients with hip OA were younger (mean age 60.4 years) and less likely to be female (54.4%) than patients with knee OA (66.3 years and 72.5 years respectively). The prevalence of generalized

OA was found to increase with age and was higher in female patients. Generalized OA was observed more often in patients with knee OA than in patients with hip OA (34.9% versus 19.3%).

Statistics on the incidence and prevalence of OA in Africa are not readily available. For instance, Hassanall and Oyoo (2011) reported that there are no figures to cite as far as epidemiological data on OA is concerned in Kenya. Symmons et al (2000) reported that about 3.2 million of the 44 million population of South Africa suffer from OA which constitutes about 7.3% of the country's population.

Although there is a scarcity of literature on the general epidemiology/prevalence of OA in Nigeria, community- and hospital-based studies have been conducted in some geographical sections of the country. Ogunlade et al (2005) reported that 70.1% of 164 OA patients aged 15 years and above presenting at the University College Hospital Ibadan were females, with knee OA accounting for 65.4% of the cases. A study by Akinpelu et al (2007a) on OA indicated that 9% of 11574 patients seen in physiotherapy facilities located in Ibadan and Lagos within the study period had knee OA which was more prevalent among females than males (3.5:1),and the knee was the joint most frequently affected by the disease. Akinpelu et al (2009) investigated the prevalence and pattern of symptomatic knee OA in Igbo-Ora (a rural community in South Western, Nigeria), and found 19.6% of the total surveyed population presenting with symptomatic OA of the knee. In a similar study carried out in North-eastern Nigeria by Akinpelu and colleagues in 2011 (Akinpelu et al, 2011b), the point prevalence of symptomatic knee OA was found to be 16.3% while prevalences of 40.1% and 13.5% were recorded for female and male participants respectively. Obese participants (by BMI and % body fat classifications) had significantly more severe knee OA than their counterparts who were overweight or had normal body weight.

## 2.3 Classification of osteoarthritis

Osteoarthritis (OA) is either primary or secondary OA in relation to aetiological history (Hag et al, 2003). Primary OA results from changes caused by specific inflammatory or metabolic conditions; has no history of specific injury or trauma, and is usually limited to one or a small number of joints (Wice, 2001).Secondary OA on the other hand is caused by other conditions that damage the cartilage, and may be limited to a small number of joints when it is injury related, but may affect numerous

joints in the body when it is disease related (Wice, 2001).Dixey and Kerr (1992) however argued that all cases of OA can be described as secondary and that the incidence of primary OA decreases as more causes are found, hence the classification might not be valid.

The classification for OA described by Kellgren and Lawrence is the most widely used radiological classification to identify and grade OA (Parson et al, 2015). According to Kellgren and Lawrence (1957), OA is classified into five grades (0, normal to 4, severe). The radiological signs found to be evidence for OA were combined to define a grading scale for severity. For the knee, important changes are:

(a) Formation of osteophytes on the joint margins or in ligamentous attachments, as on thetibial spines,
(b) Narrowing of joint space associated with sclerosis of the subchondral bone,
(c) Cystic areas with sclerotic walls situated in the subchondral bone, and
(d) Altered shape of the bone ends.

The scoring system is based on comparing films with those in a standard atlas of radiographs. Based solely on radiographic findings, osteoarthritis can be classified as:

0- absent

1-doubtful

2- minimal

3-moderate

4- severe

Usually, an individual is classified as suffering from knee OA if the knee radiograph is scored as Kellgren and Lawrence grade 2 or above (Dennison and Cooper 2003), as radiological changes are not always accompanied by symptoms such as pain, stiffness, mood, loss of muscle strength and disability; they solely may not accurately reflect the clinical burden of the disease (Symmons et al, 2000; Issa and Sharma, 2006; Parson et al,2015). A study of women aged 45-65 in the United Kingdom showed that the prevalence of knee OA was 2.3% based on symptoms, compared to 17% based on radiological criteria (Spector et al, 1991). The preferred definition for OA includes x-ray findings accompanied by symptoms such as joint pain on most days (Symmons et al, 2000). The Kellgren and Lawrence grading system was modified by Spector et al

(1992) to take into account the likelihood of separate involvement of patellofemoral and tibiofemoral components of the knee in the disease process. The following criteria were used for classification:

(a) The presence of osteophytes and joint space narrowing in both patellofemoral and tibiofemoral joints. These are graded 0 – 3.

(b) Sclerosis and joint collapse at the tibiofemoral joint graded on a scale of 0 – 1.

The severity of OA in both joints of the knee is then graded as follows:

1-2: Mild OA

3-5: Moderate OA

6-8: Severe OA

According to Symmons et al (2000), the Subcommittee on OA of the American College of Rheumatology's Diagnostic and Therapeutic Criteria Committee was formed in 1981 to establish clinical criteria for the classification of OA. They developed the following classification criteria for OA of the knee:

**(a) Clinical**

1 - Knee pain for most days of prior month

2 - Crepitus on active joint motion

3 -Morning stiffness less than 30 minutes in duration

4 -Patient's age 38 years and above

5 - Bony enlargement of the knee on examination

OA present if items 1, 2, 3, 4, or 1, 2, 5 or 1, 4, 5 are present.

**(b) Clinical and radiological**

1 - Knee pain for most days of prior month

2 - Osteophytes at joint margins (X-ray)

3 - Synovial fluid typical of osteoarthritis (laboratory)

4 - Age 40 years and above

5 - Morning stiffness less than 30 minutes in duration

6- Crepitus on active joint motion

OA present if items 1, 2 or 1, 3, 5, 6 or 1, 4, 5, 6 are present

Currently, in addition to radiographic or clinical definitions of knee OA, some epidemiological studies have implemented a self-reported, subjective, definition of knee OA (Van der Pas et al, 2013; Thomas et al. 2014). In these studies, participants have been asked to self-report whether they believe they have OA in the joint of interest, by being asked such questions as 'Do you have OA?' or 'Have you had any pain in your (joint region) over the last year?'(Parson et al, 2015). Modest agreement was found within radiographic, clinical, and self-reported methods of diagnosis of knee OA (Parson et al 2015)

## 2.4 Pathogenesis and Pathology of Osteoarthritis

### 2.4.1 Pathogenesis of Osteoarthritis

Osteoarthritis is commonly described as a non-inflammatory disease which is different from inflammatory arthritis,suchas rheumatoid arthritis or seronegative spondyloarthropathies(Hassanal and Oyoo, 2011). Despite this, inflammation is increasingly implicated in the symptoms and progression of OA. Chondrocytes are probably the most important cells responsible for the development of the osteoarthritic process. Human and animal studies indicate that chondrocytes exhibit numerous abnormal metabolic features as part of the osteoarthritic process (Hassanal and Oyoo, 2011). These include increased chondrocyte proliferative activity and matrix degradation. Other growth factors also simulate chondrocyte synthesis. Cartilage fragments and soluble proteoglycans and type II collagen have been demonstrated in the synovial fluid of osteoarthritis joints. These cartilage degradative products can stimulate the release of inflammatory mediators from macrophages.

According to Hassanal and Oyoo (2011), two principal mechanisms are thought to initiate osteoarthritis.In most patients, the initiating mechanism is when normal articular cartilage is damaged by physical forces, whichcan be either a single macro-trauma event or repeated micro-trauma. Chondrocytes react to these injuries by releasing degradative enzymes and elaborating inadequate repair responses. Less commonly, fundamentally defective cartilage initially falls under normal joint loading, thereby leading to osteoarthritis. Examples include type II collagen gene defect or ochronotic cartilage that fails because of deleterious pigment disposition. The initiation

of the osteoarthritic process therefore appears to involve abnormalities in biomechanical forces and/or cartilage. Once begun, the pathway leading to osteoarthritis involves numerous other factors. These include mechanotransduction, the interplay between proteases, protease inhibitors and cytokines on cartilage degradation and mechanisms of cartilage repair and the contributions from multiple risk factors (such as aging, mineral deposition, abnormalities in neurogenic control, obesity and systemic hormones)(Hassanal and Oyoo, 2011). An abnormality associated with osteoarthritis extends beyond the cartilage, often involving the subchondral bone, juxta-articular bone marrow and synovial membrane.

### 2.4.2 Pathology of Osteoarthritis

The pathology of OA is better appreciated when it is discussed in relation to the structures around the joint (Thompson et al, 1991). The structures affected include:

Articular cartilage

Bone

Synovial membrane

Capsule

Ligaments

Muscles

**Articular Cartilage**:Erosion of the articular cartilage is often central and frequently occurs in the weight bearing areas. The hyaline cartilage is usually the first structure to be affected in osteoarthritis (Joern et al, 2010). Fibrillation which causes softening, splitting and fragmentation of the cartilage occurs in both weight-bearing and non-weight-bearing areas. Collagen fibres split and there is disorganization of the proteoglycan-collagen relationship, such that water is attracted to the cartilage causing further softening and flaking. Flakes of cartilage break off and may be caughtbetween the joint surfaces causing locking and inflammation. Proliferation occurs at the periphery of the cartilage.

**Bone***:* The bone surfaces become hard and polished as there is loss of protectionEburnated bone becomes brittle and microfractures occur, allowing the passage of synovial fluid into the bone tissue. There may also be venous congestion in

the subchondral bone. Osteophytes form at the margin of the articular surfaces where they may project into the joint or capsule and ligaments. The bones of the joint are thus alteredin shape; for example, the femoral head becomes flat and mushroom shaped and the tibia condyles become flattened too.

**Synovial membrane***:*This undergoes hypertrophy and becomes oedematous. Later, there is fibrous degeneration. Reduction of synovial fluid results in loss of nutrition and lubrication of the articular cartilage.

**Capsule***:*This undergoes fibrous degeneration and there are chronic low grade inflammatory changes.

**Ligaments***:*These undergo the same changes as the capsule and depending on the aspect of the joint become contracted or elongated.

**Muscles***:*These undergo atrophy, which may be related to disuse due to pain which limits joint movement and function. Without adequate exercise, the muscles may undergo fibrous atrophy.

## 2.5 Risk factor of osteoarthritis

Several factors have been implicated in the pathogenesis of OA and the relative importance of risk factors may vary for different joints, for different stages of the disease, for development as opposed to progression of the disease and for radiographic versus symptomatic disease (Cooper et al, 1997; Rubinow,1998; Zhang and Jordan, 2010). Risk factors in OA have been classified into primary and secondary. The primary risk factors are: age, gender, obesity, genetics, bone density, hormonal status and ethnicity, while the secondary factors are: trauma, occupation, nutritional factors, exercise and sports and knee alignment (Doherty 2001). However, in some cases, one group of risk factors may become dominant over the others, thus supporting the theory that OA is a disease spectrum with no case attributable to a single risk factor (Hochberget al, 1991; Dequeker et al, 1995, Zhang and Jordan, 2010).

### 2.5.1 Primary risk factors

a) Age:Age is one of the strongest risk factors for OA of all joints (Lawrence et al, 2008). The increase in the prevalence and incidence of OA with age is probably a

consequence of cumulative exposure to various risk factors and biologic changes that occur with aging that may make a joint less able to cope with adversity, such as cartilage thinning, weak muscle strength, poor proprioception and oxidative damage (Hag et al, 2003).

b) Gender: Women are not only more likely to have OA than men but also have more severe OA (Srikanth et al, 2005). In men aged 60 to 64, the right knee is more commonly affected, while in women, the right and left knees are affected with nearly equal frequency (Joern et al, 2010).

c) Obesity: Obesity is a chronic condition that develops as a result of interaction between a person's genetic makeup and their environment. How and why obesity occurs are not well understood; however, social, behavioural, cultural, psychological, metabolic, and genetic factors are involved (Wolf and Tanner, 2002).

Obesity and overweight have long been recognized as potent risk factors for OA, especially OA of the knee (Felson et al, 2000). The Framingham study demonstrated that women who had lost about 5kg had a 50% reduction in the risk of development of symptomatic knee OA. It was also demonstrated that weight loss was strongly associated with a reduced risk of development of radiographic knee OA (Felson et al, 1992). Weight loss interventions have also been shown to decrease pain and disability in established knee OA (Messier et al, 2004; Christensen et al, 2007).

The effect of body mass index (BMI) on incidence and progression of knee OA has been said to be dependent on the alignment of the knee. A high BMI was associated with an increased risk of progressive knee OA in knees with neutral alignment but not in knees with varus alignment. Obesity had a modest, nonsignificant effect on OA progression among valgus-malaligned knees (Nui et al, 2009).

d) Genetics: Several researches have shown that OA is inherited and may vary by joint site (Spector et al, 1996; Felson et al, 1998; Chen et al, 2008). Twin and family studies have estimated the heritable component of OA to be between 50 and 65% with larger genetic influences for hand and hip OA than for knee OA(Spector et al, 1996; Felson et al, 1998). It has also been observed that there is an association between general joint hypermobility (a lone benign trait with hand and knee OA) and serum cartilageoligomeric matrix protein levels (Dolan et al, 2003; Chen et al, 2008).

e) Hormonal status: The definite increase in OA in women around the time of menopause has led researchers to hypothesize that hormonal factors may play a role in the development of OA. However, results on the effect of oestrogen, either endogenous or exogenous, on OA from observational studies have been conflicting (Hannan et al, 1990; wluka et al, 2000).

f) Ethnicity: According to Zhang and Jordan (2010), the prevalence of OA varies among racial and ethnic groups. Osteoarthritis of the hips is relatively more common in whites, less common among Africans and American Indians, and extremely rare in Asians (Felson and Zhang, 1998).

### 2.5.2 Secondary risk factors

a) Trauma: Knee injury is one of the strongest risk factors for knee OA (Zhang and Jordan, 2010). Severe injury to the structures of a joint, particularly a trans-articular fracture, meniscal tear requiring meniscectomy, or anterior cruciate ligament injury, can result in increased risk of OA development and musculoskeletal symptomatology (Roos et al, 2001; Lohmander et al, 2004).

b) Occupation: Repeated use of a joint at work has been associated with increased risk of OA (Zhang and Jordan, 2010). Felson et al (1991) have shown that the risk of developing knee OA was two times greater for men whose jobs require both carrying and kneeling or squatting in mid-life than for those whose jobs do not require such physical activities. Also Croft et al (1992) have submitted that there is a high prevalence of hip OA among farmers.

c) Nutritional factors: Nutritional factors in OA have generated considerable interest, with conflicting reports from studies (Zhang and Jordan, 2010). High intake of selenium has beenreported to be significantly associated with increased risk of hip and knee OA (Engastrom et al,2009), while earlier reports by Sasaki et al(1994) and Turan et al(1997) showed that selenium deficiency is associated with irregular bone formation, decreased bone strength, and abnormalities in type I and II collagen in cartilage.Vitamin C was reported to delay the onset of OA in animals(Felson, 1995) and one of the most promising nutritional factors for OA is vitamin D, for which deficiency, bones can become thin, brittle, or misshapen (Zhang and Jordan, 2010).

d) Exercise and sports: Studies examining the relationship between sports activities and subsequent OA have produced conflicting results (Zhang and Jordan, 2010). There is some evidence that elite long distance runners are at high risk for development of knee and hip OA (Kujala et al, 1995; Spector et al, 1996) while elite soccer players are at risk of developing knee OA, when compared with non-soccer players (Kujala et al, 1995). Conversely, others have shown that, in the absence of acute injury, recreational (moderate) long distance running and jogging did not appear to increase the risk of OA (Lane and Bulkwater,1993; Newton et al, 1997).

e) Knee alignment: The hip-knee-ankle angle, which is referred to as knee alignmentis a key determinant of load distribution.Any shift from the neutral or collinear alignment of hip, knee and ankle affects load distribution atthe knee; hence it may be speculated that malaligned kneesmay have a higher risk of developing OA and a higher subsequent risk of progression than knees with neutral alignment (Zhang and Jordan, 2010). The result of a prospective cohort study by Sharma et al (2001) showed that in the presence of existing knee OA, abnormal anatomic alignment was strongly associated with accelerated structural deterioration in the compartment under greatest compressive stress. Knees with varus alignment at baseline had a fourfold increase in the risk of medial progression of knee OA, and those with valgus alignment at baseline had a nearly fivefold increase in the risk of lateral progression (Sharma et al, 2001). And according to Carejo et al (2002), the impact of varus or valgus malalignment on the risk of OA progression was greater in knees with more severe baseline radiographic disease than knees with mild or moderate disease.

## 2.6 Clinical feature

Osteoarthritis is not common in younger patients and most patients with OA are past their middle age. When it does occur in younger patients, there is usually a clear predisposing cause, such as previous injury. The onset is gradual, with pain that increases almost imperceptibly over the months and years (Adams and Hamblen, 1990). The main symptom of OA is pain that worsens during activity and remits with rest. Instability of the joint is also a common feature, especially in cases of OA of the knee and first carpometacarpal joints. Early morning stiffness is common and characteristically lasts thirty minutes or less depending on the severity, and stiffness may occur following a period of inactivity (Swagerty and Hellinger, 2001). As the

disease progresses, prolonged stiffness and joint enlargement are evident, while crepitus or grating sensation in the joint is a late manifestation. Limitation of joint movement may subsequently result due to flexion contractures or mechanical obstruction (Hinton et al, 2002).

## 2.7 Diagnosis

A detailed history and complete physical examination are essential tools for diagnosing symptomatic OA of the knee (Hinton et al, 2002). The typical patient with knee osteoarthritis complains of pain and stiffness in and around the joint, with only some limitation of function (often of insidious onset) (Manek and Lane, 2000). MacAuley (2004) outlined the features as swollen and aching knee, difficulty in walking and climbing stairs, which will lead to a downward spiral of inactivity, immobility and weight gain. Plain radiographs are presently being acknowledged as the best validated method of assessing joint damage in OA (Garnero et al, 2001). However, the initial radiograph may not show all the findings (Swagerty and Hellinger, 2001) and it is not an efficient way of monitoring the progression of OA. Magnetic resonance imaging (MRI) has been indicated as the ideal technique for assessing normal and diseased articular cartilage (Bruyere et al, 2006). Other useful diagnostic tools include ultrasonography (Haq et al, 2003), computed tomography (CT-scan) and radionuclide imaging (Dieppe et al, 1993). The American College of Rheumatology set diagnostic criteria for OA in 1986. Table 1 shows the criteria for classification of idiopathic OA of the knee by Altman et al (1986).

## 2.8 Management of osteoarthritis(OA) of the knee

There is no cure for osteoarthritis (OA) and gradual, although slow, progression of the disease is most common (Grainger and Cicuttini, 2004). Although osteoarthritis is traditionally thought of as a non-inflammatory type of arthritis, inflammatory mechanisms may be present (Barron and Bernard, 2007). The goals of treatment of OA are to relieve pain (which is usually the primary reason why OA patients visit the clinic), to improve function, maintaining and improving the range of movement, and maintain/improve the stability of the affected joints (Manek and Lane, 2000; Grainger and Cicuttini, 2004).

### 2.8.1 Treatment guideline for the management of knee osteoarthritis

The American Institute of Medicine has defined clinical guidelines as 'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical conditions' (Roddy, 2005). The methodology involved in the development of treatment guidelines for OA includes evidence from peer reviewed literatures, consensus of expert opinion and a hybrid of both (Scot et al, 1993; Jordan et al, 2003; Zhang and Doherty 2006; Zhang et al 2010). Some of such treatment guidelines include: European League Against Rheumatism (EULAR) guidelines, American College of Rheumatology (ACR) guidelines, Dutch Clinical Practice Guidelines for Physical Therapy, and Osteoarthritis Research Society International (OARSI) guidelines (Zhang et al, 2007). Although these guidelines differ in some of the modalities recommended, there exists a set of common recommendations as outlined below (table 2.1).

Treatment guidelines are reviewed from time to time as new evidences emerge. A recent review by OARSI led to the current guideline on the non-surgical management of knee OA which stratified knee OA patients into sub phenotypes, according to the joint affected and associated co-morbidities. This guideline recommends self-management education, strength training, and land-based and water-based exercises as core treatments that are appropriate for all individuals with knee OA irrespective of the sub phenotype (McAllindon et al, 2014).

**Table 2.1: Recommendations for treatment of knee OA**

1.The optimal management of knee OA requires a combination of non-pharmacological and pharmacological treatment modalities.

2.The treatment of knee OA should be tailored to individual patient needs

3.Non-pharmacological treatment should include education, exercise, weight reduction and appliances.

4. Paracetamol should be considered as first line oral analgesic and if successful should be considered as the preferred long-time oral analgesic.

5. Topical non-steroidal anti-inflammatory drugs (NSAID) have clinical efficacy and are safe.NSAIDs should be considered in patients not benefitting from paracetamol.

6. Non-selective NSAIDs and gastro-protective agents or selective COX2 inhibitors should be used in patients with increased gastrointestinal risk.

7. Opioid analgesics with or without paracetamol are useful in patients in whom NSAIDs including COX2 selective inhibitors are contraindicated, ineffective, and/or poorly tolerated.

8. Glucosamine sulphate, chondroitin sulphate, diacerein and hyaluronic acid may modify structure.

9. Intra-articular injection of long lasting corticosteroid is indicated for flare of knee pain especially if accompanied by effusion.

10. Joint arthroplasty must be considered in patients with radiologic evidence of severe knee OA or who have severe pain and disability and in whom other modalities have failed.

*From Jordan et al, 2003; Zhang et al, 2008*



### 2.8.2 Pharmacological therapy

It has been recommended that pharmacologic therapy be considered as an adjunct to non-pharmacologic measures in the management of OA (Grainger and Cicuttini, 2004). Drug therapy should however be tailored toward individual needs following a careful assessment of symptoms, severity, co-morbid conditions, concomitant therapy, side effects, cost of therapy and patient preferences(Hinton, et al, 2002).

Acetaminophen (paracetamol) has been recommended as the first choice of oral analgesic and this is advocated as the initial therapy because it is relatively cheap and safe (Walker-bone et al, 2000; Hinton et al, 2002; Grainger and Cicuttini, 2004; Denoeudet al, 2005). However, a large-scale study has found no significant effect in patients with knee OA(Bjordal, 2006). Non-steroidal anti-inflammatory drugs (NSAIDs) such as naproxen, ibuprofen, piroxicam and diclofenac potassium are also

commonly used in managing knee OA. NSAIDs should however be used with caution in elderly patients who are likely to have cardiac, hepatic or renal impairment, moreover it offers only short-term relief of pain (MacAuley, 2004). Nonsteroidal anti-inflammatory drugs have also been implicated in the cause of death of 2000 of the half of 8million OA patients who use NSAIDs regularly (Bjordal, 2006). Other drugs prescribed are cyclo-oxygenase and topical analgesics such as topical capsaicin. Tetracycline (an antibiotic) is used to slow the rate of joint space narrowing in OA knees,however, its value in the early treatment of symptomatic management of OA will require further investigation (Brandt et al, 2005). The use of intra-articular injections such as corticosteroids, hyaluronic acid (which is a linear polysaccharide found naturally in synovial fluid), opioids, and alternative medicines such as glucosamine have also been documented in the management of patients with OA (Walker-bone, et al, 2000; Hinton, et al, 2002).

### 2.8.3 Non-pharmacological therapy

Various authors (Walker-bone et al, 2000; Grainger and Cicuttini, 2004; Hochberg et al, 1995; Altman et al, 2000) agree that non-pharmacologic mode of therapy plays a major role in the management of knee OA pain.Thisis in agreement with the knee OA clinical guidelines recommendation that conservative treatments be usedas first line strategy for the optimal management of the disease (Jordan et al, 2003; Crossley et al, 2008; McAlindon et al,2014). Included in this mode of therapy are: patient education, social support, physiotherapy, occupational therapy, and acupuncture (Walker-bone et al, 2000). Other components of non-pharmacologic therapy, according to Altman et al (2000), are self-management programme, joint protection and energy conservation and assistive devices for activities of daily living.

#### 2.8.3.1 Exercisein the management of knee OA

The recommendations for exercise are supported by clinical trials (Van Baar et al, 1999; Roddy et al, 2005; Hayet al, 2006; Foster et al, 2007). A systematic review concluded that exercise therapy (strengthening, stretching, and functional exercises) compared with no treatment is effective for patients with knee osteoarthritis (Smidt et al, 2005). Exercise has been shown to improve function, strength, walking speed, and self-efficacy and to reduce pain and the risk of other chronic conditions (Van Baar,

1999; Foster, 2007). Exercise has been shown to have the supplementary benefits of improving cardiovascular status, emotional wellbeing and proprioception (Baker and McAllindon, 2000; Roddy et al, 2005; Cottrell et al, 2010). It also shifts consultation behaviour away from the traditional general practitioner-led model of care and reduces the use of nonsteroidal anti-inflammatory medications. Both local and general (aerobic) exercises reduce pain and improve function and health status in patients with clinical knee OA (Roddy et al, 2005) and are acore aspect of management for every patient with knee OA, according to recent exercise recommendations (Roddy et al, 2005) and current clinical guidelines (Roddy et al, 2007). However, without adequate instruction, motivated patients may exercise with little or no benefit (Cottrell et al, 2010).

#### 2.8.3.1.1 Open and closed chain quadriceps strengthening exercises

Quadriceps strength has been associated with disability in people with knee OA and has been known to predict physical disability in this population (Fritzgerald et al, 2004). Quadriceps muscle weakness has been shown to precede pain and muscle atrophy in patients with radiographic knee OA (Slemenda et al, 1997). Based on this premise, a number of therapeutic exercises for knee OA have targeted the quadriceps muscle for strengthening and reduction in pain, and improvements in function and in health-related quality of life have been reported (Pietrosimone et al, 2014; Juhl et al, 2014).

Quadriceps strengthening exercises are basically Open Kinetic Chain Exercises (OKCEs) or Closed Kinetic Chain Exercises (CKCEs) (Glass et al, 2010). OKCEs are typically non-weight bearing, with movement occurring at a single joint. The distal segment is free to move, and the resistance is usually applied to the distal segment (Fitzgerald, 1997). Open kinetic chain exercises are exercises in which the force applied by the body is great enough to overcome the imposed resistance (Kisner and Colby, 2007). In the lower extremity, shear forces are common during OKCEs and cause the tibia to shift anteriorly and the femur posteriorly due to strong quadriceps muscle contraction (Miller, 1999). Anexample is a knee extension exercise, performed in a sitting position with resistance applied to the distal segment.

Closed kinetic chain exercises (CKCEs) are typically weight bearing. Movement at several joints is required to complete the movement.The distal segment is usually fixed to a supporting surface, and the resistance may be applied both proximally and distally (Fitzgerald, 1997).Closed kinetic chain exercises are exercises in which the force applied by the body is not great enough to overcome the imposed resistance (Chek, 1997). These exercises involve all the three links in the kinetic chain of the lower extremity since the foot remains in contact with a surface, either the ground or the base of a machine (Kisner andColby, 2007). Hence there is a resultant co-contraction of the quadriceps, hamstrings, hip flexors, soleus, and gastrocnemius muscles (Mc Ginty, 2000). The co-contraction of the quadriceps and hamstring muscles that occurs in these exercises minimizes the translation and shearing forces at the knee. An example of a CKC exercise is a squat (Irrgang and Rivera, 1994 and Fitzgerald, 1997).

It is believed that CKCEs are equally as effective as OKCEs in improving quadriceps femoris muscle force production (Fitzgerald, 1997; Mikkelsen et al,2000). Some researchers have demonstrated that a combination of these two kinetic chain exercises produce greater benefits in terms of pain reduction and improvement in function than one or the other alone (Mikkelsen et al, 2000; Alghamdi et al,2004; Minoonejad et al, 2012).

### 2.8.3.2 Self- management education in knee OA

Osteoarthritis (OA) is a common chronic disease that poses particular challenges to patients and health professionals as there is currently no cure for the condition. Consequently, the majority of chronic disease care and management is undertaken by the individual who may only have brief and infrequent interactiong14s with the health care system. Effective management of OA therefore requires *self-management.* Patient education programmes aim to impart knowledge and skills to individuals so that they may better manage their arthritis(Osborne et al, 2006). The nature of chronic disease is such that management varies over time and treatment is adjusted as the symptoms of the condition change. This makes it imperative that patients play an integral role in the management of chronic diseases (Lorig and Holman, 1993; Bodenheimer et al, 2002; Kroon et al, 2014)

Osborne et al (2006) described the core concepts promoted in patient self-management as:

• Engagement in activities which promote health, build physiological reserve, and prevent adverse sequelae;

• Appropriate interaction with healthcare providers and adherence to recommended treatments;

• Monitoring of physical and emotional status and making appropriate management decisions on the basis of the results of self-monitoring; and

• Management of the effects of illness on an individual's emotions, self-esteem, relationships with others and ability to function in important roles.

Self-management programmes facilitate the acquisition by the patient of knowledge or strategies forpreventive or therapeutic health care activities, often in collaboration with health care providers (Warsi et al, 2004). Self-management education programmes emphasize the role of patient education in preventive and therapeutic health care activities and usually consist of organized learning experiences designed to facilitate adoption of health-promoting behaviours. Such programmes are usually separate from clinical patient care, but are often run in collaboration with health care professionals(Bodenheimer et al, 2002). Self-management education programmes exist for many chronic conditions, including arthritis, asthma, diabetes, and hypertension.

Reviews and meta-analyses have shown that patient self-management education programmes can significantly improve compliance, behaviours and health outcomes but the effectiveness differs from one programme to another (Coleman et al, 2008b).

Some reviews of self-management education programmes observedthe trend that arthritis programmes yield a small benefit (Warsi et al, 2004; Nolte and Osborne, 2012). A Cochrane review of self-management education programmes for osteoarthritis also shows that self-management education programmes may slightly improve self-management skills, pain and function but may not improve active and positive engagement in life, osteoarthritis symptoms, and quality of life and dropout rates compared with usual careof the patient(Kroon et al, 2014). This trend may be because most of the existing arthritis programmes cater for all forms of arthritis. Some

of such programmes are theChronic Diseases Program and the Arthritis Self-Management Programme(ASAMP) and its various derivatives, developed at Stanford University (Lorig et al, 1993 and Lorig et al 2001). However, a disease-specific self-management programme was developed for knee osteoarthritis by Coleman et al (2008). The Osteoarthritis Knee (OAK) self-management programme was designed to positively affect pain, knee function and quality of life of patients (Coleman et al, 2008). The result of the pilot study of the programme shows a moderate benefit to knee OA patients (Coleman et al, 2008b).

#### 2.8.3.3 Cognitive Behavioural Therapy

Cognitive Behavioural Therapy (CBT) is the application of the principles of learning as well as empirically-derived methods to change the ways in which pain sufferers perceive and react to their pain and help them develop better coping skills to adjust more effectively to the continuing demands of long-term pain. Cognitive behavioural therapy approaches have been shown to have successful outcomes though they often emphasize reducing reliance on passive approaches (use of medication and increasing demand for intervention), which sometimes can be contradictory to biomedical management if both are carried out simultaneously (Almajed, 2001). Cognitive behavioural therapyis targeted at each specific area identified during the assessment process, such as: activity avoidance, depressed mood, unhelpful beliefs or fears and excessive reliance on medications (Smeets, 2001). A systematic review by Volinn et al (2004) concluded that CBT was superior to no treatment, waiting list controls or single-discipline treatments. Another review that included 25 trials on long-term pain patients concluded that when compared with the waiting list control conditions, CBT was associated with significant effect size in all domains. Compared to other active treatments, CBT produced significantly greater change in the domains of pain experience, cognitive coping and appraisal and reduced behavioural expression of pain (Frost, 2002).

### 2.8.4 Surgical management

The most common surgical intervention for end-stage knee OA is Total Knee Arthroplasty (TKA). Although more than 400,000 primary TKA surgeries are

performed each year in the United States, not all individuals with knee OA elect to undergo the procedure (Dieppe et al, 1999; NIH, 2003; Jacob et al, 2008,). No clear consensus exists on criteria to determine who should undergo TKA, however, severe pain,very high levels of disability and excessive cartilage degeneration appear to be decisive factors for the procedure (Dieppe, 1993 and Gossec et al, 2007).

The success of prosthetic joint replacements has greatly advanced management of end stage hip and knee osteoarthritis. Although issues relating to funding, waiting times, choice of prosthesis, and revision have to be faced, there is no doubt that such surgery can transform patients' lives. Other surgical approaches (arthroscopic lavage, osteotomy, and arthrodesis) may also be useful. The criteria for surgery are not definite but should probably include uncontrolled pain(particularly nocturnal pain) and severe impairment of function. Age, in itself, is not a contraindication(Jones and Doherty, 1995).

## 2.9 Relevant outcome measures in knee OA

The health care delivery system has been in the era of accountability since the mid-1980s (Yeoman, 2000), hence the importance of outcome measurement in clinical practice. Outcome measurement in clinical practice provides the means by which the health care provider, the patient, the public and the payer are able to assess the end result of care and its effect on the health of the patient and the society (Yeoman, 2000).

Various outcome measures have been designed and validated for arthritis,namely, the functional status index by Jette (1980), the Short form 36 Arthritis Specific Health Index (Ware et al, 1990), Western Ontario and McMaster universities (WOMAC) Osteoarthritis Index (Stucki et al, 1996), Knee Injury and Osteoarthritis Outcome Score (Roos et al, 1998), and Ibadan Knee/ Hip Osteoarthritis Outcome Measure (IKHOAM) (Akinpelu et al, 2007). Of the listed outcome measures for osteoarthritis, only the Knee Injury and Osteoarthritis Outcome Score and the Ibadan Knee/Hip Osteoarthritis outcome measure are specific for the knee.

Outcome measures always reflect the environment and culture of the place where they were developed (Fries, et al 1980; Jette, 1980a; Jette, 1980b; Meenan et al, 1982 and

Akinpelu et al, 2007).They are therefore not easily applicable to other cultures and environments. For example, some of the items contained in many of the outcome measures in osteoarthritis are not relevant to Nigerians. However, the IKHOAM is a Nigerian culture and environment-friendly clinical tool developed at the University of Ibadan, Nigeria for measuring end results of care in patients with knee or hip OA (Akinpelu et al, 2007) and has been translated into two of the major Nigerian languages and validated (Odole et al, 2006 and Odole et al, 2008). The outcome measures can therefore be said to be the most relevant for use in assessing the end result of care in knee OA patients in Nigeria.

### 2.8.5 Health Related Quality of Life in Arthritis

Quality of life, health status and health-related quality of life are terms used interchangeably to discuss the effect of diseases, such as arthritis on functioning and sense of well-being (Fontaine, 2012), while quality of life broadly refers to health status, environment and economic factors that can influence the well-being of a person. Health-Related Quality of Life (HRQoL) focuses on the impact of a disease or medical condition on functional health status and well-being as perceived and reported by the patient (Fontaine, 2012).

The health domains in HRQoL range from negative valued aspects of life to the more positive valued aspects such as role function or happiness (Guyatt, et al, 1993). Health-related quality of life is important for measuring the impact of chronic diseases such as OA (Guyatt, et al, 1993). This is because physiologic measures provide information to clinicians but are of limited interest to the patient as they correlate poorly with functional capacity and well-being (Guyatt, et al, 1993). Health statues and quality of life measures are widely used in the clinical assessment of rheumatoid arthritis and other forms of arthritis (Scott and Garood, 2000).

Arthritis and other rheumatic conditions seldom cause death but have a substantial impact on health. Hence, HRQoL measures are better indicators of the impact of such diseases in a community than mortality rates (CDCP, 2000). Assessment of HRQoL

also provides a way for rheumatologists and other care providers to better understand the effect of this chronic disease on the overall functioning and well-being of an individual with OA (Fontaine, 2012). Information on the impact of chronic diseases on quality of life can make health care services more patient centred (Lam and Lander, 2000). It also makes it possible for caregivers to identify significant areas of the patient's life that have suffered, and help the patient focus more accurately on his treatment and self-management effort, so he can reclaim his former life (Fontaine, 2012).

## 2.9 JUSTIFICATION FOR RESEARCH METHODOLOGY

Quadriceps Strengthening Exercises (QSE) and self-managementeducation have regularlybeen recommendation in treatment guidelines for knee OA (Jordan et al, 2003; Zhang and Doherty, 2006; Zhang et al, 2010). A recent recommendation for non-surgical management recommends QSE and SME for all categories of knee OA irrespective of severity or co-morbidity (McAlindon et al, 2014).

Knee OA is associated with a variety of pathophysiologic deficits, including joint instability, reduced joint range of motion and disuse atrophy, and weakness of the quadriceps muscle (Dekker,1993).These give rise to symptoms such as pain, instability, reduction of range of motion and consequently, deterioration in quality of life and function (Imoto et al, 2012). A number of authors have used and found QSEseffective in addressing these problems (Pietrosimone et al,2010; Pietrosimone et al, 2014; Van der Esch et al, 2014; Anwer and Alghadir, 2014). A combination of open and closed kinetic chain exercises was chosen for the QSE intervention in this study because it has been opined by researchers that a combination of the kinetic chain exercises results in greater quadriceps strength, reduced pain, joint stability, improved physical function and health related quality of life (Mikkelson et al, 2000; Adegoke et al, 2003; Olagbegi et al, 2016).

Self-management is an idea widely used across healthcare and can be generally defined as what people do for themselves to establish and maintain physical and emotional health and prevent or deal with minor illness, injury, or chronic conditions (Webber et al, 2013). This incorporates concepts such as exercise, hygiene, nutrition, medication, and environmental and socioeconomic factors (Button et al, 2015). Thus,SME hasbeen applied to the management of OA which is a chronic condition

(Warsi et al, 2004). Warsi et al's review concluded that self-management in OA results in small benefits. It has however been suggested that this may be so only in self-management programmes designed for all forms of OA (Coleman et al, 2008). Hence the choice of disease and joint specific self-management education programme for the SME intervention in this study, as this has been shown to produce moderate benefit in individuals with knee OA (Coleman et al, 2012).

Self-management education and quadriceps strengthening exercise have been shown to be effective in the management of knee OA. There is however a dearth of studies comparing self-management education and quadriceps strengthening exercises.Considering that one of the intervention modalities requires more health care resources than the other and appears to be relatively more expensive in terms of cost of hospital attendance (to the patient) and health care resources (to the Government) it is necessary to compare the effectiveness of the two. Furthermore, comparing the efficacy of the two interventions is important in the quest to face the challenge of providing optimal care at the least cost possible for knee OA sufferers, in the face of limited resources (Adegoke and Gbeminiyi, 2004; Brosseau et al, 2012). A comparison of the two treatment modalities might also give useful evidence on the relative efficacy of both modalities in order to give an informed appraisal on the choice of therapy for patients with knee OA, hence the need for this study.

**Table 2.2: Summary of Literature Review on Self-management of Knee Osteoarthritis**

| Authors | Title | Year of publication | Sample Size/ Design | Conclusion |
|---|---|---|---|---|
| McKnight et al | A comparison of strength training, self-management and the combination for osteoarthritis of the knee | 2010 | 201 | Both self-management and strength training are beneficial for patients with knee osteoarthritis |
| Warsi et al | Self-management education programs in chronic diseases: a systematic review and methodological critique of the literature. | 2004 | 71/systematic review | Self-management education is of small benefit in the management of arthritis |
| Osborne et al | Can a disease specific education program augment self-management skills and improve health related quality of life in people with hip and knee osteoarthritis | 2006 | 204/ Randomized controlled trial | |
| Devos-Conbyet al | Do exercise and self-management interventions benefit patients with osteoarthritis of the knee | 2006 | Meta-analysis | Both patient education and exercise regiments had a modest yet clinically important influence on patients' wellbeing |

| Authors | Title | Year of publication | Sample Size/ Design | Conclusion |
|---|---|---|---|---|
| Coleman et al | Short and medium effect of an education self-management program for individuals with osteoarthritis of the knee designed and delivered by health professionals: a quality assurance study | 2008 | 146/clinical trial | This disease and site specific self-management education programme improved health status of people with osteoarthritis of the knee in the short and medium terms |
| Coleman et al | A randomized controlled trial of a self-management education program for osteoarthritis of the knee delivered by healthcare professionals | 2012 | 146/randomized controlled trial | Statistically significant improvement with a control group with regard to pain, quality of life and functionfor participants in the self-management education for osteoarthritis of the knee programme |

# CHAPTER THREE

# MATERIALS AND METHOD

## 3.1 Materials

### 3.1.1 Participants

The participants comprised 79 individuals with established Osteoarthritis (OA) of one or both knees as diagnosed by a medical practitioner based on either clinical examination or radiological evidence.

#### 3.1.1.1 Inclusion criteria

The following categories of individuals with OA of the knee were recruited into the study:

1. Individuals who had been clinically diagnosed as having knee OAby a general practitioner or orthopaedic surgeon, based on the American College of Rheumatology criteria (Silver et al, 2008).
2. Individuals diagnosed with OA of the knee/knees who understand either English or Hausa language.

#### 3.1.1.2 Exclusion criteria

The following categories of patients were excluded from the study

1. Individuals scheduled for knee surgery within six months of commencing the study.
2. Individuals with physical impairment that precluded full participation in the study,for example, patients with severe lower limb deformity.
3. Individuals who were unable to perform the physical tests included in the assessments.
4. Individuals who had received a knee corticosteroid injection within three months prior to the study.
5. Individuals who had plans to move out of Kaduna before the end of the study.

### 3.1.1.3 Recruitment

During the recruitment phase, the study was actively promotedand explained to general practitioners and orthopaedic surgeons by meeting them one on one, and to the general public through hand bills and posters advertising the study.

### 3.1.2 Instruments

1. Weighing scale: A portable weighing scale(Camry model) calibrated from 0-120kilogrammes and 0-260 pounds was used for taking participants' weight to the nearest 1.0kg.
2. Height meter: A height meter (SECA, model 220, Germany) with calibration ranging from 20 to 210 centimetres was used to measure participants' heights. The measurements in centimetres were then converted to metres.
3. Knee joint chart: This was used as a visual aid for teaching participants in the SMEG.
4. Bar bell: This was used for one of the quadriceps strengthening exercises (mini-squat with weight).
5. Ankle weights: These weights were strapped to the ankle for use in kinetic chain exercises with weights.
6. Ibadan Knee/ Hip Osteoarthritis Outcome Measure (IKHOAM): Physical function was assessed using the IKHOAM, which is a Nigerian culture and environment-friendly clinical tool developed in the University of Ibadan, Nigeria for measuring the end result of care in patients with hip or knee osteoarthritis (Akinpelu et al, 2007b). IKHOAM is a 3 part, 33-item clinical instrument. Parts 1 and 2 of IKHOAM are patient-reported. Part 1measures the degree of limitations and nature of assistance required in twenty-five relevant activities of daily living on a five-point (0-4) ordinal scale. Part 2 assesses the degree of participation restriction in three activities on a four-point (0-3) ordinal scale. Part 3 comprises five physical performance tests, which are rated by the clinician on five and six-point (0-5)ordinal scales. IKHOAM has been shown to demonstrate initial criteria towards validity and responsiveness (Akinpelu et al, 2007b and Odole and Akinpelu, 2010)(Appendix B). The Hausa version (Appendix B2) of the instrument was administered by interview to Hausa-speaking participants who were not literate in the English language.

**Scoring:** Part 1 rates 25 disability attributes on a 5-point ordinal scale for degree of difficulty experienced and nature of assistance required and has a maximum obtainable score of 200. Part 2 rates 3 attributes of participation restrictions on a 4-point ordinal scale and has a maximum obtainable score of 9 while Part 3 rates 5 items on physical tasks with a maximum obtainable score of 23. The maximum obtainable score on IKHOAM is 232(200+9+23). The overall participants' percentage score on IKHOAM is calculated using the following formula:

$$\frac{\text{Score obtained x } 100}{232}$$

Higher scores on IKHOAM represent good physical function and reduced level of disability.

7. Stopwatch: A stopwatch (Quartz, Germany) was used for timing during the physical performance tests in IKHOAM, as well as for the comfortable pace walk test andthe fast pace walk test.
8. Arthritis Impact Measurement Scale 2 (Short form):The Arthritis Impact Measurement Scale 2 short form (AIMS2 SF) is a disease-specific, self-administered instrument designed as a measure of outcome in arthritis (Meenan et al, 1980, Guillmin et al, 1997). It comprises 26 items in five domains namely: physical, symptoms, affect, social, and emotional well-being (Carr, 2002). The domain scores demonstrate good discriminate validity, internal consistency and test retest reliability. Gullman scale coefficients for scalability is greater than 0.6, its coefficients for reproducibility greater than 0.9, while its internal consistency via Cronbach's alpha is greater than 0.60 for each of the domains (Carr, 2003). Its test-retest correlation over a two-week period in several studies was also found to be greater than 0.80 (Carr, 2003). This was used to assess the quality of life of the participants (Appendix C).

**Scoring and Interpretation:** The response format has been standardized across sections to 5-point scales. For scoring, the Guttman scaling is ignored and each item is scored separately without weights. Higher scores indicate greater disability. The score for each section is standardized on a 0-10 scale using a standardization formula; zero represents 'best health' while 10 denotes 'worst health'. The total

health score is calculated by summing the standardized scores for physical, symptom, affect, social and work. The instrument was also translated into Hausa (Appendix C2) by linguistic experts from the Department of Language Studies, Kaduna State University, Kaduna, to have a standard translation which was administered by interview to participants who were not literate in English.

9. Panyi Professional Measuring Tape (China): This was used to measure distance in tests involving distance. It is calibrated from 0 to 50metres.
10. Visual Analogue Scale (VAS): This was used to assess participants' average daily pain and the intensity of pain felt before and after the 50-feet (15.24m) walk test. It is a strip of paper with an uncalibrated, straight 10-centimetre-long horizontal line on the horizontal axis. At one end of the scale is written "no pain" and at the other end is written "worst pain ever felt" (Appendix B1).VAS has been found to be sensitive and reproducible in the measurement of pain intensity (Reading, 1989). Soyannwo et al (2000) also found this instrument to be easily understood by Nigerians irrespective of their level of education.
11. Ruler (China): Calibrated in one centimeter unit apart was used to measure the intensity of pain marked on VAS.
12. Knee Joint model: This is a model of the knee joint(made of plastic material). It was used as a visual aid in the self-management education class (plate 3.1).

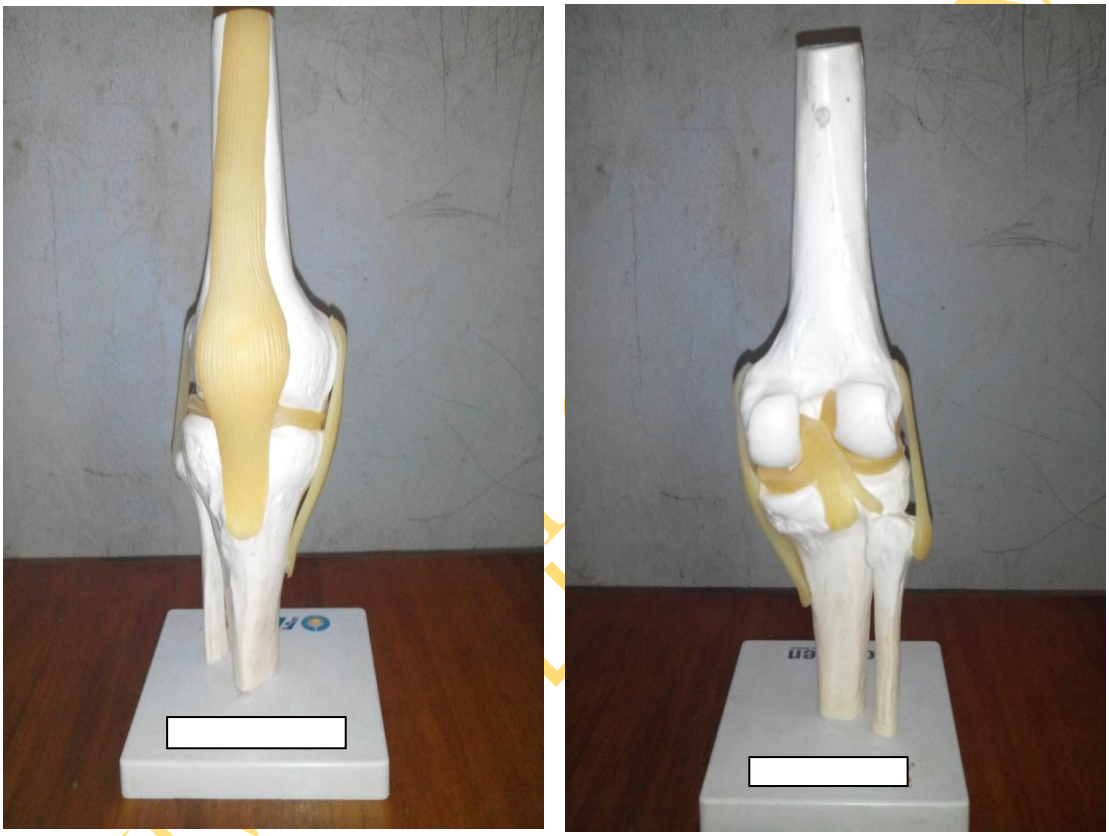

**Plate 3.1: SME Teaching Aid 2 (knee model, anterior and posterior views)**

## 3.2 Method

### 3.2.1 Sample size and sampling technique

The minimum sample size was calculated using the expression of medium effect (Marfalane, 2004).

$n = N (Z_1 + Z_2)^2 / ES^2$.

n = minimum sample size

N=number of groups

$Z_1$ = α-Confidence interval at 0.05= 1.96

$Z_2$ = β-Confidence interval at 0.20 = 0.84

ES = medium effect (0.5 was adopted for this)

$n = 2 (1.96 + 0.84)^2/0.5^2$

n = 15.86/0.25 = 62.72

n = 64

For attrition 20% rate will be computed.

n =64 + 14

n= 78

### 3.2.2 Sampling technique

The consecutive sampling technique was used to recruit participants into the study as they were referred from the medical practitioners.

### 3.2.3 Study Design

This study was a pre-test, post-test quasi experimental study. This design was chosen due to ethical considerations.

### 3.2.4 Procedure

Ethical approval for the study was sought and obtained from the joint UI/UCH EthicsCommittee and permission to carry out the study in Barau Dikko Specialist Hospital was obtained from the Medical Director of the hospital before commencement of the study. The nature, purpose and procedure of the research were explained in detail to the participants. Their informed consent for participation was sought and obtained. They were assured of the confidentiality of their data throughout the study and understood that theywere at liberty to withdraw anytime they felt they were unable to cope with the study. The safety of participants was of paramount importance throughout the research.

Participants were randomized into two groups by having them pick a wrapped paper with A or B with the tag number between 1 and 100 written on it from an opaque envelope. Participants who picked A were assigned to the Self-Management Education Group (SMEG) and those who picked B were assigned to the Quadriceps Strengthening Exercise Group (QSEG).

#### 3.2.4.1 Measurements

**a) Height**

The participants stood barefooted with their knees straight against the height metre. The distance between the vertex of the head and the heels was taken as the height and this was recorded to the nearest centimetre.

**b) Weight**

Participants in minimal clothing were asked to climb on the scale. With the participant looking straight, weight was measured to the nearest 1.0kg. Weight was assessed at baseline, 6th week, 1$^{st}$ month follow up, 2$^{nd}$ month follow up and 3$^{rd}$ month follow up.

**c) Pain Intensity**

Participants were asked to identify the Activity of Daily Living (ADL) that caused them the most pain. Then the visual analogue scale was used to assess the pain felt while performing the activity. The participant was then asked to mark the point on the

VAS that corresponded to the intensity of pain felt while performing the activity. The point marked was measured with the mathematical ruler and recorded in centimetres as participants' pain intensity. This was assessed at baseline, 6th week, 1stmonth follow up, 2nd month follow up and 3rd month follow up.

**d) Comfortable Pace Walking Time (CPWT)**

Participants were instructed to walk over a marked 50feet distance at their normal day-to-day pace. The time taken to walk the distance was measured with a stopwatch and recorded to the nearest second (Silva et al, 2008). This was assessed at baseline, 6thweek, 1stmonth follow up, 2nd month follow up and 3rd month follow up.

**e) Fast Pace Walking Time (FPWT)**

Participants were instructed to walk as fast as they could along the same marked distance as in CPWT. The time taken to walk the distance was measured with the stopwatch and recorded to the nearest second (Silva et al, 2008). This was assessed at baseline, 6thweek, 1stmonth follow up, 2nd month follow up and 3rd month follow up.

### 3.2.5 Procedure

#### 3.2.5.1 Self-management EducationGroup (SMEG)

The programme was conducted over a 6-week period thereby enabling participants to incorporate and consolidate information learned from week to week. Each weekly session comprised two topics and practical demonstration sessions of strengthening exercise, prevention of fall, joint protection or thermal therapy as it applied to the topics of the week. The class session lasted for 40-60mins (0.8-1.0hr). In addition to the weekly sessions, participants were also given an information booklet on knee osteoarthritis (published by Arthritis Research UK)(Appendix F); the Hausa translated version was given to those who did not understand English. The group size was 4-8participants, based on recruitment and randomization. Each group attended the class once a week for six weeks. Each participant was identified by a tag number in order to monitor attendance and to ensure consistency of assessments. Self-management constructs were employed to promote behavioural changes that were aimed at optimizing participants' health status. Goal setting and the development of strategies to

achieve these goals in the long term were emphasized in the class. A lesson note was developed from the outline used by Coleman et al (2012) and this was used to teach participants in the SMEG. A physiotherapist whose first language was Hausa was always present in class to explain the lesson, for the benefit of participants who did not understand English language.

Modules (Coleman et al, 2012)delivered are as listed below:

**Pathophysiology:**Information about what knee OA is, risk factors of knee OA, association between risk factors and progression of knee OA was taught in this module. A picture chart of the knee joint and a plastic knee model (Plates 3.1 and 3.2) were used as teaching aids to drive home points in this module.

**Pain management strategies (cognitive, pharmaceutical and physical agents)**: This module compriseda general overview of the different pain management strategies, including the different classes of drugs recommended in OA management, thermal therapy, cold therapy, TENS and cognitive behaviour.

**Joint protection**: This comprised lessons on the benefits of knee braces and insoles. The use of knee supports, braces and insoles was demonstrated.

**Fitness/exercise**: Participants were instructed to carry out five minutes warm up before and warm down after their exercises.The exercises involvedquadriceps strengthening and flexibility exercisesat least three times a week and walking as fast as they could for not less than 30 minutes at least three times a week. Participantswere also taught how to progress on the exercises.They were also given an exercise calendar designed for the programme to monitor adherence.

**Correct use of analgesia/medications**:Participants were taught when and how to correctly use analgesics, anti-inflammatory, and disease modifying OA drugs,as well as the benefits and adverse events of drugs for OA management.

**Balance/falls prevention/proprioception**: The relevance of walking aids and support was linked to balance, prevention of falls and proprioception and this was well demonstrated in this module.

**Cognitive techniques**: Coping skills, power of positive thinking and other cognitive behavioural techniques were presented in this module.

**Plate 3.2: SME Teaching Aid 1 (knee joint chart) (*courtesy of Novartis Pharmaceuticals)***

**Nutrition/weight control:**The relationship between body weight and (a) joint load, (b) various classes of food,(c) time of the day meals are consumed,and (d) different exercises, was explained to the participants in easy to understand terms.

**Self-management skills:** Participants were instructed on self-management, such as knowing when and how to use thermal/ cold therapy, when it is necessary to wear a brace or knee support, how to check their heart rate when exercising and their blood pressure where applicable, choosing the right analgesic/ anti-inflammatory to use and when to do so, checking their weight, choosing the type of walking aid or support when necessary, choosing the right diet for healthy weight maintenance and knowing when to exercise / progression.

**Team approach to health care:** This module was about the importance of team approach to health care. The role of each member of the health team was discussed

**SMART goals (Specific, Measurable, Achievable, Realistic,** and Time-**framed):** Participants were instructed/ encouraged on setting SMART goals. The meaning of the term was explained in an easy to understand way with examples.

### 3.2.5.2 Quadriceps Strengthening Exercise Group (QSEG)

#### 3.2.5.2.1 Exercise training procedure

Participants in this group engaged in individual quadriceps strengthening exercises (QSE) three times weekly. They were specifically instructed not to modify their activities of daily living and not to take part in additional forms of physical activity or other forms of physiotherapy for the duration of the study. Subjects in this group performed the following QSE:

**Quadriceps setting exercise (A)**

The Participant sat on a chair with his back supported, knee extended and heel on the floor. He/she then pressed the heel against the floor and the thigh against the seat of the chair. The position was held for a count of ten, after which the subject relaxed. This was done ten times (Kisner and Colby, 2007).This exercise was carried out by the subjects throughout the duration of the study (Adegoke, 2003) (Plate 3.3).

**Plate 3.3: A Participant performing quadriceps setting (A) exercise**

**Quadriceps setting (B)**

The Participantlays in supine position while contracting the quadriceps muscle of the affected lower extremity by drawing up the patella while maintaining the knee in extension. The contraction is held for a count of 10, then relaxed.This is repeated 10 times (Kisner and Colby, 2007). This exercise was carried out by the Participant throughout the duration of the study (Adegoke 2003) (Plate 3.4).

**Straight Leg Raising (SLR)**

The Participantlays in supine position while contracting his quadriceps and lifting the lower extremity up to achieve about $45^{o}$ hip flexion while maintaining the knee in extension. This position is held for a count of 10, then the limb is lowered.This is repeated 10 times. The contra-lateral knee and hip are flexed to about $45^{o}$ to avoid undue stress on the lower back (Kisner and Colby, 2007). The Participant carried out this exercise only during the third week of the study (Adegoke, 2003) (Plate 3.5).

**Straight Leg Raising (SLR) with weight**

A weight equivalent to the subject's 10RM was selected and strapped to the affected lower extremity just above the ankle. The Participant then lifted the lower extremity to about $45^{o}$ hip flexion while maintaining the knee in extension. The contra-lateral knee and hip joints were also flexed at $45^{o}$ (Kisner and Colby, 2007). A new 10RM was determined and used at the beginning of each of weeks 4,5 and 6 of the study (DeLorme and Watkins, 1948; Adegoke, 2003) (Plate 3.6).

**Mini- squats**

The Participant in standing position bent both knees about $30^{o}$ - $60^{o}$ while maintaining the trunk in upright position. This position was maintained for a count of 10, relaxed and repeated 10 times. (Kisner and Colby, 2007). This exercise was carried out in the third week of the study only; it was discontinued when the participant started mini-squats with weights (Plate 3.7).

**Plate 3.4: AParticipantperforming quadriceps setting (B) exercise**

**Plate 3.5: AParticipant performing straight leg raising exercise without weight**

**Plate 3.6: A Participant performing straight leg raising exercise with weight**

**Plate 3.7: ParticipantPerforming mini squat exercise without weight**

**Mini-squats with weights**

This exercise was the same as the mini squat except that the subject had a bar bell with weights placed across the shoulders. Each subject started with a weight equivalent to their 10RM and progressed to a new 10RM determined at the beginning of each week (Hollis, 1987). This exercise was carried out from week 4 to the end of the study (Adegoke, 2003) (Plate 3.8).

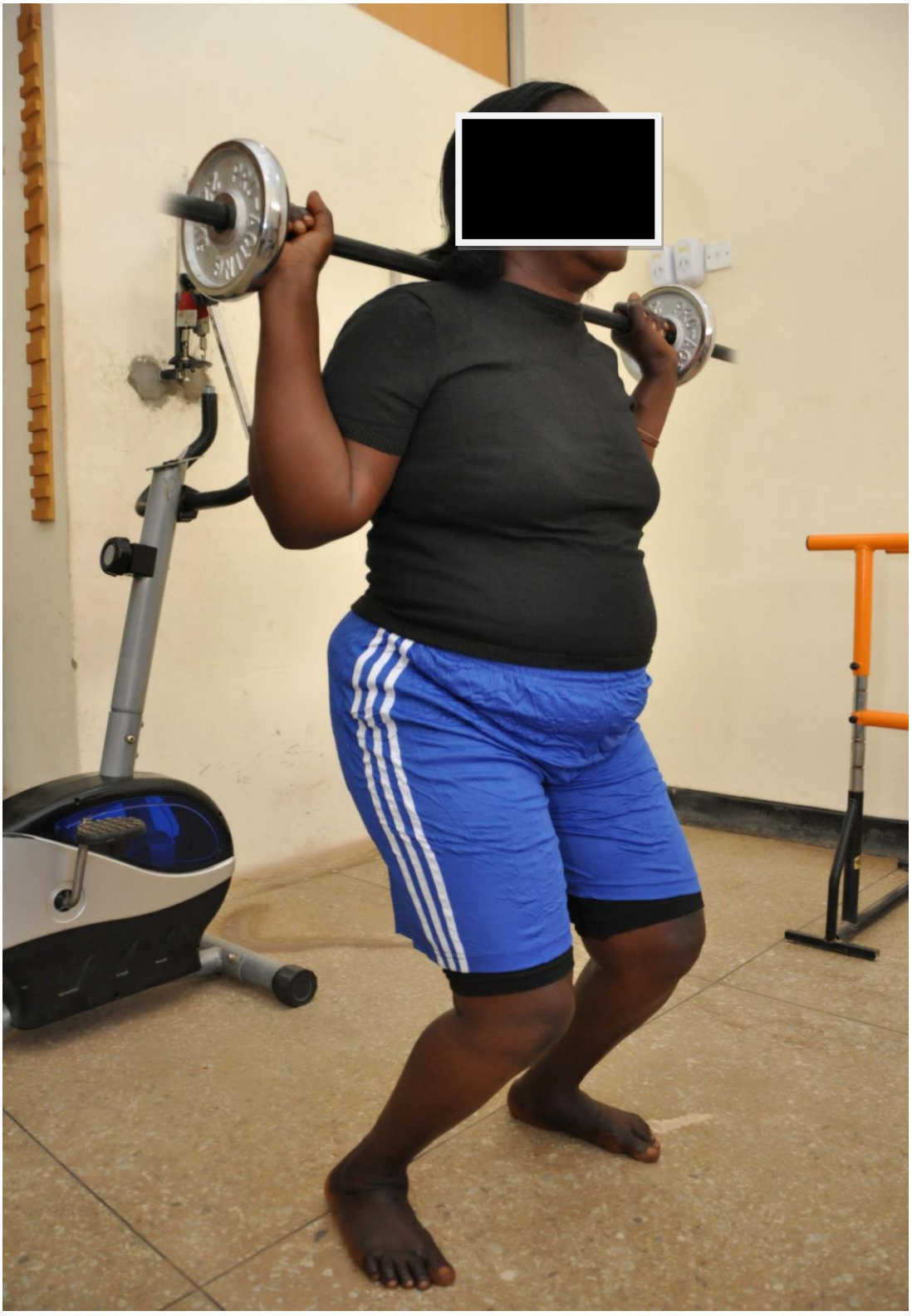

**Plate 3.8: A Participant performing mini squat exercise with weight**

### 3.2.6 Data analyses

Data obtained were analysed as follows:

1. Descriptive statistics of mean, standard deviation and percentages were used to summarize the socio-demographic data obtained from the participants.

2. Inferential statistics was computed to compare the age, body weight and body mass index of the two treatment groups.

3. Multi-level model (Mixed Effect Model) was used to:

a. Compare the mean score of all the selected outcome variables at baseline, 6$^{th}$ week, 1$^{st}$, 2$^{nd}$ and 3$^{rd}$ months follow up.

b. Compare the mean difference in the PF, PI and HRQoL of participants within each group across baseline, 6$^{th}$ week, 1$^{st}$, 2$^{nd}$ and 3$^{rd}$ months follow up.

c. Compare mean difference in the PF, PI and HRQoL of participants between the two treatment groups across baseline, 6$^{th}$ week, 1$^{st}$ , 2$^{nd}$ and 3$^{rd}$ months follow up.

d. Test the significance difference between the two groups across baseline, 6$^{th}$ week, 1$^{st}$, 2$^{nd}$ and 3$^{rd}$ months follow up.

e. Post hoc tests of significant differences within group with level of significanc

## Study Flow Diagram

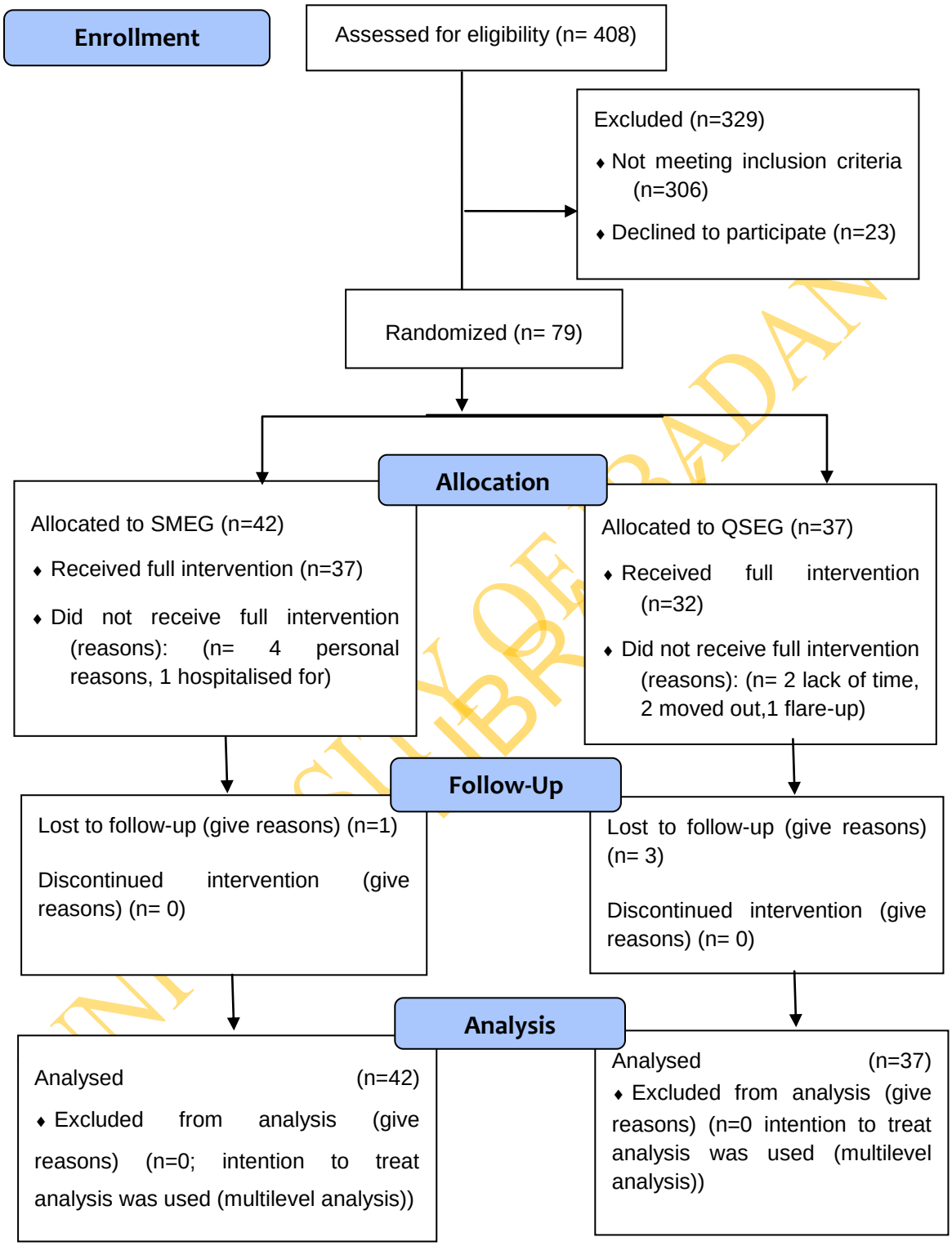


**Figure 3.1: The Study Flow Chart**

# CHAPTER FOUR

## Results and Discussion

### 4.1.1 Participants

One hundred and forty-seven participants referred by doctors from private hospitals, the general outpatient department and self-referred were seen by the orthopaedic surgeon. A hundred and six participants were referred for the research, two were further excluded as a result of other musculoskeletal diseases, while four declined to participate after reading the informed consent.One hundred subjects who gave their informed consent were randomly assigned into the Self-Management Education (SME) group and the Quadriceps Strengthening Exercise (QSE) group. Fifty subjects were randomized into the SME group and fifty-two into the QSE group. Forty-two subjects in the SME group showed up at the commencement of the intervention while thirty-seven were available for the QSE intervention. The study flow chart is presented in figure 4.1

### 4.1.2 Sociodemographic profile of the participants

Seventy-nine subjects were available for the post-intervention assessment. Forty-two subjects were in the SME group and 37 subjects were in the QSE group. The seventy-nine subjects comprised 66(83.5%) females and 13 (16.5%) males. The mean age for the SME group was 53.86 ± 10.40 while that of the QSE group was 50.11 ± 10.20(Table 4.2). Most of the subjects were married (64.6%) while the rest (35.4%) were either single (never married), divorced or widowed. Fifty-one subjects (64.6%) had OA of both knees, while 15 (19.0%) had left knee OA and 13 (16.4%) had right knee OA. The onset of knee OA was 1-2 years for 29 subjects, 3-5 years for 22 subjects and above 5years for 28 subjects. The sociodemographic profile of subjects is presented in table 4.1.

The mean age, height, weight and BMI of participants in the SMEG were 53.86 ± 10.40 years, 1.62 ± 0.07m, 80.0 ± 16.98 kg and 31.02 ± 6.95kg/$m^2$ respectively. The mean age, height, weight and BMI of QSEG were 50.11 ± 10.20 years, 1.62 ±0.07m, 81.0 ± 15.79kg and 31.00 ± 5.91 kg/$m^2$ respectively.Independent t-test at $\alpha = 0.05$ did not indicate any significant difference between the mean age, height, weight and BMI

of participants in the two intervention groups. Participants in the two groups were hence comparable in their physical characteristics (Table 4.2)

**Table 4.1: Participants' socio-demographic profile**

| VARIABLE | FREQUENCY | PERCENTAGE (%) |
|---|---|---|
| GENDER | | |
| Male | 13 | 16.5 |
| Female | 66 | 83.5 |
| **MARITAL STATUS** | | |
| Single | 28 | 35.4 |
| Married | 51 | 64.6 |
| **OCCUPATION** | | |
| Student | 3 | 3.8 |
| Unskilled | 19 | 24.1 |
| Skilled | 18 | 22.8 |
| Professional | 19 | 24.1 |
| Retired | 11 | 13.9 |
| Unemployed | 9 | 11.4 |
| **AFFECTED KNEE** | | |
| Left | 15 | 19.0 |
| Right | 13 | 16.4 |
| Both | 51 | 64.6 |
| **ONSET** | | |
| Less than 1 – 2 years | 29 | 36.7 |
| Less than 3- 5years | 22 | 27.9 |
| Above 5 years | 28 | 35.4 |

**Table 4.2: Biodata of participants**

| | Treatment Groups | | | |
|---|---|---|---|---|
| | SMEG (n = 42) | QSEG (n = 37) | | |
| Variable | X±SD | X±SD | T | p-value |
| Age (years) | 53.86 ± 10.40 | 50.11 ± 10.20 | 1.615 | 0.110 |
| Height (m) | 1.62 ± 0.07 | 1.62 ±0.07 | -0.310 | 0.611 |
| Weight (kg) | 80.0 ± 16.98 | 81.0 ± 15.79 | -0.286 | 0.776 |
| BMI ($Kg/m^2$) | 31.02 ± 6.95 | 31.00 ± 5.91 | 0.012 | 0.990 |

BMI – Body mass index

QSEG- Quadriceps Strengthening Exercise Group

SMEG- Self- Management Education Group

SD - Standard Deviation

M - Metre

Kg - kilogramme

### 4.1.3 Between-group comparison of pain intensity and physical function scores of SMEG and QSEG at baseline, 6th week, 1st, 2nd and 3rd month follow-up of study

Between-group comparison of participants' pain intensity (PI) and physical function (PF) at time points of baseline, 6th week, first, second and third months' follow-up are presented in Table 4.3. There was no significant between-group difference in PI except at the 6th week, when the SMEG had significantly higher ($p= 0.009$) PI. The groups' PF, however, were not significantly different ($p> 0.05$) at any of the time points.

The trends of the groups' PI are presented in figure 4.2. The QSEG had a more obvious fall in PI between baseline and the 6th week of the study but the SMEG had lower PI during the 3-month follow-up. The trends of the groups' PF are presented in figure 4.3. The physical function of SMEG was below that of QSEG at baseline, above it at week 6, the same with that of QSEG at 1st month follow up and above it for the rest of the study.

### 4.1.4 Between-group comparison of the walking time of SMEG and QSEG at baseline, 6th week and at 1st, 2nd and 3rd months follow-up of study

Between-group comparison of participants' comfortable pace walking time (CPWT) and fast pace walking time (FPWT) at time points of baseline, 6th week, first, second and third months' follow-up are presented in Table 4.4. There was no significant between-group difference ($p>0.05$) in both CPWT and FPWT except at baseline when the SMEG took significantly longer time ($p < 0.05$) than the QSEG. The trends of the groups' CPWT are presented in figure 4.5. The QSEG generally had lower CPWT than the SMEG except at first-month follow-up when it had higher values.The trend of the groups' FPWT is presented in figure 4.5. The FPWT for QSEG was lower than that of the SMEG at all the time points of the study.

**Table 4.3: Between-group comparison of participants' pain intensity and physical function scores at baseline, 6th week, 1st, 2nd and 3rd month follow-up of study**

| | | Treatment Groups | | | |
|---|---|---|---|---|---|
| | | SMEG (n = 42) | QSEG (n = 37) | | |
| Variable | Time | Mean (S.E) | Mean (S.E) | Diff. (S.E) | p-value |
| PI | Baseline | 6.02 (0.25) | 6.18 (0.27) | -0.34 (0.37) | 0.366 |
| | 6th Week | 3.94 (0.27) | 2.91 (0.29) | -1.03 (0.39) | 0.009* |
| | 1st MFU | 3.59 (0.27) | 3.99 (0.29) | 0.41 (0.40) | 0.299 |
| | 2nd MFU | 2.88 (0.27) | 3.61 (0.29) | 0.73 (0.40) | 0.066 |
| | 3rd MFU | 2.74 (0.27) | 3.31 (0.30) | 0.57 (0.40) | 0.158 |
| PF | Baseline | 72.63 (1.76) | 75.58 (1.88) | 2.96 (2.52) | 0.250 |
| | 6th Week | 84.33 (1.81) | 83.33 (1.93) | 4.00 (2.64) | 0.130 |
| | 1st MFU | 80.72 (1.81) | 80.96 (1.94) | 0.24 (2.65) | 0.927 |
| | 2nd MFU | 82.59 (1.81) | 81.33 (1.94) | -1.26 (2.66 | 0.636 |
| | 3rd MFU | 83.61 (1.81) | 82.4 (1.96) | -1.20 (2.67) | 0.654 |

* indicates significance at α = 0.05, S.E- standard error, PI- pain intensity, PF- physical function, MFU- month follow-up. QSEG - Quadriceps strengthening Exercise Group

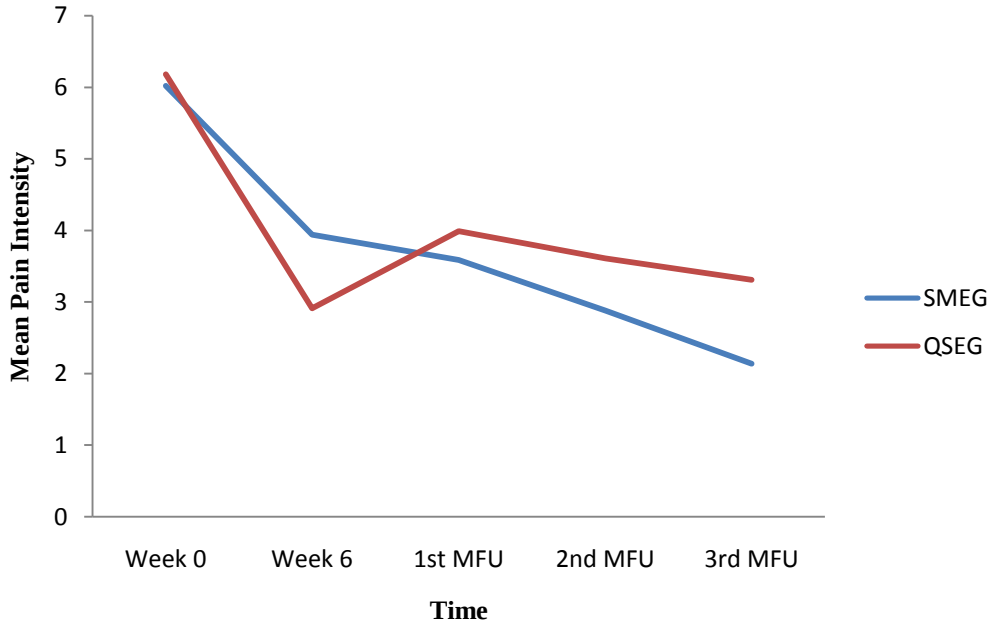


**Figure 4.1:Trends of pain intensity of participants in SMEG and QSEG at the five time points of the study**

Keys:

MFU- Month follow up

SMEG- Self-Management Education Group

QSEG- Quadriceps strengthening Exercise Group

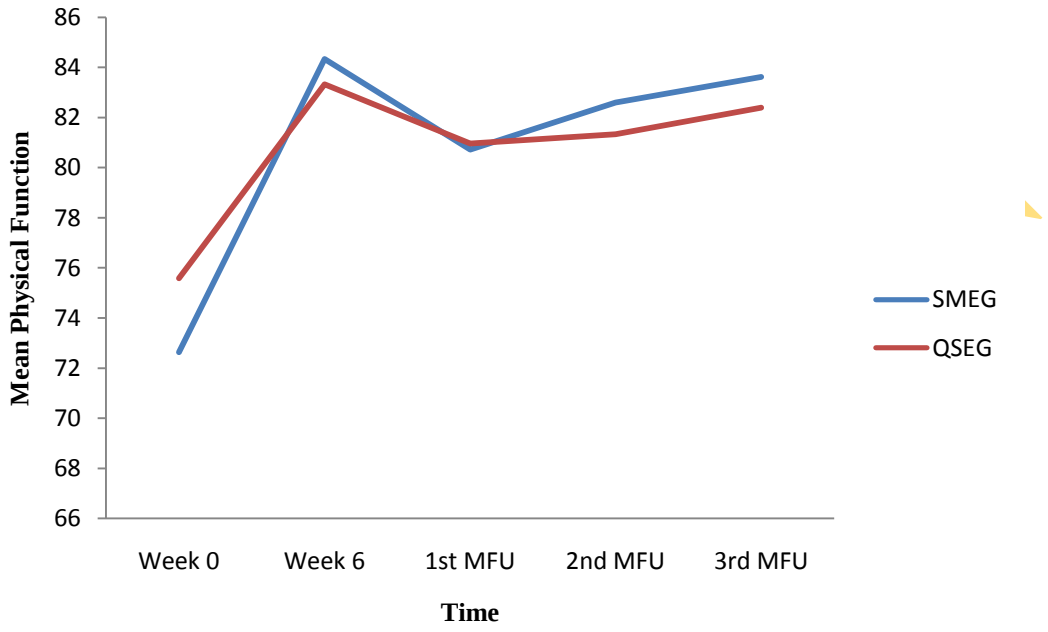


**Figure 4.2: Trends of physical function of participants in SMEG and QSEG at the five time points of the study**

Keys:

MFU- Month follow up

SMEG- Self-Management Education Group

QSEG - Quadriceps strengthening Exercise Group

**Table 4.4: Between-group comparison of participants' comfortable and fast pace walking time at baseline, 6th week, 1st, 2nd and 3rd month follow-up of study**

| | | Treatment Groups | | | |
|---|---|---|---|---|---|
| | | SMEG (n = 42) | QSEG (n = 37) | | |
| Variable | Time | Mean (S.E) | Mean (S.E) | Diff. (S.E) | p-value |
| CPWT (s) | Baseline | 14.53 (0.24) | 13.76 (0.26) | -0.77 (0.46) | 0.031* |
| | 6th Week | 12.28 (0.25) | 12.26 (0.27) | -0.02 (0.37) | 0.954 |
| | 1st MFU | 13.42 (0.25) | 13.96 (0.28) | -0.16 (0.37) | 0.668 |
| | 2nd MFU | 13.35 (0.26) | 13.22 (0.28) | -0.12 (0.38) | 0.736 |
| | 3rd MFU | 13.15 (0.26) | 13.00 (0.28) | -0.13 (0.38) | 0.639 |
| FPWT (s) | Baseline | 11.52 (0.27) | 10.58 (0.29) | -1.04 (0.40) | 0.009* |
| | 6th Week | 9.54 (0.28) | 9.08 (0.30) | -0.37 (0.42) | 0.376 |
| | 1st MFU | 10.59 (0.28) | 10.18 (0.31) | -0.41 (0.42) | 0.336 |
| | 2nd MFU | 10.67 (0.29) | 10.11 (0.31) | -0.55 (0.42) | 0.190 |
| | 3rd MFU | 10.36 (0.29) | 10.25 (0.31) | -0.11 (0.42) | 0.793 |

* indicates significance at α = 0.05, S.E- standard error, CPWT- comfortable pace walking time, FPWT- fast pace walking time, MFU- month follow-upQSEG - Quadriceps Strengthening Exercise Group

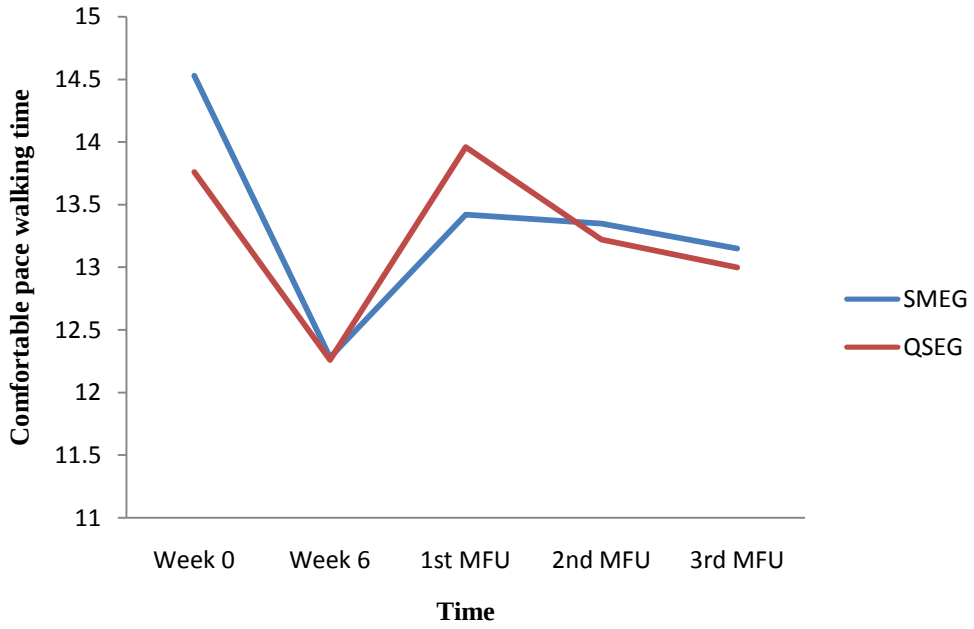


**Figure 4.3:Trends of comfortable pace walking time of participants in SMEG and QSEG at the five time points of the study**

Keys:

MFU- Month follow up

SMEG- Self-Management Education Group

QSEG – Quadriceps strengthening Exercise Group

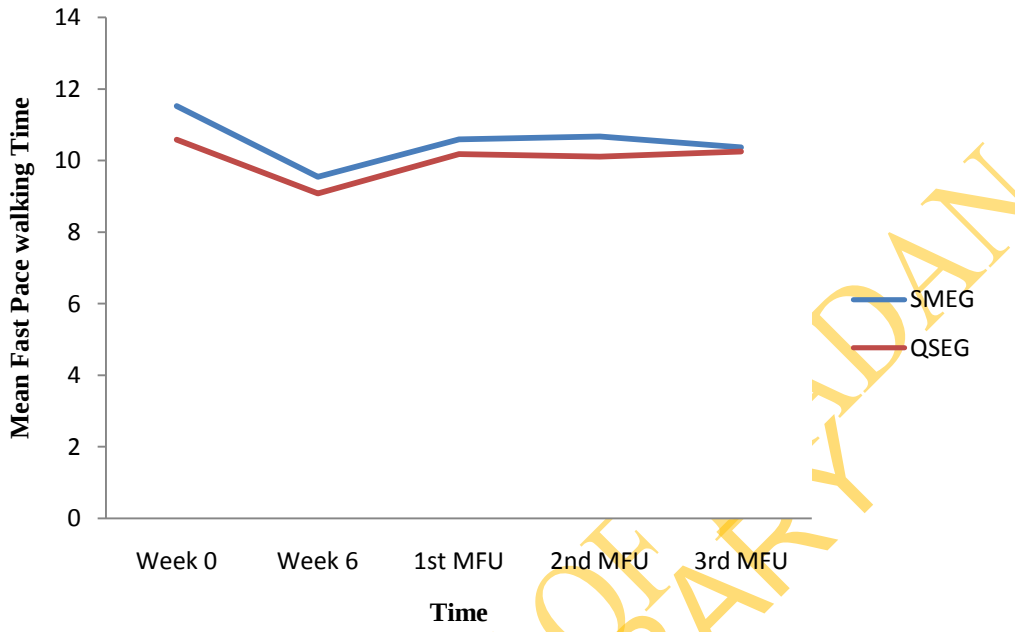


**Figure 4.4: Trends of fast pace walking time of participants in SME and QSE groups at the five time points of the study**

Keys:

MFU- Month follow up

SMEG- Self-Management Education Group

QSEG - Quadriceps strengthening Exercise Group

### 4.1.5 Between-group Comparison of the Health-related Quality of Life (HRQoL) of SMEG and QSEG at baseline, 6th week, 1st, 2nd and 3rd months follow-up of study

Between-group comparison of participants' HRQoL at the time points of baseline, 6th week, first, second and third months' follow-up are presented in Table 4.5. The groups' HRQoLs were not significantly different ($p > 0.05$) at any of the time points.

The trend of the groups' HRQoLs is presented in Figure 4.6. The mean HRQoL for the QSEG was below that of the SMEG between baseline and 1st month follow-up, but was a little higher than that of SMEG after 1st month follow-up to the end of the study.

### 4.1.6 Within-group comparison of participants' pain intensity across the time points of the study

Within-group comparison and post-hoc analysis of the SMEG and the QSEG are presented vertically in Table 4.6 with post-hoc analysis indicated with superscripts, p- value $\leq 0.001$. A multilevel analysis showed significant differences in average pain intensity across the five time points of the study for participants in the SMEG (226.61), and the QSEG (139.34) (Table 4.6).

Post-hoc analysis using pairwise comparisonfor both groups indicated that baseline PI was significantly higher than the values at 6th week, 1st MFU, 2nd MFU and 3rd MFU. There was no significant difference between the SMEG PI scores at 6th week and 1st MFU and between 2nd and 3rd MFU. For QSEG the PI score at 1st MFU was significantly higher than at 6th week but there was no significant difference between 2nd and 3rd MFU values.

**Table 4.5: Between-group comparison of participants' health-related quality of life scores at baseline, 6th week, 1st, 2nd and 3rdmonth's follow-up of study**

| | | Treatment Groups | | | |
|---|---|---|---|---|---|
| | | SMEG | QSEG | | |
| | | (n = 42) | (n = 37) | | |
| Variable | Time | Mean (S.E) | Mean (S.E) | Diff. (S.E) | p-value |
| HRQoL | Baseline | 24.61 (0.65) | 24.57 (0.72) | -0.04 (0.95) | 0.470 |
| | 6th Week | 21.41 (0.68) | 20.02 (0.72) | -1.39 (0.99) | 0.161 |
| | 1st MFU | 24.01 (0.68) | 23.14 (0.73) | -0.87 (1.00) | 0.384 |
| | 2nd MFU | 22.51 (0.68) | 23.18 (0.73) | 0.59 (1.00) | 0.554 |
| | 3rd MFU | 22.51 (0.68) | 23.08 (0.74) | 0.57 (1.01) | 0.570 |

S.E- standard error, HRQoL- health-related quality of life, MFU- month follow-up

SMEG- Self-Management Education Group

QSEG - Quadriceps strengthening Exercise Group

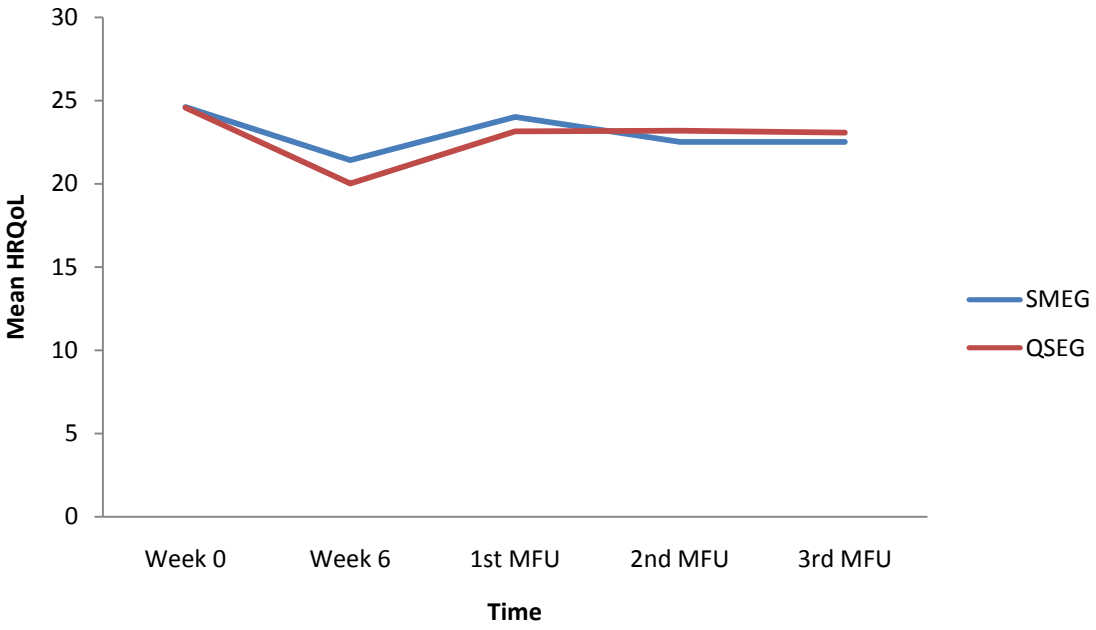


**Figure 4.5: Trends of health-related quality of life participants in SME and QSE groups at the five points of the study**

Keys:

MFU- Month follow up

SMEG- Self-Management Education Group

QSEG – Quadriceps strengthening Exercise Group

### 4.1.7 Within-group comparison of participants' physical function across the time points of the study

Within group comparison and post-hoc analysis of SMEG across the time points of baseline, 6th week, 1st month, 2nd month and 3rd month follow-up are presented vertically in Table 4.6 with post-hoc analysis indicated with superscripts, p-value ≤ 0.001. A multilevel analysis showed significant differences in average physical function scores across the five time points of the study for participants in the SMEG (122.01) (Table 4.6).

Post hoc analysis using pairwise comparison (contrast of marginal linear prediction) for the SMEGindicated that the baseline PF was significantly lower than the values forthe 6th week, 1stMFU, 2nd MFU and 3rd MFU. There was no significant difference between PF scores at 6th week and 2nd and 3rd MFU.

Within-group comparison and post hoc analysis of QSEG across the time points of baseline, 6th week, 1st month, 2nd month and 3rd month follow-up are presented vertically in Table 4.6 with post hoc analysis indicated with superscripts, p-value ≤ 0.001. The multilevel analysis showed significant differences in average physical function scores across the five time points of the study for participants in the QSEG (96.38) (Table 4.6).

Post hoc analysis using pairwise comparison (contrast of marginal linear prediction) for the QSEG indicated that the baseline PF was significantly lower than the values forthe 6th week, 1st MFU, 2nd MFU and 3rd MFU. For the QSEG, the PF score forthe 6th week was significantly higher than for the 1st and 2nd MFU but there was no significant difference within the follow-up scores.

### 4.1.8 Within-group comparison of participants' CPWT across the time points of the study

Within-group comparison and post hoc analysis of SMEG and QSEG across time points of baseline, 6th week, 1st month, 2nd month and 3rd month follow-up are presented vertically in Table 4.8 with post hoc analysis indicated with superscripts, p-value ≤ 0.001. The Mixed Effect Model showed significant differences in average CPWT scores across baseline, 6th week and 1st month follow-up of the study for participants in the SMEG (97.73), and QSEG (38.99) (Table 4.7).

**Table 4.6: The within-group multilevel analysis and post hoc comparison of participants' pain intensity and physical function scores across baseline and 6th week,1st month, 2nd month and 3rd month follow-up of study.**

| | | Treatment Groups | |
|---|---|---|---|
| | | SMEG | QSEG |
| | | (n = 42) | (n = 37) |
| Variable | Time | Mean (S.E) | Mean (S.E) |
| PI | Baseline | 6.02 (0.25)[a] | 6.18 (0.27)[a] |
| | 6th Week | 3.94 (0.27)[b] | 2.91 (0.29)[b] |
| | 1st MFU | 3.59 (0.27)[b] | 3.99 (0.29)[c] |
| | 2nd MFU | 2.88 (0.27)[c] | 3.61 (0.29)[c] |
| | 3rd MFU | 2.74 (0.27)[c] | 3.31 (0.30)[c] |
| Chibar2 | | 226.61 | 139.34 |
| p-value | | <0.001* | <0.001* |
| PF | Baseline | 72.63 (1.76)[a] | 75.58 (1.88)[a] |
| | 6th Week | 84.33 (1.81)[b] | 83.33 (1.93)[b] |
| | 1st MFU | 80.72 (1.81)[c] | 80.96 (1.94)[c] |
| | 2nd MFU | 82.59 (1.81)[b] | 81.33 (1.94)[c] |
| | 3rd MFU | 83.61 (1.81)[b] | 82.4 (1.96)[bc] |
| Chibar2 | | 122.01 | 96.38 |
| p-value | | <0.001* | <0.001* |

*indicates significant time point difference at α=0.05

*Superscripts (a,b,c,d).* For a particular variable, mean values with different superscript are significantly (p<0.05) different. Mean values with same superscripts are not significantly (p>0.05) different.

PI= Pain Intensity, PF = physical function.SMEG- Self-Management Education Group.

Post hoc analysis using pairwise comparison (contrast of linear marginal prediction) indicated significant difference in CPWT among participants in the SMEG between the baseline, 6th week and 1st month follow-up. There was however no significant difference within the follow-up period of the study.

There was significant difference in the CPWT of participants in the QSEG between the baseline, 6th week and 1st month follow-up. There was however no significant difference within the follow-up period of the study.

### 4.1.9 Within-group comparison of participants' FPWT across the time points of the study

Within group comparison and post hoc analysis, of the FPWT of the SMEG and the QSEG across the time points of baseline, 6th week, 1st month, 2nd month and 3rd month follow-up, are presented vertically in Table 4.7 with post hoc analysis indicated with superscripts, p-value= 0.001. The multilevel analysis showed significant differences in average FPWT scores across baseline, 6th week and 1st month follow-up of the study for participants in the SMEG (65.18) (Table 4.7).

Post hoc analysis using pairwise comparison (contrast of marginal linear prediction) for the SMEG indicated the baseline FPWT was significantly higher than at the other time points of the study while the value at the 6th week was significantly lower than other time points. The FPWT at 1st 2nd and 3rd MFU were however not significantly different.

Within-group comparison and post hoc analysis, of the FPWT of the QSEG across the time points of baseline, 6th week, 1st month, 2nd month and 3rd month follow-up, are presented vertically in Table 4.7 with post hoc analysis indicated with superscripts, p-value= 0.001. The multilevel analysis showed significant differences in average FPWT scores for participants in the baseline and 6th week in the QSEG (29.81) (Table 4.11).

There was significant difference in the FPWT of the QSEG between the baseline and 6th week. There was however no significant difference between the baseline and the follow-up period of the study (table 4.7).

### 4.1.10 Within-group comparison of participants' health-related quality of life scores across the time points of the study

Within-group comparison and post hoc analysis, of the HRQoL scores of the SMEG and the QSEG across the time points of baseline, 6th week, 1st month, 2nd month and 3rd month follow-up, are presented vertically in Table 4.8 with post hoc analysis indicated with superscripts, p-value= 0.001. The multilevel analysis showed significant differences in average HRQoL scores acrossthe baseline, 6th week and follow-up periods of the study for participants in the SMEG (34.59), and the same was observed in the QSEG (51.22) (Table 4.8).

Post hoc analysis using pairwise comparison indicated significantly higher scores in HRQoL among participants in the SMEG between the baseline and the 6th week. There was however no significant difference within the follow-up period of the study (table 4.8).

Within-group comparison and post hoc analysis, of HRQoL of the QSEG across the time points of baseline, 6th week, 1st month, 2nd month and 3rd month follow-up, are presented vertically in Table 4.8 with post hoc analysis indicated with superscripts, p-value= 0.001. The multilevel analysis showed significant differences in average HRQoL scores across baseline, 6th week and follow-up periods of the study for participants in the SMEG (34.59), and same was observed in the QSEG (51.22) (Table 4.13).

There was significant difference inHRQoL of the QSEG between the baseline and 6th week. There was however no significant difference within the follow-up period of the study (4.8).

**Table 4.7: The within-group multilevel analysis and post hoc comparison of participants' comfortable and fast pace walking time across baseline and 6th week of study and1st month, 2nd month and 3rd month follow up of phase of study.**

| | | Treatment Groups | |
|---|---|---|---|
| | | SMEG | QSEG |
| | | (n = 42) | (n = 37) |
| **Variable** | Time | Mean (S.E) | Mean (S.E) |
| **CPWT (s)** | Baseline | 14.53 (0.24)[a] | 13.76 (0.26)[a] |
| | 6th Week | *12.28 (0.25)[b] | *12.26 (0.27)[b] |
| | 1st MFU | *13.42 (0.25)[c] | 13.96 (0.28)[a] |
| | 2nd MFU | *13.35 (0.26)[c] | 13.22 (0.28)[a] |
| | 3rd MFU | *13.15 (0.26)[c] | 13.00 (0.28)[ab] |
| Chibar2 | | 97.73 | 38.99 |
| **p-value** | | < 0.001* | < 0.001* |
| **FPWT (s)** | Baseline | 11.52 (0.27)[a] | 10.58 (0.29)[a] |
| | 6th Week | *9.54 (0.28)[b] | *9.08 (0.30)[b] |
| | 1st MFU | *10.59 (0.28)[c] | 10.18 (0.31)[a] |
| | 2nd MFU | 10.67 (0.29)[c] | 10.11 (0.31)[a] |
| | 3rd MFU | *10.36 (0.29)[c] | 10.25 (0.31)[a] |
| Chibar2 | | 65.18 | 29.81 |
| **p-value** | | < 0.001* | < 0.001* |

*indicates significant time point difference at α=0.05

*Superscripts (a,b,c).* For a particular variable, mean values with different superscript are significantly (p<0.05) different. Mean values with same superscripts are not significantly (p>0.05) different. CPWT= Comfortable pace walking time, FPWT = Fast pace walking time. SMEG- Self-Management Education Group. QSEG – Quadriceps strengthening Exercise Group

**Table 4.8: The within-group multilevel analysis and post hoc comparison of participants' health-related quality of life across baseline and 6th week of study and1st month, 2nd month and 3rd month follow up phase of the study**

| | | Treatment Groups | |
|---|---|---|---|
| | | SMEG | QSEG |
| | | (n = 42) | (n = 37) |
| Variable | Time | Mean (S.E) | Mean (S.E) |
| HRQoL | Baseline | 24.61 (0.65)[a] | 24.57 (0.72)[a] |
| | 6th Week | *21.41 (0.68)[b] | *20.02 (0.72)[b] |
| | 1st MFU | 24.01 (0.68)[c] | *23.14 (0.73)[c] |
| | 2nd MFU | *22.51 (0.68)[c] | *23.18 (0.73)[c] |
| | 3rd MFU | *22.51 (0.68)[c] | *23.08 (0.74)[c] |
| Chibar2 | | 34.59 | 51.22 |
| p-value | | < 0.0001* | < 0.0001* |

*indicates significant time point difference at α=0.05

*Superscripts (a,b,c).* For a particular variable, mean values with different superscript are significantly ($p<0.05$) different. Mean values with same superscripts are not significantly ($p>0.05$) different.

HRQoL= Health-related quality of life.

SMEG- Self-Management Education Group

QSEG – Quadriceps strengthening Exercise Group

## 4.2 Testing of hypotheses

Fifteen hypotheses were proposed at the beginning of the study and were tested as indicated below:

Hypothesis 1: This stated that there would be no significant difference between the pain intensity (PI) of patients with knee osteoarthritis in the Self-Management Education Group (SMEG) and the Quadriceps Strengthening Exercises Group (QSEG) groups at baseline, 6$^{th}$ week of intervention phase and the 1$^{st}$, 2$^{nd}$ and 3$^{rd}$ month follow-up phase of the study.

**Baseline**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.336

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED

**6$^{th}$ week**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.009

The observed p-value was less than the 0.05 alpha level. The hypothesis was therefore REJECTED.

**1$^{st}$ month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.299

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**2nd month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.067

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED

**3rd month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.158

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

Hypothesis 2: This states that there would be no significant difference between the health-related quality of life (HRQoL) scores of patients with knee osteoarthritis in the SMEG and the QSEG at baseline, 6th week of intervention phase and the 1st, 2nd and 3rd month follow-up phase of the study

**Baseline**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.470

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**6th week**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.161

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**1st month post intervention**

Alpha level: 0.05

Test statistic: multilevel model

Observed: 0.384

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**2nd month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.554

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**3rd month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.570

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

Hypothesis 3: This states that there would be no significant difference between the physical function (PF) score of patients with knee osteoarthritis in the SMEG and the QSEG at baseline, 6th week of intervention phase and the 1st, 2nd and 3rd month follow-up phase of the study.

**Baseline**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.250

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED

**6th week**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.130

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**1st month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.927

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**2nd month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.636

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**3rd month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.654

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

Hypothesis 4: This stated that there would be no significant difference between the Comfortable Pace Walking Time (CPWT) of individuals with knee osteoarthritis in the SMEG and the QSEG at baseline, 6th week of intervention phase and the 1st, 2nd and 3rd month follow-up phase of the study.

**Baseline**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.031

The observed p-value was less than the 0.05alpha level. The hypothesis was therefore REJECTED.

**6th week**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.954

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**1st month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.668

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**2nd month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.736

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**3rd month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.639

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

Hypothesis 5: This stated that there would be no significant difference between the Fast Pace Walking Time (FPWT) of individuals with knee osteoarthritis in the SMEG and the QSEG at baseline, 6th week of intervention phase and the 1st, 2nd and 3rd month follow-up phase of the study.

**Baseline**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.009

The observed p-value was less than the 0.05 alpha level. The hypothesis was therefore REJECTED.

**6th week**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.376

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**1st month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.336

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**2nd month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.190

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

**3rd month post intervention**

Alpha level: 0.05

Test statistic: Multilevel model

Observed: 0.793

The observed p-value was greater than the 0.05 alpha level. The hypothesis was therefore NOT REJECTED.

Hypothesis 6: There would be no significant difference in the PI of individuals with knee OA in the SMEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2nd and 3rd month follow-up.

Alpha level: 0.001

Test statistic: Multilevel model

Observed :< 0.001

The observed p-value was less than the 0.001 alpha level. The hypothesis was therefore REJECTED.

Hypothesis 7: There would be no significant difference in the HRQoL of individuals with knee OA in the SMEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2nd and 3rd month follow-up.

Alpha level: 0.001

Test statistic: Multilevel model

Observed :< 0.001

The observed p-value was less than the 0.001 alpha level. The hypothesis was therefore REJECTED.

Hypothesis 8: This stated that there would be no significant difference in the PF of individuals with knee OA in the SMEG across the five time frames of baseline, 6th week intervention, and at 1st, 2nd and 3rd month follow-up.

Alpha level: 0.001

Test statistic: multilevel model

Observed :< 0.001

The observed p-value was less than the 0.001 alpha level. The hypothesis was therefore REJECTED.

Hypothesis 9: This stated that there would be no significant difference in the CPWT of individuals with knee OA in the SMEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2nd and 3rd month follow-up.

Alpha level: 0.001

Test statistic: Multilevel model

Observed :< 0.001

The observed p-value was less than the 0.001 alpha level. The hypothesis was therefore REJECTED.

Hypothesis 10: There will be no significant difference in the FPWT of individuals with knee OA in the SMEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2nd and 3rd month follow-up of the study.

Alpha level: 0.001

Test statistic: Multilevel Model

Observed :< 0.001

The observed p-value was less than the 0.001 alpha level. The hypothesis was therefore REJECTED.

Hypothesis 11: There will be no significant difference in the PI of individuals with knee OA in the QSEG across the five time frames of baseline, 6th week of intervention, and the 1st, 2nd and 3rd month follow-up of the study.

Alpha level: 0.001

Test statistic: Multilevel Model

Observed :< 0.001

The observed p-value was less than the 0.001 alpha level. The hypothesis was therefore REJECTED.

Hypothesis12: This hypothesis stated that there would be no significant difference in the FPWT of patients with knee OA in the SME group across the five time frames of baseline, $6^{th}$ week of intervention, and the $1^{st}$, $2^{nd}$and $3^{rd}$ month post-intervention

Alpha level: 0.001

Test statistic: Multilevel model

Observed :< 0.001

The observed p-value was less than the 0.001 alpha level. The hypothesis was therefore REJECTED.

Hypothesis 13: This hypothesis stated that there would be no significant difference in the HRQoL of patients with knee OA in the QSE group across the five time frames of baseline, $6^{th}$ week of intervention, and the $1^{st}$, $2^{nd}$and $3^{rd}$ month post-intervention.

Alpha level: 0.05

Test statistic: Multilevel model

Observed p:<0.001

The observed p-value was less than the 0.05 alpha level. The hypothesis was therefore REJECTED.

Hypothesis 14: This hypothesis stated that there would be no significant difference in the PF of patients with knee OA in the QSE group across the five time frames of baseline, 6th week of intervention, and the 1st, 2ndand 3rd month post-intervention.

Alpha level: 0.05

Test statistic: Multilevel model

Observed p:<0.001

The observed p-value was less than the 0.05 alpha level. The hypothesis was therefore REJECTED.

Hypothesis 15: This hypothesis stated that there would be no significant difference in the CPWT of patients with knee OA in the QSE group across the five time frames of baseline, 6th week of intervention, and the 1st, 2ndand 3rd month post-intervention.

Alpha level: 0.001

Test statistic: Multilevel model

Observed p:<0.001

The observed p-value was less than the 0.001 alpha level. The hypothesis was therefore REJECTED.

Hypothesis 16: This hypothesis stated that there would be no significant difference in the FPWT of patients with knee OA in the QSE group across the five time frames of baseline, 6th week intervention, and 1st, 2ndand 3rd month post-intervention.

Alpha level: 0.001

Test statistic: Multilevel model

Observed p:<0.001

The observed p-value was less than the 0.001 alpha level. The hypothesis was therefore REJECTED.

## 4.3 Discussion

### 4.3.1 Participants' profile

The majority of the participants in this study were female. This finding which shows that knee OA is more prevalent in women than in men is consistent with some other studies (Adrian and Doherty, 1995; Akinpelu et al, 2009; McKnight et al, 2010; Cho et al, 2010; Coleman et al, 2012)..Most of the participants were obese with BMI > 30.This is understandable as high BMI is one of the risk factors associated with knee OA (Zeni and Snyder- Mackler, 2010).

### 4.3.2 Effects of six weeks SME on pain, physical function and health-related quality of life of individuals with knee osteoarthritis

The major complaints of individuals with knee OA are pain and loss of functional ability (Adegoke et al, 2012). Patients complain of pain especially when climbing stairs, squatting or walking. That is why pain, physical function, and Health-Related Quality of Life (HRQoL) are important outcomes in OA (Xie et al, 2010). The clinical outcomes ofpain, the HRQoL and physical function improved significantly post-SME intervention, but some degree of the improvement was lost duringthe three months'follow-up period.In spite of this,the difference between baseline and the 3$^{rd}$ month follow-up was still statistically significant. These effects are attributable to the SME programme adopted in this study, which was specific for the knee and holistic in approach, as core recommendations for the treatment of knee OA were covered in the programme (NICE guideline, 2008). Furthermore, the importance of exercise was particularly emphasized with participants being taught adequate exercise dosing and progression by the physiotherapist. This approach was adopted as exercise has been shown to be a very important component of self-management education (Hurley et al, 2007; Button et al, 2015). The rationale behind the theory of OA symptoms as linked to the management was taught while using self-management construct so that participants would be able totake control of managing their OA effectively. The effects of treatments such as bracing, ice/thermal therapy, use of walking aid, and exercise were demonstrated in the SME class. Correct use of medications was also taught as well as how to manage pain induced by exercise, as fear of pain has been

identified as one of the reasons for noncompliance with exercise therapy (Alami et al, 2011).Participants were also encouraged to choose walking as their form of aerobic exercise as this is simple and does not need special equipment. Furthermore,the knee OA information booklet (Arthritis research UK) was given to participants for reference in managing their OA. A similar result was achieved with the same approach in a study carried out in Australia (Coleman et al, 2008; 2008b).Participants' walk speed as measured by comfortable pace walk and fast pace walking tests conducted at the different time frames improved. This was probably directly related to improvement in compliance with exercise prescription which in turn led to improvement in the physical function score and consequently the increased walk speed observed in the study. This was contrary to the opinion of some researchers who opined that SME produces little or no benefit in individuals with OA (Warsi et al, 2004; Kroon et al 2014). It was noted that many of the previous SME interventions for OA were not joint specific and might have included other forms of arthritis (Lorig et al, 1996; Warsi et al, 2004), which may explain the small benefit noted in the reviews.

The general trend observed during the follow up in this study was significant loss of some of the improvementsgained. This trend has also been reported in other SME programmes (Newman et al, 2004; Coleman et al, 2012).

### 4.3.3 Effects of six weeks QSE on pain, physical function and health related quality of life in individuals with knee osteoarthritis

Quadriceps Strengthening Exercises (QSE) had positive effects on all the outcome variables assessed. Pain intensity, the HRQoL and physical function improved significantly post intervention compared to the baseline. The quadriceps muscles were targeted for strengthening with a combination of open and closed kinetic chain exercises three times a week under the supervision of a physiotherapist. Quadriceps muscle weakness, one of the modifiable risk factors for knee OA, has been associated with pain and disability in patients with knee OA (Fransen et al, 2000; Segal et al, 2012).This has informedthe recommendation of quadriceps strengthening exercises as one of the core interventions in the management of knee OA (Jordan et al, 2003; Richmond et al, 2009) as some randomized control trials have shown that

they have statistically significant positive effects on pain and function (Roddy et al, 2005; Segal et al, 2012). It has also been observedthat a combination of open and closed kinetic chain quadriceps strengthening exercises results in stronger quadriceps than closed kinetic chain exercises alone(Mikelson et al 2000). Furthermore, as was observed in a studyby Minoonejad et al (2012), the combination of closed and open kinetic chain quadriceps strengthening exercises in participants with patella-femoral pain syndrome resulted in significantly greater reduction in pain than in the control. It could therefore be submitted that the choiceof a combination of open and closed kinetic chain exercises in this study may have been responsible for the statistically significant improvement achieved with this intervention.

Following an improvement in physical function scores, the walk speeds also improved. Joints are stabilized and held in proper alignment by strong muscles.They also reduce shocks transmitted to the joints, thereby minimizing the effect of impact on them.It could be conjectured that improvement in muscle strength could be the main cause of reduction in pain, improvement in function and conversely walk speed which is also a measure of function. This agrees with some of the findings from the systematic review of some studies involving strength training exercise in knee OA which showed improvements in thewalk speed, in pain and physical function, compared to control (Lange et al,2008).

### 4.3.4 Comparative effect of six weeks SME and QSE programmes on pain intensity in subjects with knee OA

The QSEG had a significantly lower pain score than the SMEG at the end of the 6$^{th}$ week of the study. Exercise has been directly linked to reduction in pain, as well as improvement in quality of life and function, however, it is not enough to advise a patient to exercise, it is important that the patient understands the exercise to be carried out and carriesit out correctly; only then can the benefits ascribed to exercise be gained (Cottrell et al, 2010). Roddy et al (2005), in a systematic review of home-based quadriceps strengthening exercises and aerobic walking exercises, noted that adherence to exercise was a key predictor of response and encouraging patients with knee osteoarthritis to maintain exercise programmes beyond a supervised period of instruction is a major challenge. That opinion might have been reflected in the results

of this study, as the QSEG was supervised by a physiotherapist. Though theparticipants in the SMEG had the exercises demonstrated and were given instructions, including adequate dosing and progression and a diary to keep a record of the exercises carried out at home; just a handful returned the diary at the end of the study. Moreover, quadriceps specific exercise has been shown to produce greater reduction in pain than generalized lower limb exercise in knee OA, especially when supervised and performed at least three times a week (Juhl et al, 2014).

The pain reduction in the SMEG was comparable to the QSEG at one-month follow-up with the SMEG having a slightly lower score than the QSEG, although the difference was less than was observed at immediate post intervention assessment. This shows that the effect of the QSE was not maintained post intervention and most likely many of the participants did not continue the exercises at home especially since they were not specifically instructed to do so. The SMEG continued to demonstrate greater improvement than the QSEG (though not significant) till the end of the study. Similar results from other studies on SME have contributed to the body of evidence supporting the recommendation of SME for the management of knee OA (Zhang et al, 2007; McAllindon et al, 2014).

### 4.3.5 Comparative effect of six weeks SME and QSE programmes on physical function in subjects with knee OA

Participants in both groups had comparable significant improvement in physical function scores. The lack of significant difference may be due to the nature of the intervention in the two groups. The two groups' interventions have components that have been shown to have direct impact on pain reduction, which is the leading complaint by individuals with OA and drives health care use (Connelly et al, 2015). Pain reduction has been shown to have a direct relationship with reduction in disability and hence increase in physical function (Coleman et al, 2012; Anwer and Alghadir 2014). Connelly et al (2015), in a recent study of 197 individuals with OA, observed a strong correlation between physical functioning and pain, indicating worse physical functioning with higher pain. Another reason for the lack of difference between the two groups could be because both groups had exercise components which also have direct impact on physical function,although the exercise in the QSEG was supervised and specific for the lower limb while the SMEG were

only taught about the exercises. Supervised quadriceps strengthening exercises have been shown to improve strength in some clinical trials (Awotidebe et al, 2011; Odole and Ojo, 2013), while increased quadriceps strength has been shown to improve knee joint stability which in turn improves physical function in individuals with knee OA (Anwer and Alghadir, 2014).

The comparable physical function observed between the groups is similar to the finding of McKnight et al (2010) who reported no significant difference in physical function when they compared strength training, self-management education and a combination of both in individuals with early OA. Some of the SMEG participants may have augmented the stability of their knees with braces and supports. This may explain the lack of significant difference in physical function between the groups, despite the supervision of the QSEG which could be theorized to have resulted in better compliance and in turn greater quadriceps strength and as a result higher joint stability leading to increased physical function.

Furthermore, some of the limitations of this study, such as the lack of a no treatment control group, not categorizing participants according to severity of symptoms and the short duration of the study may have also affected the results of this study.

### 4.3.6 Comparative effect of six weeks SME and QSE programmes on health-related quality of life in subjects with knee OA

This study shows that HRQoL of participants in the SMEG was comparable to that of the QSEG throughout the study. This result is consistent with the only study identified that compared SME with strength training (McKnight et al, 2010),although the strength training was longer than in this study and the outcome measure used for HRQoL was generic, that is the Short Form 36 (SF 36). The disease-specific Arthritis Impact Measurement Scale 2 Short Form (AIMS 2 SF) was used for this study in line with the suggestion by Guyatt et al(1993) that disease specific instruments are more appropriate for clinical trials than generic instruments. A number of authors have linked pain to functional disability indicating that pain and even fear of pain may prevent individuals with knee OA from carrying out physical activities (Chacon et al, 2004; Cubukcu et al, 2012; Coleman et al, 2012).Further a significant relationship has been reported between knee pain and total AIMS score (Chacon et al, 2004). It is therefore plausible to expect that the reduction in pain and

improvement in physical function by both groups, although through relatively different mechanisms, resulted in improvement in the HRQoL. The QSEG would have been expected to do better in terms of HRQoL due to the interrelation between pain, physical function and health-related quality of life, especially at the 6th week when the QSEG had a lower pain score than the SMEG. It could however be theorized that there was no significant difference in the HRQoL scores of both groups because the SMEG may have made up with cognitive behavioural therapy (one of the components of SME) where the QSEG gained in pain reduction.

### 4.3.7 Comparative effect of six weeks SME and QSE programmes on walk speed in subjects with knee OA

Quadriceps strength was not a focus of this study.It is plausible to assign greater quadriceps strength to the QSEG as there were more young participants in the group. Moreover, knee OA is considered the most common cause of difficulty in walking in older adults, causing them to have slower gait speed (White et al, 2013). It is also possible that there were more participants with severe knee OA in the SMEG as severity of symptoms was not an exclusion criterion in this study (Coleman et al, 2012). This is because SME and QSE had been foundto be appropriate in the management of knee OA, no matter the co-morbidity, radiographic/ symptomatic severity, or age (McAlindon et al, 2014). The comfortable and fast pace walking times of the two groups were comparable post intervention. Pain severity has been observed to be the most common factor affecting gait speed in knee OA (White et al, 2013), hence it would have been expected that the QSEG which had significantly lower pain score would have a significantly lower walking time than the SMEG.However, that was not the casein this study.This probably implies that other factors apart from pain reduction may have influenced the improvement made by the SMEG. The coping skills learned may have improved the self-efficacy of the group as arthritis function self- efficacy has been cited alongside pain, opioid use and age as affecting gait speed (Marcum, et al 2014). This finding is consistent with the finding by McKnight et al (2010), thatno significant between-group differenceexists in physical function when self-management education is compared with strength training.

### 4.3.8 Clinical Implication of Findings

The outcome of this study shows that SME and QSE are comparatively effective in improving physical function and the health-related quality of life of individuals with knee OA. However, QSEs were more effective than SME at the 6$^{th}$ week of intervention. Incorporating supervised QSE in the once weekly sessionwith the physiotherapist in the SME programme may improve the effect of SME on pain, physical function and the health-related quality of life of individuals with OA. This will reduce the patient load on the physiotherapy facility and likely reduce the financial burden on the patient because of reduced number of hospital visits. This approach has been proven to be effective up to 24 months in the management of knee pain (Hurley et al, 2012).

# CHAPTER FIVE

# SUMMARY, CONCLUSION AND RECOMMENDATION

## 5.1 Summary

Osteoarthritis (OA) of the knee is the most common form of OA and has become a major public health problem. It is characterized by slow degradation of the joint cartilage resulting in chronic pain, reduction in functional abilities and reduced quality of life. Techniques such as Self-Management Education (SME) and Quadriceps Strengthening Exercises (QSE) have been employed in the management of knee OA. It is however not clear which of these two techniques will be more effective in the management of pain and loss of function associated with knee OA. This study was therefore carried out to compare the efficacy of self-management education and quadriceps strengthening exercises on pain, physical function and Health-Related Quality of Life (HRQoL) among individuals with knee OA. The carry-over effect of the two interventions were also compared at the end of three consecutive months of follow-up.

The literature review included the definition, epidemiology, pathology and pathogenesis as well as risk factors, clinical features and diagnosis for osteoarthritis of the knee. The management of knee osteoarthritis was reviewed in the light of the treatment guideline with emphasis on exercise and self-management education. Surgical management of knee osteoarthritis as well as cognitive behavioural therapy were also reviewed. Relevant outcomes in knee osteoarthritis were also studied. The literature review concluded with a summary of the literature reviewed in self-management education and quadriceps strengthening exercises.

A pre-test/post-test quasi-experimental study trial was carried out. Ethical approval for the study was obtained from the Health Research Ethics Committee of the University of Ibadan/University College Hospital (Ref no: UI/EC/13/0256). Informed consent of the participants was sought and obtained after the rationale and procedure of the study had been explained to them. Seventy-nine consenting individuals with knee OA who met the inclusion criteria for the study participated in the trial. They were consecutively recruited from the outpatient physiotherapy clinics

of Barau Dikko Specialist Hospital, Kaduna, Nigeriaand randomly assigned into the Self-Management Education Group (SMEG) and the Quadriceps Strengthening Exercise Group (QSEG). The SMEG had self-management education class once weekly for six weeks while the QSEG had quadriceps strengthening exercises thrice weekly for six weeks. The selected outcome variables were: Physical Function (PF) using the Ibadan Knee/Hip Osteoarthritis Measure (IKHOAM), Pain Intensity (PI) using the Visual Analogue Scale (VAS), Health Related Quality of Life (HRQoL) using the Arthritis Impact Measurement Scale Short Form 2 (AIMS 2 SF), Walking time [Comfortable Pace Walking Time(CPWT) and Fast Pace Walking Time (FPWT)]. Thesevariables were assessed at baseline, end of the 6$^{th}$ week, and at first, second and third month follow-up. Data were analysed using descriptive statistics and multilevel modelling at p= 0.05.

The age of participants in the SMEG (53.86 ± 10.40 years) was comparable with the QSEG (50.11 ± 10.20 years) andfemales constituted the majority (83.3%) of the participants. At baseline, there were no significant differences observed in the physical function, pain intensity and health related quality of life scores of the two groups. The walking time of the SMEG (14.53 ± 0.24s) was significantly slower than QSEG (13.76 ± 0.26s). At the end of the 6th week, the QSEG had significantly lower pain intensity (2.91(0.29)) than the SMEG (3.94(0.29)). There was no significant difference in scores of physical function, health related quality of life and walk time of both groups. The two groups were not significantly different at 1$^{st}$, 2$^{nd}$ and 3$^{rd}$ month follow-up in the scores of all the outcome variables.

The results were discussed by comparing and contrasting the outcomes of the study with previous related studies. Literature was appropriately cited to validate the findings from this study. Plausible reasons for the findings from the study were also offered. It was concluded that quadriceps strengthening exercises had greater and quicker effect on pain intensity than self-management education during treatment, though both groups were comparable in their improvement at the 1$^{st}$ to 3rd month after treatment.

## 5.2 Conclusion

The following conclusions were drawn from the findings of this study:

1. Self-management education and supervised quadriceps strengthening exercise programmes were comparable in their effects on physical function, quality of life, Comfortable Pace Walk Test and Fast Pace Walk Test, after 6 weeks of treatment.
2. Supervised quadriceps strengthening exercise programme led to greater reduction in pain intensity after 6 weeks of treatment.
3. Self-management education and supervised quadriceps strengthening exercise programmes were comparable in their effects on pain intensity, physical function, quality of life, Comfortable Pace Walk Test and Fast Pace Walk Test across 3-months follow-up.

## 5.3 Recommendations

Based on the findings from the study the following recommendations are made:

1. It is recommended that self-management education programme be included in the treatment protocols of patients with knee osteoarthritis.
2. Quadriceps strengthening exercise should be included in self-management education programmes for knee osteoarthritis.
3. Self-management education, with emphasis on quadriceps strengthening exercises should be facilitated by a physiotherapist where one is available.
4. Self-management education with quadriceps strengthening exercisesshould be adopted for management of patients with knee osteoarthritis by the Centre for Disease Control in Nigeria as obtains in countries some European countries and Australia.

## REFERENCES


Adams, J.C. and Hamblen, D.L. 1999: *Outline of Orthopaedics* 12th ed. London: Harcourt Brack and Company Limited: 120, 338

Adegoke, B.O.A. 2003: Comperative efficacy of open and closed kinetic chain exercise in the treatment of osteoarthritic knees. *An unpublished PhD thesis submitted in physiotherapy dept University of Ibadan 70-81*

_____. and Gbeminiyi, M.O. 2004. Efficacy of ice and shortwave diathermy in the management of osteoarthritis of the knee – a preliminary report. *African Journal of Biomedical Research* 7: 107 – 111

_____, Akodu, A.A. and Oyeyemi, A.L. 2008: Work-related musculoskeletal disorders among Nigerian Physiotherapists. *Biomedical Central* 9:112

_____., Alao, R, and Odole, A. 2012. Comparison of health-related quality of life of Nigerian patients with knee osteoarthritis and age-matched controls. *Journal of Physical Therapy* (6): 13-20.

Aiyejusunle, C.B., Kola-Korolo, T.A. and Ajiboye, O.A. 2007: Comparison of the effects of Tens and sodium salicylate iontophoresis in the management of osteoarthritis of the knee. *Quality Journal of Hospital medicine*. 17: 82-86.

Akinbo,S.R.A., Ojetunde, A.M., Otinwa, G.O. and Oremosu, A.A. 2005: Comparison effect of kinesiotaping on pain and joint flexibility in patients with knee sports injury. *NigerianJournal of Medical Rehabilitation*. 10: 18-22.

Akinpelu, A.O., Akinwola M.O, Odole, A.C, Gbiri, C.A. 2011a. The reliability of the English version of Ibadan Knee/Hip Osteoarthritis Outcome Measure (IKHOAM). *Physical and Occupational Therapy in Geriatrics Early online*: 1-8 DOI: 10.3109/02/02703181.2011.589566

_____., Maduagwu, S.M., Odole, A.C. and Alonge, T.O. 2011b. Prevalence and pattern of knee osteoarthritis in a North Eastern Nigerian rural community. *East African Orthopaedic Journal* 5: 5-11.

_____., _____, Adekanla, B.A. and Odole, A.C. 2009. Prevalence and pattern of symptomatic knee osteoarthritis in Nigeria. A community-based study. *Internet Journal of Health Sciences and Practice* Vol 7 No3: 1-7.

_____., _____., _____. and _____. 2007: Patterns of osteoarthritis seen at physiotherapy facilities in Ibadan and Lagos, *Nigeria African Journal of Biomedical Research.* Vol. 10: 111-115.

_____., Odole, A.C., Adegoke, B.O.A. and Adeniyi, A.F. 2007: Development and Initial Validation of the Ibadan Knee/ Hip Osteoarthritis Outcome Measure (IKHOAM). *South African Journal of Physiotherapy*. 63: 3-8

Alami, S., Desjeux, D., Lefevre-Colau, M.M., Boisgard, A.S., Boccard, E., Rannou, F., Poiraudeau,S. 2011. Management of pain induced by exercise and

mobilization during physical therapy programs: views of patients and care providers. *BMC Muskuloskeletal Disorder*. 12: 172

Albright, J., Altman, R., Bonligho, R.P., Conill, A., Dobkin, B., Guccione, A.A., Hasson, S., Russo, R., Shekelle, P., Susman J. L. 2001: PhiladelphiaPanel Evidence- Based Clinical Practice Guidelines on Selected Rehabilitation Interventions for Knee Pain. *Physical Therapy*.81: 1675- 1694.

Alnahdi A.H., Zeni J.A. and Snyder-Mackler L. 2012. Muscle impairments in patients with knee osteoarthritis. *Sports Health*4 (4): 284-282

Altman, R.D., Hochberg, M.C., Moskowitz, R. W. and Schnitzer, T.J. 2000: Recommendations for the medical management of osteoarthritis of the Hip and Knee. *Arthritis andRheumatism.* Vol. 43: 1905-1915.

_____., Asch, E., Bloch, D, Bole, G., Borenstein, D., Brabdt, K., Christy, Cooke, T.D.; Greenwald, R., Hochberg, M., Howell, D., Kaplan, D., Koopman, W. Longey,S III., Mankin, H., Mcshane, D.J, Medsger, T Jr., Meenan, R., Mikkelson, W., Moskowitz, R., Murphy, W., Rothchild, B., Segal, M., Sokoloff, L. and Wolfe, F. 1986: Development of criteria for the classification and reporting of osteoarthritis: Classification of osteoarthritis of the knee. *Arthritis and Rheumatism*.29:1039-1049.

Anwer, S. and Alghadir, A. 2014. Effect of isometric quadriceps exercise on muscle strength, pain, and function in patients with kneeosteoarthritis: a randomized controlled studyJournal of Physical Therapy Science26: 745–748.

Baker, K and McAllindon, T. 2000: exercise for Knee Osteoarthritis. *Current Opinion in Rheumatology*.12: 1039- 1049.

Baker, K.R., Nelson, M.E., Felson, D.T., Layne, J. E., Sarne, R and Roubenoff. R 2001: The efficacy of home based progressive strength training in older adults with knee osteoarthritis: a randomized controlled trial. *Jornal of Rheumatology* 28:1655-65

Barron, M.C. and Bernard, R.R. 2007: Managing Osteoarthritis Knee Pain, *The Journal of the American Osteopathic Association.*107: 21-27.

Bennell, K.L. and Hinman R.S. 2011. The role of resistance training in the management of knee osteoarthritis. *European Musculoskeletal Review* 6.1: 10-3.

Bezalel, T., Carmeli, E. and Katz- Leurer, M. 2010: The effect of a group education programme on pain and function through knowledge acquisition and home based exercise amongpatients with knee osteoarthritis: a parallel randomized single blind clinical trial. *Physiotherapy*. 96: 137-43.

Bjordal, J.M., Johnson, M.I., Lopes-Martins, R.D., Bogen, B., Chow, R. and Ljunggren, A.F. 2007: Short term efficacy of physical interventions in osteoarthritis knee pain. A systematic review and meta-analysis of randomized placebo. *Biomedical Centre for MusculoskeletalDisorder.*8:51.

Bohannon, R.W. 1997. Comfortable and maximum walking speed of adults aged 20-79 years: reference values and determinants. *Age Ageing*. 26: 15-19

_____ and Williams, A.A. 2011. Normal walking speed: a descriptive meta-analysis. *Physiotherapy*. 97: 182- 189

Brandt, K.D., Mazzuca, S.A., Katz, B.P., Lane, K.A., Bukwalter, K.A., Yocum, D.E., Bruyere, O., Collette, J., Kothan, M., Zaim, S., White, D., Genant, H., Peterfly, C., Burlet, N., Ethgen, D., Montague, T., Dabrowski, C. and Reginster, J.Y. 2006: Osteoarthritis, magnetic resonance imaging and biochemical markers: A one year prospective study. *Annals of the Rheumatic Diseases*. 65: 1050-1054.

Brosseau, L., Wells, G.A., Kenny, G.P., Reid, R., Maetzel, A., Tugwell, P., Huijbregts, M., McCullough, C., De Angelis,G., Chen. L. 2012. The implementation of a community-basedaerobic walking program for mild to moderate knee osteoarthritis (OA): a knowledge translation (KT) randomized controlled trial (RCT): Part I: The Uptake of the Ottawa Panel clinical practice guidelines (CPGs). . *BMC Public Health*. 12:871

Buckwalter, J.A. and Mankin, H.J. 1998: Articular Cartilage: Degeneration and Osteoarthritis, repair regeneration and transplantation. Instructional Course *Lectures*. 47: 487-504.

Button,K., Roos,P.E., Spasic, I., Adamson, P., van Deursen, R.W.M. 2015. The clinical effectiveness of self-care interventions with an exercise component to manage knee conditions: A systematic review. *Knee*. 22: 360- 371

Cambridge University Press. 2004: Cambridge Advanced Learner's Dictionary. Thomson press limited, India.

Carnes, D. Anwer, Y., Underwood, M., Harding, G. and Parsons, S. 2008: Influences on Older People's decision making regading choice of topical or oral NSAIDs for knee pain: Qualitative Study. *British Medical Journal* 336; 142-145.

Carr, A. 2003. Measures of quality of life. *Arthritis& Rheumatism*49.5S: S113–S13.

Centre for Dsease Control and Prevention (US), 2000: Health related quality of life among adult with behavioural risk factor surveillance system: 11 states, 1996-1998.Mobidity and Mortality Weekly Report 49: 17: 366-369

Cerejo, R., Dunlop, D.D., Cahue, S., Channin, D., Song, J. and Sharma, L. 2002: The influenceof alignment on risk of knee osteoarthritis progression according to baseline stage ofdisease. *Arthritis and Rheumatism* 46, 10: 2632-6

Cetin, N., Avtar, A., Atalay, A. and Akman, M.N. 2008: Comparing hotpack, shortwave diathermy, ultrasound and TENS on isokinetic strength, pain, and functional status women with osteoarthritis knees: a single- blind randomized controlled trial. *American Journal of Physical Medicine and Rehabilitation*. 87: 443-451.

Chaipinyo, K. and Karoonsupcharoen, O. 2009. No difference between home-based strength training and home-based balance training on pain in patients with knee osteoarthritis: a randomised trial. *Australian Journal of Physiotherapy* 55: 25-30

Chen, H.C., Shah, S.H., Li Y.J., Stabler, T.V., Jordan, J.M. and Kraus, V.B. 2008. Inverse association of general joint hypermobility with hand and knee osteoarthritis and serum cartilage oligomeric matrix protein levels. *Arthritis and Rheumatism* 58.12 :3854–64.

Chek, P. 1997: Knee extension and power lifting. pchek@compuserve.com

Christensen, R., Bartels, EM., Astrup, A. and Bliddal, H. 2007. Effect of weight reduction in obese patients diagnosed with knee osteoarthritis: a systematic review and meta-analysis. *Annals of Rheumatic Diseases* 66(4):433–9.

Coleman, S; Briffa, K; Conroy, H; Prince, R; Carroll, G and Mcquade, J. 2008: Short and medium effects of self-management program for individuals with osteoarthritis of the knee, designed and delivered by health professionals: a quality assurance study. *Biomedicalcentral musculoskeletal disorder*.117: 1471- 2474 9.

_____., _____, Carroll, G., Inderjeeth, C., Cook, N and Mcquade, J. 2008: Effects of self management, education and specific exercises delivered by health Professionals in Patients with osteoarthritis of the knee. *Biomedical central musculoskeletal disorder* 1471-2474. 9-133

_____., _____., _____; _____., _____ and _____. 2012: A randomized controlled trial of a self-management education program for Osteoarthritis of the knee delivered by health Professionals. *Arthritis Research & Therapy* 14: R21.

_____, Mc Quade, J., Rose, S., Inderjeeth, C., Carroll, G. and Briffa, N.K. 2010: Self-management for osteoarthritis of the knee: Does mode of delivery influence outcome? *BMC musculoskeletal disorder* 11: 56 1471-2474

Cooper, C. 2003: Osteoarthritis: Epidemiology and classification. In Hochberg M. (ed) *Rheumatology* 3rd ed. Mosby 1781-1791

Cotterel, E., Roddy, E. and Foster, N. E. 2010: The attitudes, beliefs and behaviours of GPs regarding exercise for chronic knee pain: a systematic review. *Biomedical central family Practice*.1471-2296 11:4

Creamer, P., Lethbridge-Cejku, M. and Hochberg, M.C. 2000: Factors associated with functional impairment in knee osteoarthritis. *Rheumatology*. 39: 490-496.

Croft, P., Cooper, C., Wickham, C. and Coggon D. 1992: Osteoarthritis of the hip and occupational activity. *Scandinavian Journal of Work Environmental Health* 18, 1:59-63

Crossley, K.M., Vicenzino, B., Pandy, M.G., Schache, A.G and Hinman, R.S. 2008: Targrted Physiotherapy for patellofemoral joint osteoarthritis: A protocol for

randomized, single blind controlled trial. *BioMedical Central Musculoskeletal Disorders*. 9: 122

Cubukcu, D., Ayse Sarsan, A., and Alkan, H. 2012.Relationships between Pain, Function and Radiographic Findingsin Osteoarthritis of the Knee: A Cross-Sectional Study*Arthritis* Vol. 2012, Article ID 984060, pages 1-5 doi:10.1155/2012/984060

Cuperus, N., Smink, A.J., Bierma-Zeintra, S., Dekker, J., Schers, H.J., Boer, F. 2013. Patient reported barriers and facilitators to using a self-management booklet for hip and knee osteoarthritis in primary care: results of a qualitative interview study. *BMC Family Practice.* 14: 181

Denoeud, L., Mazieres, B., Payen-Champensois, C. and Ravaud, P. (2005): First line treatment of knee osteoarthritis on outpatients in France: adherence to the EULAR 2000 Recommendations and factors influencing adherence. *Annals of the Rheumatic Diseases*.64: 70-74.

Dequekert. J., Mokassa, L. and Aerssens, J. 1995: Bone density and Osteoarthritis.*Journal of Rheumatology*.22: 98-100.

Deyle, G.D., Allison, S.C., Matekel, R.H., Ryder, M.G., Stang, J.M., Gohdes, D.D., Hutlon, J. P., Henderson, N. E. and Garber, M. B. 2005: Physical Therapy Treatment Effectiveness for osteoarthritis of the knee: A Randomized comparison of supervised clinical exercise and manual therapy procedures versus a home. *Physical Therapy*. 85: 1301-1317.

Dieppe, P., Cushbaghan, J and Young P.1993: Prediction of progression of joint space narrowing in osteoarthritis of the knee by bone scintigraphy. *Annals of Rheumatic diseases.*52: 557-563.

_____. 1993: Management of Osteoarthritis of the hip and knee joints. Current Opinion in Rheumatology. 5: 487-493

_____., Baster, H.D., Chard, J., Croft, P., Dixon, J., Hurley, M., Lohmanders, S and Raspe, H. 1999: Knee replacement surgery for knee osteoarthritis: Effectiveness practice variation, indications and possible determinants of utilization. *Rheumatology*. 38: 73-83

Distefano, V. 1979. Functional Anatomy and biomechanics of the knee. Athletic training (Fall) 113-118

Doherty, M. 2001: Risk factors for progression of knee osteoarthritis. *Lancet*. 356-9284:775.

_____. 2002: Pain in osteoarthritis. In Giamberardino (ed). An updated Review: Refresher Course Syllabus. International Association for the Study of Pain, Press. Seattle. 51-57.

Dolan, A.L., Hart, D.J., Doyle, D.V., Grahame, R. and Spector, T.D. 2003: The relationship of joint hypermobility, bone mineral density, and osteoarthritis in the general population: The Clingford study. *Journal of Rheumatology* 30, 4:799-803

Durmus, D., Alayli, G. and Canturk, F. 2007: effects of quadriceps electrical stimulation programme in the Patients with knee osteoarthritis. *Clinical Rheumatology*. 26: 674-678.

Engastrom, G., De Verdier, M.G., Nilsson, P.M., Lohmander, S. 2009: Incidence of severe knee and hip osteoarthritis in relation to dietary intake of antioxidants beta-carotene, vitamin C, vitamin E and selenium: a population-based prospective cohort study. *Arthritis and Rheumatism* 60:s235-s236

Eti, E., Kouakou, H.S., Daboiko, J.C., Quali, B., Gabla, K.A., Kouakou, N.W. 1998: Epidemiology and features of knee osteoarthritis in the Ivory

Ernst, E., 2006: Acupuncture – a critical analysis. *Journal of Internal Medicine*, 259: 125-137.

_____, Pittler, M.H., Wider, B. and Boddy, K. 2007: Acupuncture: Its evidence-base is changing. *American Journal of Chinese Medicine* 35: 21-25

Farr, J.N., Going, S.B., McKnight, P.E., Kasle, S., Cussler, E.C. and Cornett, M. 2010: Progressive resistance training improves overall physical activity levels in patients with early osteoarthritis of the knee: A randomized controlled trial. *Physical Therapy 90: 356-66*

Felson, D.T., Hannan, M.T., Berkeley, J., Gordon, G., Wilson, P.W. and Anderson, J. 1991: Occupational physical demands, knee bending, and knee osteoarthritis: result from the Framingham study. *Journal of Rheumatism* 18, 10:1587-92.

_____., Zhang, Y., Anthony, J.M., Naimark, A. and Anderson, J.J. 1992. Weight loss reduces the risk for symptomatic knee osteoarthritis in women. The Framingham Study. *Annals of Internal Medicine* 116(7):535–9.

_____. and _____. 1998. An update on the epidemiology of hip and knee osteoarthritis with a view to prevention. *Arthritis and Rheumatism* 41:1345-1355.

_____., Couropmitree, N.N., Chaisson, C.E., Chaisson, C.E., Hannan, M.T., Zhang, Y., McAlindon, T.E., Lavalley, M., Levy, D. and Myers, R.H. 1998. Evidence for a Mendelian gene in a segregation analysis of generalized radiographic osteoarthritis: the Framingham Study. *Arthritis and Rheumatism* 41(6):1064–71.

_____., Lawrence, R.C., Hochberg, M.C., McAllindon, T., Dieppe, P.A., Minor, M.A., Blair, S.N., Berman, N.M., Fries, J.F., Weinberger, M., Lorig, K.R., Jacobs, J.J. andGoldberg, M. 2000: Osteoarthritis: New insights. Part 1: The disease and its risk factors. *Annals of internal Medicine* 133, 635-646

Fisher, M.N., Pendergast, D.R., Greshham, G.E. and Calkins, E. 1991: Muscle rehabilitation: Its effects on muscular and functional performance of patients with knee osteoarthritis. *Archives of Physical Medicine*72 367-374

Fitzgerald, G. K. 1997: Open versus Closed Kinetic Chain Exercises: Issues in Rehabilitation After Anterior Cruciate Ligament Reconstructive Surgery. *Physical Therapy*. 77: 1747-1754

Fontaine, K. 2012. Arthritis and health related quality of life: The John Hopkins Arthritis Retrieved Sept 25, 2012 from www.bookinarthritis.org: 2:00pm.

Foster, N.E., Thompson, K.A., Baxter, G.D., Allen, J.M. 1999: Management ofnon-specific low back pain by physiotherapists in Britain and Ireland. A descriptive questionnaire of current clinical practice. *Spine.* 24: 1332-1342.

_____., Thomas, E., Barlas, P., Hull, J.C., Yong, J., Mason, E. and Hay, E.M. 2007: Acupuncture as an adjunct to exercise based physiotherapy for osteoarthritis of the knee: randomized controlled trial. *British Medical Journal*.335: 436.

Fransen, M., Crosbie J. and Edmonds J.2001. Physical therapy is effective for patients with osteoarthritis of the knee: a randomized controlled clinical trial. Journal of Rheumatology.28: 156-164

_____. and McConnell S (2009): Land-based exercise for osteoarthritis of the knee: a meta-analysis of randomized controlled trials. *The Journal of Rheumatology* 36: 1109-1117.

_____., _____., Harmer, A.R., Van der Esch, M., Simic, M., Bennell, K.L. 2015. Exercise for osteoarthritis of the knee.*Cochrane Database of Systematic Reviews* Issue 1. Art. No.: CD004376. DOI: 10.1002/14651858.CD004376.pub3.

Fries, J. F., Spitz, P., guy-Kraines, R and Holman, R.H. 1980: Measurement of Patient Outcome in arthritis. *Arthritis and Rheumatism*. 23: 137-145

Garnero, P., Rousseau, J.C. and Delmas, P.D. 2000: Molecular basis and clinical use of biochemical markers of bone, cartilage and synovial joint disease. *Arthritis and Rheumatism.* 43: 953-968.

Glass, R., Waddel, J. and Hoogenboom, B. 2010: The effect open versus closed kinetic chain exercises on patients with ACL deficient or reconstructed knee: A systemic review. *North American Journal of SportsPhysical Therapy* 5. 2:74-84

Gossec, L., Hawker, G., Davies, A.M., Maillefert, J.F., Lohmander, L.S., Altman, R., Cibere, J., Conaghan, P.G., Hochberg, M.C. and Jordan, J.M. 2007: OMERACT/ OARSI Initiative to define states of severity and indication for joint replacement in hip and knee osteoarthritis. *Journal of rheumatology*. 36: 1432-1435

Grainger, M. and Cicuttini, F.M. 2004: Medical management of osteoarthritis of the knee and hip joints. *Medical Journal of Australia.* 180: 232-236.

Guillemin F, Coste J, Pouchot J, Ghezail M, Bregeon C, Sany J, 1997. and the French Quality of Life in Rheumatology Group. The AIMS2-SF: a short form of the Arthritis Impact Measurement Scales 2. *Arthritis and Rheumatism* 40:1267–74.

Gunther, K.P., Sturmer, T., Sauerland, S., Zeissig, I., Sun, Y., Kessler, S., Scharf H.P., Brenner H. and Puhl W. 1998. Prevalence of generalised osteoarthritis in

patients with advanced hip and knee osteoarthritis: The Ulm Osteoarthritis Study. *Annals of the Rheumatic Diseases* 57: 717-723

Guyatt, G.H., Feeny, D.H. and Patrick, D.L. 1993: Measuring health related quality of life. *Annals of internal Medicine* 118(9): 622-629.

Hag, S.A., Darmawan, J., Islam, M.N., Uddin, M.Z., Das, B.B., Rahman, F., Chowdhury, M.A., Alam, M.N., Mahmud, T.A., Chowhury, M.R. and Tahir, M. 2003: Prevalence of rheumatic diseases and associated outcome in rural and urban communities in Bangledesh: A COPCORD study. *Journal of Rheumatology. 32: 348-353.*

Hannan, M.T., Felson, D.T., Anderson, J.I., Naimark, A. and Kannel, W.B. 1990. Estrogen use and radiographic osteoarthritis of the knee in women. The Framingham Osteoarthritis Study. *Arthritis and Rheumatism* 33 4:525-32

Hansson, E.E., Jonsson-Lundgren, M., Ronnheden, A.M., Sorensson, E., Bjarnung, A., Dahlberg, L.E.2010. Effect of an education programme for patients with osteoarthritis in primary care a randomized controlled trial. *BMC Musculoskeletal Disorder* 11: 244

Hassanall, M.C. and Oyoo, G.O. 2011: Osteoarthritis: A look at pathophysiology and approach to new treatments: A review. *East African Orthopaedic journal*

Hay, E.M., Foster, N.E., Thomas, E., Peat, G., Phalen, M., Yates, H.E., Blnkinsopp, A. and Sim, J. 2006: Effectiveness of community physiotherapy and enhanced Pharmacy review for the knee pain in people aged over 55 presenting to primary care: pragmatic randomized trial. *British Medical Journal*.333: 995.

Hinman, R.S., Heywood, S.E., and Day, A.R. 2007: Aquatic Physical Therapy for Hip and Knee Osteoarthritis: Result of a Single–Blind Randomized Control Trial. *Physical Therapy. 87: 32-43.*

_____., Crossley, K.M., McConnell, J. and Bennell, K.L.2003: Efficacy of knee tape in the management of osteoarthritis of the knee: Blinded randomized controlled trial. *British Medical Journal*.327:135.

Hinton, R., Moody, R.L., Davis, A.W. and Thomas, S.F. 2002: Osteoarthritis: diagnostic and therapeutic considerations. *American Family Physicians*. 65: 841-848.

Hippisley-Cox, J. and Coupland, C. 2005.Risk of myocardial infarction in patients taking cyclo-oxygenase-2 inhibitors or conventional non-steroidal anti-inflammatory drugs: population based nested case-control analysis. *Biomedical Journal*. 330: 1366

_____., Coupland, C., and Logan, R. 2005. Risk of adverse gastrointestinal outcomes in patients taking cyclo-oxygenase-2 inhibitors or conventional non-steroidal anti-inflammatory drugs: population based nested case-control analysis. *Biomedical Journal*. 331: 1310-1316

Hochberg, M.C. 2008: Traditional Chinese medicine in the management of osteoarthritis. *Future Rheumatology*. 3: 7-9.

_____., Altman, R.D., Brandt, K.D., Clark, B.M., Dieppe, P.A., Griffin, M.R., Moskowitz, R.W. and Schnitzer, T.J. 1995: Guidelines for the Medical Management of Osteoarthritis. *Arthritis and Rheumatism*. 38: 1541-1546.

_____., Letherbridge-Cejku, M., Plato, C.C., Wigley, F.M. and Tobin, J.D. 1991: Factors associated with osteoarthritis of the hand in males: data from the Baltimore Longitudinal Study of aging. *American Journal of Epidemiology*.134: 1121-1127.

Hogue, J.H. and Mersfelder, T.L. 2002: Pathophysiology and first-line treatment of osteoarthritis. *Annals of Pharmacotherapy*. 23: 122-30.

Hollis, M. 1987: Practical Exercise Therapy (2nd Ed.) Oxford Blackwell Science Publications, 123-124

Irrgang, J. J. and Rivera, J. (1994): Closed Kinetic Chain exercises for the lower Extremity. Theory and application in Current Concepts in Rehabilitation of the knee. Brandy, W.D (Ed.) A publication of sports *"Physical Therapy Section of the American Physical Therapy Association. 1-12*

Iversen, M. D. 2010. Managing hip and knee osteoarthritis withexercise: what is the best prescription? *Ther Adv Musculoskeletal Disorder*. 2: 279- 290

Iwamoto, J., Sato, Y., Takeda T. and Matsumoto, H. 2011. Effectiveness of exercise for osteoarthritis of the knee: A review of the literature. *World Journal of Orthopedics* 2.5: 37-42.

Jacobs, J., Anderson, G., Bell, J. and Weinstein, S. 2008: The Burden of Musculoskeletal Diseases in the United States- Executive statement. *Bone and joint Disease*. Rosemont

Jette, M.A. 1980: FUNCTIONAL Status Index: An empirical approach. *Archives of PhysicalMedicine and Rehabilitation. 61: 85-89*

_____. 1980: Functional Status Index; reliability of a chronic disease evaluation instrument. *Archives of Physical Medicine and Rehabilitation*. 61: 395-400

Joern ,W.P., Michael, K U. Schlüter-Brust and Peer, E. 2010.The Epidemiology, Etiology, Diagnosis, and Treatment of Osteoarthritis of the Knee.*Deutsches Ärzteblatt International*.107: 152-162

Johnson, M.I. 2006: The Clinical Effectiveness of Acupuncture for Pain Relieve – you can be certain of uncertainty. *Acupuncture Medicine* 24: 71-79

Jordan, J.E and Osborne, R.A 2007: Chronic disease self-management education program: Challenges ahead. *World Hospital Health Service* 43: 32-36

Juhl, C., Christensen, R., Roos, E.M., Zhang, W., Lund, H. 2014. Impact of exercise type and dose on pain and disability in knee osteoarthritis: a systematic review and meta-regression analysis of randomized controlled trials. *Arthritis Rheumatology*.66:622-636.

Kalman, D.S., Heimer, M., Valdeon, A., Schwactz, H. and Sheldon, E. 2008 Effect of a natural extract of chicken combs with a high content of hyaluronic acid (Hyal-joint) on pain relief and quality of life in subjects with knee osteoarthritis: a pilot randomized double blind placebo controlled trial. *Nutrition journal* 10 1186/1475-2891 -7-3

Kawasaki, T., Kurosawa, H., Ikeda, H., Takazawa, Y., Ishijima, M., Kutoba, M., Kajihoma, H., Maruyama, Y., Kim, S.G., Kanzawa, H and Doi, T. 2009: Therapeutic home exercise versus intraarticular hyaluronate injection for osteoarthritis: 6 months prospective randomized open labelled trial. *Journal of Orthopaedic science* 14: 182-191.

Kellgren, J.H. and Lawrence, J.S. 1958. Osteoarthritis and disk degeneration in an urban population.*Annals of Rheumatic Diseases* 17:388-397

Kim, I., Kim, H.A., Seo, Y., Song, Y.W[2] ., Jeong, J. and Kim, D.H. 2010: The Prevalence of Knee Osteoarthritis in Elderly Community Residents in Korea. *Jornal of Korean medical science*. 25: 293- 298

Kisner, C. and Colby, L.A. 2007 *Therapeutic Exercises*: *Foundations and Techniques.*Philadelphia, F. A. Davis Company 314-316, 475-476

Knoop, J., Steultjens, M.P., Roorda, L.D., Lems ,W.F., van der Esch ,M., Thorstensson ,C.A., Twisk, J.W., Bierma-Zeinstra, S.M., van der Leeden, M., Dekker, J. 2015. Improvement in upper leg muscle strength underlies beneficial effects of exercise therapy in knee osteoarthritis: secondary analysis from a randomised controlled trial.*Physiotherapy*. 101:171-7

Kroon, F.P., van der Burg LR., Buchbinder, R., Osborne, RH., Johnston, RV., Pitt, V. 2014. Self-management education programmes for osteoarthritis**.** *Cochrane Database Systematic Review.* 15;1:CD008963. doi: 10.1002/14651858.CD008963.pub2.

Kujala, U.M., Kettunen, J. and Paananen, H. 1995: Knee osteoarthritis in former runners, soccer players, weight lifters and shooters. *Arthritis and Rheumatism* 38, 4:539-46

Lam, C.L.K. and Lauder, L.J. 2000: The impact of chronic diseases on the health relate3d quality of life of Chinese Patients in primary care. *Family Practice*. 172: 539-546.

Lane, N. E. and Buckwalter, J. A. 1993: Exercise: A cause of Osteoarthritis? *Rheumatic Diseases Clinics of North America*. 19: 617-29.

Lange, A.K., Vanwanselle, B. and Fiatarone Singh, M.A. 2008: Strenght training for treatment of osteoarthritis of the knee: a systematic review. *Arthritis Rheumatology* 59: 1488-94

Lawrence, R.C., Felson, D.T., Helmick, C.G., Arnold, L.M., Choi, H., Deyo, R.A., Gabriel, S., Hirsch, R., Hochberg, M.C., Jordan, J.M., Katz, J.N., Kremers, H.M. and Wolfe, F. (National Arthritis Data Workgroup) 2008: Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Part II. *Arthritis and Rheumatism* 58 1:26-35

Lohmander, L.S., Ostenberg, A., Englund, M. and Roos, H. 2004: High prevalence of knee osteoarthritis, pain and functional limitations in female soccer players twelve years after anterior cruciate ligament injury. *Arthritis and Rheumatism*50 10:3145-52

Lorig, K.R., Manzonson, P.D. and Holman, H.R. 1993: Evidence suggesting health education for self-management in patients with chronic arthritis has sustained health benefits while reducing health costs. *Arthritis and Rheumatism.* 36: 439-446.

_____., Sobel, D.S., Ritter, P.L., Laurent, D and Hobbs, M. 2001: Effect of a self-management program on patients with chronic disease. Effective *Clinical Practice* 4: 256-262

_____ and Holman H.R. 2003. Self-management education: History, definition,

outcomes, and mechanisms. *Annals of Behavioural Medicine.*26: 1-7

Losina,E., Burbine, S.A., Suter, L.G., Hunter, D.J., Solomon, D.H., Daigle, M.E., Katz,J.N. 2014. Pharmacologic regimens for knee osteoarthritis prevention: Can they be cost-effective? *Osteoarthritis Cartilage*. 22: 415-430

MacAuley, D. 2004: Managing osteoarthritis of the knee. *British Medical Journal*. 329:1300-1301.

Madsen, M.V., Gotzsche, P.C. and Hrobjartsson, A. 2009: Acupuncture Treatment for Pain: Systemic Review of Randomized Clinical Trials with Acupuncture, Placebo and NoAcupuncture Groups. *British Medical Journal* 338: 3115

Manek, N.J., and Lane, N.E. 2000: Osteoarthritis: Current concepts in diagnosis and management. *American Family Physician*. 61: 1795- 1804

McAlindon, T.E., Bannuru, R.R., Sullivan, M.C., Arden, N.K., Berenbaum,F., Bierma-Zeinstra,S.M., Hawker, G.A.,Henrotin, Y., Hunter, D.J., Kawaguchi, H., Kwoh, K., Lohmander, S., Rannou,F., Roos, E.M., Underwood, M. 2014. OARSI guidelines for the non-surgical management of knee. *osteoarthritis. Osteoarthritis and* Cartilage 22: 363-388

McGinty, G., Irrgang, J.J. and Pezzullo, D. 2000: Biomechanical considerations for rehabilitation of the knee. *Clinical Biomechanics.* 15 2000 160-166

McKnight, P.E., Kasle, S., Gring, S., Villaneuva, I.; Farr, J., Wright, J., Streefer, C. and Zautra, A. 2010 A comparison of strength training, self-management and the combination for early osteoarthritis of the knee. *Arthritis care Research* 62: 45-53

McLeod, W.D. and Hunter, S. 1980. Biomechanical analysis of the knee. Primary functions as elucidated by anatomy. *Physical Therapy* 60: 1561-1564.

Meenan, R.F., Gertman, P.M. and Mason, J.H. 1980. Measuring health status in arthritis: the Arthritis Impact Measurement Scales. *Arthritis and Rheumatism* 23:146–52.

_____ 1982: The AIMS approach to health status measurement: conceptual and measurement properties. *Journal of Rheumatology*. 9: 785-788

Messier, S.P., Loeser, R.F. and Miller, G.D. 2004. Exercise and dietary weight loss in overweight and obese older adults with knee osteoarthritis: the arthritis, diet and Activity Promotion Trial. *Arthritis and Rheumatism.* 5:1501-10

Michael, J., Schlüter-Brust, K.U. and Eysel, P. 2010: The Epidemiology, Etiology, Diagnosis, and Treatment of Osteoarthritis of the Knee. *Dtsch Arztebl Int*.107; 152-162.

Mijiyawa, M. and Ekoue, K. 1993: Osteoarthritis of Limbs in hospital practice in Lome (Togo). *Revue de Rheumatologic*. French Edition. 60: 514-517.

Mikkelsen, C., Werner, S. and Erikson, E. 2000. Closed kinetic chain alone compared to combined open and closed kinetic chain exercises for quadriceps strengthening after anterior cruciate ligament reconstruction with respect to return to sports: A prospective matched follow-up study. *Knee Surgery Sports Traumatology Arthrosc*opy8.6:337-342.

Mitchel, C.A. and Adebajo, A. 2005: Managing Osteoarthritis of the knee: holistic approach is important. *British Medical Journal*.330:673.

Moore, K.L. and Dalley, A.F. 2006. *Clinical Oriented Anatomy*, 5th edition, Toronto, Lippincott and Wilkins: 556-637.

Murray, C.J and Lopez, A.D. 1997. The global burden of disease. Geneva: World Health Organization.

Murphy, L., Schwartz, T.A., Helmick, C.G., Renner, J.B., Tudor, G., Koch, G., Dragomir, A., Kalsbeek, W.D., Luta, G. and Jordan J.M. 2008. Lifetime risk of symptomatic knee osteoarthritis. *Arthritis and Rheumatism* 5.9:1207–13.

Ndongo, S., Ka, M.M., Leye, A, Diallo, S., Niang, E.H., Sy ,M.H., Moreira Diop, T. 2003.Epidemiological and clinical features of the knee osteoarthritis. .*Dakar Medical* 48:171-175.

Nelson, A.E, Allen, KD., Golightly, Y.M., Goode A.P., Jordan J.M. 2014. A systematic review of recommendations and guidelines for the management of osteoarthritis: The chronic osteoarthritis management initiative of the U.S. bone and joint initiative. *Seminars in Arthritis Rheumatism.* 43:701-12

Newton, P.M., Mow, V.C., Gardner, T.R., Buckwalter, J.A. and Albright, J.P. 1997: Winner of 1996: Cabaud Award. The effect of lifelong exercise on canine articular cartilage. *American Journal of Sports Medicine* 25 3:282-7

Nguyen, U.D.T., Zhang,Y.,Zhu, Y.,Niu,J.,Zhang, B., Aliabadi, P., Felson ,D.T. 2011. Increasing Prevalence of Knee Pain and Symptomatic Knee Osteoarthritis. *Annals of Internal Medicine.* 155: 725-732

National Institute for Health and Clinical Excellence (NICE) Guideline. 2008: Care and management of Osteoarthritis in adult. *British Medical Journal*.336: 502-505

Odole, A.C., Akinpelu, A.O. and Bamgboye, E.A. 2006: validity and Internal consistency of a Yoruba Version of the Ibadan Knee/ hip Osteoarthritis Outcome Measure (IKHOAM). *African journal of Medical Science.* 35: 349-357

_____. and _____. 2008: Validity and internal consistency of a Hausa version of the Ibadan Knee/Hip Osteoarthritis Outcome Measure (IKHOAM). *Health and Quality of Life Outcomes.*6:86

_____., and _____. 2009. Translation and alternate forms reliability of the Visual Analogue Scale in the three major Nigerian Languages. *The Internet journal of Allied Health Sciences and Practice* 7 (3):1-5.

Ogunlade, S.O., Alonge, T.O., Omololu, A.B. and Adekolujo, O.S. 2005: Clinical spectrum of large joint soteoarthritis in Ibadan, Nigeria. *European Journal of Scientific Research.* 11: 116-122.

Olagbegi, O.M., Adegoke B.O.A., Odole, A. 2016: Effectiveness of combined chain exercises on pain patients with knee osteoarthritis. *Bangladesh Journal of Medical Sciences*15: 178- 188

Oliveria, S.A., Felson, D.T., Reed, J.I., Cirillo, P.A. and Walker, A.M. 1995. Incidence of symptomatic hand, hip, and knee osteoarthritis among patients in a health maintenance organization. *Arthritis and Rheumatism* 38.8:1134–41.

Oniankitan, O., Fianyo, E. and Mijiyawa M. 2009. Osteoarthritis of the knee in hospital outpatients in Lomé (Togo). Mali Medical. 24:4-6.

O'Reilly, S.C., Jones, A., Muir, K.R., and Doherty, M. 1998. Quadriceps weakness in knee osteoarthritis: the effect on pain and disability. *Annals of Rheumatic Diseases*57:588-94.

_____., Muir,K.R and Doherty, M. 1999. Effectiveness of home exercise on pain anddisability from osteoarthritis of the knee: a randomised controlled trial. *Annals of rheumatic Disorders.*58: 15-19

Osborne, R.H.; Buchbinder, R and Ackerman, I.N. 2006. Can a disease-specific education program augment self-management skills and improve Health-related quality of life in people with hip or knee osteoarthritis. *BMC musculoskeletal Disorder* 7: 90 1471-2474

Parson, C., Clynes, M., Syddall, H., Jagannath, D., Litwic, A., van der Pas, S., Cooper, C., Dennison, E.M., Edwards, M.H., and the EPOSA research group. 2015. How well do radiographic, clinical and self-reported diagnoses of knee osteoarthritis agree? Findings from the Hertfordshire cohort study. *Springerplus.* 4: 177

Pietrosimone, B., Thomas, A.C., Saliba, S.A., Ingersoll, C.D. 2014**.** Association Between Quadriceps Strength and Self-Reported Physical Activity in People with Knee Osteoarthritis. *The International Journal of Sports Physical Therapy*. 9: 320

Porter, S.B. 2004: Definition and classification of osteoarthritis. *Tidy's Physiotherapy 13th edition.* Manchester, Butterworth-Heinmann.197-206.

EULAR recommendations for the management of knee osteoarthritis: report of a task force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT)

Reading, A.E. 1989. Testing Pain Mechanism in Persons. In Wall, P.D. and Melzack, R. eds. *Textbook of Pain* 2nd ed. Churchill Livingstone.

Roddy, E., Zhang, W., Doherty, M., Ardan, N.K., Barlow, J., Birrel, F., Car, A., Chakravarty, K., Dickson, J., Hay, E., Hosie, G., Hurley, M., Jordan, K.M., McCarthy, C., McMurdo, M., Mockett, S., O'Reilly, S., Peat, G., Pendleton, A., Richards, S. 2005. Evidence-based recommendations for the role of exercise in the management of osteoarthritis of the hip or knee – the MOVE consensus. *Rheumatology*. 44: 67-73.

_____, _____. and _____. 2005: Aerobic walking or strengthening exercise for osteoarthritis of the knee? A systematic Review.*Annals of Rheumatic Diseases. 64: 544- 548*

Roos, E. M., Ostenberg, A., Roos, H., Ekdahl, C. and Lohmander, L. S. 2001. Long-tewrm outcome of meniscectomy: symptoms, function and performance tests in tests in patients with or without radiographic osteoarthritis compared to matched controls. *OstearthritisCartilage* 9 4:316-24

_____., Roos, H.P., Lohmander, L.S., Ekdahl, C and Beynom, B.D. 1998: Knee Injury and Osteoarthritis Outcome Score (KOOS) Development of a self-administered outcome measure. *Journal of Orthopaedic and Sport Physical Therapy*. 28: 88-96

Rubinow, A. 1998: Pain in osteoarthritis and its management in rheumatic pain. *Newsletter of ISAPS Special Interest Group on Rheumatic Pain* (July) 1-5

Salemenda, C.N. 1993: The Epidemiology of Osteoarthritis of the Knee. *Current Opinion on Rheumatology.* 4: 546-551.

Sasaki, S., Iwata, H., Ishiguro, N., Habuchi, O. and Miura, T. 1994.Low-selenium diet, bone, and articular cartilage in rats. *Nutrition* 10.6:538–43.

Scarpignato, C., Lanas, A., Blandizzi C.,Lems, W.F., Hermann, M., Hunt, R.H. 2015. Safe prescribing of non-steroidal anti-inflammatory drugs in patients with osteoarthritis – an expert consensus addressing benefits as well as gastrointestinal and cardiovascular risks. *Biomedical Central.* 13: 55

Scott, D.C., Smith, C., Lohmander, S. and Chard, J. 2002: osteoarthritis. *Clinical Evidence.* 8:1212-1237.

Scott, D.L. and Garrood, T. 2000: Quality of life measures: use and abuse, Clinical *Rheumatology*. 14:4:663-687.

Segal, N.A., Glass, N.A., Torner, J., Yang, M., Felson, D.T., Sharma, L., Nevitt, M., Lewis, C.E. 2010. Quadriceps weakness predicts risk for knee joint space

narrowing in women in the MOST cohort. *Osteoarthritis Cartilage.* 18: 769-775

_____., Findlay C., Wang, K., Torner, J.C., Nevitt, M.C. 2012. The longitudinal relationship between thigh muscle mass and the development of knee osteoarthritis. *Osteoarthritis Cartilage.* 20: 1534-1540

Sharma, L., Song, J., Felson, D.T., Cahue, S., Shamiyeh, E. and Dunlop, D.D. 2001. The role of knee alignment in disease progression and functional decline in knee osteoarthritis. *Journal of American Medical Association* 286 2:188-95

Silver, L.E., Valim, V., Pessanha, A.P.C., Oliveira, L.M., Myamoto, S., Jones, A. and Natour, J. 2008: Hydrotherapy versus conventional land-based exercise for the management of patients with osteoarthritis of the knee: A randomized clinical trial. *Physical therapy* 88:12-21

Snell, R.S. 1992. Clinical Anatomy for medical students, 4th edition, Boston, Little Brown and Company 669-675

Soderberg, G.L. 1997. Kinesiology: Application to Pathological Motion 2nd edition, Philadelphia, Williams and Wilkins 263-310

Soyannwo, O.A., Amanor-Boadu, S.D., Sanya, A.O. and Gureje, O. 2000. Pain assessment in Nigerians-visual analogue scale and verbal rating scale compared. *West African Journal of Medicine*19: 242-245

Spector, T.D., Cicuttini, F., Baker, J., Loughlin, J. and Hart, D. 1996: Genetic influence on osteoarthritis in women: A twin study. *British Medical Journal* 312 7036:940-3

_____., Harris, P.A., Hart, D.J., Cicuttini, F.M., Nandra, D., Etherington, J., Wolman, R.I. and Doyle, D.V. 1996: Risk of osteoarthritis associated with long-term weight bearing sports: A radiologic survey of the hips and knees in female ex-athletes and population controls. *Arthritis and Rheumatism* 39 6:988-95

Stueki, G., Meier, D., Stuck, L.S., Micheal, B.A., Tyndal, A.G., Dick, W. and Theiler, R. 1996: Evaluation of a German version of western Ontario and McMaster Universities Athritis Questionnaire. *Arthritis Index*. 55: 40-49

Superio-Cabuslay, E., Ward, M.M and Lorig, K.R. 1996. Patient education interventions in osteoarthritis and rheumatoid arthritis: a meta-analytic comparison with nonsteroidal antiinflammatory drug treatment. *Arthritis Care Res.*9:292-301.

Swagerty, D.L., and Hellinger, D. 2001: Radiographic assessment of osteoarthritis. *American Family Physicians*. 64: 279-286.

Symmons, D., Mathers, C. and Pfleger, B. 2000. The global burden of osteoarthritis. *Global Burden of Disease.*

Thomas, K.S., Muir, K.R., Doherty, M., Jones, A.C., O'Reilly, S. C. and Bassey, E.J. 2002: Home based exercise programme for knee pain and knee osteoarthritis: randomizedcontrolled trial. *Biomedical Journal*.325: 752.

Thompson, A., Skinnor, A. and Piercy, J. 1991: *Tidy's Physiotherapy* ed 12, Oxford, Butterworth– Heinemann Limited. 110

Turan, B., Balcik, C. and Akkas, N. 1997. Effects if dietary selenium and vitamin E on the biochemical properties of rabbit bones. *Clinical Rheumatology* 16 5:441-9

Underwood, M.R. 2004: Community management of knee pain in the older people: is knee pain the new back pain? *Rheumatology*. 43: 2-3.

Van Baar, M.E., Dekker, J. and Bosveld, W. 1998: A survey of physical Therapy Goal and Interventions for patients with Back and Knee pain: *Physical Therapy*.78:33-42.

_____., Assendelft, W.J., Dekker, J., Oostendorp, R.A. and Bijisma, J.W. 1999. Effectiveness of exercise therapy in patients with osteoarthritis of the hip or knee: a systematic review of randomized clinical trials. *Arthritis and Rheumatism* 42:1361-1369

van der Esch ,M., Holla, J.F., van der Leeden ,M., Knol, D.L., Lems W.F., Roorda, L.D., Dekker, J. 2014. Decrease of muscle strength is associated with increase of activity limitations in early knee osteoarthritis: 3-year results from the cohort hip and cohort knee study. *Archives of Physical Medicine and Rehabilitation*.95:1962 -1968

Vanhoof, J., Declerk, K. and Guesens, P. 2002: Prevalence of Rheumatic diseases in a Rheumatological outpatient practice. *Annals of the Rheumatic Diseases*. 61:453-455.

Walker-Bone, K., Javaid, K., Arden, N. And Cooper, C. 2000: Clinical Review-Medical Management of osteoarthritis. *British Medical Journal*. 321: 936-940.

Warsi, A., Wang, P.S., LaValley, M.P., Avorn, J. and Solomon, D. H. 2004: Self-management education programs in chronic disease: a systematic review and methodological critique of the literature. *Archives of Internal Medicine* 164: 1641- 1649

Warwick, R. and Williams, P.L. 1985. *Grays Anatomy*, ed 37, Philadephia, W.B. Sounders, 482-490.

White, D.K., Niu,J. and Zhang, Y. 2013. Is symptomatic knee osteoarthritis a risk factor for a fast decline in gait speed? Results from the Osteoarthritis Initiative. *Arthritis Care Research.* 65: 187-194

Wice, C. 2001 Osteoarthritis; In Dale, D.C, Federman, D.D. *Scientific American Medicine* 3.15: 1-8

Wolf, C and Tanner, M. 2002: Straight to point- Obesity. *West Journal of Medicine*. 76: 23-28.

Wluka, A.E., Cicuttini, F.M. and Spector, T.D. 2000. Menopause, oestrogens and arthritis. Maturitas 35 3:183-99

Zhang, W and Doherty, M. 2006: EULAR recommendations for knee and hip osteoarthritis: a critique of methodology. *British Journal of Sports Medicine* 40: 664-669

_____. Nuki, G., Moskowitz, R.W., Abramson, S., Altman, R.D., Arden, N.K., Bierma-Zeinstra, S., Brandt, K.D., Croft, P., Doherty, M., Dougados, M., Hochberg,M., Hunter, D.J., Kwoh, K., Lohmander, L.S., Tugwell, P. 2010. OARSI recommendations for the management of hip and knee osteoarthritis Part III: changes in evidence following systematic cumulative update of research published through January 2009. *Osteoarthritis and Cartilage*. 18: 476-499

Zhang, Y. and Jordan, J. M. 2010: Epidemiology of Osteoarthritis *Clinics in Geriatrics Medicine* 26 3:355-369

Zeni Jr,J. A. and Snyder-Mackler, L.2010. Most patients gain weight in the 2 years after total knee arthroplasty: comparison to a healthy control group. *Osteoarthritis Cartilage*. 18: 510- 514

## APPENDIX A

## eINFORMED CONSENT

**COMPARATIVE EFFICACY OF SELF- MANAGEMENT EDUCATION AND QUADRICEPS STRENGTHENING EXERCISES ON QUALITY OF LIFE, PAIN, AND PHYSICAL FUNCTION. IN INDIVIDUALS WITH KNEE OSTEOARTHRITIS**

Dear Sir/Ma

This study is aimed to investigate the comparative efficacy of the two treatments mentioned above in the management of knee osteoarthritis. The program is expected to be of benefit to you by decreasing your pain; improving your functional capabilities and helping you manage your condition by yourself on the long run.

You will be organized into group A and B. Group A will be the self- management education group while group B will be the quadriceps strengthening exercise group

Group A will be required to attend the self- management education class once a week for a period of six weeks. The program consists of 2 hours 30 minutes instructions on knee osteoarthritis as well as specific exercises for managing the disease and a practical session of the exercise.

Group B will be required to visit the physiotherapy unit to perform some exercises under the supervision of a Physiotherapist three times a week for six weeks

All information pertaining to your participation in this program will be kept confidential and used strictly for research purpose. Please note that participation is voluntary, you are not under obligation to participate and are free to withdraw your participation anytime.

Thank you

Funmilayo R. Egwu (Principal Investigator)
Department of Physiotherapy
College of Medicine
University of Ibadan

_____ _____

Signature of participant Date

_____ _____

Signature of Witness Date

## APPENDIX A2

## LITAFFIN BAYANI NA SA HANNU A SHIRIN

Nufin wannan bincike shine bincika jiyya da ya fi kyau tsakanin jiyyoyi da an ambata dazu game da yadda aka lura da amosanin gaɓɓai na gwiwa. Za ka amfana daga shirin nan, ta wagen ragen zafin ciwon ka; inganta iyawan ka da kuma taimaka maka ka sarrafa yanayin ka da kan ka a nan gaba.

Za a raba ku cikin rukunin biyu wato rukunin A da B. Rukunin A za su sarrafa yanayin su da kan su, rukunin B za su yi motsin jiki da zai karfafa gwiwan su.

Ana bukata rukunin A su halarci aji na ilmantar da sarrafa yanayi da kan su sau daya a cikin sati, har sati shida. Shirin ya kunshi awa 2 da mintoci 30 a kan umarni game da amosanin gaɓɓai na gwiwa da kuma wdannsu iri mostin jiki da zai sa ka kula da ciwon da kuma yin wadannan mosta jiki a zahiri.

Ana bukata Rukuni B  su je ga wurin likita mai gyran juyoji su yi wadan su mosta jiki sa'anda likitan yana duba su, sau uku cikin sati har sati shida.

Duk bayanin ka game da wannan shiri zai zama asirce kuma don wannan bincike kawai. Don Allah ka san cewa sa hannu a wannan tsarin na son rai ne, kuma ba wajibi ne ka sa hanu ba, kuma za ka iya bijire a lokaci da ka ga dama.

Na Gode

Funmilayo R. Egwu (Mai Bincike)
Department of Physiotherapy
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## APPENDIX B

## IBADAN KNEE/HIP OSTEOARTHRITIS OUTCOME MEASURE (IKHOAM)

**Part I: Indicate the extent of limitations you experience in carrying out the following activities using these scales:**

**Degree of difficulty:** 4 = no difficulty; 3 = mild difficulty; 2 = moderate difficulty; 1 = severe difficulty; 0 = inability to carry out the activity.

**Nature of Assistance:** 4 = requires no assistance; 3 = requires use of aid(s)/device(s) only; 2 = requires assistance of one person only; 1 = requires assistance of one person and the use of aid(s); 0 - unable to perform the activity.

| | Difficulty | Assistance |
|---|---|---|
| 1. Washing all body parts during shower. | | |
| 2. Walking within the house | | |
| 3. Sweeping with a short broom | | |
| 4. Walking outside the house for 15-20 minutes | | |
| 5. Putting on under clothes | | |
| 6. Getting in and out of a salon car | | |
| 7. Hand washing of clothes at floor/low level | | |
| 8. Rising from bed/mat | | |
| 9. Rising from high chair (dining/office chair) | | |
| 10. Putting on/lacing shoes or buckling sandals | | |
| 11. Rising from an easy chair or sofa | | |
| 12. Sweeping with a long brush/broom or using mop stick | | |
| 13. Participating in coitus | | |
| 14. Incomplete kneeling/prostrating to show courtesy/greet elders | | |
| 15. Getting on/off water closet toilet | | |
| 16. Getting in and out of a bus/high vehicle | | |
| 17. Standing for at least 15 minutes (waiting at bus stop/working in a modern kitchen with high cooker) | | |
| 18. Manual grass cutting/hoeing/gardening | | |

| | | |
|---|---|---|
| 19. Sitting on the heels (Islamic praying posture) | | |
| 20. Climbing stairs | | |
| 21. Picking things from floor/low level (kitchen cabinet) | | |
| 22. Kneeling (Christian praying posture) | | |
| 23. Sitting on a very low stool (e.g. when cooking on a low stove or firewood at floor level) | | |
| 24. Descending stairs | | |
| 25. Using pit/Asiatic toilet | | |

**Part II: Indicate the extent of restriction you experience participating in the following life situations using the scale below Extent of restriction: 3-full participation, 2- at risk full participation, 1-participation with restriction, 0-no participation**

| | Extent |
|---|---|
| 1. Performing duties at work (office or at home. | |
| **2.** Travelling for one hour or more | |
| **3.** Participation in social gatherings (e.g. wedding, naming, funeral, birthday parties) | |

Part III: Physical performance tests

**250m Walk Test**

5 - able to walk 250m or more at one stretch

4 - able to walk 200-<250m at one stretch

3 - able to walk 150-<200m at one stretch

2 - able to walk 100-<150m at one stretch

1 - able to walk 50-<100m at one stretch

0 - able to walk <50m at one stretch

**Squat Test**

4 - $\geq 100^0$ knee flexion

3 - $70\text{-}99^0$ knee flexion

2 - 40-69$^0$ knee flexion

1 - 10-39$^0$ knee flexion

0 - < 10$^0$ knee flexion

**One leg Stance Test**

5 - can be maintained for 4 minutes or more

4 - can be maintained for 3-<4 minutes

3 - can be maintained for 2-<3 minutes

2 - can be maintained for 1-<2 minutes

1 - can be maintained for <1 minute

0 - unable to perform the test

**Stairs Climbing Test**

4 - can climb with no difficulty and no assistance

3 - can climb with mild difficulty (one railing)

2 - can climb with moderate difficulty (two railings)

1 - can climb with severe difficulty (two railings and help)

0 - unable to climb.

**Balance Test on a Balance Board**

5 - can balance for 45 seconds or more

4 - can balance for 30-<45 seconds

3 - can balance for 20-<30 seconds

2 - can balance for 10-<20 seconds

1 - can balance for <10 second

0 - unable to balance at all.

**APPENDIX B2**

**(Hausa version of IKHOAM)**

**MA'AUNIN SAKAMAKON BINCIKEN CIWO SANYIN KASHI NA GWIWA DA KWATANGWALO NA IBADAN**

**Karchi na farko: Nuna matsalolin da kake fuskanta wajen aiwatar da wadanna aiyuka masu zuwa ta hanyar amfani da ma'aunai kamar haka**:

**Matsayin wahala:** 4 = babu wahala; 3 = 'yar wahala; 2 = matsakaiciyar wahala; 1 = matsananciyar wahala; 0 = kasa aiwatar da aikin.

**Yanayin taimako:** 4 = ba a bukatar taimako; 3 = bukatuwa ga amfani da kayan aiki kawai; 2 = bukatuwa ga taimakon mutum daya; 1 = bukatuwa ga taimakon mutum daya da amfani da kayan aiki; 0 – baza a iya aikin ba.

| | **Matsayi** | **Taimako** |
|---|---|---|
| 1. Wanke dukkan bangarorin jiki lokacin wanka | | |
| 2. Tafiya a cikin gida | | |
| 3. Shara da gajeriyar tsintsiya | | |
| 4. Tafiya a wajen gida na tsawon minti 15 – 20 | | |
| 5. Sanya tufafin ciki | | |
| 6. Hawa ko sauka daga karamar mota | | |
| 7. Wanke - wanke /wankin tufafi a tsaye wajen famfo ko daidai misalign Tebur | | |
| 8. Tasowa daga gado/ tabarma | | |
| 9. Tasowa daga kujera mai tsawo | | |
| 10. Sanya takalmi mai igiya | | |
| 11. Tasowa daga kujera ta zamani | | |
| 12 Shara da togon burushi ko tsinstiya | | |

| | | |
|---|---|---|
| 13. Halin yanayin jiki yayin jima'i | | |
| 14. Lankwas gwiwa da kwatangwalo a halin tsayuwa domin girmamawa ko gaida na gaba | | |
| 15. Zama akan/tasowa daga masai na zamani | | |
| 16. Hawa ko sauka daga babbar mota | | |
| 17. Tsayuwa t akalla minti 15 | | |
| 18. Shema/Noma ta hanyar amfani da kayan aiki na gargajiya (misali yayin dafa abinci a risho na ajiya a kasa ko yin amfani da icce a kasa) | | |
| 19. Zaman salla | | |
| 20. Hawa matakala | | |
| 21. Dukawa don duako abu daga ma'ajiyin dakin girki ko firiji | | |
| 22. Tsugunawa (irin yaddakirista ke yi wajen addu'a) | | |
| 23. Zama a gajeruwar kujera | | |
| 24. Hawa ko sauka daga matakalar bene | | |
| 25. Amfani da masai na gargajiya | | |

**Kachi na biyu: Nua matsayin waha'ar da kake sha a lokacin da kake wandannan al'amuran rayuwa:**

**Matsayin wahalar:** 3-cikakken iyawa, 2- hatsari wajen iyawa, 1-amma da wahala, 0-rshin iyawa

| | **Matsay** |
|---|---|
| **1. Yin aikace** – aikacen ofis ko na gida | |
| **2. Motsa jiki da Shakatawa**: Shiga harkokin motsa jiki dashakatawa kamar wasan dara, ludo, kwallon tebur, kwallon sanda, tafiya, sassarfa, ninkaya. Kamar | |

| | |
|---|---|
| **3.** Harkokin Zamantakewa: Shiga taron Jama'a ko na addini, watomasallaci ko coci, daurin aure, radin suna, jana'iza, da bikin murmarzagayowar ranar haihuwa | |

Kashi na uku: Gwajin Aiki a Aikace

**Gwajin Tafiya na mita 250.**

5 - Iya tafiyar 250 ko fiye da haka a lokaci daya

4 - Iya tafiya kasa da mita 250zuwa mita 200 a lokaci daya

3 - Iya tafiya kasa da mita 250zuwa mita 150 a lokaci daya

2 - Iya tafiya kasa da mita 150zuwa mita 100 a lokaci daya

1 - Iya tafiya kasa da mita 100zuwa mita 50 a lokaci daya

0 - Iya tafiya kasa da mita 50 a lokaci daya

**Gwaji na Tsugune**

4 - Sama da daraja 100 na lankwasa gwiwa

3 - Daraja 70 zuwa 99 na lankwasa gwiwa

2 - Daraja 40 zuwa 69 na lankwasa gwiwa

1 - Daraja 10 zuwa 39 na lankwasa gwiwa

0 - Knasa da daraja 10 na lankwasa gwiwa

**Gwaji na Tsayawa akan Kafa Daya**

5 - za'a iya yinta na tsawon minti 4 zuwa fiye da haka

4 - za'a iya yinta na kasa da minti 4 zuwa 3

3 - za'a iya yinta na kasa da minti 3 zuwa 2

2 - za'a iya yinta na kasa da minti 2 zuwa 1

1 - za'a iya yinta na kasa da minti 1

0 - ba za'a iya yin wanna gwaji ba.

**Gwajin Hawa Matakalar Bene**

4 - za'a iya hawa ba tare da wata matsala ko taimako ba

3 - za’a iya hawa jerin matakala daya tare da ‘yar karamar wahala

2 - za’a iya hawa jerin matakala biyu tare da matsakaiciyar wahala

1 - za’a iya hawa jerin matakala biyu tare da matsanciyar wahala

0 - ba za’a iya hawa ba.

**Gwaji na Tsayuwa akan Ma’aunin Daidaituwa**

5 - za’a iya daidatuwa na tsawon dakika 45 ko sama da haka

4 - za’a iya daidatuwa na tsawon kasa da dakika 45 zuwa 30

3 - za’a iya daidatuwa na tsawon kasa da dakika 30 zuwa 20

2 - za’a iya daidatuwa na kasa da dakika 20 zuwa 10

1 - za’a iya daidatuwa na tsawon dakika 10.

0 - ba za’a iya daidatuwa ba gada daya.

## APPENDIX C

### ARTHRITIS IMPACT MEASUREMENT SCALES 2 (SHORT FORM) (AIMS 2 SF)

Instructions: Please answer the following questions about your health. Most questions ask about your health during the past 4 weeks. There are no right or wrong answers to the questions and most can be answered with a simple check (X). Please answer every question.

| DURING THE PAST 4 WEEKS. | All Days | Most Days | Some Days | Few Days | No Days |
|---|---|---|---|---|---|
| 1. How often were you physically able to drive a car or use public transportation? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2. How often were you in bed or chair for most of the day? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3. Did you have trouble doing vigorous activities such as running, lifting heavy objects or participating in strenuous sports? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 4. Did you have troubles walking several blocks or climbing few flight of stairs ? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 5. Were you unable to walk unless assisted by another person or by a cane, crutches or a walker? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 6. Could you easily write with a pen or pencil? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 7. Could you easily button a shirt or blouse? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 8. Could you easily turn a key in a lock? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 9. Could you easily comb or brush your hair? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 10. Could you easily reach shelves above your head? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 11. Did you need help to get dressed? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 12. Did you need help to get in or out of bed? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 13. How often did you have severe pain from your arthritis? | ☐ | ☐ | ☐ | ☐ | ☐ |

| | All Days | Most Days | Some Days | Few Days | No Days |
|---|---|---|---|---|---|
| 14. How often did your morning stiffness last more than one hour? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 15. How did your pain make it difficult for you to sleep? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 16. How often have you felt tense of high strung? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 17. How often have bothered by the nervousness of your nerves? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 18. How often have you been in low or very l ow spirits? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 19. How often have you enjoyed the things you do? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 20. How often did you feel burden to others? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 21. How often did you get together with friends or relatives? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 22. How often were on telephone with close friends or relatives? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 23. How often did you go to a meeting of a church, club, team or other goup | ☐ | ☐ | ☐ | ☐ | ☐ |
| 24. Did you feel your family or friends were sensitive to your needs? | ☐ | ☐ | ☐ | ☐ | ☐ |
| *If you are unemployed disabled or retired, end of questionnaire* | All Days | Most Days | Some Days | Few Days | No Days |
| 25.How often were you unable to do any paid work, house work or school work? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 26. On the day you did work, how often did you have to work a shorter day? | ☐ | ☐ | ☐ | ☐ | ☐ |

## APPENDIX C2

### (Hausa translation of AIMS 2 (SF))

## MA'AUNIN GWAJIN TASIRIN AMOSANIN GABOBI NA BIYU (KARAMIN ZANGON) (AIMS 2 SF)

**UMURNI**:- Amsa wadannan tambayoyi dangane da lafiyarka/ki mafi yawa daga cikinsu suna tuntubar matsayin lafiyarka/k ice sati hudu da suka bagata. Amsoshin ba suna bukatar a ce "ee ko aa" ba ne. Da yawa daga ciki suna bukatar ayi wata yar alama c eta (X) a inda ake ganin ya kamata. Don Allah a amsa a wadannan tambayoyi duka.

| A cikin sati hudu da suka gabata | **Kowace Rana** | **Mafi Yawan Ranaku** | **Wasu Ranaku** | **Yan Ranaku** | **Babu Kowane Rana** |
|---|---|---|---|---|---|
| 1. Menene adadin da kake iya Tuka motar ka/ki ko na Haya? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2. Menene adadin dakake iya Zama a gado ko kujera a yini? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3. Kana samun matsala yin Ayyuka masu nauyi kamar Gudu, daga abu mai Nauyi ko Wasannin motsa jiki masu Wahala? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 4. Kana samun matsala yin tafiya Mai tsawo ko hawa bene? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 5. Ka taba kasa tafiya saida Taimakon wani ko sanda koAbin tafiya? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 6. Kana iya rubutu da alkalami Ko Pensir cikin sauki? | ☐ | ☐ | ☐ | ☐ | ☐ |

7. Kana iya balle boturi din Riga ko Bulawus cikin sauki?

8. Kana iya juya mukulli a cikin kwado cikin Sauki?

9. Kana iya taje kai ko buroshi cikin sauki?

10. Kana iya dauko abu daga kanta da tasha kanka cikin sauki?

11. Kana iya shiryawa ba tare da taimako ba?

12. Ka taba bukatar taimako katashi ko zaunawa a gado?

13. So nawa kake samun zafi kwarai daga ciwon kashin ka.

14. So nawa kagewan kashin ka na safiya ya jima fiye da awa daya?

15. Yaya ciwonka yasa barcinka yayi wahala?

16. So nawa kaji ciwonka ya tsananta?

17. So nawa ciwonka ya dameka ta jijiyoyinka?

18. So nawa kake jin rashin nishadi kadan ko sosai? ☐ ☐ ☐ ☐ ☐

19. So nawa kake jin dadin aikace – aikacenka? ☐ ☐ ☐ ☐ ☐

20. So nawa kake jin ka kaya ne wajen wasu? ☐ ☐ ☐ ☐ ☐

21. So nawa kake saduwa da Yan'uwa da abokai? ☐ ☐ ☐ ☐ ☐

22. So nawa kake sadarwa dawaya da Abokan arziki ko yan'uwa? ☐ ☐ ☐ ☐ ☐

23. So nawa kake zuwa taro a coci, club ko wani kungiya? ☐ ☐ ☐ ☐ ☐

24. Ka na jin yan'uwanka ko abokanka sun damu da larurarka? ☐ ☐ ☐ ☐ ☐

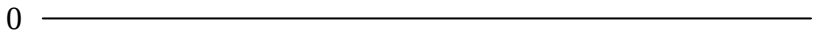
**Idan baka da aiki, ko kasasshe ne kai, ko ka yi ritaya, karshen tambayoyi ne?**

25. So nawa kake gaza yin aikin kudi, ko na gida ko makaranta? ☐ ☐ ☐ ☐ ☐

26. Ranar da ka samu yin aikin, so nawa, ka samu yin aiki a gajeruwar rana? ☐ ☐ ☐ ☐ ☐

## APPENDIX D

VISUAL ANALOGUE SCALE (VAS) (Hawker et al., 2011)




No Pain Worst Pain

**APPENDIX D2**

**(Hausa translation of VAS)**

MA'AUNIN GWAJIN GANI (Hawker et al., 2011)

UMURNI:- A sa alama a layukan da ke kasa wanda zai nuna iya tsananin zafin ciwon da kaka ji a wannan lokaci.

0 ——————————————————————— 10

Babu ciwo Matsanancin ciwo Kowace Iokaci

## APPENDIX E

KNEE OSTEOARTHRITIS SELF MANAGEMENT EDUCATION PARTICIPANT INFORMATION BOOKLET

CONTENT





What is knee osteoarthritis?

Knee osteoarthritis is one of the most common form of arthritis. It is the wear and tear process occurring in the knee joint leading to the destruction of the thin layer of smooth cartilage covering the end of the bones which makes up the joint.

Who does it affect?

Knee osteoarthritis can affect almost anyone. However, it is most likely to affect you if you are:

In your late 40's or older

A woman

Your parents or siblings have it.

You have had previous injury to the knee.

Signs and symptoms

General aching in joint

Stiffness in the joint with inactivity

A grating or grinding sensation in the knee joint when it moves.

Swelling, which could be hard or soft

Sometimes the knee may either lock or give way when weight is put on it

Misalignment and or joint deformity

Causes

The exact initiating factor is still uncertain, but the condition could be aggravated by a combination and variety of factors such as:

Excess weight/ obesity

Previous knee injury

Overuse or lack of use of the knee joint

The natural aging process

The durability of cartilage varies from individual to individual due to genetic factors

Treatment

There is no cure for knee osteoarthritis as yet, but there is a lot that can be done to improve the symptoms.

Your doctor could give some of the following treatment:

Pain killers (analgesics)

Anti- inflammatory creams and gels

Non-Steroidal Anti- Inflammatory Drugs (NSAIDs)

Steroid injections

Hyaluronic acid injections

Surgery

However self-management measures play a very important part in relieving the pain, stiffness and reduce the chances of your arthritis becoming worse. Self-management measures include:

Weight management: If you are overweight, there will be too much stress passing through your knee. The force put through your knee joints when you walk, run, and go up and down stairs can be up to 5-6 times your body weight due to the way the knee joint works. Losing even a small amount of weight can make a big difference to the strain on your knee joint. Reduced calorie diets combined with exercise can help you reduce your weight.

Reduce strain on your knee by pacing your activities through the day. Do not tackle all physical jobs at once, break the harder jobs into chunks and do something gentler in between. Use rail for support when you go up and down the stairs. Go up the stairs with your good leg first but come down the stairs with your bad leg first. Keep using your knee but rest it a little when it becomes more painful.

Footwear: wear low heeled shoes with thick soft soles. Thicker soles act as shock absorbers. While high heels alter the angle of the hip and knee joints putting additional strain on the knee joint.

Walking aids: Use walking stick to reduce the weight and stress on your knee.

Pain relieving techniques: ice/ heat- Applying warmth to a painful knee often helps to relieve the pain and stiffness in the knee.Heat lamps, hot water bottle and reheat able pads are effective means of applying warmth. Ice can also be used but it should not be applied directly to the skin.

Anti- inflammatory creams and gels could be applied directly to the knee during acute exercitation of symptoms. It is considered safer to use these creams and gels because it has less gastrointestinal side effect than oral anti- inflammatory drugs.

Exercise: even if you don't need to lose weight, it is important to keep moving. You will need to find a balance between rest and too little as overuse could worsen your arthritis and too little movement of your knee could stiffen your knee. Frequent moderate exercise is the best. There are two types of exercise you need to do; i) strengthening exercises will improve the tone and strength of the thigh muscles which are usually weakened by knee osteoarthritis. It will also help in reducing the pain and help in preventing the knee from giving way and reducing the tendency to fall or stumble. An example of such exercise is straight leg raise in sitting or lying position.(ii) Aerobic exercises are any exercise that increases your pulse rate and makes you a bit short of breath. Regular aerobic exercise should help you sleep better, improves your general health and well-being as well as reducing pain by stimulating the release of pain relieving hormones called endorphin. Simple brisk walking 3-5 times a week for 30- 40min each time is a good example of such exercise.

The information in this booklet are adapted from" Arthritis research UK: Osteoarthritis of the knee".

## APPENDIX E2

**(Hausa translation of knee osteoarthritis self-management education participant information booklet)**

KARIN ILIMI AKAN SAYIN KASHI GWIWA

LITTAFIN BINCIKE

ABIN DA KE CIKI

- Mene ne Sanyin Ƙashin Gwiwa?
- Wane ne zai iya fama da shi?
- Mene ne alamun wannan cutar?
- Abin da ke kawo Sanyin Ƙashin Gwiwa.
- Yadda ake jinya wannan cutar
- Motsa Jiki
- Hanyoyi da za a bi da nauyin jiki.
- Hanyoyi taimako domin tafiya.
- Taƙalma da ta dace.
- Magunguna
- Wasu abubuwa da za su taimaka a rege zafi

- Mene ne Sanyin Ƙashin Gwiwa?
  Sanyin Ƙashin Gwiwa daya ne daga cikin bangarorin Sanyin Ƙashi. Wannan cutar tana lalatar da fata da ke a magamin gwiwa har ya kai go halakar ƙasusuwa dake a tattare a wannan magamin gwiwar.
- Wane ne zai iya fama da sanyin ƙashi gwiwa? kowane irin mutum zai iya kamuwa da sanyin ƙashin gwiwa, musamman ma wadda ya bar shekaru 40 baya.
- Mene ne alamun wannan cutar?
  - Yawan ƙaiƙai a magamin gwiwar.
  - Rashin motsiyar gwiwar a yadda ya kamata.
  - Yawan ƙara a duk lokacin da kafar ya yi motsi.
  - Ƙumburin gwiwar.
  - Gwiwar na iya daina motsi domin nauyin jiki.
  - Gaucewar gwiwa daga magamin.
- Abin da ke kawo Sanyin Ƙashin Gwiwa. Ba a gano asalin abin da ke kawo irin wannan cutar ba tukuna, amma sau da yawa abin da ke jawo matsalar Sanyin Ƙashin Gwiwa sune;

- Yawan ƙiba
- Idan an taɓa jin rauni a gwiwar
- Idan ana yawan taƙura magamin gwigwar
- Shigewar shekaru – tsufa
- Babanci da ke tattare da yanayin ƙasusuwan jikunanmu.

- Yadda ake jinyar wannan cutar A yanzu babu taikamaman maganin da zai iya warkar da wannan cutar. Amma dai ana dan samun taimakon magunguna da ke taimakawa don rege zafin ciwon.
  Likitoci suna iya yin amfani da waddanan hanyoyi don taimakawa;
  - Kwayoyin rege zafi.
  - Mai shafawa domin hana ƙumburi.
  - Alurai na magani.
- Tiyata.
  A wasu lokaci, yadda muke iya bi da wannan ciwon na taimakawa wurin rege zafin da ƙumburi da zai taimaka regen munin ciwon. Ga wasu da za mu iya bin da wannan yanayi.
- Yadda za a bi da nauyin jiki:- yawan nauyin jiki na da illa sosai ga jiki kuma hakan na iya taƙura gwiwar sosai. Yayin da mutum ya yi gudu ko kuma tafiya da kafa ko kuma yah au wani tsani, hakan zai iya taƙura magamin gwiwar musamman ma idaj wannan mutumin ya yi ƙiban jiki sosai.
-

  Zai fi dacewa mutum mai yawan jiki ko wanda ya yo ƙiba sosai ya yi kokarin regu yawan jiki sosai. Yin hakan zai rege taƙura a magamin gwiwa wadda take sa sanyi ƙashin gwiwa. Wani mataki mai kyau wadda mai ƙiba zai iya daukawa domin rege jiki shi ne ɗaina cin abin mai maiko, sa'anan kuma ya zama mai son motsa jiki akai akai.

  Mutum zai iya rege nauyi a gwiwa ta wurin daidaita ayukan da yake yi a ƙullum. Zai dace a din ga wa'asu ayuka da ked a saukin yi a tsakanin waddanda suka fi tsanani. Ya kamata mutum ya nemi taimako yayinda zai hau tsani kuma ya yi amfani da kafan day a fi ƙarfi idan zai taƙa mataƙalwar, sa'anan yayinda zai sauka wannan mataƙalwar musaman na gidajen bene ya yi amfani da ƙafar da gwiwar na ciwo ya taka zuwa kasa.
- Takalma:
  Zai fi dacewa a saka takalma da kasan babu tsawo sosai. Takalman da ke da tsowon kasa na yawan taƙura idon kafa da kuma magamin gwiwar kafa.
  Taimako don yin tafiya:
  Zai fi dacewa mutum da ked a sanyin ƙashin gwiwa ya yi amfani da sanda sa'alin da zai yi tafiya domin ya rege yawan taƙura da kuma nauyi.
  Hanyoyi rege zafi.

Za a iya yin amfani da rowan zafi domin a matsa gwiwar da ke ciwo, ko kuma garwashin wuta domin jin ɗimni. Ana ma iya yin amfani da ƙankara a matsa gwiwar da ke ciwo. A wasu lokotai an fi amince a yi amfani da mai shafawa da ke rege zafi fiya da magungunan rege zafi musamman ma a lokaci da ciwo ya yi tsanani.

- Motsan Jikki: Motsan Jikka na da amfani sosai ko da ma mutum baya son ya rege nauyin jikkinsa. Ya kamata mutum ya san lokaci day a dace ya mots jikki da kuma lokaci dab a ya bukatan ya yi hakan ba. Motsan jikki a yadda ya kamata a ɗan gajeren lokaci ya fi ƙyau.

  Masu fama da sanyin ƙashin gwiwa na bukatan motsa jikki kashin biyu

  - Motsan jikki da ta ƙunshi was an miƙe jikki musamman kafafuwa zai taimaka a warware jijiyoyin cinya. Kuma hakan zai taimak wurin rege zafin da kuma guacewar gwiwa dai zai iya sa mutum ya fadi.
  - Girgizan jiki na sa jinni guduwa sosai a jikki kuma yin hakan a kullum na sa mutum barci mai lafiya. Wannan yanayin motsan jikki na inganta lafiyar jikki sosai kuma yana rege zafin kikki. Mutum zai iya yin irin wannan ta wurin yin tafiya ma tsowon minti 30-40 sau uku zuwa sau biyar a mako ɗaya.

An ƙimanta wannan shashen labaabbaren daga “Hukumar bincike na Sanyin ƙashi a Amirka: Shashen Sanyin Ƙashi Gwiwa”.

INSTITUTE FOR ADVANCED MEDICAL RESEARCH AND TRAINING (IAMRAT)
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UI/UCH EC Registration Number: **NHREC/05/01/2008a**

**NOTICE OF FULL APPROVAL AFTER FULL COMMITTEE REVIEW**

**Re: Comparative Efficacy of Self-Management Education and Kinetic Chain Exercises on Quality of Life, Pain and Physical Function in individuals with Knee Osteoarthritis**

UI/UCH Ethics Committee assigned number: UI/EC/13/0256

Name of Principal Investigator: **Egwu R. Funmilayo**

Address of Principal Investigator: Department of Physiotherapy,
College of Medicine,
University of Ibadan, Ibadan

Date of receipt of valid application: 25/07/2013

Date of meeting when final determination on ethical approval was made: **24/04/2014**

This is to inform you that the research described in the submitted protocol, the consent forms, and other participant information materials have been reviewed and *given full approval by the UI/UCH Ethics Committee.*

This approval dates from 24/04/2014 to 23/04/2015. If there is delay in starting the research, please inform the UI/UCH Ethics Committee so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of these dates. *All informed consent forms used in this study must carry the* UI/UCH EC *assigned number and duration of* UI/UCH EC *approval of the study.* It is expected that you submit your annual report as well as an annual request for the project renewal to the UI/UCH EC early in order to obtain renewal of your approval to avoid disruption of your research.

*The National Code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the Code including ensuring that all adverse events are reported promptly to the* UI/UCH EC. *No changes are permitted in the research without prior approval by the* UI/UCH EC *except in circumstances outlined in the Code. The* UI/UCH EC *reserves the right to conduct compliance visit to your research site without previous notification.*

UI/UCH EC
24 APR 2014
APPROVED
COLLEGE OF MEDICINE

**Professor A. Ogunniyi**
Director, IAMRAT,
Chairman, UI/UCH Ethics Committee
E-mail: uiuchirc@yahoo.com